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Scientific Section

Scientific Oral Abstract Plenary Session

P1-030A

Massive Transfusion in Cardiac Surgery: The Impact of Blood Component Ratios on Clinical Outcomes and Survival

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Background/Case Studies: Cardiac surgery is the most common setting for massive transfusion in medically advanced countries. Studies of patients with traumatic injuries suggest that the ratios of plasma and platelets (PLT) to red blood cells (RBCs) affect clinical outcomes and mortality. The Red Cell Storage Duration Study (RECESS) was a large randomized controlled trial of major cardiac surgery patients which provided data to investigate the relationship between blood components ratios used in massively transfused patients and subsequent mortality and organ function. **Study Design/Methods**: Massively transfused subjects enrolled in RECESS were defined as those who received $\geq$6 units of RBCs and/or $\geq$8 total blood components. Subjects were analyzed to determine whether the ratios of blood components transfused impacted clinical outcomes. For plasma transfusion, high ratio was defined as $\geq$1 plasma unit:1 RBC unit. For PLT transfusion, high ratio was defined as $\geq$0.2 PLT doses:1 RBC unit; PLT dose was defined as one apheresis PLT or 5 whole blood PLT equivalents. Clinical outcomes were tabulated using the mortality and the Multiple Organ Dysfunction Score ($\triangle$MODS) comparing pre-op score to the highest composite score through day 7 (or death/hospital discharge, if earlier), between patients transfused with high and low ratios. Linear and Cox regression were used to explore relationships between predictors and continuous outcomes and time to event outcomes, respectively. **Results/Findings**: 324 out of 1098 RECESS subjects met the definition of massive transfusion. The 7-and 28-day ΔMODS was on average 1.06-1.54 points lower ($p<0.017$), indicating less organ dysfunction, in those receiving high plasma:RBC ratio and/or high PLT:RBC ratio compared to those receiving low ratio transfusions, respectively. Subjects who received low ratio plasma:RBC transfusion had excess 7-day mortality compared to those who received high ratio (7.2% vs 1.7%, respectively, $p<0.032$), which remained significant at 28 days ($p=0.035$). The ratio of PLT:RBCs was not associated with differences in mortality. The treatment arm from the original study, the time to hospital or ICU discharge, hemoglobin and creatinine values were not significantly different. The bilirubin level was lower (-0.67 to -0.86 in high PLT and plasma groups, respectively, $p<0.05$) on day 2, however these changes are unlikely to be clinically significant. **Conclusion**: This analysis suggests a significant association between the composition of blood products used in massive transfusion resuscitation due to cardiac surgery and clinical outcomes. Specifically, when $\geq$6 units of RBCs and/or $\geq$8 total blood components are transfused, there was less organ dysfunction in patients receiving high ratio transfusions (plasma and PLTs) and less mortality when receiving high ratio plasma resuscitation.

P2-030A

Safety of the Use of Thawed Group A Plasma in Trauma

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Background/Case Studies: Availability of thawed plasma facilitates concurrent provision of plasma and RBCs during trauma resuscitation but can be challenging due to a limited supply of universally compatible group AB plasma. As an alternative, some centers are now using emergency issued group A thawed plasma during the initial resuscitation of traumatically injured patients. This study was undertaken to evaluate the safety of this practice. **Study Design/Methods**: Fourteen US trauma centers using emergency issued group A plasma in trauma patients of unknown blood group provided data for group A, B and AB patients who received at least one unit of group A plasma. Patient age, gender, number of blood products transfused during the initial resuscitation, early mortality (initial 24 hours) and overall in hospital mortality were assessed. The outcomes of group B and AB patients were compared to group A patients using the Trauma and Injury Severity Score (TRISS) method to determine whether the use of emergency issued group A plasma in group B and AB patients was associated with a higher mortality rate when compared to mortality predicted at baseline. **Results/Findings**: Data from 316 group A and 171 group B and AB were collected and reviewed (Table 1). The two groups did not differ significantly in terms of age, gender, total number of red blood cells, plasma or platelets transfused. The M score of 0.90 indicated an excellent degree of matching between the two groups. There were also no differences in the TRISS probability of survival, initial 24 hour mortality or overall in hospital mortality. Not

TABLE. Trauma Patient Characteristics

	GROUP A PATIENTS (316)	GROUP B AND AB PATIENTS (166)	P VALUE
GENDER (MALES)	235 (74%)	130 (78%)	0.37
AGE (YEARS)	45 (15-95, 20)	43 (14-90, 20)	0.41
SURVIVAL PROBABILITY (%)	62 (0-100, 37)	64 (0-99, 37)	0.51
TOTAL RBC (UNITS)	11 (0-105, 16)	9 (0-96, 16)	0.21
TOTAL ALL PLASMA (UNITS)	9 (1-116, 15)	8 (1-90, 13)	0.31
TOTAL A PLASMA (UNITS)	8 (1-116, 14)	4 (1-58, 6)	$<$0.0001
TOTAL PLT (DOSES)	2 (0-23, 3)	1 (0-14, 2)	0.42
SURVIVAL INITIAL 24 HOURS	259 (82%)	133 (80%)	0.62
SURVIVAL TO DISCHARGE	208 (66%)	114 (69%)	0.54

Data presented as number (%) or mean (range, SD).

unexpectedly, group A patients received significantly more units of group A plasma compared to group B and AB patients ($p<0.0001$). The number of deaths among group B and AB patients who received incompatible group A plasma in the initial resuscitation did not exceed the number of deaths predicted from baseline (Z score −1.92, not significant). **Conclusion**: The use of emergency issued group A plasma during the initial resuscitation of traumatically injured patients was not associated with increased mortality. The study supports a growing body of evidence indicating the safety of this practice for centers that are unable to maintain thawed AB plasma inventories.

P3-030A

Transcriptome Analysis of Immune-function Genes as Early Predictor of Graft-versus-Host Disease

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Background/Case Studies: Allogeneic hematopoietic cell transplantation (HCT) is curative for hematological malignancies. However, Graft versus host disease (GVHD) is the most common and debilitating complication of HCT as 10-15% HCT recipients die and 25% suffer long-term due to GVHD. Effective but toxic prophylaxes for GVHD (e.g., anti-thymocyte globulin) exist that can be given preemptively to patients with high risk of GVHD. The major barrier to this 'preemptive therapy' is the lack of sensitive and specific assays that can identify patients at high risk of GVHD. Since allo-immune responses generated through recognition of host antigens by donor T cells culminate into GVHD, we performed the transcriptome analysis of 594 immune-function genes at different posttransplant time points to predict ensuing GVHD. **Study Design/Methods**: A total of 157 RNA specimens from 65 first allogeneic HCT recipients were analyzed. RNA was extracted from cryopreserved peripheral blood mononuclear cells (PBMNCs) collected at three early post-transplant time points: one week (n=32), one month (n=65) and two months (n=60) post transplantation. Transcriptome analysis for 594 immune-function genes and 15 internal reference genes was performed using Nanostring based gene expression CodeSet profiling. Empirical Bayes statistics for differential gene expression, receiver operating characteristic (*ROC*) and principle component analyses were performed to identify the gene sets with highest sensitivity and specificity for early prediction of clinically significant GVHD(grade II-IV acute GVHD and/or chronic GVHD requiring systemic therapy). **Results/Findings**: A 'GVHD transcript signature' comprising of highly upregulated 6 genes with T cell related pro-inflammatory functions were identified at one month post transplantation in patients with clinically significant GVHD (median day of onset = 100 days). The genes identified were CD27 (AUC=0.93; $p=3.4X10^{-8}$); *B- and T-lymphocyte attenuator, BTLA ((*AUC=0.92; $p=3.4X10^{-8}$), Inducible T-cell Co-stimulator, ICOS (AUC=0.90; $p=3.5X10^{-7}$), CD5 (AUC=0.87; $p=8.5X10^{-7}$), CD3D (AUC=0.88; $p=8.8X10^{-7}$) and CD28 (AUC=0.91; $p=9.9X10^{-7}$). The GVHD transcript panel predicted clinically significant GVHD with sensitivity of 85% and specificity of 95%. **Conclusion**: The findings strongly suggest that early posttransplant transcript profile of genes with T cell related pro-inflammatory functions has a prominent impact on the occurrence of GVHD. The identified '6-genes GVHD transcript signature panel' is highly sensitive and specific in early posttransplant prediction of patients at high risk of developing GVHD and could pave the way to precision HCT medicine.

P4-030A

Male Plateletpheresis Donors Are an Unrecognized Group with Risk for Iron Depletion

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Background/Case Studies: Most single donor platelet (SDP) donors transition to plateletpheresis donation after a history of whole blood (WB) or double red cell apheresis donations. Many are recruited for SDP donation after a routine CBC screen reveals a high platelet count, a finding often associated with iron depletion (ID). These factors, together with an allowable donation frequency of 24 times per year and an estimated red cell loss up to 54mL per donation, suggest that SDP donors might be at risk for ID. Male SDP donors make up an increasingly large share of the SDP donor population due to TRALI mitigation strategies, so unrecognized ID could adversely impact both donor wellbeing and SDP supply as the new Hb cutoff of 13.0 g/dL for male donors is implemented. **Study Design/Methods**: Male SDP donors considered at risk for ID were identified on the basis of a fingerstick hemoglobin (Hb) < 13.5 g/dL. Routinely collected plasma samples were tested for ferritin by chemiluminescence using a commercial assay, and donors whose results were ≤ 26 ng/mL were mailed a letter with results and counseling messages recommending iron supplements. SDP donor Hb and iron status were characterized by donation intensity, weight, and self-reported use of supplemental iron, which was assessed with a brief survey completed prior to health history. SAS v9.4 was used to merge survey and ferritin results with operational data via the DIN, and to perform data analysis and multivariable logistic regression. This research was supported commercially as an investigator-initiated study and was Institutional Review Board-approved. **Results/Findings**: During the first 8 weeks of this program across 7 regional collection centers, 738 male donors completed 846 SDP donations with a qualifying Hb < 13.5 g/dL (12% of 7030 male SDP procedures). Of these, 62% had low ferritin (LF, ≤ 26 ng/mL) and 31% had Absent Iron Stores (AIS, ferritin < 12 ng/mL). Donation frequency was strongly associated with iron status, with 76% of those giving 16-24 SDP donations in the prior year having LF, 5 times the odds of those giving 0 to 5 times after controlling for Hb, weight, and iron supplementation. Lack of supplemental iron consumption doubled the odds for LF in regression analysis. Future monitoring will assess return behavior and increments in Hb and ferritin by changes in reported supplemental iron use. **Conclusion**: A surprisingly high proportion of male SDP donors have Hb levels below the normal range and will be subject to deferral under the new FDA guidelines, and a large proportion of them have low or absent iron stores. The prevalence of iron depletion in frequent male SDP donors appears comparable to that in male WB donors. Blood center efforts to monitor donor iron status and protect donor health should be extended to donors who primarily or exclusively donate apheresis platelet products.

P5-030A

Non-transferrin-bound Iron Derived from RBC Transfusion Contributes to *Pseudomonas aeruginosa* Biofilm Formation

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Background/Case Studies: Transfusion of older, stored RBCs has been shown to produce circulating non-transferrin-bound iron (NTBI). Human tissues are iron-restricted and iron promotes biofilm formation by certain bacteria, including *Pseudomonas aeruginosa*. Biofilms are responsible for the development of central line-associated blood stream infections (CLABSI) and RBC transfusions are a risk factor for CLABSI. We hypothesize that transfusion of RBCs stored for prolonged periods of time result in an acute increase of circulating NTBI, forming an environment conducive to the development of biofilms and promoting CLABSI. **Study Design/Methods**: Mice (male CD-1) with central venous catheters were transfused one equivalent mouse unit of RBCs retroorbitally and with $1x10^6$ CFU of luciferase-expressing *P. aeruginosa* Xen 41 by tail vein injection. The following day, the mice were transfused another single mouse equivalent of RBCs retroorbitally. Transfusions were either fresh (<24 hours old; n=15) or old (14 days old; n=24). Additional mice received old transfusions plus either apotransferrin (n=15) or vehicle (n=18). CLABSI formation was monitored by biophotonic imaging of microbial bioluminescence. Log-rank statistics were used to compare survival curves. An in vitro biofilm assay was used to test whether elevated transferrin saturation and/or NTBI enhances *P. aeruginosa* biofilm formation. Ferric citrate was added to human serum from a healthy volunteer to create varying iron levels. *P. aeruginosa* ($1x10^6$ CFU) was added to 200μL serum in wells of a 96-well polystyrene plate. Planktonic bacterial growth was monitored by absorbance at OD 600. After 24 hours, biofilm formation was quantified by crystal violet staining. **Results/Findings**: There was a significant survival advantage for mice transfused with fresh rather than old stored RBCs (median survival time not met vs. 84 hours; $P<0.01$), which was abrogated when mice were co-infused with apotransferrin prior to the old RBCs (median survival time not met). Three different *P. aeruginosa* research strains and 2 of 6 patient isolates formed biofilms best in serum with circulating NTBI. The relationship between increasing serum iron and biofilm formation was not linear, with a clear enhancement of biofilm formation only when NTBI was present. Furthermore, 3 of 3 research strains and 4 of 6 patient isolates exhibited increased planktonic bacterial growth in serum with NTBI. The presence of NTBI also changed the kinetic growth curve of the bacteria. **Conclusion**: Together, these data support the hypothesis that the presence of NTBI, in particular, enhances biofilm formation of *P. aeruginosa* in vitro and in vivo in a CLABSI model. Future studies will examine the mechanisms by which NTBI enhances biofilm formation in some, but not all isolates.

P6-030A

Informing Fresh Versus Old Red Cell Management (INFORM) Trial: A Large International Pragmatic Randomized Trial

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Background/Case Studies: Observational studies have suggested that transfusion of older red blood cells (RBCs) compared with fresher RBCs is associated with an increased risk of death. Subsequent randomized controlled trials (RCT) - most underpowered - have not demonstrated harm. We undertook a large pragmatic and adequately-powered RCT to inform this issue. **Study Design/Methods**: In this international, pragmatic RCT, we allocated eligible hospitalized patients who required RBC transfusion to receive the freshest (experimental intervention) or oldest (standard care) RBC units available in the inventory using a 1:2 allocation and waived consent. Inclusion criteria included adult hospitalized patients for whom a RBC transfusion was requested; exclusion criteria included massive hemorrhage, request for uncross matched blood, red blood cell alloimunization, or a clinical need for fresh blood. All study data were obtained from hospitals' transfusion laboratory information systems and electronic medical records. The primary outcome was in-hospital mortality among transfused hospitalized patients with the most common blood groups (A and O); patients of all blood groups were included in a secondary analysis. The primary analysis followed a modified intention to treat approach in which patients who did not receive a transfusion or those not admitted to hospital were excluded. The effect of fresh blood was estimated via a logistic regression analysis adjusting for centre and patient blood group. **Results/Findings**: Between January 2012 and October 2015 we randomized 31,497 patients at 7 hospitals in 4 countries (Canada, USA, Australia and Israel). The primary modified intention to treat analysis included 20,859 group A/O patients: n= 6,937 in the freshest group; and n= 13,922 in the oldest group. The median number of RBC units transfused per patient was 2 (IQR: 2-4) for each group. The median age of the RBCs transfused was 11 days (IQR: 8-16) in the freshest group and 23 days (IQR: 16-31) in the oldest group. The frequency of in-hospital mortality was 9.1% (634/6937) in the freshest group and 8.7% (1213/13,922) in the oldest group: OR 1.05 (95% CI 0.95-1.16; P=0.34). Mortality rates were similar when patients of all blood groups were considered (n=24,737): 9.1% (freshest group) vs. 8.8% (oldest group); OR 1.04 (95% CI 0.95-1.14; P=0.38). **Conclusion**: This large international trial found no difference for the outcome of in-hospital mortality between patients randomized to transfusions of the freshest versus the oldest blood.

Cellular Therapies and Immunotherapies

S1-010A

Processing of G-CSF Mobilized Peripheral Blood Stem Cells (PBSC) from Parental Haploidentical Sickle Cell Trait Donors Undergoing CD34 Enrichment with T cell Addback in Children, Adolescents and Adults with HighRisk Sickle Cell Disease (IND 14359)

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Background/Case Studies: HLA-matched sibling donor (MSD) allogeneic stem cell transplantation (AlloSCT) remains the only curative therapy in high risk patients with sickle cell disease (SCD). Less than 15% of SCD patients have an unaffected HLA MSD and there is a 10-15% increase in graft failure and transplant related mortality (Talano/Cairo et al EJH, 2015). Haploidentical familial donors with SCD trait initiate an opportunity for a new donor source for children with high risk SCD. To overcome haploidentical barriers, it has been shown that CD34 enriched HPC products with T cell addback transplanted in pediatric recipients utilizing a MUD was associated with 100% engraftment and $\leq$15% incidence of grade II-IV aGVHD (Geyer/Cairo et al, BJH, 2012). To collect GCSF-mobilized PB from familial haploidentical SCD trait donors engineered to contain $10x10^6$ CD34+/kg with a T cell addback dose of $2x10^5$ CD3/kg to facilitate engraftment in children with high risk SCD. **Study Design/Methods**: Parental donors (maternal 12, paternal 3) were GCSF mobilized (15mcg/kg/day bid x 4 days) and underwent HPC PB apheresis (Spectra OPTIA, Terumo BCT) beginning day 5. Collection goal was to obtain $10x10^6$ CD34/kg after CD34 enrichment and cryopreservation. CD34 enrichment was performed using the CliniMACS CD34 system (kits were generously provided by Miltenyi Biotec, Cambridge MA). Unseparated cells were cryopreserved separately and added back at time of transplant for a total CD3 dose of $2x10^5$CD3/kg. CD34 and CD3 enumeration was performed by flow cytometry and CD71 (RBC chimerism) by STR. **Results/Findings**: A total of 31 HPC PB products were collected for the 15 SCD patients requiring 2.0 ± 0.32 (SEM) collections (1-5/patient). HPC PB products contained $7.1 \pm 2.$ $x10^{10}$ TNC, 1.3 ± 6.7 $x10^{10}$ CD3 and 5.3 ± 3.7 $x10^8$ CD34. The outcome per HPC product processed was $65 \pm 17\%$ CD34 recovery with $97 \pm 4\%$ CD34 purity, log T cell depletion was $5 \pm .7$ and the target dose cryopreserved per patient was $14 \pm 5x10^6$ CD34/kg. Myeloid and platelet engraftment of all patients was robust with a median of 10 and 16 days. RBC chimerism was $\geq$95% at 6 months and 1 yr. The cumulative incidence of grade II-IV aGVHD was 11.1%. **Conclusion**: These preliminary results demonstrate that CD34 enriched products and T cell addback processed from GSCF mobilized parental SCD trait donors is safe, feasible and results in rapid engraftment, sustained donor chimerism and low incidence of aGVHD. This research was supported by FDA grant 5R01FD004090 (IND14359).

TABLE.

		MB Patients (BMI > 40)			Controls vs	
	Controls	ABW	IBW+30%	IBW	ABW	IBW+30%
Weight (kg)	83 + 18	130 + 24	83 + 15	64 + 12	<0.0001	0.78
CD34/kg/procedure	3.32 + 4.66	2.03 + 2.29	3.15 + 3.61	4.07 + 4.67	0.0013	0.47
Lymphoma	3.09 + 5.88	1.74 + 2.39	2.77 + 3.79	3.56 + 4.90	0.07	0.69
Myeloma	3.46 + 3.75	2.28 + 2.19	3.58 + 3.5	4.51 + 4.44	0.008	0.81
CD34/kg/mobilization	7.48 + 5.95	5.11 + 3.05	8.0 + 4.66	10.34 + 6.07	0.004	0.54
Lymphoma	6.9 + 8.13	3.75 + 2.92	6.17 + 4.48	7.90 + 5.90	0.037	0.65
Myeloma	7.92 + 4.0	6.73 + 2.36	10.1 + 4.09	13.14 + 5.08	0.15	0.014
CD34 Target Reached (% Patients)	130/154 (84%)	32/58 (55%)	47/58 (76%)	52/58 (90%)	0.00009	0.55

S2-010A

Modeling Adjusted Body Weights for CD34 Target Yields in Morbidly Obese Patients

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Background/Case Studies: Autologous peripheral blood stem cell collection (A-PBSCC) in the morbidly obese (MB) can be challenging. In an earlier study, we showed decreased mean CD34/kg yields & CD34 collect rate in MB (n=16) relative to other patients (n=154). In this study, we examined a larger cohort of MB patients undergoing A-PBSCC & modeled the impact of using actual body weight (ABW), ideal body weight (IBW), & IBW+30% for CD34/kg target yields. **Study Design/Methods**: Retrospective study of MB patients undergoing A-PBSCC between 2008-2015. MB were compared against a non-MB control group (n=154 patients, 349 A-PBSCC). Data included age, sex, weight, height, blood volume (BV), diagnosis, mobilization (G-CSF-only; chemotherapy; plerixafor [PXF]), peripheral blood counts, BV processed, #procedures, & CD34 yield. CD34/kg yield per procedure & mobilization were determined at ABW, IBW+30% & IBW. CD34 collect rate (m,slope) was determined by linear regression & corrected for BV processed (CD34/kg/BV), weight (ABW, IBW+30%, IBW) & mobilization regimen. A $P<0.05$ was significant (t-test, X^2). **Results/Findings**: A total of 212 patients & 502 procedures were analyzed, including 58 MB patients &153 procedures. MB patients were significantly heavier than controls (Table: mean BMI=46; range, 40.1-61.3) & required more procedures (p=0.03), especially in myeloma patients (3 vs 1.9, p=0.0002). Mean CD34/kg yields per procedure & mobilization were significantly lower than controls, with 45% of patients failing to reach CD34/kg goal for 1 ($3x10^6$/kg, lymphoma: 42% vs 80%, p=0.0003) or 2 transplants ($6x10^6$/kg, myeloma: 70% vs 87%, p=0.036). Furthermore, mobilization failures were 2-fold higher in MB patients for 1 (12% vs 5.8% controls; p=0.13) & 2 transplants (15% vs 6.3%; p=0.16). As before, the CD34 collect rate was decreased relative to controls (m=0.012 vs m=0.017). Using an IBW+30% adjusted weight for A-PBSCC in MB patients normalized both the CD34 collect rate (m=0.019) & CD34/kg yields (Table) relative to non-MB controls. An IBW+30% also led to a 16% decrease in procedures & 14-22% decrease in PXF usage, especially in G-only mobilized myeloma patients, for a potential total savings of $167,875 in patient charges ($~3000/patient). **Conclusion**: An IBW+30% adjusted weight could be considered for calculating CD34/kg yields in MB patients, with improved collection outcomes & cost savings. Ref: J Clin Apheresis 2011;26:59-60.

S3-010A

Clinical Islet Transplantation Consortium (CIT) Multicenter Analysis of Pancreas Donor Factors Affecting Human Islet Isolation Success

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Background/Case Studies: Beta cell replacement through pancreas or islet transplantation dramatically improves metabolic control in subjects with severe cases of Type 1 Diabetes. As success rates depend on a scarce source, the deceased donor pancreas, identification of donor factors associated with successful islet isolations is critical. The National Institutes of Health established the Clinical Islet Transplantation (CIT) Consortium and eight manufacturing facilities jointly developed and implemented a harmonized process for manufacturing of islets from human pancreases. Identifying donor-based specific markers of islet isolation success may indeed provide a means of improving the success rate of the subsequent islet transplantation. Previous studies have reported donor factors associated with higher success rates in terms of attaining adequate islet numbers for transplantation; however, large-scale trials are lacking. **Study Design/Methods**: In this study, 324 pancreatic islet isolations data including donor variables were analyzed (Univariate and multivariate analyses). The pancreases were processed with the intention to transplant. Donor characteristics and islet isolation characteristics were collected from master batch production record. Donor variables evaluated included age, gender, height, weight and body mass index (BMI). Procurement variables included cause of death, insulin administration, history of hypertension as well as routine biochemical blood screen. Pancreas and isolation variables included pancreas preservation method, pancreas weight, fat content, edematous condition, cold ischemia time, types of collagenases used and digestion time. The outcome was defined as successful or failed islet isolation based on final islet yield of 5,000 IEQ/kg patient body weight. **Results/Findings**: After processing, 154 pancreases did not yield sufficient number for transplantation (47.5%), however 170 preparations were successfully transplanted. Univariate analysis showed that donor gender, weight, BMI, pancreas weight and digestion time positively influence outcome. Multivariable logistic regression analysis identified the positive impact on male donors (OR=0.326, p<0.001) with high BMI (OR=1.123, p<0.001), Roche collagenase (OR=2.409, p<0.0111) and pancreas digestion time (OR=0.921, p<0.0072). **Conclusion**: In summary, this multi-center analysis revealed that careful donor selection may be of assistance to improve islet isolation outcomes and increase the odds of manufacturing islet cell products that can meet product release criteria for clinical transplantation.

S4-010A

Building an Ethnically Diverse Cord Blood Bank

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Background/Case Studies: In 2011 the provincial and territorial governments approved funding for a national public cord blood bank (CBB), which was subsequently established by Canadian Blood Services. The mandate from government is that the CBB adequately represent the unique ethnic diversity of the Canadian population in order to increase transplant opportunities for Canadian patients who are unable to find a stem cell match. The selection of the collection sites in four Canadian cities was achieved through a Request for Proposal process with a number of critical factors including: the hospital having a minimum of 4000 deliveries annually as well as a minimum of 20% ethnic diversity of mother/infants delivering at the hospitals. In addition, to promote an ethnically diverse inventory, acceptance criteria for qualifying cord blood units (CBU) was implemented; pre-production Total Nucleated Cell (TNC) of $1.5X10^9$ for Caucasian and $1.3X10^9$ for non-Caucasian. The slightly lower threshold was established to allow for larger numbers of CBUs while maintaining quality standards for donors with less common haplotype HLA frequencies. **Study Design/Methods**: This study analyzed the ethnic breakdown of all CBUs currently in inventory at the CBB. Quality control characterization including collection volume, TNC, CD34, viability and CFU content was reviewed within the different ethnic groups. **Results/Findings**: Between Sept 30, 2013 and Jan 19, 2016 the CBB collected a total of 7,812 CBUs. 1,361 CBUs have qualified for banking with 813 of the qualifying units currently released/available for transplant.

TABLE. Cord Blood Bank Inventory Analysis (Sept 30, 2013 - Jan 19, 2016)

Ethnicity Group	CBU Inventory	% of Total Inventory	Collection Volume (mL)	TNC (x107)	Total CD34+ (x106)	Viability (%)	Total CFU-GM (x105)
Caucasian	398	49.0	118.1	144.85	6.26	96.7	23.35
Non-Caucasian	415	51.0	114.9	136.34	5.70	96.5	21.81
Non-Caucasian Breakdown							
Multiple Ethnicity	196	24.1	112.6	130.89	5.35	96.5	20.84
Asian	122	15.0	108.9	125.00	4.79	95.8	18.50
Black	47	5.8	113.6	124.19	4.74	96.1	19.47
Arab	34	4.2	112.3	121.71	5.30	97.2	18.00
Hispanic	10	1.2	117.5	144.20	6.05	96.4	22.40
Aboriginal	3	0.4	130.6	135.96	9.91	95.1	16.67
Other	3	0.4	122.4	156.55	4.45	96.0	18.00
Total Inventory:	813	100.0					

Ethnic breakdown of CBB inventory (self reported ethnicity 51% non Caucasian vs. 49% Caucasian), as well as quality characterization is identified below. **Conclusion**: Cord blood inventory should not only be ethnically diverse but must be at a certain "quality" for selection at transplant sites. The Cord Blood Bank, an AABB accredited bank, is fulfilling its mandate to provide ethnically diverse, HLA-diverse, quality cord blood units to patients that reflect Canada's ethnic diversity. A lower TNC has allowed for inclusion of more non-Caucasian donors without compromising quality.

S5-010A

Comparative Analyses of Industrial Scale Human Platelet Lysate (PL) Preparations

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Background/Case Studies: Efforts are underway to eliminate fetal bovine serum (FBS) in cultures of mesenchymal stromal cells (MSC) that are destined for clinical use. An emerging viable replacement option for FBS is human platelet lysate (PL) either as a plasma (PL-P) or serum (PL-S) based product. **Study Design/Methods**: Using current Good Manufacturing Practices (cGMP), seven industrial scale PL manufacturing runs (i.e. lots) were initiated with average volumes of 24.2 ± 2.3 liters of pooled platelet-rich-plasma (PRP). An evaluation of the manufactured lots was conducted by comparing the biochemical and protein compositions of each PL lot. The stability of PL was assessed over a two-year time frame. Proliferation and differentiation responses of MSCs and the global gene expression profiles of MSC produced in culture with PL were compared to MSC generated with FBS. **Results/Findings**: Electrolyte and protein levels were relatively consistent among PL lots with only slight variations in glucose and calcium levels. Quantitative protein arrays showed that 367 of 423 proteins were present in all three of the tested PL lots. Hierarchical cluster profiling indicated that two PL lots were more similar to one another than to a third lot. All seven lots were as good as or better than FBS in expanding MSCs. Greater differences in gene expression profiles of MSC produced from different starting cellular materials were observed than from MSCs cultured with PL or FBS. PL-S stored at −80°C remained stable over two years of storage. **Conclusion**: These data support the use of PL as a substitute for FBS in MSC cultures. MSCs produced from the same starting material show comparable gene expression profiles when cultured with FBS or PL. Similarities as well as differences in the protein composition of PL exists and more experiments are required to determine the significance of this observation as it relates to specific applications of PL.

S6-010A

A Potential Cell Therapy Candidate for Autoimmune Disease Treatment by Ex Vivo Selectively Induced and Efficiently Expanded CD8$^+$ Regulatory T Cells

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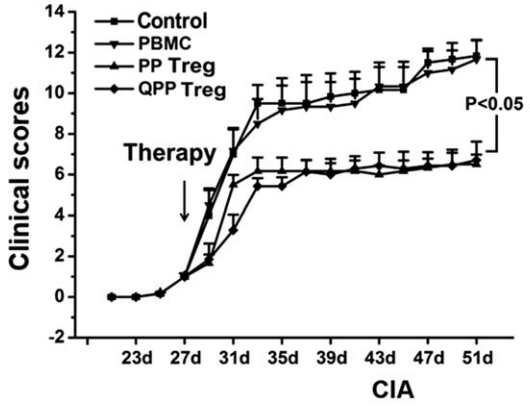
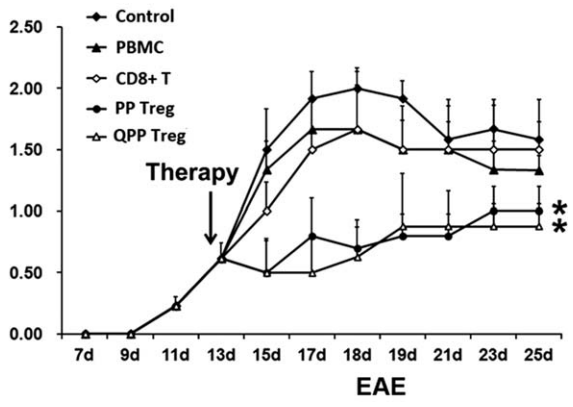
Background/Case Studies: Autoimmune disease (AID) such as rheumatoid arthritis and multiple sclerosis is an immune system disease which were painful and caused serious destruction to the human body. Research shows that regulatory T cells (Treg) in AID patients are deficient or disfunctional and transfusing Treg has an efficient therapeutic function on AID models. However, due to the limited number of natural Treg, amplify Treg in vitro is needed. Unfortunately, expanded CD4$^+$Treg could transform into effect T cell in inflammation. Therefore, we aim to investigate the potential therapeutic function on AID by a novel cell: ex vivo selectively induced and expanded human polyclonal CD8$^+$Treg. **Study Design/Methods**: Collagen-induced arthritis (CIA) and experimental autoimmune encephalomyelitis (EAE) mice were established as AID models. Human CD8$^+$T cells (from PBMC) were cultured with anti-CD3/28 beads and IL-2, induced with TGF-β1 or TGF-β1+rapamycin or TGF-β1+rapamycin+all-trans retinoic acid in vitro. The selectively induced Tregs were restimulated for another 3 rounds. The 1st and the 4th round Tregs (PP and QPP) were transfused into CIA and EAE mice. The therapeutic function and mechanism were investigated. **Results/Findings**: Ex vivo induced and expanded human CD8$^+$Treg has an efficient therapeutic function on CIA and EAE mice. Compared the suppression and amplification ability we found that TGF-β1+rapamycin was the most appropriate induced condition. The obtained Tregs were Foxp3$^+$IL-17A$^-$, were stable in inflammation, expanded 10000 times and adopted vigorous suppression and anergy ability. Both PP and QPP Treg therapy could significantly alleviate the severity of diseases. In CIA, the clinical score, the level of anti-collagen IgG antibody and cartilage destruction were significantly reduced after Treg treated. In EAE, the clinical score and lymphocytic infiltration in brain were reduced as well. Moreover, CD8$^+$Treg treatment significantly reduced IFN-r$^+$ and IL17A$^+$ CD4$^+$T cells in CIA spleen and EAE brain, increased self CD4$^+$Foxp3$^+$Treg in CIA spleen, revealing the fact that through this way the damage to the tissues can be reduced. **Conclusion**: The results revealed that ex vivo efficiently induced and expanded human CD8$^+$Treg has an effective therapeutic function on AID models: CIA and EAE mice. This research can provide a novel cell for potential cell therapy on AID and improve the utilization of blood component.





Donor Recruitment, Retention and Adverse Events

S7-010B

Non-Compliance with Men Who Have Sex with Men Criterion in Blood Donors

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Background/Case Studies: Our deferral period for men who have sex with men (MSM) was changed in July 2013 from indefinite to 5 years. A study was conducted to evaluate donors' compliance with the new MSM criterion. **Study Design/Methods**: An anonymous online survey was conducted on male donors who gave blood between January 20 and August 9, 2015. Questions related to donor demographics, drug use, sexual history including MSM activity, whether donors had ever omitted to disclose relevant information in their donor questionnaire, whether donors had donated blood in order to be tested, and attitudes towards MSM donating blood. **Results/Findings**: A total of 12,127 donors were invited via email; 4636 answered. After excluding cases that did not meet inclusion criteria, 4,167 questionnaires were analyzed (response rate 34.4%). Respondents were older and less likely to be first-time donors than all those who donated during the study period. Proportion of donors who had MSM activity was: ever 1.01%; in past 6 months 0.29%; 6-12 months 0.02%; 1-5 years 0.10%. Our non-compliance (NC) rate was 0.41%. Compared to compliant donors, non-compliant ones were younger, more likely to be first-time donors and more likely to be non-compliant to other selection criteria (table). After adjusting for age NC increased to 0.65%. Overall 56.18% of respondents believe that MSM should be allowed to donate blood if they meet all other selection criteria. Following the change in the deferral period, there has been no male donor screened as HIV positive. **Conclusion**: Compliance with a 5-year deferral period for MSM was very high in our study.

Since there was no increase in the prevalence of HIV infection in our donor population, reducing the deferral period from indefinite to 5 years has not jeopardized the safety of blood. Our results even indicate that a one year deferral would reduce non-compliance to 0.31%. This is similar to what has been observed in Australia and United Kingdom.

S8-010B

The Effect of Iron Replacement on Platelet Counts in Blood Donors

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Background/Case Studies: Thrombocytosis is associated with iron deficiency in patients with anemia or chronic bleeding and resolves with iron therapy. Many healthy blood donors have low iron stores, with or without anemia. In a blood center that has offered iron tablets to blood donors since 2005, we evaluated the effect of iron status and replacement therapy on platelet counts (PLT). **Study Design/Methods**: A record review of 1,273 deferred whole blood donors [fingerstick hemoglobin (Hb) < 12.5 g/dL] between 12/08/2005 to 01/29/2014 extracted laboratory results (CBC, serum iron panel) and self-reported compliance with oral iron. A subset of 291 donors (243 females; 48 males) returned to donate, reported taking at least 7 days of iron, and had complete laboratory data. These donors comprised a group with normal ferritin (iron replete) or low ferritin (iron-depleted) at first visit, defined as ferritin < 20 μg/L for women and <30 μg/L for men. Platelet counts and iron parameters before and after iron replacement were compared in a paired analysis in each group. **Results/Findings**: Among 1,273 deferred whole blood donors, 55% (619 of 1128) of the women and 70% (102 of 145) of the men were iron depleted. The average platelet count was significantly higher in donors with low iron stores compared to iron-replete donors (PLT, females, 286 vs. 268 x $10^3/\mu$L, p<0.0001; males, 246 vs. 222 x $10^3/\mu$L p=0.045). Thrombocytosis (PLT > 400 x $10^3/\mu$L) was observed in 4.4% of iron-depleted and 2.0% of iron-replete donors (p-value, 0.017). In the subset analysis (Table), oral iron significantly improved iron status in both groups, and significantly increased Hb in iron-depleted but not in iron-replete donors. Oral iron therapy caused a significant decrease in platelet counts of about 20 x $10^3/\mu$L in female donors who were iron depleted at their first visit, but no change in the iron-replete group. In the smaller subset of male donors, the same trends were seen. **Conclusion**: Blood donors with low iron stores had higher average platelet counts than those with normal iron balance, but the incidence of thrombocytosis with iron depletion was only 4.4%. Iron therapy caused a significant but modest decrease in platelet counts in iron-depleted donors but not in donors with adequate iron stores. The results suggest that iron balance influences platelet counts in healthy blood donors.

		Compliant		Non-compliant		p-value
		N	%	N	%	
Age	18-19	86	2.08	3	17.65	<0.0001
	20-24	247	5.97	6	35.29	
	25-29	236	5.71	2	11.76	
	30-39	443	10.71	4	23.53	
	40-49	640	15.47	0	0	
	≥50	2 484	60.06	2	11.76	
First time donor	NO	3 925	94.94	11	68.75	0.0009
	YES	209	5.06	5	31.25	
Ever snorted drugs	NO	3 731	91.87	13	76.47	0.0448
	YES	330	8.13	4	23.53	
Snorted in the past 6 months	NO	3872	99.64	16	94.12	0.0001
	YES	14	0.36	1	5.88	
Sex with an HIV+ partner	NO	4 057	99.66	15	88.24	0.0019
	YES	14	0.34	2	11.76	
Tattoo in past 6 months	NO	3906	99.72	16	94.12	<0.0001
	YES	11	0.28	1	5.88	
Number of sexual partners in past 12 months	None	573	14.34	0	0	<0.0001
	1	3 187	79.73	9	52.94	
	2-4	186	4.65	5	29.41	
	5-9	31	0.78	3	17.65	
	10-29	14	0.35	0	0	
	30-49	2	0.05	0	0	
	≥50	4	0.10	0	0	

S9-010B

High Ferritin in Blood Donors

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Background/Case Studies: Ferritin measurements were implemented to prevent iron deficiency in regular blood donors. The question arose regarding blood donors with high ferritin levels. Are they ill with unrecognized infection or cancer? Is it alcohol? Or do they have genetic determined increased uptake? To answer this question, collaboration between Centre for Donor Haemoglobin and Iron, Department of Haematology and Department of Genomic Medicine was established. **Study Design/Methods**: Between January 30th 2012 and March 24th 2014, 49 (f=6, m=43) consecutive donors were included prospectively. One additional male had initial HFE testing done (he was heterozygous for HFE282), but did not want further investigations. Inclusion criteria were either ferritin value above 1000μg/L or repeated high ferritin with at least one value above 500μg/L. These donors were offered relevant clinical examination including laboratory tests and genomic analysis for mutation in HFE, HFE2, HAMP and TFR2. **Results/Findings**: In the 49 donors included, the haemoglobin concentration was above the limit for donation (≥12.5 and 13.5 g/dL in female and male donors respectively), and all were accepted for donation. Mean and range for age was 41 (21-63) years for the men and 46 (22-66) years for the women. The median and range for ferritin at inclusion was 539 (389-1370) μg/L for the men and 433 (354-550) μg/L for the women. Median and range for number of donations was 5 (1-100) for the men and 21 (4-115) for the women. Forty (82%) were positive for one or more mutations and 9 (18%) were negative. Two (4%) of the mutation negative donors had previously unrecognised chronic gut and lung infection respectively. One donor of Korean origin had clinical hemochromatosis, but was negative for the mutations investigated for in this study. One donor heterozygous for HFE 63 reported high alcohol consumption. Seventeen had classical HFE hemochromatosis mutations, with 10 homozygous for HFE282 and 7 compound heterozygous for HFE 282 and 63. All mutations are shown in table1. **Conclusion**: Among 49 blood donors with ferritin > 500μg/l, 82% had mutations relevant for iron-uptake. The study only caused 4% of these donors, namely the two donors with chronic inflammation, to be deferred temporarily. In general this group of donors with high ferritin tolerate regular donations well and donors with hemochromatosis mutations may tolerate donation 4 times/year or more.

TABLE.

Female Donors	Iron Depleted (n=151)			Iron Replete (n=92)		
Mean (SD)	Visit 1	Visit 2	p-value	Visit 1	Visit 2	p-value
Venous Hb (g/dL)	12.0 (0.7)	12.6 (0.7)	<0.0001	12.5 (0.6)	12.5 (0.7)	0.87
PLT (x1000/μL)	296.6 (72.0)	276.8 (61.1)	0.011	270.9 (56.2)	270.4 (56.7)	0.95
Ferritin (μg/L)	9.8 (4.2)	23.4 (12.0)	<0.0001	43.6 (28.6)	56.2 (35.3)	0.009
Male Donors	**Iron Depleted (n=37)**			**Iron Replete (n=11)**		
Mean (SD)	Visit 1	Visit 2	p-value	Visit 1	Visit 2	p-value
Venous Hb (g/dL)	12.5 (0.8)	14.1 (1.0)	<0.0001	12.9 (0.5)	13.2 (0.8)	0.41
PLT (x1000/μL)	257.4 (69.5)	234.3 (52.5)	0.11	213.5 (60.8)	208.3 (47.7)	0.83
Ferritin (μg/L)	10.5 (5.7)	32.4 (16.4)	<0.0001	59.9 (31.7)	86.5 (43.5)	0.12

TABLE. Mutations

Donors with Ferritin>500	Donors	Mutations	HFE282	HFE63	HFE65	HFE2	HAMP	TFR2
0 mutations	9	0						
1 mutation	18	18	4	9		1		4
2 mutations	18	36	22	9	1		1	3
3 mutations	3	9	4	2			1	2
4 mutations	1	4	2			1		1
Total	49	67	32	20	1	2	2	10

S10-010B

Donor Adverse Events Requiring Outside Medical Care: Donor Hemovigilance Results 2012-2014

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Background/Case Studies: A Donor Hemovigilance (DHV) program allows blood collecting organizations (BCOs) to report and benchmark donor adverse events on a centralized platform. Reports of donors who seek or are referred for medical care outside of the donor center can be an important indication of the severity of a donor reaction. Here, medical care that was delivered outside of the blood center to donors having adverse reactions from 2012-14 was analyzed based on reports by participating BCOs. **Study Design/Methods**: US BCOs participating in the DHV program from 2012-14 (8 blood centers and 2 hospitals) reported their monthly donations and adverse reactions based on various donor attributes including age, gender, race, collection site, donor history, donation type, and any outside medical care. Reaction rates were calculated as reactions per 1,000 donation procedures. For the calculation of reaction rates, reactions without corresponding reports of monthly denominators were excluded. **Results/Findings**: A total of 3,641,762 donations (1,175,262 donations in 2012, 1,154,370 donations in 2013, and 1,312,130 donations in 2014) were reported to the DHV program. There were 84,145 donor adverse reactions reported (<2.5% of donations). The overall reaction rate for non-therapeutic donations was 23.1/1,000 donations. Vasovagal reactions were the most common adverse donor reaction 16.1/1,000 donations. Of all types of reactions reported, there were 954 donors who were referred to or reported receiving outside medical care (1:88 reactions). These donors were most likely to receive outpatient care (38.1%), 9.1% of which were treated in the Emergency Room. Of the donors receiving additional medical care, 4.2% required hospital admissions. Of the reaction types, 38.6% of all injuries (not needle related), 33.3% of major cardiovascular events, 13.3% of allergic reactions, 1.6% of local needle-related injuries, 0.8% of vasovagal and 0.2% of apheresis reactions required some outside medical care. Among those donors receiving outpatient care, 40.5% (147/363) were related to local injury due to needle; of which 53.7% (n=79) had hematoma/bruise. Among the hospital admissions, 80.0% (32/40) were related to vasovagal reactions; of which 68.8% (n=22) were due to loss of consciousness (LOC). **Conclusion**: Less than 2.5% of blood donations results in adverse donor reactions. Of these only a very small fraction led to severe reactions with donors seeking or being referred for outside medical care. The most frequent type of reaction, vasovagal reactions (1:62 donations), was least likely to require additional medical care, although when care was required these donors were more likely to be admitted to the hospital. Most reactions of any type that required additional care were treated on an outpatient basis.

S11-010B

Comparison of Donor and General Population Demographics: A BEST Collaborative Group Study

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Background/Case Studies: Both the general population and the donor base are aging in most developed countries, with possible adverse consequences for blood availability. We compared the age and sex of blood donors vs. the general population in 2001 and 2011. **Study Design/Methods**: The numbers of male and female whole blood/apheresis donors and males and females in the general population in 12 countries (17 blood centers) in 2001 and 2011 were obtained from local donor databases and population statistics and divided into demographic categories. The % of total donors and % of the general population in each demographic category was calculated, as was the difference in the % of the donor vs. the general population for each category. A positive % indicates over-representation of the age and gender category in the donor population, a negative % indicates under-representation. The difference between 2011 and 2001 was similarly calculated, with a positive % indicating increased representation of the category in 2011 vs. 2001. **Results/Findings**: Results from selected jurisdictions are shown in the table. Overall female donors are over-represented in younger and under-represented in older age groups. In North America, the youngest age group is over-represented; in many other countries middle-aged donors tend to be over-represented. In 2011, in general, the over- representation of the youngest age cohort increased, the middle-aged peak donation cohort aged, and there was increased participation by 61-71 year old donors.

		% donor – % general population							
		16-25*		26-40		41-60		≥61**	
		Male	Female	Male	Female	Male	Female	Male	Female
USA	2001	1.8	3.6	−0.8	0.4	3.2	1.6	−2.8	−6.9
	2011	6.5	7.5	−2.8	−1.8	0.4	0.0	−3.0	−6.9
	Change	**4.7**	**3.9**	−2.0	−2.2	−2.8	−1.6	−0.2	0.0
CBS, Canada	2001	1.3	4.6	0.1	2.1	5.5	1.9	−6.0	−9.7
	2011	1.9	5.1	−0.9	−0.5	4.7	3.3	−5.1	−8.5
	Change	**0.5**	**0.5**	−1.0	−2.6	−0.8	**1.4**	**0.9**	**1.2**
Héma-Québec Canada	2001	−0.8	2.7	0.7	1.5	10.1	2.0	−5.8	−10.6
	2011	3.2	7.5	−1.9	−0.1	5.2	1.7	−4.9	−9.9
	Change	**4.0**	**4.8**	−2.6	−1.6	−4.9	−0.3	**0.7**	**0.7**
England & N. Wales	2001	−1.1	2.0	2.1	4.9	6.6	6.1	−8.4	−12.3
	2011	−0.5	2.4	−1.6	1.5	6.3	6.5	−5.9	−8.8
	Change	**0.6**	**0.4**	−3.7	−3.4	−0.3	**0.4**	**2.5**	**3.5**
Netherlands	2001	−4.5	−2.1	−1.4	1.0	15.1	4.3	−3.1	−9.3
	2011	−3.9	0.5	−2.9	1.6	8.4	6.2	−1.7	−8.2
	Change	**0.6**	**2.6**	−1.5	**0.6**	−6.7	**1.9**	**1.4**	**1.1**
Australia	2001	−2.6	3.2	−2.3	1.6	5.2	6.6	−4.7	−7.5
	2011	1.0	5.1	−1.0	−0.4	2.8	2.4	−3.7	−6.2
	Change	**3.6**	**1.9**	**1.3**	−2.0	−2.4	−4.2	**1.0**	**1.3**

Disclosure of Commercial Conflict of Interest

TABLE. Plasma Protein and 99.9% Confidence Intervals for Difference in Means Stratified by First and Multiple Donations

Protein Type	First Mean	First Range	Multiple Mean	Multiple Range	Change Mean %	99.9% C.I. Mean Difference First - Multiple	p
Total Protein	6.926	1.3-9.9	6.463	3.0-9.0	−7%	0.441, 0.485	<.0001
Albumin	4.097	0.8-6.1	3.840	1.6-5.4	−6%	0.244, 0.272	<.0001
Alpha-1 Globulin	0.300	0.1-1.9	0.303	0.1-0.7	+1%	−0.004, −0.001	<.0001
Alpha-2 Globulin	0.696	0.1-1.4	0.666	0.2-1.2	−4%	0.027, 0.035	<.0001
Beta Globulin	0.814	0.1-3.4	0.778	0.3-2.6	−4%	0.032, 0.040	<.0001
Gamma Globulin	1.020	0.0-4.0	0.878	0.0-2.8	−14%	0.132, 0.152	<.0001
Albumin/TP Ratio	0.593	0.3-0.8	0.595	0.4-0.7	+0.3%	−0.004, −0.001	<.0001

Conclusion: Over-representation of young donors in North America dissipates by young adulthood. Increased reliance on an aging cohort of middle-aged donors is evident in many countries. These differences likely reflect variable recruitment and retention strategies, but perhaps also different interest in donation at different life stages.

S12-010B

A Comparative Study of Plasma Protein Levels within Source Plasma Donors

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Background/Case Studies: The effects of frequent and long-term plasma donation effects are unknown; therefore, an accurate assessment of Total Protein (TP) and protein fractions are critical to ensure donor safety. Source plasma donors are closely monitored using Total Protein and serum protein electrophoresis (SPE). The purpose of this study was to evaluate Total Protein and Serum Protein fractions within first time and repeat donors. Repeat donations are defined as the second and subsequent units. The purpose of this analysis is to determine if frequent plasma donation alters plasma protein levels. **Study Design/Methods**: Over a 4-month period, 131,816 donors (first donation 116,520; second and multiple donations 15,296) were tested using automated instruments (AU680 and Capillarys) for serum Total Protein and protein fractions (Albumin, Alpha-1 globulins, Alpha-2 globulins, Beta globulins (Beta-1 and Beta-2), and Gamma globulin), respectively. Source plasma donors are deferred from subsequent donation when their Total Protein level is <6g/dL or >9g/dL and when individual SPE fractions are outside reference ranges. Descriptive statistics (Means, T-tests for the differences in means, and 99.9% Confidence Intervals) were performed using SAS 9.4. **Results/Findings**: When comparing means, the second and subsequent donations were significantly lower for serum Total Protein, Albumin, Alpha-2 globulin, Beta globulin, Gamma globulin variable proteins; only Alpha-1 globulin was slightly higher in the multiple donations category. Of particular note is the large reduction, 14%, in the mean Gamma globulin of donors who gave multiple times. There was also a small increase in the Albumin to Total Protein ratio in the multiple donors. For Total Protein levels: 7.31% (8513/116520) of first donation donors were deferred as compared to 18.21% (2786/15296) second/multiple donations donors, $p<0.0001$. **Conclusion**: Source plasma donors with subsequent donations are more often deferred and have decreased levels of serum Total Protein and protein fractions with multiple, frequent donations. The clinical significance of reduced Gamma globulin in the plasma of donors with multiple donations is not known.

Transfusion-Transmitted Infectious Diseases: Zika Virus

S13-010C

Detection of Zika Virus in Puerto Rico Blood Donations

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Background/Case Studies: The U.S. FDA issued recommendations in February 2016 to reduce the risk of transfusion-transmitted Zika virus (ZIKV), including cessation of blood collections in areas of active ZIKV transmission, unless donations are screened with a ZIKV nucleic acid test (NAT) or are pathogen reduced (PR). Puerto Rico was required to discontinue collections, as no FDA-approved NAT test was available and PR is available only for plasma and platelet products. In response to FDA recommendations, a qualitative PCR NAT assay was developed to detect ZIKV RNA in plasma from donors of whole blood and blood components. **Study Design/Methods**: The cobas®

TABLE. Summary of Testing Results on Donations Reactive with cobas® Zika

	cobas® ZIKA		Modified CDC		Serology		
Sample ID	IDT	Simulated MP	PCR	Mean VL	IgG	IgM	PRNT
1	R	R	Equivocal	4.20E+02	Negative	Negative	N/A
2	R	R	Positive	2.70E+03	Positive	Positive	Pending
3	R	R	Positive	5.90E+06	Negative	Negative	N/A
4	R	R	Positive	7.90E+03	Negative	Negative	N/A
5	R	R	Positive	5.40E+04	Negative	Negative	N/A
6	R	NR	Positive	3.20E+02	Inconclusive	Equivocal	N/A
7	R	R	Positive	4.90E+05	Negative	Negative	N/A
8	R	R	Positive	7.10E+03	Negative	Negative	N/A
9	R	R	Positive	7.60E+04	Equivocal	Negative	N/A

R, Reactive; NR, Non-Reactive; N/A, Not applicable

Zika test for use on the cobas® 6800/8800 Systems was developed to detect all ZIKV lineages. Performance was established with studies including specificity, sensitivity, limit of detection (LoD), potential interfering substances, matrix equivalency, and cross reactivity. The FDA approved use of the test as an Investigational New Drug (IND). Testing of individual blood donor (IDT) samples from Puerto Rico began April 3, 2016. Reactive index donations were retested in simulated mini-pools (MP) of 6. Reactive index donations were also tested by a reference laboratory using a modified CDC PCR ZIKV assay, estimated viral load (VL), ZIKV IgM and IgG antibody ELISA, and plaque reduction neutralization test (PRNT) for IgM reactive samples. Donors with reactive results were invited to enroll in a follow-up study. **Results/Findings**: To date, 3,560 donations have been screened by cobas® Zika, and 10 (0.28%) tested reactive. Additional results for the first 9 of these donations are available to date (Table 1). **Conclusion**: The cobas® Zika test successfully identified ZIKV positive donations and permitted resumption of collections in Puerto Rico. The incidence is expected to increase as mosquito season peaks. This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201600010C. cobas® Zika and cobas® 6800/8800 Systems are not commercially available in the U.S. for blood screening use.

S14-010C

The Risk of Transfusion-transmitted Zika in a Non-endemic Country: A Monte Carlo Simulation to Evaluate this Risk and the Efficacy of Travel Deferral Scenarios

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Background/Case Studies: Many non-endemic countries apply a 28-day deferral for blood donors who recently traveled in countries affected by Zika. However, the quantitative rationale for this 28-day period is not clear. Zika appears to behave like other, similar flaviviruses, with periods of incubation and viremia that usually do not exceed five to seven days. There is however some uncertainty around these data; some persons might remain viremic for longer periods, due to intrinsic variability of the infectious process. Other parameters that will determine the risk to transfusion are also prone to variability. We used Monte Carlo simulations to better quantify this risk and also to estimate the efficacy of various temporary deferral scenarios. **Study Design/Methods**: The model considered the following parameters: 1) The probability that a donor recently returned (8 weeks or less) from a Zika-endemic region, based on a donor travel survey conducted in our jurisdiction: uniform distribution, 5.87% to 6.88%; 2) The duration of travel: triangular distribution, centered at 10 days, extremes of 7 and 14 days; 3) The daily risk of acquiring Zika, estimated at 1/13,400, based on a previously published estimate of the risk of acquiring Dengue while travelling to Singapore, adjusted for the relative attack rates of the Zika and Dengue epidemics; 4) An incubation period with a loglinear distribution (mode at 5 days; 99th percentile at 12 days); and 5) A duration of asymptomatic viremia with a loglinear distribution (mode at 5 days; 99th percentile at 18 days). We assumed a 100% risk of transmission of Zika by a product obtained from a viremic donor. We ran the simulation 20 times, each with 10 million iterations. **Results/Findings**: In the absence of any travel deferral, our 20 simulations showed that on average, 32 donors (range: 20 to 46) would be able to donate while still being at risk of transmitting Zika, corresponding to a rate of 1:312,500 (range: 1:217,000 to 1:500,000). None of these donors would be viremic beyond 21 days after returning from their travel. Therefore, the risk of obtaining a donation from a viremic individual, under a 21-day deferral scenario, is less than 1:200,000,000. With a 14-day temporary deferral, only 9 donors out of 632 infected donors would be able to donate beyond this deferral period while still being viremic, a risk of 1:22,222,000. **Conclusion**: A 21-day temporary travel deferral offers an extremely wide margin of safety for the possible transmission of Zika by a donation obtained from someone who recently returned from a country where the virus is circulating. Longer periods would offer no significant additional protection, while increasing donor deferrals unnecessarily.

S15-010C

Clinical Performance of Hologic/Grifols NAT and CDC Real-Time PCR Assays for Detection of Zika Virus

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Background/Case Studies: Zika virus (ZIKV), an arbovirus transmitted by Aedes mosquitoes, has spread rapidly throughout most of Latin America during 2015 and early 2016, with severe neurological consequences in fetuses and adults. ZIKV has the potential for transfusion transmission (TT), with high rates of viremia documented in donors during the 2013-2014 French Polynesia outbreak and several cases of probable TT recently reported in Brazil. A ZIKV IgM ELISA test and a ZIKV real-time RT-PCR (rRT-PCR) test developed by the CDC for diagnostic applications received emergency use authorization (EUA) from the US FDA in February-March 2016. A ZIKV-specific nucleic acid amplification test (NAT) on an automated high-throughput NAT system (Panther) is under development by Hologic/Grifols. We characterized the analytical performance of the rRT-PCR and NAT assays and compared their clinical sensitivities using clinical plasma samples from the 2015-2016 Brazilian ZIKV outbreak **Study Design/Methods**: The analytical performances of the rRT-PCR and NAT assays were compared using a 25 member coded ZIKV NAT panel developed by BSRI. Clinical specimens, consisting of 144 plasma samples (500-1000 uL volume) collected from Brazilian subjects with clinical symptoms suggesting possible Zika, Chikungunya or Dengue virus infection, were diluted and tested by ZIKV rRT-PCR (1:7 dilution) and NAT (1:8 dilution). Samples that tested positive after dilution and had adequate volumes remaining were re-tested neat for detection of ZIKV RNA and IgM. **Results/Findings**: The Hologic/Grifols NAT assay was >100-fold more sensitive than diagnostic rRT-PCR assays (95% Limits of Detection [LOD] ~12 vs. ~1400 copies/mL, respectively). rRT-PCR testing of diluted clinical plasma samples identified 30 ZIKV+ samples out of a total 144 samples. Half the PCR+ samples and all PCR- samples were tested by NAT in a simulated 8 sample pool. All PCR+ specimens and 18 PCR- specimens were reactive by NAT. Of the 18 incremental NAT yield samples, 14 samples were tested neat by rRT-PCR, of which 4 tested positive. One of 18 incremental NAT yield samples was ZIKV IgM+ (negative by PCR). Of 73 samples that tested negative by NAT in a simulated 8 sample pool, 11 samples were positive when tested neat by NAT. **Conclusion**: The Hologic/Grifols NAT assay detected an additional 21 ZIKV RNA+ clinical samples out of 106 total samples tested, at least 10 of which were missed by the EUA ZIKV PCR assay, resulting in a 38% (21/55) incremental yield rate. Use of a highly sensitive NAT assay enhances detection for clinical diagnosis and monitoring. A subset of low viral load samples has ZIKV antibodies that may be detectable if clinical cases are tested for both ZIKV RNA and IgM.

S16-010C

Effective Inactivation of Zika Virus by Nucleic Acid Targeted Adducts

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Background/Case Studies: The mosquito-transmitted Zika virus (ZIKV) caused sporadic cases in Africa and Asia since its discovery (1947), followed by a major outbreak in Yap (2007). A 28,000-case epidemic in French Polynesia (2013), brought attention to the previously obscure virus, and 3% of asymptomatic blood donors tested positive for ZIKV RNA. In 2015 an outbreak occurred for the first time in the Americas, beginning in Brazil and spreading across the American continent and the Caribbean. Infection is usually asymptomatic, or causes mild symptoms, however the Americas outbreak has highlighted ZIKV's infrequent neurologic conditions including microcephaly and Guillain-Barré syndrome. Frequent asymptomatic infections, as well as the potential for sexual transmission, raises the possibility of transfusion-transmitted infection (TTI) and complicates ZIKV control with standard measures. Two probable TTI cases have been reported in Brazil. The risk of TTI may be reduced by use of the photochemical INTERCEPT™ Blood System pathogen reduction (PR) technology previously demonstrated to be effective for other arboviruses (CHIKV, WNV, DENV). The same PR system was effective for the inactivation of >6.57 log ZIKV in human plasma (Aubry M, *et al.*). The mode of action (MOA) of the technology is through formation of irreversible covalent adducts with nucleic acids, and a technology with the same MOA is under development for RBC, using amustaline and glutathione (GSH). Here we report that these PR technologies inactivate ZIKV in RBC, and platelet (PC) components irrespective of the suspension medium. **Study Design/Methods**: PC in either 65% platelet additive solution (PAS) or 100% plasma, or RBC prepared in AS-5 (n=3; one with none - LR RBC), were inoculated with ZIKV (CDC PRVABC59 strain; ~10^7pfu/mL). PC were treated with amotosalen and low energy UVA (3 J/cm^2) light. RBCs were treated with amustaline/GSH (0.2 mM/20 mM) at RT for 18-24h. Inactivation was determined by comparing infectivity titers (log_{10}) before and after treatment. **Results/Findings**: Initial titers in PC suspended in either 65%PAS or 100% plasma were 4.0 and 4.3 log pfu/mL, respectively. Following inactivation, no infectivity was observed, resulting in a mean inactivation of >4.6

log pfu, or >4.1 log pfu/mL. Initial mean titers in AS-5 RBCs were 4.3 log pfu/mL. Following inactivation, no plaques were observed, resulting in a mean inactivation of > 5.0 log pfu, or >4.3 log pfu/mL. In all cases extent of inactivation was limited by the initial input. **Conclusion**: Amotosalen/UVA and Amustaline/GSH PR technologies, appear to effectively inactivate ZIKV in Platelets, Plasma and RBC. The INTERCEPT Blood System for RBC is not approved for use. These data have not been reviewed by the FDA.

S17-010C

Estimated Risk to the Canadian Blood Supply from Sexually Transmitted Zika Virus

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Background/Case Studies: Some non-endemic countries recommend that female donors self-defer after sexual contact with a man diagnosed with Zika virus infection, or who has risk travel. In Canada a travel deferral of 21 days post travel to anywhere outside of Canada, continental US or Europe was implemented in February, 2016. We carried out a quantitative risk assessment based on conservative assumptions to inform decision making regarding risk of sexual transmission of Zika virus in Canada. **Study Design/Methods**: Based on a method proposed by Hoad and colleagues at the Australian Red Cross, risk was the product of the infection rate in female donors from sexual contact, the proportion of donors who are female and the duration of viremia. The first term of the equation was estimated as follows. Incidence of infection in endemic areas was estimated from the reported data in risk areas. Because reporting of confirmed cases will underestimate symptomatic cases, it was assumed all reported suspected cases were true cases. These were multiplied by 5 because only 1/5 infections would be symptomatic. Based on this and published risk to travelers to an epidemic area, risk of infection in male partners due to travel to endemic areas was estimated. It was assumed that 10% of women with a Zika virus infected partner will be infected. The percentage of male donors who travel to risk areas was estimated to be 16.8% based on a donor survey of 8,908 donors. Thus the first term (Zika virus infection rate in female donors due to sexual contact) was the product of incidence of infection in male travelers to risk areas (1 in 1,915), the rate of infection from sexual contact (10%) and the travel rate of male donors (16.8%). The second term of the risk equation was 50%. The third term (duration of viremia) assumed the usual duration of the incubation period of Zika virus is 5 days, and that the donor would donate once in a six-month period (5 days/182.5). There was no adjustment for higher frequency of donation in male donors. **Results/Findings**: The infection rate in female donors from sexual contact was estimated to be 1 in 133,999 female donors. The risk of a viremic donation from a female donor infected by sexual contact was estimated to be 1 in 8,333,333 donations (95% CI 1 in 14,925,373 to 1 in 5,263,158). **Conclusion**: Very conservative assumptions took into account the uncertainty of travel-related Zika virus infection, duration over which the virus may be present in semen, and the frequency of infection via the sexual route. Many female donors at risk of infections by the sexual route would already be deferred if they also have travel risk. Notwithstanding, the results indicate that risk of Zika virus in the blood supply due to sexual transmission is very low, and that additional deferral criteria are not warranted.

S18-010C

Impact of Enhanced Screening for Zika Virus on Blood Donor Deferrals

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Background/Case Studies: Emerging infectious diseases such as Ebola hemorrhagic fever and Zika virus can potentially impact the United States blood supply due to exposure from travelers. Enhanced screening recommended by organizations such as AABB may restrict the number of eligible blood donors. We measured any impact on blood supply related to more rigorous travel related donor screening criteria at our institution [a transfusion service (~195,000 blood products transfused annually) with multiple blood donor centers and mobile drives (~30,000 collections annually)]. **Study Design/Methods**: We evaluated donor questionnaires from all donor encounters at our institution from January 2013 to March 2016 for deferral criteria. These data were extracted from our information systems (eProgressa, MAK-SYSTEM, Paris, France, and El Dorado Donor/Donor Doc ®, Haemonetics, Braintree, Massachusetts). Deferrals based on questionnaire responses included deferrals related to behaviors (e.g. travel, sexual activity, tattoos) but not medical conditions or medications. Travel deferrals could be related to questions on potential exposure to malaria, Zika virus, variant Creutzfeldt-Jakob disease (vCJD), and Leishmaniasis. Deferrals due to Zika virus are 28 day temporary deferrals based on guidance from AABB starting in February 2016. **Results/Findings**: From January 2013 to March 2016, we had a per year average of 32,000 donor encounters with 557 deferrals based on questionnaire responses and 176 deferrals due to travel related criteria. See Table. Sixty percent of the increase in deferrals in 2015 was due to travel related questions. This increase did not occur in the immediate aftermath of increased awareness due to Ebola (Q4 2014). International travel increased during this overall time period according to the United States Air Travel Statistics Program (number of US outbound travelers: 60.7m in 2012, 61.6m in 2013, 68.2m in 2014, and 73.4m in 2015) with a 24.1% increase in travel to Mexico (US Department of Homeland Security). Questions related to Zika virus accounted for a forty-two percent increase in travel deferrals. **Conclusion**: Additional screening questions for Zika virus resulted in increased blood donor deferrals. The increase in travel related deferrals may be due to an overall increase in international travel particularly to areas with active Zika virus transmission.

Recipient Non-Infectious Adverse Events

S19-020A

Prophylactic Pre-procedure Platelet Transfusion is Associated with a High Risk of Thrombosis and Mortality

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Background/Case Studies: Platelets perform an important function in hemostasis, and virtually all pro-hemostatic treatments have thrombosis as their major side effect. Previous studies have shown that patients who received platelet transfusions had increased risks of venous and arterial thromboembolism as well as death. Platelet transfusion has also been linked to coronary stent thrombosis in several studies. The overall rate of venous thromboembolism (VTE) in hospitalized patients is 0.24%. Prophylactic platelet transfusion is common prior to invasive procedures but the frequency of thrombosis post-procedure has not been characterized. In this retrospective observational

TABLE. Blood Donor Deferrals

Time Period	Total Donor Encounters	Total Deferrals Based on Questionnaire Responses	Travel Deferrals	Zika Virus Deferrals
Q1 2016	6168	152 (2.4%)	78 (1.2%)	32 (0.5%)
Q1 2015	8855	254 (2.9%)	76 (0.8%)	
Q1 2014	6688	112 (1.7%)	36 (0.5%)	
2015	32422	897 (1.5%)	350 (1.1%)	
2014	34372	500 (1.5%)	112 (0.3%)	
2013	31137	401 (1.3%)	79 (0.3%)	

study, we characterize for the first time the thrombosis and mortality rate of hospitalized patients receiving prophylactic platelet transfusion prior to an invasive procedure. **Study Design/Methods**: We collected transfusion information on every platelet request prior to an invasive procedure at our 800 bed university hospital between January 2015 and February 2016. Patient age and underlying medical condition(s), pre-procedure and post-procedure platelet counts type of procedure, number of platelet products transfused and any complications, including thrombosis, within 7 days of the transfusion and death within 30 days of the pre-procedure platelet transfusion were recorded. **Results/Findings**: A total of 332 prophylactic pre-procedure platelet transfusions were identified. Of the 332 transfusions, a total of 18 thrombotic events were identified for a thrombosis rate of 5.4%. This rate of thrombosis is 22.5 times higher than the CDC- reported rate of thrombosis in hospitalized patients. A total of 57 deaths (17% of all patients) occurred within 30 days of pre-procedure platelet transfusion. Notably, the majority of thrombotic events occurred in older individuals. **Conclusion**: The practice of pre-procedure prophylactic platelet transfusion is associated with a dramatically higher risk of thrombosis than hospitalized patients overall. The 30-day mortality was also very high. Whether these findings are due to substantially higher incidence of co-moribidities and confounding, or to cause and effect, and to what degree, is not known. However, this study highlights an association between prophylactic platelet transfusion and thrombosis and death/poor outcome. Platelets are known to be highly activated and pro-inflammatory during storage, and it may be that these previously unknown aspects of platelet biology account for some of these findings. The association that nearly one in five patients dies within 30 days of transfusion is particularly concerning. The widespread practice of prophylactic platelet transfusions should be the subject of randomized trials to assess both efficacy and safety.

S20-020A

Incidence of Transfusion Reactions: A Multicenter Study Utilizing Systematic Active Surveillance and Expert Adjudication

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Background/Case Studies: Prevalence estimates of serious hazards of transfusion vary widely. We hypothesized that the current reporting infrastructure in the United States fails to capture many transfusion reactions, and undertook a multi-center study utilizing active surveillance, data review, and adjudication to test this hypothesis. **Study Design/Methods**: A retrospective record review was completed for a random sample of 17% of all inpatient transfusion episodes over 6 months at 4 academic tertiary care hospitals. A transfusion episode was defined as all blood products released to a single patient separated by an interval of 6 hours from other blood products released. Trained clinical research nurses reviewed data including blood components transfused, vital sign trends, chest x-ray (CXR) results, arterial blood gas (ABG) results, other laboratory results, and clinical notes. Extended data forms were completed for transfusion episodes potentially associated with serious transfusion reactions, and data from these cases were adjudicated by a panel of transfusion medicine experts. **Results/Findings**: In total, 4857 transfusion episodes (17.4% of all transfusion episodes at the 4 sites) were evaluated by the nurse coordinators over the course of this 6-month retrospective study. Of these transfusion episodes investigated, 1.1% were associated with a serious reaction. Transfusion associated circulatory overload (TACO) was the most frequent serious reaction noted, being identified in 1% of transfusion episodes. Compared to patients without pulmonary edema, TACO patients were transfused with more units of blood products (odds ratio = 4.5, 95% CI 2.2-9.3 for 3 units versus 1 unit). Despite clinical notes describing a potential transfusion association in 59% of these TACO cases, only 5.1% were reported to the transfusion service. Suspected transfusion-related acute lung injury (TRALI/possible TRALI), anaphylactic, and hypotensive reactions were noted in 0.08%, 0.02%, and 0.02% of transfusion episodes. Minor reactions, including febrile non-hemolytic and allergic, were noted in 0.62% and 0.29% of transfusion episodes, with 30%-50% reported to the transfusion service. **Conclusion**: Consistent with the findings from prior studies, TACO was the most common serious transfusion reaction identified in this study. Underreporting of cardiopulmonary transfusion reactions is striking among academic, tertiary care hospitals. Complete and accurate reporting is essential to identify, define, establish pathogenesis, and mitigate/treat transfusion reactions. A better understanding of the failure to report may improve the accuracy of passive reporting systems.

S21-020A

RBC-Derived Microparticles Prime Neutrophil Respiratory Burst and Cause Lung Injury in a Two-events Mouse Model

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Background/Case Studies: Microparticles are plasma vesicles which exist in transfused blood components. Studies have suggested microparticles released from stored RBCs were potential mediators for non-antibody induced transfusion-related acute lung injury (TRALI). We hypothesize that RBC derived microparticles (RMP) may prime polymorphonuclear neutrophil (PMN) respiratory burst and cause acute lung injury in a two-events model. The aim of this study is to investigate the effects of RMP primed PMN respiratory burst on human pulmonary microvascular endothelial cells (HMVEC) damage and mouse acute lung injury. **Study Design/Methods**: RMP were isolated by centrifugation of supernatant from stored RBCs at 20,000×g for 1 hour; RMP depletion was achieved by filtration of the supernatant through a 0.1μm filter. RMP in supernatant were dual labeled with fluorescent CD235a monoclonal antibody and carboxyfluorescein succinimidyl ester (CFSE), then counted by flow cytometric analysis; Priming of fMLP activated PMN oxidase activity with supernatant or RMP was measured; and RMP induced HMVEC damage was investigated. BALB/c mice were injected intraperitoneally with lipopolysaccharide (LPS) followed by infusion of approximately 3.0 x 10^7 RMP or heat-treated supernatant through tail vein in 2 hours, then killed after another 2 hours. Lung was harvested for myeloperoxidase (MPO) assay, histology, and pulmonary edema assessment. A bronchoalveolar lavage (BAL) was performed, and then protein content was measured. **Results/Findings**: The amount of RMP increased significantly during storage (from day1 to day35: 8.81 ± 4.96 x 10^2/μl to 1.45 ± 0.43 x 10^4/μl, $P<0.05$). Either supernatant or RMP primed PMN respiratory burst effectively. RMP induced PMN mediated HMVECs damage, which was fully protected by inhibition of the PMN respiratory burst with 1200μM of apocynin. After LPS treatment, the activity of MPO in lung tissue increased significantly. Infusion RMP to LPS treated mouse caused acute lung injury which showed: a) alveolar wall became thickened with increasing deposits of cells and protein in alveolar spaces; b) the rate of wet/dry lung weight increased significantly (LPS vs LPS+RMP: 4.53 ± 0.09 vs 4.93 ± 0.18 $P<0.05$); and c) the protein concentration of BALF increased significantly (LPS vs LPS+RMP: 145.13 ± 12.39μg/mL vs 247.65 ± 38.33μg/mL, $P<0.05$). RMP depleted supernatant of stored RBCs showed significant reduction in their priming activity. Protein concentration of BALF but not rate of wet/dry lung weight was reduced significantly by infusion of RMP depleted supernatant. **Conclusion**: Conclusion RBC derived microparticles accumulated during storage may prime polymorphonuclear neutrophil respiratory burst and cause acute lung injury in a two-events mouse model. The involved mechanisms still need to be explored.

TABLE. Recipient characteristics

	FNHTR (n=69)	No FNHTR (n=106)	p value
Age (years)	57 (16)	65 (17)	0.002
Gender (male)	43 (60%)	58 (55%)	0.35
RBC and/or PLT in prior 24hr (units)	2 (1)	2 (2)	1.0
BMI	30 (7)	28 (7)	0.049

Data presented as number (%) or mean (SD).

S22-020A

Adiposity and Age are Risk Factors for Febrile Nonhemolytic Transfusion Reactions

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Background/Case Studies: Febrile nonhemolytic transfusion reactions (FNHTRs) are a common complication of allogeneic blood product transfusions. FNHTRs are perpetuated by pro-inflammatory cytokines, including tumor necrosis factor alpha (TNF-α) and interleukin-6 (IL-6). Adipose tissue is an endogenous source of TNF-α and IL-6 thus we hypothesize that overweight patients, defined as body mass index (BMI) >/=25, are over-represented in the population of transfusion recipients who experience a FNHTR. **Study Design/Methods**: This retrospective case control study included adult (>18 years old) transfusion recipients of red blood cells (RBC) or platelet (PLT) products on the hematology oncology, cardiothoracic surgery, and orthopedic surgery services who experienced an FNHTR between 2011 through 2015. Transfusion recipients on the same services who had no FNHTR were randomly selected from the first week of each month between 2011 through 2015 and served as controls. Recipient age, gender, number of RBC and PLT products transfused within prior 24 hours, and BMI were assessed. Proportion of recipients with BMI >/=25 and FNHTR was compared to proportion with BMI <25 and FNHTR to determine if overweight recipients are over-represented in FNHTR to RBC and PLT products. **Results/Findings**: Data from 69 transfusion recipients with FNHTR and 106 transfusion recipients without FNHTR were collected and reviewed (Table). The two groups did not differ significantly in terms of gender and total number of RBC and PLT products transfused within prior 24 hours. The FNHTR group was significantly younger with a higher BMI than controls. Linear regression analysis showed no relationship between age and BMI (R square = 0.005). The proportion of transfusion recipients with BMI >/=25 who experienced a FNHTR was 0.45 [95% CI 0.37-0.55] compared to 0.28 [95% CI 0.18-0.40] in recipients with BMI <25. Odds ratio of FNHTR in recipients with BMI >/=25 was 1.6 [p=0.024]. **Conclusion**: Transfusion recipients with BMI >/=25 are at increased risk of FNHTR after RBC or PLT transfusion compared to recipients with BMI <25 suggesting that adiposity may be a risk factor for developing a FNHTR. Additionally, younger age was identified as an independent risk factor for FNHTR.

S23-020A

Transfusion-Associated Circulatory Overload Among the Inpatient U.S. Elderly Medicare Beneficiaries, as Recorded During 2011-2014

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Background/Case Studies: Transfusion-Associated Circulatory Overload (TACO) is an acute transfusion complication resulting in pulmonary edema, dyspnea, and respiratory distress. TACO may cause prolonged hospitalizations and death. The study objective was to assess TACO occurrence and potential risk factors among inpatient elderly Medicare beneficiaries, ages 65 and older, during 2011-2014. **Study Design/Methods**: This retrospective claims-based study utilized large Medicare databases for calendar years 2011-2014 in coordination with Centers for Medicare & Medicaid Services. Blood transfusions were identified by recorded ICD-9-CM procedure and revenue center codes, and TACO was ascertained via the diagnosis code. Our study evaluated TACO rates (per 100,000 inpatient transfusion stays) among the elderly, overall, and by calendar year, age, sex, race, blood components, and number of units transfused. Fisher's exact tests were performed to compare TACO rates, and Cochran-Armitage tests ascertained trends by calendar year, age, and transfusion volume. **Results/Findings**: Among 8,310,566 inpatient transfusion stays for elderly during 2011-2014, 5,922 had a TACO diagnosis recorded, for an overall rate of 71.3 per 100,000 stays. TACO rates (per 100,000) varied by calendar year, blood components and number of units transfused, as well as by age, sex, and race. Annual TACO rates were 62.9 in 2011, 68.0 in 2012, 76.2 in 2013 and 79.9 in 2014 (p< 0.001). TACO rates by blood component groups were: 75.4 for RBCs only, 64.1 for plasma only, 31.1 for platelets only, 57.0 for platelets and plasma, 196.9 for RBCs and plasma, 176.8 for RBCs and platelets, and 150.6 for RBCs, plasma and platelets. TACO rates for age categories 65-69, 70-74, 75-79, 80-84, 85 and over were 45.4, 60.1, 67.7, 81.3, and 96.9, respectively (p<0.001). Females and males had TACO rates of 79.7 and 60.6, respectively (p<0.001); whites and non-whites had TACO rates of 75.3 and 52.1, respectively (p<0.001). TACO rates by number of units transfused were: 31.8 for 1 unit, 65.7 for 2-4 units, 108.0 for 5-9 units, and 141.8 for >9 units (p<0.001). **Conclusion**: Our population-based study is the largest investigation on TACO occurrence and risk factors among the U.S. elderly. Overall, the study shows a significant increase in TACO occurrence over time, with advancing age, and with greater number of units transfused. The study also shows substantially higher TACO rates for RBCs transfused in combination with plasma and/or platelets as well as suggests increased TACO risk in females and in whites, which need further confirmation. Study was based on claims data, and thus limitations include potential under- or mis-recording of transfusion procedures and units, as well as lack of clinical details to validate TACO diagnoses.

S24-020A

IgA Deficiency is Not Prevalent Among Patients Who Experience Allergic Transfusion Reactions to Platelets

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Background/Case Studies: Platelet allergic transfusion reactions (ATRs) are problematic and frequent, with an incidence of 1% to 4%. The plasma fraction has been shown as the stimulus for the reactions. Patients with IgA deficiency who develop an anti-IgA antibody can have serious complications with products containing IgA, and require special transfusion considerations. Understanding the prevalence of IgA deficiency among mild and severe ATRs can help guide management and prognostication after an ATR. In this study we try to estimate the prevalence of IgA deficiency among patients with mild and severe ATRs and patients who never had an ATR. **Study Design/Methods**: Subjects from a previously reported two institution platelet transfusion cohort and the Trial to Reduce Alloimmunization to Platelets (TRAP) plasma IgA were quantified by ELISA (Immunology Consultants Laboratory, Portland OR). Age appropriate IgA concentrations were used to define normal plasma IgA (>61 mg/dL). When available, clinical lab IgA measurements were used to corroborate ELISA results. IgA results were coded as binary ("normal" or "low"). The two institution study defined a severe (anaphylactic) ATR as mucocutaneous (urticaria, flushing, angioedema, and/or pruritus) plus cardiopulmonary and/or gastrointestinal symptoms. TRAP recorded "extensive urticarial eruptions" without a case definition. **Results/Findings**: We analyzed IgA levels in 96 patients from the two institution cohort and 27 samples from the TRAP trial. In the two institution cohort, 74 subjects had 99 ATRs, and 22 subjects had no history of an ATR. In the JHH/BWH cohort, all subjects with an ATR history (n=74), including those with anaphylactic reactions (n=12), had normal IgA levels. The anaphylaxis manifestations were pulmonary compromise (9/12), gastrointestinal symptoms (4/12), and shock (1/12); all experienced urticarial symptoms. Premedication was given to 16% of the severe ATRs (2/12). Two subjects had a low IgA and no history of ATRs despite multiple transfusions (9/22). One had a history of common variable immune deficiency. In the TRAP cohort, all 14 subjects, representing a total of 22 severe urticarial reactions, had normal IgA. Of control cases tested in the TRAP trial, 1 of 23 (4%) of subjects without an severe urticarial reaction had low plasma IgA. **Conclusion**: IgA deficiency is not prevalent among patients experiencing mild or severe ATRs. While IgA deficiency may contribute, in rare cases, it does not appear that lack of IgA correlates with a more severe reactions. This study provides higher quality evidence than passive reporting schemes that IgA deficiency is uncommon among ATRs. Although IgA deficiency may not be a prognostic marker for ATR severity, further studies are needed to investigate whether anti-IgA is prevalent in patients who experience ATRs.

Transfusion Practice I

S25-020B

Group O Utilization Patterns: The GROUP Study

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Background/Case Studies: Group O red blood cells (RBCs) are the universal donor red cells; they can be given to a recipient with any other blood group. Although it is usually the standard practice to select ABO group specific blood as the first choice for patients requiring transfusion, there are many situations where group O blood is given to non-O recipients. Transfusion of group O blood to non-O recipients, or the transfusion of Rh negative (D-) blood to Rh positive (D+) recipients, can result in shortages of O or D- blood, respectively. Current patterns of group O and D- blood utilization are not well understood. **Study Design/Methods**: Hospital transfusion services collected ABO and Rh groups of transfused RBC units and of recipients during the 2013 calendar year. Units administered to recipients of unknown ABO or Rh group were excluded. Two analyses were performed: How often group O RBCs were transfused to non-O recipients, and how often D- units (of any ABO group) were transfused to D+ recipients. The hospitals were divided into 3 categories: Small (<250 beds), medium (250-1000 beds), and large (>1000 beds). **Results/Findings**: Data was received from 30 centers in 9 countries. There were 7 small, 17 medium and 6 large hospital respondents. In total, these 30 centers transfused a total of 415,696 RBC units, of which 2257 (0.5%) were units excluded from the D mismatch analysis because the D type of the recipient was unknown. The ABO groups of all recipients were known. Overall 11.1% of the O units were transfused to non-O recipients. The percentage of O RBCs transfused to non-O recipients was similar among the small, medium and large sized hospital respondents (12.4, 12.8 and 8.5%, respectively). The rate of group O RBC transfusion to non-O recipients at the small hospitals ranged from 0-33.0%, at the medium hospitals from 0-22.0%, and at the large hospitals from 5.0-10.0%. In terms of D- RBC transfusion to D+ recipients, overall 29.8% of the D- units were transfused to D+ recipients of any ABO group. However, there were differences between the hospitals: Overall, 21.8% of the D- units at the large hospitals were transfused to D+ recipients, whereas this proportion was 35.3% and 36.3% at the medium and small hospitals, respectively. The variability of D- RBC transfusion to D+ recipients at the small hospitals ranged from 0-50.3%, at the medium hospitals from 12.5-76.7%, and at the large hospitals from 6.4-31.7%. **Conclusion**: This is the first time that the ABO and D groups of RBC recipients have been investigated on a large scale. A significant proportion of O and D- RBCs were transfused to non-O and D+ recipients, respectively. Whether transfusing 29.8%of D- RBC units to D+ recipients is the ideal inventory management strategy remains to be determined.

S26-020B

Transfusion of ABO Non-identical Red Cells and Mortality in Patients Undergoing Massive Transfusion

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Background/Case Studies: Massive transfusion often requires use of ABO non-identical red cells. ABO non-identical transfusions are associated with increased bleeding, organ failure and mortality. We investigated whether ABO non-identical transfusions in massively transfused patients are associated with increased mortality. **Study Design/Methods**: 24 hour(h) and overall hospital mortality in 403 patients undergoing massive transfusion at a single Level 1 trauma center from 2008-2014, as well as recipient ABO blood group and number of ABO non-identical transfusions were determined and differences tested by Chi square. **Results/Findings**: Overall 24h survival (68%) and discharged alive (53%) did not differ by ABO blood group (O=192;A=143;B=51;AB=17). Receipt of 1-4 ABO non-identical transfusions was not associated with inferior survival (n=73)(75% 24h and 65% overall survival) vs. (n=288)(69% and 53%) in recipients of only ABO identical. However, receipt of 5+ ABO non-identical transfusions (primarily RBC) (n=42) was associated with poor survival at both 24h (48%; p=0.006) and overall (31%; p=0.0015). We analyzed subsets of patients receiving comparable numbers of transfusions to evaluate whether receipt of ABO non-identical was confounded with total transfusions. The receipt of 5+ ABO non-identical components was consistently associated with increased mortality across strata of total transfusions. We examined those surviving at least 24h (n=275) to evaluate if receipt of ABO non-identical transfusions was confounded with early fatal hemorrhage. In patients surviving 24h, the adverse association with 5+ ABO non-identical transfusions remained significant. Patients received 5+ ABO non-identical RBCs due to being group AB (mean=13 RBCs), and, to a lesser extent, group A (1.6) or B (2.1). Group O patients rarely received non-identical transfusions (exclusively platelets). Amongst 24h survivors, group O individuals (n=129) had reduced overall mortality (18%) compared with non-Os (n=146)(27%) (p=0.053). Mortality was highest in group AB (n=14) (43%), then group A (n=101) (28%) and group B (n=31)(16%) (p=0.06). **Conclusion**: Larger numbers (5+) of ABO non-identical RBCs are associated with greater mortality than receipt of ABO identical RBC only, or 1-4 ABO non-identical RBCs. Group AB & A recipients had increased mortality among 24h survivors. Whether this is due to a biologic effect or confounding is not ascertainable from our data. However these results are consonant with the relative potency of anti-A/-B antibodies. The superior survival of group O patients, who have low FVIII/vWF levels, is unexpected, providing evidence the increased mortality in group A/AB patients may be antibody-mediated. Transfusion of ABO identical or plasma-reduced O rbcs are potential testable strategies to improve survival after massive transfusion.

S27-020B

Advances in the Use of Whole Blood in Combat Trauma Resuscitation

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Background/Case Studies: The resuscitative benefits of whole blood in trauma management are well known and documented. The evolution of whole blood use has resulted in the development of a Clinical Practice Guideline (CPG) for Fresh Whole Blood Collections to provide theater guidance for the collection and transfusion of type-specific product. The ability to obtain a blood type from a patient can prove to be a challenge in austere settings where our Special Operations personnel operate. The 75th Ranger Regiment Trauma Management Team (Tactical) has partnered with the Army Blood Program (ABP) and US Army Institute of Surgical Research (USAIR) to identify Low anti-A/anti-B Titer Group O donors prior to deployment. This program has evolved throughout FY15-16 and allows the Regiment to deploy with known donors to support casualty care at Point-Of-Injury (POI). In addition, the ABP has implemented a process to ship whole blood into theater through the Armed Services Blood Program (ASBP) Theater Distribution System to support the Ranger Regiment. **Study Design/Methods**: Volunteer Group O donors assigned to the 75th Ranger Regiment were screened for donation using the DD Form 572 (Donor Screening Record) and interviewed by ABP personnel. The donor was issued a unique Donor Identification Number (DIN) and the tubes for the required viral marker and titer testing were collected and processed. Transfusion Transmitted Disease (TTD) and titer testing tubes were processed and shipped to the designated reference laboratories and the units were established in the Theater Medical Data Store (TMDS). All results were placed in TMDS for theater access by the Regimental Surgeon. Donors with a positive TTD were identified as deferred and counseled by Preventive Medicine as required. Concurrently, the ASBP initiated shipments of Group O Low Titer Whole Blood to support the Rangers. **Results/Findings**: 967 Rangers were tested. Group O Rangers with a titer ≥1:256 are considered "high titer" (n=344) and will not be used as donors. Group O Rangers with a titer <1:256 are considered "low titer" (n=617) and may be used as whole blood donors. 64% of Group

O Rangers are identified as Group O Low titer Donors. Upon retesting of randomly selected donors, only 13 changed titers (1%). There were no donors deferred for confirmed TTD results. Low volume shipments of licensed whole blood units occur every two weeks. **Conclusion**: The implementation of the Group O Low Titer Donor Screening program with the 75th Ranger Regiment will continue to have a positive impact on readiness and allow the Regiment to deploy with known donors that will be available at POI and in support of Prolonged Field Care. The ABP has standardized the process at 10 blood donor centers and initiated donor screening events with Special Forces Groups.

S28-020B

ABO Antibody-Mediated Hemolysis is not Detectable Following Cold-Stored Uncrossmatched Whole Blood Transfusion in Civilian Trauma Patients

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Background/Case Studies: This study evaluated the safety of administering up to 4 units of uncrossmatched low titer group O cold stored whole blood (cWB) during civilian trauma resuscitation. **Study Design/Methods**: Male trauma patients with hemorrhage-induced hypotension who received uncrossmatched, leukoreduced, platelet replete, low titer (<50) anti-A and -B, TRALI risk mitigated group O+ cWB during their initial resuscitation were included. The following data was collected: Biochemical markers of hemolysis (lactate dehydrogenase, total bilirubin, haptoglobin, creatinine and serum potassium) were measured on the day of cWB receipt (day 0) and for the next 2 days, reports of adverse events related to the cWB administration, and the total blood product administration in the first 24 hours of admission. **Results/Findings**: Data was collected on 22 non-group O and 9 group O cWB recipients. The median number of cWB units transfused was 2 (range 1-2) and 1 (range 1-4; p=0.52), respectively. The median day 0 haptoglobin concentration was lower in the non-group O recipients vs. group O recipients [18.3 mg/dl (range 5.8-96.6) vs. 47.5 mg/dl (range 39.3-109.5), respectively; p=0.013; laboratory reference range 36-195 mg/dl], however there were no significant differences in any of the other biochemical parameters at any of the other time points. Two non-O patients and 4 group O patients had polyspecific DATs performed within 3 days of cWB receipt; all were negative. The median volume of ABO incompatible plasma transfused to non-group O recipients was 400 mL (range: 200-10,400 mL). There were no adverse events related to the cWB transfusion in either group reported to the blood bank. There was no statistically significant difference in the median total quantity of blood products transfused to the non-group O vs. group O recipients in their first 24 hours of hospital admission, although non-O patients received a median of 5 (range 1-54) RBC units to a median of 1 (range 1-20) RBC unit for the group O patients (p=0.26). The average plasma:RBC ratio over the first 24 hours was not significantly different between the non-group O recipients compared to the O recipients (1.11 ± 0.74 vs. 1.20 ± 0.73, respectively; p=0.92), nor was the average PLT:RBC ratio over the first 24 hours different between these 2 groups (1.11 ± 0.80 vs. 0.86 ± 0.26, respectively; p=0.58). **Conclusion**: Administration of cWB in civilian trauma resuscitation in these quantities does not appear to cause hemolysis or other clinically significant adverse events. The lower haptoglobin in the non-group O recipients on day 0 likely reflects the trend towards receipt of more RBC units in these patients. The clinical efficacy of transfusing cWB will be determined when larger quantities are transfused.

S29-020B

Cold-stored Apheresis Platelets in Treatment of Postoperative Bleeding in Cardiothoracic Surgery

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Background/Case Studies: Platelet storage has undergone changes since the 1950s. Platelets were initially stored under refrigeration, but a practice shift towards room temperature storage began in the 1970s in order to optimize circulation time for prophylactic transfusion. Cold storage, however, continued until the 1980s, due to superior hemostatic properties. Split inventories pose logistical challenges for transfusion services, but as Personalized Medicine advances, reevaluation of the hemostatic properties of cold stored platelets in bleeding patients is warranted. **Study Design/Methods**: A two-armed randomized pilot study was designed to evaluate if leukoreduced apheresis platelets in PAS stored for up to 7 days cold (4CPLT) or at room temperature (RTPLT) are equally effective in treatment of postoperative bleeding in patients undergoing major cardiothoracic surgery. The primary objective is to compare coagulation responses by change in platelet aggregation measured by impedance aggregometry (Multiplate™). The secondary objectives are to compare postoperative blood loss until day 1 after surgery, to analyze biochemical and hemostatic changes as well as complications. Patients are enrolled prior to surgery, and we aim to include 60 patients receiving platelet transfusion. Statistical analysis is performed by use of Independent samples T-test (SPSS version 22), and results presented as mean ± SD. **Results/Findings**: By 1st of April 2016, 65 patients have been enrolled in the study. 11 out of 15 women and 15 out of 49 men have received platelet transfusion according to protocol. 14 patients received 4CPLT and 12 received RTPLT. The Multiplate™ results from first transfusion episode (average 2 units in both arms) are as follows: Changes in ADP Area Under the Curve (AUC, units) immediate after transfusion are 28.57 ± 15.05 (4CPLT) and 14.58 ± 17.99 (RTPLT) (p=0.045). Measured ratios ΔADP/ΔTPK are 0.50 ± 0.55 (4CPLT) and 0.29 ± 0.38 (RTPLT) (p=0.259). Platelet counts before $124x10^9$/L ± 54 (4CPLT) vs $118x10^9$/L ± 78 (RTPLT) and after transfusion $167x10^9$/L ± 48 (4CPLT) vs $164x10^9$/L ± 71 (RTPLT) are similar in the two groups. No significant difference in total number of platelet units given 2.1 ± 0.7 (4CPLT) vs 2.8 ± 1.3 (RTPLT) or postoperative bleeding (chest drain output after chest closure) 775 ml ± 534 (4CPLT) vs 1055 ml ± 677 (RTPLT) are observed. 24-hour platelet counts are similar $140x10^9$/L ± 73 (4CPLT) vs $155x10^9$/L ± 80 (RTPLT). **Conclusion**: Preliminary data from 26 patients shows that the change in Multiplate ADP-induced platelet aggregation is higher in patients receiving cold-stored platelets. There is a trend towards lesser postoperative bleeding. Preliminary results indicate that transfusion of cold-stored apheresis platelets is efficient in treatment of postoperative bleeding in patients undergoing major cardiothoracic surgery.

S30-020B

Implementation of Cold Stored Platelets for Combat Trauma Resuscitation

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Background/Case Studies: Studies indicate that cold stored (CS) platelets (PLT) provide superior hemostatic function compared to room temperature (RT) stored PLT in the resuscitation of bleeding patients. US Military PLT apheresis collection teams are deployed to combat zones to support hemostatic resuscitation of wounded personnel. In order to improve options for trauma care, the US Military initiated a program in October 2015 for validation of 3-day CS-PLT at the Craig Theater Hospital, Bagram Air Field, Afghanistan. This program was to provide CS-PLT for bleeding trauma patients and validate cold storage by deployed apheresis collection teams. **Study Design/Methods**: A US Army Blood Support Detachment validated CS-PLT collected with the Haemonetics MCS-9000 at Bagram. PLT were stored in 100% plasma. Given the limited donor availability, 10 PLT units were collected and stored at 1-6°C for 5 days. Samples were taken on day of collection, day 3, and day 5 of storage for pH, PLT count, and unit volume measurements. Unit appearance was recorded for each day of storage. Bacterial detection was not performed for CS products. Acceptance criteria for pH, count, yield, volume and appearance were the same as required for 5 day RT-PLT based on FDA and AABB requirements. **Results/Findings**: All 10 CS-PLT units met acceptance criteria over 5 day storage. With these data and recent FDA approvals for cold storage of apheresis PLT, units stored for up to 3 days at 1-6°C were approved for use starting in January 2016. In

April 2016, a 49 year old Afghan male sustained gunshot wounds to the left side of his body including a transection of his axillary artery resulting in hemorrhagic shock. His prehospital resuscitation included 1 gm tranexamic acid (TXA), 1U freeze-dried plasma and 2U whole blood. He underwent damage control surgery with a forward surgical team that included vascular shunting and transfusion (6U RBC, 4U FFP). Upon transfer to Bagram he underwent reconstruction of the axillary artery, intramedullary nailing of the humerus, forearm fasciotomy, left thigh debridement and external femur fixation. He received massive transfusion (13 RBC, 14 FFP, 3 RT-PLT, 3 CS-PLT, 10-pack CRYO). He required repeat debridements of his wounds and fasciotomy closure, and antibiotics for pneumonia, but overall recovered from surgery and was well on postoperative day 15. There were no thrombotic complications. **Conclusion**: DoD successfully implemented CS-PLT in a combat theater. This unique program provides a lifesaving product to wounded military and civilians. Opportunities for development of this capability include collection of PLT in additive solution (PAS) and shelf life extension in order to provide PLT far forward, earlier in resuscitation. Currently PLT are unavailable to forward surgical teams due to the 5-day shelf life.

RBC Molecular Testing and Genetics

S31-020C

D Typing Discrepancies and Anti-D Production Associated with Six New RHD Alleles

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Background/Case Studies: *RHD* diversity is evident at the serologic and molecular level. Novel alleles are reported every year; more are anticipated with next generation sequencing that gives whole gene coverage. We investigated 6 samples with novel RHD alleles and report serologic reactivity and associated risk of anti-D. **Study Design/Methods**: Genomic DNA was isolated from WBCs. RHD BeadChip prototype assay and *RHD* sequencing was performed. RhD-specific cDNA analysis was done for some samples. Serologic testing was by standard methods with multiple anti-D and ALBAclone Partial D kit was used to test samples with sufficient quantity. **Results/Findings**: The table summarizes results. Sample 1 was from a D+ Black woman with plasma anti-D and -U. RBCs gave variable reactivity 2+-4+ with anti-D and were Go(a+). The ALBA Partial D kit was consistent with partial DIV. RHD BeadChip was indeterminate, but RhD-cDNA identified hybrid *DIIIa-CE(4-7)-D in cis* to *RHD* with c.1048G>C (Asp350His). Sample 2 was from a D+ (1+/2+) Hispanic woman with anti-D, -C, and -K. RHD BeadChip had no changes, but sequencing found c.95C>A (Thr32Asn). Sample 3 RBCs gave 0 to 2+ reactions with anti-D requiring IAT for detection. RHD BeadChip detected c.689G>T (Ser230Ile) and reported D/DAU1; however, only one *RHD* was present, the sample did not have c.1136C>T associated with DAU; sequencing identified a new c.689G>A change (Ser230Asn). RBCs did not react with 3 clones in ALBA Partial D kit but did not match any indicated partial D. Sample 4 was from a historically D− Caucasian but the RBCs reacted 1+-3+ with anti-D. RHD BeadChip had no changes. Sequencing identified a new c.956T>G (Val319Gly). Sample 5 was from a female who previously typed D− but RBCs were 2+ by IAT only. RHD BeadChip had no changes, but sequencing identified intron 4 +5g>a, predicted to cause aberrant splicing. Sample 6 was from a D+ sickle cell patient referred for RH genotyping. RHD BeadChip detected c.667T/G and interpreted as D/DFV. Sequencing confirmed c.667T/G (Phe223Val) and identified a novel change c.800A>T (Lys267Met) on the same allele with *RHD in trans*. **Conclusion**: We report 6 new RHD alleles, all but one associated with variable weak or discrepant D typing and 2 associated with alloanti-D sensitization. None was correctly defined with a commercial RHD genotyping kit, and it is important that variable D typing or D+ with anti-D samples be further investigated for clinical significance to determine relevance for transfusion medicine practice.

S32-020C

*RHCE*CeRN* Encodes a D+ RBC Phenotype, in the Absence of a RHD Gene, withaAn Epitope Pattern Identical to Partial D, DBT

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Background/Case Studies: RHCE*CeRN is a hybrid allele that has exon 4 of *RHCE*Ce* replaced with exon 4 of *RHD*. The altered RhCe protein expresses partial and weakened C and e antigens, low-prevalence antigens Rh32 and DAK, and lacks the high-prevalence antigen Rh46. The haplotype is referred to as R^N and reflects the common (*in cis*) linkage of this altered allele with *RHD*. Here we report the molecular and serologic investigation of a sample from a 61-year-old female whose RBCs typed strongly D+, but who lacked *RHD* genes and had anti-D in the plasma. **Study Design/Methods**: Serologic testing was done by standard hemagglutination. RBCs were tested with the ALBAclone Partial D kit according to manufacturer instructions. Genomic DNA was isolated from whole blood. Laboratory developed testing included PCR-multiplex for *RHD* exons 4 and 7 and *RHC/c*, PCR for *RHD* exons 2, 8, and 10, PCR-RFLP for *RHCE* c.254C>G and c.577A>G changes, and *RHD* and *RHCE* BeadChip prototype assays. RNA was isolated from RBCs for RhCE-specific cDNA analysis. **Results/Findings**: The patient's RBCs reacted 4+ with Immucor Series 4, Series 5, ALBAclone alpha and blend anti-D, 3+ with Gamma-clone and $2+^s$ with Ortho BioClone anti-D. Alloanti-D reactive 3+ to 4+ (by IgG gel) was identified in the plasma. Her RBCs reacted with only 2 clones in the ALBA Partial D kit, a pattern consistent with partial D, DBT. However, on PCR amplification the sample was negative for *RHD* exons 2, 4, and 10, inconsistent with DBT, and also negative for exons 8 and 7. *RHD* BeadChip testing gave LS (low signal) for all exons, consistent with absence of the *RHD* gene, i.e. *RHD*01N*. Her RBCs also typed E−c+e+ and C+ with two commercial anti-C, but were non-reactive with an unlicensed monoclonal anti-C (P3X25513G8). *RHCE* BeadChip testing indicated the sample was *RHCE*Ce/*ce* with no changes, and ruled out the presence of *RHCE* alleles associated with a D+ serologic phenotype, such as Crawford (*RHCE*ceCF*) and DHar (*RHCE*ceHAR*). PCR-RFLP targeting the c.577A>G change associated with *RHCE*CeRN* was positive, and the RBCs were tested and found to be Rh32+, D^W−, and DAK+. AS-PCR for c.254C>G associated with *RHCE*ceAG* was positive, and RhCE-cDNA analysis showed the c.254G was on *RHCE*ce* and confirmed the RHCE genotype as *RHCE*CeRN/*ce254G*. **Conclusion**: We report the first indication that *RHCE*CeRN* encodes for D antigen expression as evident by the strong reactivity of the RBCs with commercial anti-D in the absence of a *RHD* gene. The D-epitope expression corresponds to partial DBT, which can confuse interpretation of the D phenotype. This has not been previously reported for *RHCE*CeRN* due to frequent linkage *in cis* to *RHD*, masking the D epitope reactivity. This observation gives insight into

TABLE.

Sample	Referral	Serology IS/IAT	ALBApartial D	RHD BeadChip	Sequence resultsnt. change	Amino Acid change
1	anti-D	2+ to 4+	DIV	Indeterminate	c.1048G>C	p.Asp350His
2	anti-D	1+/2+	NT	No changes	c.95C>A	p.Thr32Asn
3	D typingdiscrepancy	0/2+	3 non-reactive No pattern	D/DAU1	c.689G>A	p.Ser230Asn
4	D typingdiscrepancy	0 to 3+	NT	No changes	c.956T>G	p.Val319Gly
5	D typingdiscrepancy	0/2+	NT	No changes	Intron 4, +5g>a (c.634 + 5g>a)	splice
6	Routine RH genotype	Not informative	NT	D/DFV	c.667T>Gc.800A>T	Phe223Val Lys267Met

the D epitopes encoded by *RHD* exon 4, and to residues involved in expression of DAK.

S33-020C

The DAU Cluster: A Comparative Analysis of 18 RHD Alleles

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Background/Case Studies: The *DAU* cluster of *RHD* alleles is characterized by a single nucleotide change causing the T379M amino acid substitution. The *DAU-0* allele with T379M has been postulated to be the primordial allele, from which all other alleles of the *DAU* cluster have eventually evolved. In the present study, we describe 2 new *DAU* alleles, investigate the phylogenetic relationship among the 18 known *DAU* alleles and the distribution of their amino acid substitutions in the RhD protein. **Study Design/Methods**: Standard hemagglutination and flow cytometry tests were performed and *RHD* gene was sequenced. A phylogenetic tree for the *DAU* alleles was established. Computational modeling of the RhD protein was done with RhCG crystal structure (PDB ID 3HD6) as template. **Results/Findings**: We characterized 2 *DAU* alleles, *DAU-5.1* and *DAU-11*, closely related to *DAU-5* and *DAU-3* respectively. The D antigen density was approximately 6200 per RBC for DAU-5.1 and 2400 for DAU-11. We collated the 18 known *DAU* alleles characterized by T379M substitution. There were 18 nucleotide substitutions encoding 14 non-synonymous and 4 synonymous changes in the RhD protein. The non-synonymous *DAU* substitutions were found to be dispersed over the entire RhD protein with no evidence of clustering around the central pore of the RhD protein. All non-synonymous *DAU* mutations occurred inside the red cell membrane with the only exception of the DAU-1 (S230I). A phylogenetic analysis of the *DAU* alleles indicated point mutations and interallelic recombination contributing to diversification of the *DAU* cluster. **Conclusion**: The *DAU* alleles encode a group of partial D antigens, some or all of them may permit anti-D in carriers and are also known to cause anti-D alloimmunization in patients. Knowledge of *RH* alleles, their phylogeny and prevalence will aid in identifying the clinically relevant *RHD* alleles occurring in patient samples by high throughput technologies, such as next generation sequencing (NGS). Our results suggest that the cluster of *DAU* alleles represent a clade, and that they evolved through random mutation in the primordial *DAU-0* allele or through recombination among *DAU* and other *RHD* alleles. The defining T379M mutation in exon 8 may represent a neutral amino acid substitution that became originally fixed in an isolated African population.

S34-020C

Mixed-Field Agglutination in RhD Typing as a Marker of Fibrotic Transformation in Thrombopoietin Receptor-Mutated Essential Thrombocythemia

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Background/Case Studies: A 65-year-old female with history of essential thrombocythemia (ET) and W515K *MPL* (thrombopoietin receptor) mutation developed secondary myelofibrosis and was admitted for HLA-matched hematopoietic cell (HPC) transplantation. The patient had been typed as Group A RhD positive in her youth, but transfusion history revealed that she was classified as group A RhD negative two months prior to this admission using an automated platform. The patient had never received transfusions or HPC transplantation. **Study Design/Methods**: Serologic ABO, RhD, RHCE and Fy typing was performed by gel column agglutination testing. Cytogenetics was investigated initially by G-banding, and subsequently by using a high-density single nucleotide polymorphism (SNP) microarray comprising 1.9 million probes and 750,000 SNPs. Fluorescence in situ hybridization (FISH) was performed using standard techniques. **Results/Findings**: Gel immunoagglutination revealed group A red blood cells (RBCs) and a mixed-field reaction for the RhD phenotype, with a predominant RhD-negative population and a small subset of circulating RBCs carrying the RhD antigen. G-banding of the bone marrow cells revealed a 46XX karyotype. FISH analysis was negative for monosomy 7, trisomy 8, and deletions 5q31, 7q31 and 20q12. Subsequent genomic microarray SNP profiling revealed a copy-neutral loss of heterozygosity (CN-LOH) of chromosome 1 p36.33-p34.2, a known molecular mechanism underlying fibrotic progression of *MPL*-mutated ET. The chromosomal region affected by this CN-LOH encompassed the *RHD, RHCE*, and *MPL* genes. Serologic testing confirmed concomitant mosaicism of the C antigen and no alterations in the Duffy phenotype, which is encoded in the opposite arm of chromosome 1 by the *DARC* gene. **Conclusion**: The *RHD* and *RHCE* genes are telomeric in relation to the *MPL* gene in chromosome 1p. The findings described above indicate that this patient's acquired RhD mosacism is due to the following chronologic molecular events: 1) congenital heterozygous RHD^{+}/RHD^{-} (D/d) genotype; 2)acquired W515K *MPL* mutation (with associated ET) *in cis* with the RHD^{-} (d) allele; 3) CN-LOH of 1p leading to clonal acquired homozygosity for both the *RhD* deletion and the W515 *MPL* mutation, with associated myelofibrotic progression and a largely RhD-negative RBC phenotype. This case illustrates that acquired changes in the RhD phenotype of patients may signal a progressing underlying myeloproliferative neoplasm. Detection of mixed-field reactivity requires a sensitive methodology and must be followed up by correlation with transfusion and transplantation history. Investigation of Rh discrepancies is important to avoid erroneous typing of these patients and unnecessary depletion of the Rh-negative blood supply.

S35-020C

Detection of DNA Variation in *RHD* and *RHCE* using Next-Generation Sequencing

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Background/Case Studies: The *RHD* and *RHCE* genes are paralogs which exhibit many types of genetic variation, including single nucleotide variants (SNVs), insertions and deletions, and larger structural variants (SVs) such as, *RHD-RHCE* hybrid alleles. These DNA variants can direct the expression of highly immunogenic antigens in the Rh system. Current DNA-based testing methods can be confounded by the presence of uncommon and complex variants at the *RH* locus. We sought to develop a next generation sequencing (NGS) approach for the systematic, unbiased characterization of the *RH* locus for all types of genetic variation. **Study Design/Methods**: 1135 samples were selected for DNA sequencing from a parent study of blood donors self-identified to be of Asian American or Native American descent. Four WHO reference DNAs were purchased from NIBSC. Donors had been tested for D and C by serology and for CcEe by SNVs. All 1139 samples were sequenced using the BloodSeq NGS targeted panel which captures a 269kb region spanning the RH locus. Captured DNA was multiplexed and sequenced on Illumina Hiseq machines using paired-end 100-bp reads. Raw sequence data was aligned to the human reference genome (hg19) using BWA-MEM and SNVs assessed using GATK. For SVs, we used a custom read-depth based approach to detect deletions, duplications, gene conversions, and to assign zygosity. A subset of samples with *RHD-RHCE* hybrid alleles detected by NGS were validated by quantitative multiplex PCR of short fluorescent fragment (QMPSF) analysis. Variants were cross-referenced to ISBT. Expression of DCcEe antigens was predicted and compared to Rh serology and SNV results. **Results/Findings**: BloodSeq predicted D and C in 1139 samples in high concordance with serology (99.6% and 99.0%, respectively). SNVs also predicted C accurately compared to serology in 1059/1069 (99.1%) of samples (80 subjects had indeterminate SNV calls). BloodSeq and SNV had high correlation for Ee (99.9%). Analysis of BloodSeq data found that all samples from donors which were C+ by serology had an *RHCE-RHD-RHCE* gene conversion event involving *RHD* exon 2, with variation in the size of the accompanying flanking regions. In 22 samples, complex recombination events indicative of *RHD-RHCE* hybrid alleles were identified. Additionally, 10 SNVs indicative of rare named ISBT alleles were detected, as was a novel frameshift *RHD* variant and numerous other previously undescribed variants in both genes. **Conclusion**: Our results demonstrate that a targeted NGS approach followed by a customized analysis pipeline can simultaneously detect both small and large DNA variants at the *RH* locus. This work provides the foundation for a DNA-based, high resolution Rh blood-typing method for the detection of clinically relevant *RH* locus genetic variation.

S36-020C

Blood Group Alleles in the Population: Lessons from the Thousand Genomes Project

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Background/Case Studies: The Thousand (1K) Genomes project provides a database of over 80 million genomic variants found across 2504 individuals from 26 populations. A current priority of the genomics field is to design information systems to translate this knowledge into clinically relevant (actionable) information. The applications and advantages of red blood cell (RBC) antigen prediction through genotyping are widely accepted in transfusion medicine. Current technologies address a limited number of single nucleotide polymorphisms (SNPs) in 12 blood group genes, and our background knowledge of RBC phenotype distribution is often limited to a few ethnic groups. We analyzed the 1K Genomes database to determine allele distributions of 39 blood group genes across the 5 genotyped superpopulations: Africa, East Asia, Europe, South Asia and Americas; determine the feasibility of blood group genotyping by next-generation sequencing (NGS); and establish a scaffold of chromosomal coordinates to interpret NGS output files into a predicted RBC phenotype. **Study Design/Methods**: The 1K Genomes Database was accessed through the UCSC Genome Browser hg19 assembly, and analysis was performed with Table Browser, Variant Annotation Integrator, and LiftOver tools. **Results/Findings**: We investigated 30 of 39 genes in 31 blood group systems which met the strict criteria for accessibility through short, paired-end NGS reads. A total of 453 known alleles resulting from SNPs or short insertions/deletions in coding sequences, promoters, and splice sites were mapped to the hg19 and hg38 assemblies; 361 of these passed strict accessibility criteria, and 83 were identified in the 1K Genomes database and their population frequencies extracted. This analysis yielded novel population distributions, such as the presence of the *KEL*02.03* allele in Africa and South Asia, and detection of *KEL*02.M04* in East Asia. The average read depth of the variants studied here was 17,490. All variants, including the *ACKR1* erythroid promoter silencing mutation, are located within exon pull-down target boundaries. Additionally, the 1K Genomes project identified 53 previously-unreported genomic variants in 6 blood group genes, which are predicted to be deleterious and potentially antigenic. Most of the new predicted deleterious alleles are found in the *KEL* and *SLC14A1* genes. **Conclusion**: The 1K Genomes Project provides a worldwide overview of 83 blood group alleles and 53 novel predicted-deleterious variants. All queried clinically-relevant alleles are amenable to targeted exome sequencing, and 75% of them can be addressed with a short, paired-end NGS strategy. NGS can allow quick, high-throughput RBC phenotype prediction, and we provide a comprehensive database of hg19 and hg38 chromosomal coordinates as a basis for this clinical application.

Pediatric Transfusion Medicine

S37-030B

Frequency of Alloantibodies Associated with Delayed Transfusion Reactions in Children with Sickle Cell Disease

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Background/Case Studies: Children with sickle cell disease (SCD) frequently form antibodies following red cell transfusion. A clinically significant antibody is typically defined as one that is associated with a hemolytic transfusion reaction (HTR) or a notable decrease in transfused red cell survival. The degree of hemolysis can vary considerably, even with the same specificity. We aimed to determine the frequency of alloantibodies associated with a delayed transfusion reaction (DTR) at time of first detection in patients with SCD at a single pediatric institution over a 13-year period. **Study Design/Methods**: This is a retrospective analysis of pediatric patients transfused with prophylactic C, E, K-matched red cells from primarily African-American donors. We reviewed the medical history and recorded all clinical HTRs. To determine whether transfused red cell survival was decreased in chronically transfused patients, we compared hemoglobin (hgb) and %hgb S levels at first detection of an antibody to the mean pre-transfusion values for the 6-12 months prior. Poor red cell survival was defined as a rise in %hgb S or a fall in hgb >2 times the standard deviation of their individual mean. For those transfused episodically, we compared the %hgb S and hgb at time of new antibody detection to baseline outpatient hgb levels and expected %S post transfusion. **Results/Findings**: A total of 246 antibodies were detected among 138 immunized individuals during the study period (1/1/03 - 12/31/15). The mean age at time of detection was 12.2 years. We excluded 75 from the transfused red cell survival analysis due to concomitant medical complication, insufficient data to calculate baseline values, or antibody detection >1 month after an episodic transfusion. Of 171 remaining antibodies, 58 (34%) were associated with a HTR or poor transfused red cell survival at time of first detection. Sixteen of the 58 antibodies were found simultaneous with another specificity; thus one or both could have caused the DTR. Anti-Rh antibodies were most common despite prophylactic matching, and 33 of 113 (29%) showed evidence of a DTR. Eight clinical HTRs were reported with no specificity identified. Several cases of anti-M, -Knops A, -Lea and -HE were associated with a DTR. It is possible that an additional specificity may not have been detected in these cases. Among chronically transfused patients, the duration of antibody detection with or without a DTR was not different. **Conclusion**: In children with SCD, 34% of antibodies at first detection were associated with a clinical HTR or decreased transfused red cell survival. HTRs were reported for which no specificity was identified or with a specificity typically not associated with hemolysis. The duration of antibody detection in the chronically transfused did not correlate with clinical significance.

S38-030B

Transfusion Reactions in Children Reported to the Norwegian Hemovigilance System (2004-13)

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Background/Case Studies: The Norwegian Hemovigilance system was launched in 2004. Between 2004 and 2013, a total of 2.6 million blood components were transfused. More than 3 000 transfusion reactions were reported. **Study Design/Methods**: We analyzed all transfusion reaction reports received between 2004 and 2013. We compared the types of reactions in children aged 0-19 with those in adults, and looked at the blood components responsible for the reactions. All red cell concentrates (RCC) transfused in Norway are leukoreduced. Approximately 70% of platelet concentrates are produced from buffy coat and 30% from aphaeresis. All platelet concentrates are leukoreduced. The only plasma product used in Norway is Octaplas. Our calculated ratios are based on the assumption that pediatric transfusions (patients from 0-19 years old) account for approximately 4.5% of all transfusions, since data from other Nordic countries and UK indicate that children receive approximately 3.3-9.7% of all transfusions. **Results/Findings**: From 2004 to 2013 we received 323 reports on transfusion reactions in children, including incorrect blood component transfused (IBCT), 298/100 000 transfused units, compared to 106/100 000 in adults. Errors leading to IBCT were reported in 33 cases. Children receive 4.5% of the blood components, but are involved in 16% of all reported cases of IBCT. In most of the cases there was a failure to provide blood component of the appropriate specification, such as failure to irradiate (nine cases), too old blood product (nine cases) or failure to meet phenotype requirements (six cases). In five cases, the blood product was transfused to the wrong patient. In five cases other errors occurred. In one case, several errors occurred. Seven reactions were life-threatening (anaphylactic reactions). Fourteen reactions were serious (13 anaphylactic reactions and one case of bacterial transmission). 43.7% of all reactions in children were allergic, compared to 16.4% in adults. 26.9% were febrile non-hemolytic reactions (FNHTR), compared to 49.7% in adults. 72% of the allergic reactions occurred after platelet transfusion, 25% after RCC transfusion and 3% after transfusion of Octaplas. 43% of the FNHTR occurred after platelet transfusion, 54% after RCC transfusion and 3% after Octaplas. **Conclusion**: In our material, the risk of allergic reactions seems to be higher in children than in adults. Allergic reactions occur most frequently after platelet transfusions. FNHTR seems to be less frequent in children than in adults. IBCT occur relatively more often in children (10% of all adverse events) than in adults (5.4% of all adverse events). The total risk of adverse events in transfusion seems to be higher in children than in adults.

S39-030B

Transfusion Premedication Practices in Pediatrics: Results of a Canadian Survey

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TABLE. Reported barriers to change in premedication practice

Education-based barriers	Institution-based barriers
1) lack of staff education about which reactions require premedication or blood product manipulation; 2) lack of teaching during residency; 3) difficulties changing a learned behavior; 4) fear/assumption that reactions will recur; 5) belief that the benefits of premedication outweigh the risk of none; 6) lack of evidence or clinical guideline.	1) lack of appropriate documentation of previous reactions forcing healthcare providers to confirm with parents; 2) pressure to abide by standardized practices instead of individualizing patient care; 3) the need to avoid hospital admissions for empiric antibiotic treatment of fever (e.g. febrile neutropenia); 4) advice from the oncologist to premedicate when patient is under non-oncology care.

Background/Case Studies: Though not supported by strong evidence, premedication (pre-transfusion medication) is commonly prescribed to patients who have had a transfusion reaction to prevent future reactions. The research questions were: 1) What are Canadian pediatric practitioners' views and practices regarding premedication; 2) What are barriers to reducing premedication overuse in pediatrics? **Study Design/Methods**: An online survey targeted hematology/oncology, emergency medicine, general surgery, intensive care, and cardiac intensive care practitioners in all 16 Canadian pediatric tertiary hospitals. The survey included 26 questions in four sections: 1) demographic information, 2) clinical questions, 3) future directions, and 4) organizational information. A descriptive analysis of the survey results was performed. **Results/Findings**: Fifty-five individuals from 15/16 pediatric tertiary care sites completed the survey: 53 physicians and 2 nurse practitioners. Over half of respondents (55%; 30/55) were pediatric hematology/oncology providers, and 35% (19/55) were Directors of their respective divisions. The majority of respondents (87%; 48/55) estimated that they premedicate up to 25% of red blood cell transfusions (RBCTx), and 13% (7/55) premedicate 26-50% RBCTx. Proportions were similar for platelet transfusions. Most respondents reported that trainees are involved in transfusion and premedication order decisions. The top three factors that influence a prescriber's decision to premedicate are: 1) history of transfusion reaction, 2) severity of previous reaction, and 3) parent request for premedication. Only 22% of respondents (12/55) consider blood product type (RBC vs. platelets) when deciding to premedicate. Four respondents (7%) believe their hospital does not use leukoreduced products and 15 respondents (27%) are not sure. Thirty-six respondents (65%) were not aware of a clinical practice guideline (CPG) or a standard order set (SOS) at their institution: 51% are interested in having both available. Identified barriers to practice change are summarized in the table. **Conclusion**: Four important messages were derived: 1) there is a lack of standardized practices in Canadian pediatric academic hospitals; 2) there is a knowledge-to-action gap regarding universal leukoreduction in Canada, the importance of transfusion reaction reporting, and risk factors for febrile and allergic transfusion reactions; 3) premedication CPG and SOS are desirable future steps to overcome identified barriers to practice change; and 4) further research is needed regarding the benefits of premedication and the risks of not premedicating. There were perceived educational and institutional barriers to practice change.

S40-030B

Outcomes Related to the Use of Single-Donor Plasma or Pooled Solvent/Detergent Plasma in Critically Ill Children

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Background/Case Studies: FFP and FP 24 (plasma) are single donor products that are frozen within 8 and 24 hours respectively. Pooled solvent detergent plasma (SDP) is processed from over 1000 donors and is treated to inactivate pathogens and white blood cells to improve its safety profile. Studies have not been performed to compare the efficacy and safety of these different plasma products in children. The objective of this study was to determine if plasma processing methods are associated with INR reduction and ICU mortality rates in critically ill children. **Study Design/Methods**: This is a secondary analysis of a prospective observational study in which we *a priori* planned to analyze if there was an independent association between the type of plasma transfused with either INR reduction or ICU mortality in critically ill children. One hundred one pediatric intensive care units in 21 countries participated on 6 predefined weeks. Study groups were defined as those transfused either plasma or pooled SDP. Multivariate logistic regression was used to adjust for confounding factors on outcomes measured. All variables that were associated with the outcome of interest were included in the multivariate regression models. **Results/Findings**: There were 443 critically ill children analyzed with 43% male patients. The median (IQR) age and weight were 1 year (0.2-6.3) and 9.1 kg (4.0-20.8). Children received either plasma or pooled SDP exclusively. While the primary indication for transfusion was different between the study groups, there was no difference in illness severity parameters between the two groups such as PELOD2 scores, pre-transfusion INR or highest lactate on day of transfusion. The difference in total volume of plasma transfused in the single donor plasma group (21.3 ml/kg) compared to the SD group (15.1 ml/kg) and approached significance ($p=0.07$). There was no difference between study groups in INR reduction pre and post transfusion ($p=0.99$). ICU mortality was lower in the pooled SDP vs plasma group (14% vs 29%), respectively. Upon multivariate logistic regression, there was an independent association of pooled SDP use with reduced ICU mortality that approached significance, Odds Ratio 0.43 (95% CI, 0.18-1.02), ($p=0.06$). **Conclusion**: Pooled SDP use compared to plasma in critically ill children had similar effects on INR reduction but may be associated with reduced ICU mortality. This hypothesis generating data supports a randomized controlled trial comparing SDP to single donor plasma products such as FFP or FP24.

S41-030B

Oxidation Reduction Potential (ORP) is Predictive of Complications following Cardiac Surgery in Pediatric Patients

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Background/Case Studies: ORP or Redox is the ratio of activity between oxidizers and reducers. Redox imbalance results in oxidative stress (OS). While OS can cause cellular injury and death, it is also important in the regulation of a healthy immune response to injury or disease. In the present study we investigated changes in the redox system as a function of cardiopulmonary bypass (CPB) in pediatric patients. **Study Design/Methods**: 664 plasma samples from 162 patients were available from a prospective randomized controlled trial of washed transfusions in pediatric patients undergoing cardiac surgery. All blood products were leukoreduced, irradiated and ABO identical, without restrictions on storage age. Citrated blood samples were collected at pre-op, immediately post CPB, 6 and 12 hours after CPB. C-reactive protein (CRP), IL-6, IL-10, and hemoglobin were measured as markers of inflammation. Static ORP was evaluated as an additional marker of inflammation, poor outcome, and/or development of complications. **Results/Findings**: There was no significant difference in ORP values at any time between the washed and unwashed transfusion groups. When the two groups were combined, lower ORP values at 12h post-CPB were associated with poor survival (mean 138 ± 19 versus 167 ± 20, $p=0.005$) and higher rate of thrombotic complications (mean 153 ± 21 versus 168 ± 20, $p<0.008$). Patients who developed infections had lower ORP values at 6h (mean 149 ± 19 versus 160 ± 22, $p=0.02$) and 12h (mean 156 ± 17 versus 168 ± 21, $p=0.004$) post-CPB. Patients that developed subsequent post-complications also had lower 6h (mean 149 ± 17 versus 161 ± 23, $p=0.002$) and 12h (mean 157 ± 18 versus 170 ± 21, $p=0.0007$) post-CPB ORP values. The risk adjustment for congenital heart surgery (RACH) score correlated with both 6h and 12h post-CPB ORP scores. Patients with lower RACH scores had higher ORP and those with higher RACH scores had lower ORP

(p=0.008 at 6h and p=0.0008 12h post-CPB). There was no significant difference in ORP values when examined with respect to comorbidities. The patients with cyanotic heart disease had lower ORP values at all times. After CPB, all patients had decreases in ORP that recovered over time. However, patients with cyanotic cardiac lesions were significantly slower in recovering their ORP values at 6h and 12h. Finally, increasing RBC transfusion dose was associated with decreasing ORP levels. Free hemoglobin and IL-6, IL-10 and CRP were not associated with ORP levels. **Conclusion**: These data demonstrate that a lower ORP value serves as a marker for poor outcome and is also predictive of development of thrombosis, infections, and other complications in pediatric cardiac surgery patients. These results suggest that redox imbalance from OS, in part due to transfusion, may contribute to poor outcomes in pediatric CBP patients.

S42-030B

Comparison of Blood Utilization Policies across Tertiary Care Centers that Care for Children

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Background/Case Studies: Hospital blood utilization policies are used to guide transfusion practice, however there is little level 1 evidence in pediatric patient populations to guide transfusion practice. Regulatory requirements require monitoring of transfusion practice to ensure appropriateness. We hypothesize there is practice variation in transfusion indications contained in hospital blood transfusion policies as well as auditing procedures at hospitals that care for children. **Study Design/Methods**: Blood utilization policies were obtained from 9 pediatric tertiary hospitals in North America in order to develop an understanding of the variation of content of blood utilization policies. The indication for blood transfusion from each center's policy was manually extracted and populated as database fields. Database fields were defined as either numeric variables such as grams/dL of hemoglobin, or nominal variables such as "dysfibrinogenemia in surgery." Descriptive analysis of practice variation was performed in Microsoft Excel 2010 and JMP Pro 11, SAS Institute. **Results/Findings**: The institutions had an average of 311 (range 42-620) total beds, 68 (range 20-171) neonatal intensive care beds, and 30 (range 0-69) pediatric intensive care beds. The majority were stand-alone pediatric medical centers (7 of 9). Seven of nine centers audited transfusion practice based on written policies. Altogether, there were 329 distinct blood transfusion indications identified from the policies; many specific indications were used only at one of the centers (Table 1). Only 52 (15%) transfusion indications were common to multiple institutions. Indications for red blood cells (RBC) made up 55% of all transfusion indications, suggesting a large degree of variation in practice. Cryoprecipitate had the least amount of indications, representing approximately 10% of all blood indicators. **Conclusion**: This exploratory analysis suggests substantial policy driven variability in blood transfusion policies across tertiary care institutions that care for children. The findings exemplify the lack of high quality evidence in pediatric transfusion to guide practice. Future work will expand analysis of transfusion indicators in hospital policies, and survey of auditing processes for blood transfusion in hospitals that care for children.

TABLE. Pediatric Transfusion Indications in Blood Utilization Policies in 9 Tertiary Care Hospitals Caring for Children

Blood Component Associated with Indication	# of Indications found in 1 Hospital	# of Indications Common to >1 Hospital
RBC	161 (88%)	20 (12%)
Platelet	48 (80%)	12 (20%)
Plasma	41 (77%)	12 (23%)
Cryoprecipitate	27 (77%)	8 (23%)

TABLE. pH and Dose of INTERCEPT Platelet Components

FDA Parameter	Timepoint	Results	Meeting Requirement #/N (%)	1-sided 95% CI[b]
pH(22°C) [≥6.2][a]	D5	7.1 ±0.2 [5.7-7.6]	461/464 (99.4%)	≥98.3%[c]
≥3.0×10[11] platelets[a]	Post-INT D1/2	3.9 ±0.9 [2.5-7.5]	440/463 (95.0%)	≥93.0%
	D5	3.8 ±0.9 [2.5-7.5]	410/450 (91.1%)	≥88.6%

[a] 21 CFR 640.25 (b)(2)
[b] Lower bound of a one-sided 95% Clopper Pearson CI
[c] The two-sided-95%-exact-CI for the difference in D5 pH failure rates (INTERCEPT platelets – Historical Controls, where pH<6.2 is considered a failure): -0.028 to 0.001

Transfusion Practice II

S43-030C

Evaluation of Platelets in 100% Plasma Treated with Amotosalen-UVA

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Background/Case Studies: The INTERCEPT® Blood System for platelets is FDA approved for the *ex vivo* preparation of pathogen-reduced apheresis platelet components (PC) to reduce the risk of TTI, including sepsis, and to potentially reduce the risk of transfusion-associated GVHD. The initial FDA licensure was for INTERCEPT treatment of PC suspended in plasma and platelet additive solution (PAS)-3, collected on the Amicus separator. The label was expanded in 2016 to allow for INTERCEPT treatment of PCs suspended in 100% plasma, collected on the Trima separator. This *in vitro* study was performed to support a US label extension for apheresis platelets in 100% plasma. **Study Design/Methods**: The objective of this prospective, multi-center, *in-vitro*, non-inferiority study was to evaluate the Day (D) 5 pH and platelet dose of INTERCEPT platelets suspended in 100% plasma. Apheresis donations (n=425) were collected using the Trima (Terumo BCT), 61.2%, and Amicus (Fenwal Inc.), 38.8%, separators. Input PCs containing an average of $4.9 \pm 1.3 \times 10^{11}$ platelets, in 364 ± 37mL of plasma, were treated by the end of D1 using the small volume (SV), large volume (LV) or Dual Storage (DS) INTERCEPT processing sets. Samples were collected from the input PCs and from components post-treatment and D5 post-donation. The acceptance criteria for the study were (1) the INTERCEPT pH failure rate on D5 is not inferior to the historical control failure rate of 13/668 (approximately 1.946%) using a non-inferiority margin of 3% at the 2-sided 0.05 alpha level and (2) at least 75% INTERCEPT PCs contain $\geq 3 \times 10^{11}$ platelets with 95% confidence. **Results/Findings**: D5 INTERCEPT PCs in 100% plasma contained, on average, 3.8 ± 0.9 platelets in 301 ± 64mL. The dose and volume recovery post the INTERCEPT process were 86.8 ± 4.8% and 92.5 ± 1.8%, respectively. The results for pH and dose are summarized in Table 1. **Conclusion**: INTERCEPT-treated PCs met the US CFR requirements for Day 5 pH and dose. Furthermore, non-inferiority between the Day 5 pH failure rates (13/668) of INTERCEPT platelets and Historical Controls (Tudisco *et al*, 2005) was achieved.

S44-030C

Longevity and Retransfusion Rates of Major ABO-Incompatible Platelets

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Background/Case Studies: Transfusion of major ABO-incompatible platelets is thought to result in shorter platelet survival due to anti-A and anti-B

TABLE. Time to retransfusion, quartiles, by ABO incompatibility of index transfusion

Incompatibility	n	Q1	Median	Q3	p (vs. no incompatibility)
None	1980	24.4h	47.5h	94.2h	N/A
Major	233	25.0h	48.1h	71.8h	0.108
Minor	109	23.9h	44.2h	76.9h	0.344
Bidirectional	29	25.5h	47.1h	72.5h	0.865

antibodies in patient plasma. Minor ABO-incompatible platelet transfusions can promote immune complex formation which is speculated to affect transfused platelet survival. There are limited data on the utilization impacts of ABO-mismatched platelet transfusions. We examined the occurrence and timing of repeat platelet transfusion in severely thrombocytopenic adult hematology inpatients to determine if ABO mismatching influences platelet usage rates. **Study Design/Methods**: This retrospective cohort study used anonymized adult inpatient data dated March 3, 2009 - October 1, 2015 from a hospital blood bank's laboratory information system. Data included platelet counts, ABO groups, and platelet transfusions occurring within 48 hours of a platelet count result. Transfusions to hematology and bone marrow transplant patients with platelet counts below 10 x 10^9/L were included. Transfusions more than 48 hours after the last platelet count measurement, or with no measurement since the last platelet dose were attributed to severe bleeding and excluded as index cases. Transfusions given with no patient blood group or platelet count available were also excluded. Cases were grouped as follows: ABO-identical, major ABO-incompatible, minor ABO-incompatible, and bidirectionally incompatible. Time to retransfusion was analyzed using the Kaplan-Meier product-limit method, right-censored at 120 hours. **Results/Findings**: Hematology patients received 5353 platelet units during the study period; 2351 transfusions were included. Compared with ABO-identical transfusions, there was no difference in the time to retransfusion for ABO incompatible groups. (see table; p for trend = 0.357). Only 13.3% of patients receiving ABO-major incompatible transfusions were free from retransfusion at 120 hours compared to 20.6% of those receiving ABO-identical transfusions ($p = 0.007$). Retransfusion rates at 120 hours in cases of minor ABO-incompatibility and bidirectional incompatibility did not significantly differ from ABO-identical transfusions. **Conclusion**: In inpatients with severe, largely hypoproliferative thrombocytopenia, major ABO-incompatible transfusions led to higher retransfusion rates at 120 hours. There was no difference in the time to retransfusion. More data is required to elucidate the impact of ABO-major incompatibility on platelet utilization.

S45-030C

Use of HLA Antigen-Negative Platelets Further Allosensitizes Platelet Refractory Patients

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Background/Case Studies: Human leukocyte antigen (HLA) alloimmune antibodies are an important cause of platelet refractoriness. In patients with HLA alloimmune platelet refractoriness (alloPR), current transfusion support strategies involve selection of HLA compatible platelets. These include matching donor and recipient HLA types (HLA matching) and avoidance of platelet donors whose antigens a recipient has made anti-HLA antibodies against (antigen-negative). Although these strategies are widely utilized, it is unclear whether differences exist between them in terms of further immune allosensitization. **Study Design/Methods**: Patients were diagnosed with HLA alloPR if they failed to display platelet count increments following allogeneic platelet transfusion and had documented anti-HLA antibodies. Transfusion support strategies primarily relied on the provision of HLA matched (at HLA-A and -B) or antigen-negative platelets. We retrospectively identified alloPR patients over a two-year period who underwent at least two anti-HLA antibody tests by single antigen (SAG1) flow-cytometric bead array and received HLA compatible platelets between tests. We tabulated HLA Class I phenotypes of transfused HLA compatible platelet units and determined if newly formed antibody specificities arose from HLA antigen mismatches. The theoretical impact of newly identified antibodies was determined by calculating their effect on the calculated panel reactive antibody (cPRA) percent using an online calculator. **Results/Findings**: A total of 14 alloPR patients were included in this study. Eleven of the 14 were women. The median interval between SAG1 tests was 2 months, and the average number of apheresis platelet doses received during this time was 10 (average of 6 HLA-compatible and 4 random-donor). Thirteen of the 14 (93%) patients formed at least one new reportable anti-HLA antibody between consecutive SAG1 tests. Notably, 4 patients (28%) formed new antibody specificities against mismatched antigens present on one or more selected antigen-negative platelets. The newly detected alloantibodies appear to represent both memory and *de novo*/primary antibody responses. The median increase in the cPRA attributable to these newly identified antibodies alone was 32% (range 7-84%). **Conclusion**: Although antigen-avoidance is a common approach for transfusion support, our data shows that over a quarter of alloPR patients can develop newly detectable antibodies against mismatched antigens present on such donor units. This increased allosensitization can further restrict selection of HLA compatible platelets. Though limited, these data suggest that when the clinical situation permits, antigen-negative platelet selection may not be the most optimal approach for HLA alloPR transfusion support.

S46-030C

Restricted Transfusion Management Decreases Plasma and Platelet Utilization among Adult Patients Receiving Extracorporeal Membrane Oxygenation

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Background/Case Studies: Hospitalized adult patients requiring extracorporeal membrane oxygenation (ECMO) support are at high risk for both bleeding and thrombosis. Currently, limited data exist regarding blood transfusion strategies in this setting. **Study Design/Methods**: We performed a retrospective review of adult ECMO patients treated at a single tertiary care center from 1/1/2013 to 5/31/2015. All consecutive inpatients who received ECMO for >24 hours were included. Patients initiated on ECMO before admission were excluded. Initial transfusion management protocol was based on current literature, subsequently modified to a restricted protocol after the first 6 months of use. Student's t-test and Chi-square test were used to compare outcomes between pre-specified subgroups, defined by survival, bleeding, and thrombotic events. **Results/Findings**: Forty-eight patients were included in the analysis, 26 on veno-arterial ECMO and 22 on veno-venous ECMO. Average age was 47.4 years. Indications for ECMO included cardiogenic shock (23, 47.9%), respiratory failure (20, 41.7%) and post solid organ transplantation (5, 10.4%). Eight (20%) patients were treated with a standard transfusion protocol and 40 (80%) with a restricted protocol. Following implementation of the modified transfusion protocol, patients received less plasma (4.3 v. 1.2 units,/day, $p=0.04$) and platelets (2.8 v. 1.1 units/day, $p<0.01$). Despite the restrictive transfusion protocol, patients experienced significantly less bleeding (8, 100% vs. 13 patients, 32.5%, $p<0.01$). Average heparin administration rate was similar pre and post-protocol implementation as were thrombosis and survival rates. In the combined cohort, patients required an average of 4.7 units of red blood cells units, 1.8 units of plasma, 1.4 apheresis platelet units, and 0.3 units of cryoprecipitate per ECMO day. Blood product use was similar independent of cannulation type and ECMO indication, and was not associated with mortality. The average hospital length of stay was 57 days; 45.8% of patients survived to hospital discharge. **Conclusion**: Refined transfusion parameters led to significant reduction in plasma and platelet use without bleeding complications. Further research is needed to guide transfusion management among adult ECMO patients.

S47-030C

Alloimmunization to RhD-Incompatible Red Blood Cell Units in Cancer Patients

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Background/Case Studies: RhD is a potent immunogen and as little as 0.03 ml of RhD positive blood can immunize an RhD negative (D-) recipient. The earliest studies done on healthy D negative volunteers who were exposed to RhD positive (D+) RBCs, reported alloimmunization rates of more than 80%. Patients with cancer have been shown to have varying degrees of immunosuppression, which put them at much lower risk for alloimmunization. Due to limited availability of the Rh negative blood components at our cancer center, we frequently have to issue D+ RBCs for D- patients. The purpose of the study was to report on the rate and elucidate risk factors for primary RhD alloimmunization in cancer patients. **Study Design/Methods**: Charts of all D-negative cancer patients who received D-positive RBCs between Jan 2011 to Dec 2014 were reviewed to identify anti-D antibodies on subsequent type and screens (T&S). Primary immunization was defined as anti-D formation after 28

days from the first exposure to D+ RBCs. This retrospective study focused on incombatible RBC units. None of the recipients were treated with Rh immunoglobulin. A recent negative T&S had to be documented before issuing D+ components to D- patients. All the patients where the follow up T&S was available less than 28 days post transfusion of D positive units were excluded. The association between responder (patients who become immunized after D+ transfusion) and the following variables were investigated: age, gender, race, ABO type, diagnosis, and number of units transfused. Fisher's exact test was used for association to categorical factors of interest while the Wilcoxon rank-sum test was used for continuous factors. Logistic regression models were used to assess the odds ratio and 95% confidence intervals for significant factors. **Results/Findings**: A total of 224,396 RBCs of all types transfused were transfused over the 4 year period out of which 5576 (2.5%) units of D+ RBCs were transfused to 936 D- oncology patients. Of these 936 D- recipients, 391 were excluded due to the lack of a T&S available 28 days after transfusion. The remaining 545 recipients were transfused 4294 units of D+ RBCs (mean volume 369 ml; range 174 - 547ml). Overall, 76 out of 545 (14%) D- recipients formed anti-D. Diagnosis type was the only significant factor associated with responders. Logisitic regression model indicated that patients with MDS and solid tumors (previously known) were more likely to be responders than those with acute leukemia (p=0.008, OR 4.3 [1.5-12.7], p=0.0002, OR 4.1 (2.0-8.7]). **Conclusion**: To date, this is the largest study on RhD incompatible RBC transfusions in oncology patients. The new finding that MDS patients had a higher odds ratio of forming anti-D after RBC transfusion has resulted in a significant practice change at our institution.

S48-030C

Comparison of Laboratory Role and Rh Immune Globulin Dose Calculation Accuracy

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Background/Case Studies: Accurate dosing of Rh immune globulin (RhIg) is necessary to prevent RhD alloimmunization in pregnant, RhD-negative women. Laboratories are often tasked with calculating postpartum RhIg dosage based on fetomaternal hemorrhage (FMH) quantitation. We analyzed responses to supplemental questions in the College of American Pathologists (CAP) proficiency testing for the Fetal RBC Detection Survey (HBF-B 2013), comparing the accuracy of RhIg dose calculation to the role of the individual submitting the dose recommendation. **Study Design/Methods**: Participants of the HBF-B 2013 survey were asked three survey questions: 1) based on results of FMH quantitation, indicate the total number of full (300 mcg) vials of RhIg that the participant would recommend, 2) does your laboratory calculate and recommend the number of RhIg vials to be administered to patients?, and 3) if your laboratory recommends the number of vials of RhIg to be administered, who submits the recommendation from the laboratory? Individual roles for those recommending RhIg dosage were categorized into technologist, physician, non-MD administrator, laboratory information system (LIS) and other. Calculations for RhIg dosage were performed using the AABB Technical Manual method (assuming a maternal blood volume of 5,000 mL) and based on the individual participant reported value for FMH quantitation. All analyses including the Chi-squared test, logistic regression, and Concordance Correlation Coefficient (CCC) were conducted using SAS software (SAS Institute Inc., Cary, NC). **Results/Findings**: Of 2,176 total participating laboratories, 1,392 reported recommending RhIg doses. The percent of laboratories reporting a physician or technologist as submitting the recommended RhIg dosage was 30.46% and 60.7%, respectively, with 3.81% of analyzed participants reporting the LIS and 0.79% reporting non-MD administrators. According to laboratory role, the percentage of correct RhIg doses reported were: LIS, 84.78%; physician, 74.8%; and technologist, 77.7%. There was no significant difference in RhIg dosage accuracy between: LIS and physicians (O.R. =1.899; 95% CI: 0.815-4.423), LIS and technologists (O.R. =1.599; 95% CI: 0.699-3.654), and physicians and technologists (O.R. =0.842; 95% CI: 0.610-1.162). The CCC between the AABB Technical Manual calculation and laboratories' calculations was 0.882 (95% CI: 0.868-0.895, $p<0.05$), indicating poor agreement and an overall lack of accuracy. **Conclusion**: While there was no significant difference among LIS, technologists, and physicians calculating the correct RhIg dose, a significant percent of all laboratories submitted an incorrect dose recommendation. Greater vigilance is needed to ensure proper calculations and RhIg dose recommendations for women with FMH.

Components and Component Processing I

S49-030D

Amotosalen and UVA are More Effective in the Inactivation of T-Cells Than Gamma Irradiation When Assessed by a Limiting Dilution Assay (LDA)

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Background/Case Studies: Transfusion Associated Graft *vs.*Host Disease (TA GVHD) results in high morbidity and mortality caused by contaminating T-cells present in transfused blood products. Gamma irradiation (GIRR) of platelet components (PC) with 2500 cGy is used to prevent TA GVHD when these products are transfused to high-risk patients. An alternative methodology to prevent TA GVHD is the photochemical treatment of PC with amotosalen/UVA (PCT; INTERCEPT^{TM} Blood System). PCT has replaced GIRR in Europe for more than 10 years and was recently recognized as an alternative to GIRR by AABB. In this study, we compared PCT with GIRR to inactivate T-cells in human plasma using a highly sensitive limiting dilution assay (LDA) method. **Study Design/Methods**: An LDA assay that allows the culture of 10^7 PBMCs in a single well and the detection of proliferating T-cells with high sensitivity was validated by comparison of T-cell proliferation in culture media, plasma, and plasma containing 10^7 inactivated T-cells. PBMCs harvested by leukapheresis from individual donors (AllCells, Alameda, CA) were spiked (10^6/mL) into identical units of human plasma and inactivated using either the INTERCEPT system, GIRR, or retained as an untreated control. For the LDA assay, PCT- or GIRR-treated cells were incubated (10^7/mL) for a period of 14 days in the presence of pooled allostimulator cells from 10 unrelated donors ($5X10^6$ treated with 7500 cGy) and growth stimulating factors (PHA and IL-2) under standard culture conditions. The levels of T-cells inactivated by PCT treatment (10^7 PBMC/well) were compared to T- cell levels inactivated by gamma irradiation (10^5, or 10^6 PBMC/well). Proliferation was assessed by tritiated thymidine (6.7 Ci/mmol) incorporation into PBMC. In addition, wells were inspected microscopically and scored for evidence of growth. T-Cell precursor frequency was measured for each donor by incubation of viable PBMCs (50, 25, 13, 6.5, 3, 1/well) in the presence of 10^7 inactivated PBMCs. 12 wells were used for each dilution and the protocol was carried out in 6 replicates. **Results/Findings**: No T-cell growth for PCT-treated PBMCs was detected by ^{3}H-Thy incorporation above the cutoff for viable PBMCs with 10^7 cells/well cultured. However, ^{3}H-Thy incorporation above the cutoff was observed when 10^6 GIRR PBMCs per well were cultured. No incorporation was observed when 10^5 GIRR PBMCs were cultured. Proliferating T-cell colonies were observed in 4/6 replicates with 10^6 GIRR PBMCs/well, and in none of the cultures with 10^5 GIRR or PCT PBMCs/well. **Conclusion**: Treatment of T-cells with amotosalen/UVA results in more robust T-cell inactivation (>6.2 $\log_{10}$) than with 2500 cGy gamma irradiation ($4.2\log_{10}$ - 6.2 $\log_{10}$). The data in this study have not been reviewed by the FDA; current approved claim is for $\log_{10}$.

S50-030D

In Vitro Evaluation of DEHT (Bis(2-Ethylhexyl) Terephthalate) Plasticized PVC Blood Bags for Red Blood Cell Storage in AS-1 and PAGGSM Preservative Solutions

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Background/Case Studies: Di-(2-ethylhexyl) phthalate (DEHP) makes PVC film flexible and useful for blood bags. Use of DEHP also has a beneficial membrane-stabilizing effect on RBCs resulting in lower hemolysis levels. During storage, DEHP can leach from the bag film into solution and be metabolized. Studies in rodents have suggested that exposure to DEHP may be associated with adverse health effects. Both the FDA and EU laws allow the use of DEHP in medical devices. Nevertheless, there have been many attempts to find DEHP alternatives for blood bags, made difficult by DEHP's membrane-stabilizing effect. This study tests an alternative non-phthalate plasticizer bis(2-ethylhexyl) terephthalate (DEHT). Although structurally and functionally similar to DEHP, DEHT is very distinct from a metabolic and toxicological standpoint since DEHT can undergo complete hydrolysis. Introduced in 1975 DEHT has an excellent toxicological profile: it is not a carcinogen, mutagen, or reproductive toxicant. **Study Design/Methods**: The in vitro study objective was to evaluate RBC stability while stored in DEHT plasticized containers with AS-1 and PAGGSM preservative

TABLE. Day 42 Results (Mean ± SD), N = 12

	Bag and Preservative Type		
	DEHP with AS-1	DEHT with AS-1	DEHT with PAGGSM
Hemolysis (%)	0.32 ± 0.07	0.49 ± 0.13*	0.38 ± 0.10*
ATP (μmol/g Hb)	3.34 ± 0.46	3.13 ± 0.46*	3.03 ± 0.36*
ATP % of Initial Value	76.9 ± 5.6	70.8 ± 6.4*	72.7 ± 3.3*
Potassium (mmol/L)	51.8 ± 2.9	51.3 ± 2.8	52.9 ± 2.4

*p<0.05 from Day 42 Control

solutions compared to RBCs stored in conventional DEHP plasticized containers with AS-1 solution. Thirty-six (36) whole blood units were collected into CPD anticoagulant, leukoreduced, centrifuged, and separated into RBCs and plasma. Twelve (12) pools of 3 ABO-identical RBCs were mixed together and then divided equally among three different plasticizer and preservative solution combinations: DEHP/AS-1 (Control), DEHT/AS-1, and DEHT/PAGGSM. In vitro RBC testing (CBC, rWBC, ATP, 2,3-DPG, hemolysis, pH, pCO2, pO2, RBC morphology score, and plasma hemoglobin, potassium, glucose, and lactic acid) was done on Days 0, 35, and 42 of 1 to 6°C storage. **Results/Findings**: Table 1 summarizes the key results from the study. No individual bag at Day 42 exceeded the U.S. 1.0% hemolysis criteria or the EU 0.8% hemolysis criteria. ATP retention was above 70% and potassium levels were as expected regardless of plasticizer. Additional RBC parameters exhibited some statistically significant differences but were not viewed as clinically important. **Conclusion**: DEHT with PAGGSM provides similar hemolysis protection to that of DEHP. Although hemolysis values with DEHT and AS-1 are higher than that of DEHP, DEHT can be considered a viable replacement of DEHP in RBC storage bags.

S51-030D

Anaerobic Conditions Reduce Deterioration of Rheological Properties of Stored Red Blood Cells

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Background/Case Studies: Red blood cells (RBCs) are stored in polyvinylchloride (PVC) bags containing additive solution at 2-6°C for up to 6 weeks prior to transfusion. During this hypothermic storage the biochemical and mechanical properties of stored RBCs deteriorate progressively. Oxidative damage is believed to be a primary mediator of this so called storage lesion. We reasoned that storing RBCs under anaerobic conditions may attenuate storage lesion and thereby preserve rheological properties better than conventional (aerobic) storage. Here we describe a split-unit comparison study of rheology of anaerobically and conventionally stored RBCs over 6 weeks of hypothermic storage. **Study Design/Methods**: RBCs were obtained from consenting volunteers (n=9). O_2 and CO_2 levels of RBCs to be stored anaerobically were reduced with a neonatal membrane oxygenator. All RBCs were stored in 150mL PVC blood bags. Anaerobically stored RBCs were overwrapped in oxygen-impermeable bags containing oxygen sorbents. Paired RBC units were evaluated weekly for 6 weeks. The mechanical properties of RBCs were evaluated with custom microfluidic devices - artificial microvascular network (AMVN) and multiplexed microcapillary network (MMCN) - and using two ektacytometers (LORRCA and RheoScan-D). RBC morphology was quantified biweekly. A paired, two-tailed t-test was used to compare groups; with $p<0.05$ considered significant (marked by *). **Results/Findings**: AMVN (**Table**) and MMCN bulk perfusion rates were consistently higher for anaerobically stored RBCs. The time individual MMCN capillaries spent in a plugged state (**Table**) and the total number of plugging events were consistently lower for anaerobically stored RBCs. The fraction of RBCs with irreparably damaged morphologies (**Table**) was consistently lower in anaerobically stored units. Interestingly, neither ektacytometer showed a consistent, significant difference between anaerobically and conventionally stored RBCs. **Conclusion**: This study shows that anaerobic conditions decrease the rate of RBC rheological property deterioration during hypothermic storage. Our data suggests that anaerobic storage may preserve RBC function better than conventional storage, potentially improving the quality and efficacy of stored RBCs.

S52-030D

Identification of Metabolomic Signatures that Correlate with Post-Transfusion Survival of Human RBCs

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Background/Case Studies: A requirement for US regulatory approval of RBC collection, treatment and storage methods is adequate *in vivo* survival of ^{51}Cr-labeled autologous RBCs at maximum storage time; target RBC recovery is 75% at 24-hrs post-transfusion. While rarely mentioned, a wide distribution in RBC recoveries is seen in these studies. Although RBCs from most donors repetitively display 75-85% post-transfusion survival, RBCs from other donors consistently show comparatively poor (<75%) or excellent (>90%) recoveries. We reasoned that studying RBCs from these donors may reveal important metabolic polymorphisms that underlie the observed differences in RBC survival. **Study Design/Methods**: Leukoreduced pRBC units were collected from 9 donors with repetitively poor (<75%; n=3), excellent (>90%; n=3), or typical (75-90%; n=3) historical

TABLE. Comparison of conventionally and anaerobically stored RBC properties

		Wk 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6
AMVN perfusion rate (pL/s)	Anaerobic	216 ± 13	205 ± 11*	195 ± 14*	180 ± 11	180 ± 13*	169 ± 15	163 ± 18*
	Conventional	214 ± 13	197 ± 10*	190 ± 12*	178 ± 11	176 ± 12*	166 ± 15	155 ± 16*
MMCN plugging event time (%)	Anaerobic	23.1 ± 9.5	39.2 ± 7.5*	44.0 ± 12.6*	54.3 ± 10.6*	64.8 ± 9.8*	65.9 ± 9.4*	68.9 ± 6.6*
	Conventional	26.6 ± 11.1	47.5 ± 10.6*	51.3 ± 14.9*	60.3 ± 5.7*	70.7 ± 8.0*	72.1 ± 8.3*	74.9 ± 6.0*
Irreparably damaged RBCs (%)	Anaerobic	0.1 ± 0.3	–	0.6 ± 0.6	–	2.1 ± 1.4	–	4.8 ± 2.0*
	Conventional	0.0 ± 0.0	–	0.8 ± 0.7	–	3.4 ± 1.1	–	7.0 ± 2.2*

24-hr RBC recoveries. Serial RBC aliquots (storage days 1-42) were subjected to metabolomics analysis and quantitation of *in vitro* physiologic parameters (spontaneous hemolysis, hemolytic propensity, ATP and 2,3-DPG). Samples were then decoded, and biostatistical methods (Principal Component Analysis, PCA; multilevel sparse Partial Least Squares Discriminant analysis, msPLSDA) were used to identify metabolites that differentiated between poor- vs excellent-storing RBCs. **Results/Findings**: From among 6600 distinct mass spectrometric m/z features, msPLSDA identified the top 300 metabolites that discriminated between poor vs excellent storing RBCs; these 300 were separated into 3 PCs. PC3 was of particular interest due to its strong association with RBC recovery. In fact, initial PC3 values (storage day 1) correlated with poor vs excellent 24-hr post-transfusion survival after 42 days of storage ($P=0.016$; results were similar when PCA used all 6600 m/z features). Surprisingly, when the *in vitro* physiologic parameters were similarly studied, network analysis showed only a 4% overlap between the metabolites that correlated with 24-hr *in vivo* RBC survival and also with *in vitro* hemolysis, hemolytic propensity, ATP or 2,3-DPG. **Conclusion**: Metabolomics on samples from donors selected based on their historic, reproducible RBC recoveries revealed distinct RBC metabolomic signatures seen as early as day 1 of storage that correlated with subsequent 24-hr post-transfusion RBC survival after the units had been stored 42 days; if verified, these metabolites could be useful to identify donors with desirable RBC storage characteristics. Furthermore, our results also suggest that 96% of metabolites that correlate with *in vitro* measures of stored RBC physiology (eg, ATP and hemolysis) do not correlate with post-transfusion survival. Pathway analysis is underway to identify enzymatic polymorphisms that produce these donor-specific metabolic variations.

S53-030D

Dynamic Metabolic Flux Analysis of Stored Red Blood Cells

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Background/Case Studies: The metabolism of red blood cells (RBCs) is affected during the storage of erythrocyte concentrates (ECs) in saline adenine glucose mannitol (SAGM) solution for up to 42 days at 4°C. This alteration impacts RBCs in a cascade of events that leads to molecular and cellular lesions. The study of RBC metabolism is of particular interest since end-of-storage RBCs can induce clinically adverse effects on transfused patients. **Study Design/Methods**: Ex vivo RBC aging was weekly studied by targeted metabolomics based on a list of 190 metabolites. Intracellular metabolites from 5 ECs (independent donors, 3 males O Rh+, 2 females A Rh+) were extracted using a methanol-based protocol, analyzed in triplicates by liquid chromatography (ZIC-pHILIC column) coupled to an Exactive Plus Orbitrap mass spectrometer (full-scan acquisition, resolution = 140,000 at m/z 200). Extracted-ion chromatograms were constructed for relative metabolite quantification. Metabolite flux analyses were based on a limited number of biologically relevant reactions (75) that belong to the main metabolite pathways in RBCs. Reaction rates were composed of Michaelis-Menton kinetics. **Results/Findings**: Seventy-one metabolites exhibited significant variations ($p\text{-value} < 0.05$ and max fold change of 2) over the storage time (42 days) and the principal component analysis discriminates 7 groups related to ex vivo aging. Three zones were identified (day 2 to 16, 16 to 23 and 23 to 44). Differences were exacerbated at the beginning of the storage since the highest variations were reported during the first 2 weeks of storage. A decrease in glycolysis during the first weeks was observed as well as a decrease of glutathione synthesis and an accumulation of metabolites in purine metabolism such as hypoxanthine and xanthine at the end of the storage. These accumulations clearly indicates that an important part of the purines were derivate to non usable products for ATP synthesis. Metabolite fluxes will be discussed considering the known lesions on proteins and particularly on enzymes, and the evolution of antioxidant power. **Conclusion**: This simplified dynamic metabolic flux analysis allowed to probe metabolites concentration evolution during the storage of RBCs. This approach based on omics and in silico modeling will improve knowledge on RBC chemistry and biology. Moreover, it could simulate RBC storage under different conditions, which goes further the hematological gold standards to better predict RBC storage efficacy. Since the last weeks of storage appear the most deleterious for transfused patients, efforts should be put on the improvement of cellular metabolism to delay the storage lesions, in addition of reviewing the blood management.

S54-030D

A High-Throughput Microfluidic Device for the Selective Removal of Activated Granulocytes from Recirculating Whole Blood during Cardiopulmonary Bypass

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Background/Case Studies: Clinical studies have shown a correlation between improved patient outcomes and the removal of activated granulocytes (primarily neutrophils) from recirculated blood during cardiopulmonary bypass (CPB). Conventionally, in-line leukoreduction (LR) filters are used to trap leukocytes during CPB. Trapped leukocytes become activated and release cytokines, endotoxins and adhesion molecules into the patient's bloodstream, resulting in increased inflammatory response, pulmonary failure and even death. Here we describe a high-throughput microfluidic device for selective extraction of granulocytes from recirculating blood during CPB, while allowing other types of leukocytes (e.g. lymphocytes) as well as red blood cells and platelets to pass through back into the patient. **Study Design/Methods**: The microfluidic device for selective removal of granulocytes was designed using the 'controlled incremental filtration' approach recently developed by our group, and fabricated using soft lithography from poly(dimethylsiloxane). Whole blood was obtained from healthy consenting volunteers (n=5) and the hematocrit was adjusted to 25% with normal saline to mimic current CPB practice. The blood was passed through the device with a peristaltic pump at a flow rate of 5 mL/min. A complete blood count with 3-part differential was performed on all blood samples using a hematology analyzer. **Results/Findings**: The microfluidic device was able to remove 97% of granulocytes, while returning 66% of lymphocytes, 97% of red blood cells (RBCs) and 92% of platelets to the circulation (Table) (which meets current FDA performance requirements established for the in-line LR filters). Our device was able to simply divert granulocytes from continuously flowing blood, thus preventing the release of pro-inflammatory molecules (e.g. IL-6, IL-8) into the blood stream, and avoiding eventual reduction of efficiency plaguing conventional in-line LR filters used in CPB. **Conclusion**: This work represents the first step towards enabling selective removal of granulocytes from recirculating blood during cardiopulmonary bypass. Our high-throughput microfluidic device was able to remove 97% of granulocytes (leukocyte subtype primarily responsible for inflammation), while preserving most of lymphocytes (which are responsible for immunity). The ability to remove activated granulocytes with consistent efficiency, while minimizing the release of harmful cytokines into the bloodstream, could have a potentially transformative impact on well-being of CPB patients.

TABLE. Performance of the microfluidic device vs conventional in-line LR filter

Leukoreduction method	Granulocytes removed (%)	Lymphocytes removed (%)	Platelets removed (%)	RBCs Removed (%)
Microfluidic device	97.21	34.34	8.56	2.97
Conventional LR filters	~98	~98	~11	~1

RBC Immunohematology: CD38 Interference with Serologic Testing and KEL Expression Effects

S55-030H

Daratumumab (anti-CD38) Induces Loss of CD38 on Red Blood Cells

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Background/Case Studies: Recent advances in cancer therapeutics allow more specific targeting of neoplastic disease. However, most new cancer

targets still display significant expression on normal tissue, resulting in off target engagement. A classic example of this is Daratumumab (DARA), a recently approved anti-CD38 monoclonal antibody used to treat patients with multiple myeloma. As CD38 is also present on RBCs, DARA often induces pan-reactive antibody screens (ABSs). However, simultaneous direct antiglobulin tests (DATs) often are unexpectedly negative. As recent studies in animal models suggest that anti-RBC antibodies can modulate or otherwise remove target antigens, we hypothesized that DARA may actually induce loss of CD38 on RBCs isolated from treated patients. **Study Design/Methods**: Samples were obtained from patients receiving weekly DARA and from non-treated controls. Routine ABSs and DATs were performed by a blood bank technologist; DATs and CD38 antigen detection (using DARA as the primary antibody) were also performed by flow cytometry. To investigate the specificity of DARA effects, CD38, Kell (K) and Duffy (Fy) antigen levels were determined in parallel by flow cytometry and Western Blot. Additionally, complement bound to RBCs was quantified. **Results/Findings**: During routine blood bank testing, 23/24 samples from DARA-treated patients had positive ABSs but negative DATs; all 24 non-treated controls had negative ABSs and DATs. Consistent with the negative blood bank DATs, RBC samples from both patient groups showed negative flow DATs (based on low mean fluorescence intensities [MFI] which were comparable between groups). However, CD38 antigen levels (after adding exogenous DARA to all RBC samples), were significantly higher on RBCs isolated from non-treated compared to DARA-treated individuals. In contrast, K and Fy RBC expression remained unchanged following DARA treatment. No bound complement was detected in either group. Additionally, serial samples obtained from one DARA-treated patient before and after treatment demonstrated a decline in CD38 antigen levels following DARA infusion, while similar changes in K and Fy failed to occur. Western blot analysis demonstrated complete absence of CD38 on RBCs following DARA-treatment. **Conclusion**: Here we describe the first reported example of CD38 antigen loss on RBCs attributable to DARA treatment. Loss of CD38 was confirmed by both quantitative flow cytometry and Western blot. The DARA effect was antigen specific, as no changes in K or Fy antigen levels were seen. No complement was detected on the RBC surface, indicating that DARA-mediated CD38 antigen loss occurs independent of complement. These results suggest that DAT negative DARA treated patients have likely experienced DARA-mediated removal of the CD38 antigen.

S56-030H

Validation and Use of Serological CD38-Negative "DARA RBCs" as a Novel Method in Antibody Identification in Patients on Daratumumab Therapy

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Background/Case Studies: Daratumumab (DARA) is an FDA-approved human monoclonal anti-CD38 to treat multiple myeloma and will enter further clinical trials to treat selected CD38+ hematological malignancies. DARA binds to CD38 expressed on RBCs and interferes in serological testing. Two approaches to circumvent this are the use of 0.2M DTT or trypsin-treated panel cells. However, DTT and trypsin destroy antigens in some blood group systems (e.g., LU, DO, YT) that have clinically significant antibodies. To overcome this, we describe the validation and use of serological CD38- RBCs (i.e, RBCs from patients receiving DARA) or "DARA RBCs" as a novel tool in antibody identification (Id). **Study Design/Methods**: This study aimed to show that DARA therapy does not change RBC antigen expression and that "DARA RBCs" can be used in antibody Id of patients receiving DARA. Standard hemagglutination tests were used. RBCs were tested and qualified on day 1 of use for antigens in RH, MNS, P1PK, LE, LU, KEL, FY, JK, DO, YT systems. Genomic DNA was isolated from WBCs and tested using HEA PreciseType. A set of 5 RBC samples from patients receiving DARA were tested for the study. Patients were transfusion-free with no history of allogenic stem cell transplant. 4 RBC samples, "DARA RBC 1" to "DARA RBC 4" were recovered from liquid nitrogen (LN2) storage. "DARA RBC 5" was a fresh EDTA sample. All RBCs were stored in Alsever's at 4°C and tested weekly for 3 or 4 weeks for change in RBC antigen expression and stability. "DARA RBCs" were also included as in-house panel cells for antibody Id of samples from patients on DARA therapy as DARARBCs express antigens destroyed by trypsin or DTT treatment, specifically Do^a/Do^b, Jo^a, Hy, Gy^a; Lu^b, Yt^a, LW; MER2; IN; JMH and high-prevalence Kell antigens. "DARA RBCs" were tested with patient plasma samples of the following specificities: anti -k,-Kp^b,-Lu^b,-Yt^a,-Gy^a and monoclonal anti-Do^b. **Results/Findings**: All "DARA RBCs" were DAT-negative throughout the study. No overt hemolysis or weakening of antigen expression was observed. These "DARA RBCs" were used to test 125 plasma samples containing anti-CD38 over 5 months and interference from anti-CD38 was circumvented by their use. **Conclusion**: We describe a novel tool to test patient samples containing anti-CD38. "DARA RBCs" can be used as adjunct panel cells in antibody Id to rule out clinically significant antibodies that may be missed by testing DTT or trypsin treated RBCs. "DARA RBCs" are readily available and can be phenotyped/genotyped for antigen profiles. Antigen expression was stable for the fresh or the LN2 RBCs and they can be stored for at least 3 weeks. 125 plasma samples with anti-CD38 reactivity were non-reactive with our DARA RBC panel, thus ruling out clinically significant antibodies not detected by other methods.

S57-030H

Serologic Characteristics of Samples Sent to an Immunohematology Reference Lab from Patients Receiving Anti-CD38 (Daratumumab)

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Background/Case Studies: Daratumumab (DARA; monoclonal anti-CD38) was FDA approved Nov 2015 for treatment of multiple myeloma (MM). DARA can bind to CD38 on RBCs and cause positive (pos) indirect antiglobulin tests (IATs) and some pos direct antiglobulin tests (DATs). Pretreatment of reagent RBCs with dithiothreitol (DTT) has been reported to eliminate DARA interference, allowing identification of underlying antibodies (abs), except those to DTT-sensitive antigens, e.g., anti-K. Cord RBCs and Lu(a−b−) RBCs have been reported to be nonreactive with DARA. **Study Design/Methods**: We retrospectively reviewed data on patients (pts) whose samples were sent to our Immunohematology Reference Lab (IRL) from Nov 2015 to Apr 2016 and in whom anti-CD38 was detected. Methods included tube DATs (anti-IgG and anti-C3), acid eluates, EDTA glycine acid (EGA) and chloroquine (CDP) RBC treatments, and IATs by LISS, PEG, ficin, and 0.2M DTT (tube methods). Relative CD38 levels on selected RBCs were determined by flow cytometry (FC). **Results/Findings**: In the first 5 months since FDA approval of DARA, our IRL reported anti-CD38 in 39 pts from 26 hospitals; 34 had MM (but this was not always indicated on the IRL request form), 1 had diffuse large B cell lymphoma, and 4 diagnoses were oncology or pneumonia. Number of samples tested = 75 (range: 1-9/pt). Twelve (31%) pts had pos DATs [microscopic (micro)−1½+]; 11/12 (92%) had RBC-bound IgG only. Thirteen of 15 pts with multiple samples had either all pos or all negative (neg) DATs. Ten of 12 (83%) eluates from DAT pos RBCs were nonreactive. Five of 6 (83%) pts' RBCs became DAT neg after EGA or CDP treatment. Plasma reactivity of anti-CD38 with untreated (UT) RBCs varied from micro+ to 4+. Some pts were initially worked up for warm autoabs or alloabs to high prevalence antigens. DTT-treated (DT) RBCs were nonreactive in most pts; 4 pts had reactivity with 1 or 2 DT RBCs (2 had newly identified anti-C; anti-Jk^b was not excluded in 1), 2 samples (1 each from 2 pts) were panreactive with DT RBC (common alloabs were ruled out using other nonreactive RBCs). Neg or significantly weakened results were seen with UT cord RBCs, some Lu(a−b−) RBCs, and RBCs from two in-house IRL panel donors [#1 and #2; both Fy(a−b−) with weak LU antigens]. FC analysis showed CD38 levels of DARA-reactive UT RBCs much greater than nonreactive Lu(a−b−) RBCs, cord RBCs, and IRL donor #1; DT RBCs and IRL donor #2 had the weakest CD38 levels. **Conclusion**: Positive DATs and/or IATs in DARA pts can cause misinterpretation of results, especially if an eluate is reactive and/or history is inadequate, which can lead to delays receiving blood. DTT pretreatment of RBCs did not always eliminate reactivity with anti-CD38; for these samples, use of selected RBCs with low levels of CD38 helped to rule out common alloabs.

S58-030H

Modulation of the KEL Glycoprotein on Transfused Murine RBCs Appears Critical for Passively Administered KELIg to Prevent Alloimmunization

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Background/Case Studies: Passively administered anti-RBC antibodies are known to prevent alloantibody formation in humans and in mice. The mechanism(s) of action of these immunoprophylaxis therapies remain unknown, however, and this lack of knowledge is a barrier in the development of effective therapies beyond RhIg. We hypothesized that the modulation of RBC antigens previously described to occur in humans and mice in the presence of auto or alloantibodies may be critical to the mechanism of action of immunoprophylaxis therapies. **Study Design/Methods**: Wild-type

recipient mice were multiply transfused with murine RBCs expressing the KEL glycoprotein (previously published as KEL2B), in the presence of poly (I:C), to generate high-titer anti-KEL sera (KELIg). KELIg or saline was passively administered to wild-type mice, mice lacking complement receptors (C3KO), mice lacking Fc gamma receptors (FcγR KO), mice lacking both C3 and FcγRs (double KO), and mice lacking B-cells (MuMT). The recipients were then transfused with a mixture of KEL and wild-type RBCs labeled with different lipophilic dyes. Post-transfusion RBC recoveries and KEL antigen expression were evaluated by flow cytometry, as were recipient anti-KEL responses. **Results/Findings**: In 2/2 experiments (3 mice/group/experiment), rapid clearance of KEL expressing RBCs and modulation of the KEL antigen were observed in wild-type, C3KO, FcγR KO, and MuMT recipients treated with KELIg but not a saline control. The KEL antigen modulation began immediately after transfusion, and no antigen could be detected by flow cytometry within 24 hours of transfusion using polyclonal anti-KEL as a detection reagent. In contrast, no clearance of KEL expressing RBCs and no modulation of the KEL antigen were observed in double KO mice lacking both C3 and Fcγ receptors in the first week after transfusion. Whereas KELIg prevented or decreased recipient anti-KEL responses in wild-type, C3KO, FcγR KO, and MuMT recipients, double KO mice lacking both C3 and Fcγ receptors generated similar levels of anti-KEL in the presence or absence of KELIg. **Conclusion**: Modulation of the KEL glycoprotein antigen on transfused KEL RBCs appears critical to the immunoprophylaxis effect of KELIg. Neither C3 nor Fcγ receptors are independently required for RBC clearance or antigen modulation in this KEL model, yet the absence of both renders KELIg ineffective at preventing alloimmunization. A better understanding of the mechanism(s) of antigen modulation, including identifying recipient cell subsets on which C3 and Fcγ receptors are most critical, may serve to advance the development of next generation immunoprophylaxis therapies for humans.

S59-030H

B Cells Require Type 1 Interferon Signaling to Produce Alloantibodies to Transfused KEL-expressing RBCs in Mice

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Background/Case Studies: The frequency of RBC alloimmunization, which can lead to hemolytic transfusion reactions and hemolytic disease of the newborn, has recently been shown to be increased in patients with inflammatory disease. In addition, pro-inflammatory stimuli, including polyinosinic:polycytidylic acid (poly(I:C)), profoundly enhance alloantibody responses in transfusion mouse models. However, the cellular and molecular mechanisms, including the role of critical inflammatory cytokines, underlying this process are poorly understood. As poly(I:C) is known to induce type 1 interferons (IFNα/β), we hypothesized that IFNα/β production and signaling might play a pivotal role in regulating alloimmune responses to RBC antigens. **Study Design/Methods**: Donor murine RBCs expressing the human KEL glycoprotein (KEL RBCs, previously published as KEL2B) were leuko-reduced and transfused into control mice (WT), mice lacking the unique IFNα/β receptor (IFNAR1$^{-/-}$) on all cells, or bone marrow chimeric mice lacking IFNAR1 expression on a specific population of cells (Table 1). Anti-KEL IgG alloantibodies were quantified by flow cytometric cross-match, expressed as mean fluorescence intensity (MFI). **Results/Findings**: WT mice transfused with KEL RBCs produced anti-KEL glycoprotein IgG alloantibodies (peak response mean MFI=50.4 $\pm$ 13.3, standard error). However, the alloimmune response of IFNAR1$^{-/-}$ mice was almost completely abrogated in 3/3 experiments (MFI=4.2 $\pm$ 1.7, $p<0.01$, n=5/group per experiment). Bone marrow chimeric mice lacking IFNAR expression in specific cell types, namely non-hematopoietic cells, dendritic cells, or T cells, produced IgG alloantibodies at similar levels to control chimeras. However, the response of chimeric mice lacking IFNAR1 expression in all hematopoietic cells or specifically in B cells was greatly reduced in 2/2 experiments. (MFI= 3.8 $\pm$ 0.66 and 5.4 $\pm$ 1.6, respectively, compared to control chimeras, MFI=79.8 $\pm$ 30.1, $p<0.05$, n=5/group per experiment). **Conclusion**: This study demonstrates that B cells require signaling from IFNα/β to produce alloantibodies to the human KEL glycoprotein in mice. Although it is not yet clear whether these findings extend to other RBC antigens in mice and humans, IFNα/β is produced in inflammatory diseases associated with high rates of alloimmunization. Thus, identifying risk factors for IFNα/β production in transfusion recipients may improve transfusion safety by allowing for personalized transfusion protocols for at risk patients.

S60-030H

Red Cell Antibodies in Patients with Sickle Cell Disease Undergoing Hematopoietic Progenitor Cell Transplantation

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Background/Case Studies: Hematopoietic progenitor cell transplantation (HPCT) can cure sickle cell disease (SCD). A nonmyeloablative conditioning regimen has lower mortality and typically results in donor-derived erythrocytes and stable mixed chimerism of recipient- and donor-derived leukocytes in the patient's blood. There is a risk of immunohematologic complications due to red blood cell (RBC) antibodies induced by transfusions during the peri-transplantation period or exposure to donor antigens. We sought to determine the nature, frequency, and outcomes associated with RBC antibodies occurring during and after HPCT for SCD. **Study Design/Methods**: All patients with SCD (42 with HLA-matched and 19 with haploidentical donors) in 3 clinical trials were retrospectively evaluated for the formation of new RBC antibodies after HPCT or any RBC incompatibility between donor and recipient. **Results/Findings**: Of 61 patients, 9 experienced immunohematologic complications. Before HPCT, 3 patients had antibodies that were incompatible with their donors. After HPCT, new antibodies were observed in 6 patients (11 allo- and 2 auto-, Table 1), 3 of whom developed antibodies that were incompatible with donor or recipient RBCs, while 3 developed antibodies that were compatible. We have not yet identified any baseline characteristics that correlated with antibody development.

The clinical course of these 9 patients was variable; some had no significant effects attributable to the antibodies, while others experienced prolonged hemolysis or became almost untransfusable. We have not yet found any statistical correlation between immunohematologic complications and graft failure, rejection or death. **Conclusion**: Immunohematologic complications occurred in 15% of patients with SCD undergoing nonmyeloablative HPCT. Clinical effects ranged from seemingly insignificant to potentially fatal. In individuals with SCD, evaluation of donor and recipient RBC phenotypes before HPCT aids in preventing and managing immunohematologic complications.

TABLE. Alloimmune Responses of Bone Marrow Chimeras

IFNAR1-deficient cell type	Peak anti-KEL IgG (Mean MFI $\pm$ SE)	Difference in IgG level (compared to control chimeras)
Hematopoietic	3.8 $\pm$ 0.66	$\downarrow$ ($p<0.03$)
Non-hematopoietic	67.8 $\pm$ 21.0	Not significant (NS)
B cells	5.4 $\pm$ 1.56	$\downarrow$ ($p<0.05$)
T cells	40.7 $\pm$ 18.0	NS
Dendritic cells	25.9 $\pm$ 10.8	NS

TABLE. Red cell alloantibodies newly observed after enrollment

Antibody specificity					Cognate antigen	
Antigen	ISBT Number	ISBT Symbol	Clinically relevant	New alloantibodies	Recipient	Donor
D	004.001	RH1	Yes	1	+	-
C*	004.002	RH2	Yes	1	-	-
E*	004.003	RH3	Yes	1	-	+
V*	004.010	RH10	Yes	1	-	+
K*	006.001	KEL1	Yes	1	-	-
Jsa*	006.006	KEL6	Yes	2	-	-
Leb	007.002	LE2	No	1	-	-
McCa	022.003	KN3	No	1	n.t.	n.t.
Rh†	004	RH	Yes	1	-	-
Knops†	022	KN	No	1	n.t.	n.t.
Total				11		

*Recipient and donor pairs tested by red cell genotyping.
†Antibody directed to an antigen in the system; exact antigen not determined.
n.t. - not tested.

Transfusion-Transmitted Infectious Diseases: Babesia, Chagas, and Other Infectious Diseases

S61-030I

Autochthonous Chagas Transmission in the United States: Is One-time Anti-*Trypanosoma cruzi* Donor Testing Adequate?

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Background/Case Studies: Seven transfusion-transmitted (TT) cases of Chagas disease were reported in the United States/Canada through 2006. Universal licensed testing for anti-*Trypanosoma cruzi* was implemented by most US blood centers in 2007. Since then, two additional TT cases were documented, for a total of one TT case every 4 years (since 1986) or a rate of <1% TT based on lookback (2 positive recipients of 259 tested). An incidence study involving over 6 million person-years of follow-up showed no new infections among 4.22 million repeat donors in southern states, where the Chagas insect vector is present, for an upper 95% risk bound of 0.61/million donations. Similarly, autochthonous transmission was documented at a rate of 1:354,000 screened donations in comparable areas. Concern has been raised that the current policy of a one-time negative test for donor qualification introduced in August 2009 is not adequately safe. **Study Design/Methods**: Prevalence rates of first-time (FT) donors testing anti-*T. cruzi* confirmed positive (CP) from 2007-2015 using 3 different algorithms involving two different screening tests and two different confirmatory methods (Ortho ELISA/RIPA, Abbott PRISM/RIPA, Abbott PRISM Enzyme Strip Assay, ESA, combined with the Ortho ELISA) were compared by year and by testing method to determine if significant differences existed (by Poisson regression for time and by Pearson Chi-square for method). Comparisons were done nationally (involving 44 States of collection) and for the Southern California (SCA) region responsible for ~45% of all anti-*T. cruzi* confirmed positive (CP) FT donors in this blood system (and ~50% of all anti-*T. cruzi* CP donors). **Results/Findings**: Over 9 million FT donors were screened in our blood system over the 9-year period, of which 585 were anti-*T. cruzi* CP for an overall prevalence of 1 per 15,544 (or 64 per million). The prevalence varied from 57-70 per million by year/method. Note that the 585 FT CP donors represented 73% of the total 805 CP donors identified from 2007-2015. In SCA, FT donor prevalence varied from 284-491 per million by year (282 FT CP donors of 355 total CP donors, 79%) for an overall rate of 1 per 2717 (or 368 per million). Neither nationally nor in SCA were patterns suggestive or indicative of a meaningful change in CP rates. Results nationally did not differ by year ($p=0.65$) or screening/confirmatory method ($p=0.86$) used. **Conclusion**: As an indicator of change in incidence, prevalence was stable both nationally and in the highest Chagas endemic region of this US blood system; these findings have not changed the conclusions of the prior incidence study that the rate of new infections in the US is <1 per million. Thus, a one-time, anti-*T. cruzi*-negative test result used to qualify donors for future donation appears to provide adequate safety.

S62-030I

Improved Bacterial Culture of Platelet Product: Preliminary results after Implementation of a Two-bottle System with 48-hour Sampling

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Background/Case Studies: Despite implementation of the diversion pouch and bacterial culture of all platelet product using a one-bottle system and 24-hour delay before sampling, three septic reactions, one of which was fatal, were observed after transfusion of 275,000 products. It was therefore decided to improve the early bacterial culture procedure. **Study Design/Methods**: The amount of sample taken was increased from 10 to 20 mL: 10 mL each was inoculated into one aerobic and one anaerobic blood culture bottle. The delay before inoculation was increased from 24 to 48 hours and a 12-hour holding period before labeling and distribution was introduced. The regulator allowed extension of platelet shelf life to 7 days. Data on outdates, rates of positive culture (at 48-hour sampling and at outdate), age of product at transfusion, and platelet use were collected from registries at the blood center and from the provincial registry of products distributed to the hospitals. **Results/Findings**: Outdates were reduced by 71%. The rate of positive cultures went from 0.011% to 0.044%. None of the 908 platelet cultures done at outdate were positive. Modal age of platelet at transfusion went from 4 to 6 days. There has not been to date any case reported to the provincial hemovigilance system of a septic reaction following the transfusion of a contaminated platelet concentrate. There was a slight increase in platelet orders in the first two months following implementation of the improved bacterial culture procedure, but the platelet orders soon came back to levels seen previously: there was no evidence from discussion with customers that this temporary increase was related to loss of efficacy of components. **Conclusion**: Bacterial contamination of platelets remains the greatest infectious risk related to blood transfusion in Canada. There is still room for improvement in our risk mitigation approach to this problem. Increased sample volume and increased delay before sampling can be implemented as risk reduction measures with satisfactory results from the inventory management perspective, as long as shelf life can be extended.

S63-030I

Dynamics of *Babesia microti* Parasitemia and Minimal Infectious Dose in a Murine Model

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Background/Case Studies: *Babesia microti* is a protozoan parasite that infects erythrocytes in mammals. It is transmitted to humans primarily by tick bites but can also be transfusion-transmitted. Babesiosis is an emerging public health concern in the United States and a leading cause of transfusion-related fatalities due to microbial infection. Its recognition as a significant

threat to the blood supply has spurred efforts to develop assays for blood donor screening. Substantial progress in understanding Babesia seroprevalence and natural history in infected donors have informed testing paradigms and mitigation strategies. However, the minimal infectious dose, transmissibility from different stages of asymptomatic infection, and the length of the window period remain poorly characterized. We sought to establish a mouse model of *B. microti* infection to address gaps in knowledge relevant to blood transfusion. **Study Design/Methods**: DBA/2 immunocompetent and NSG immunodeficient mice were used to evaluate the minimal infectious dose necessary to establish infection after inoculation with *B. microti* parasitized blood. Mice were injected via the intraperitoneal route with serial dilutions of parasitized blood ranging from 10e5 to 10e0 *B. microti* parasite-infected mouse red blood cells (pRBCs). Five mice were infected with each dose, and parasitemia was monitored longitudinally over 3 to 8 months using Babesia-specific quantitative real-time PCR on tail blood samples. Anti-*B. microti* antibodies were measured in DBA/2 mice by ELISA. **Results/Findings**: In DBA/2 mice infected with as few as 100 pRBCs, parasitemia was detectable in 5/5 mice at 1 week after infection. Conversely, 2/5 mice infected with 10 pRBC showed detectable parasitemia at 2-4 weeks post-infection, whereas parasitemia was detected in 0/5 mice infected with 1 pRBC. At 2-3 weeks post-infection, peak parasitemia reached approximately 10e7 pRBC/mL, followed by chronic parasitemia ranging between 10e4 and 10e6 pRBC/mL up to 8 months post-infection. Anti-Babesia antibodies were detectable approximately 2-3 weeks post-infection, peaking at 10-11 weeks post-infection and persisting up to 6 months. In NSG mice, at infectious loads of 63, 16 and 4 pRBC, 5/5, 4/5 and 2/5 mice were chronically infected, respectively. In these mice, peak parasitemia was observed at 4-6 weeks post-infection reaching approximately 10e10 pRBC/mL, and maintaining high levels of PCR positivity at 3 months post-infection. **Conclusion**: Immunocompetent DBA/2 and immunodeficient NSG mouse strains are highly susceptible to *B. microti* infection using as few as 1-2 log pRBCs and maintain chronic parasitemia over the course of several months. This model may be used to evaluate the infectivity of blood collected during various phases of infection as measured by various assays including nucleic acid, antibody and antigen detection assays.

S64-030I

Differential Bacterial Attachment to Apheresis and Buffy Coat Platelet Storage Containers

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Background/Case Studies: Platelet concentrates (PCs) are stored in gas-permeable plastic bags containing a glucose-rich additive solution with neutral pH, at 22 ± 2°C, under agitation. This environment favors bacterial growth and makes PCs the blood component most susceptible for bacterial contamination. *Staphylococcus epidermidis* is the aerobic bacterium most frequently isolated from contaminated PCs. It can adhere to the inner walls of PC storage bags where it forms aggregates known as biofilms. These biofilms increase the risk of missed bacterial detection during PC screening. It is unclear if attachment of *S. epidermidis* to the PC plastic bags depends on the biomaterial of the containers or on its interaction with PC residual materials attached to the bags. This study was aimed at comparing *S. epidermidis* adherence to the inner surface of apheresis and buffy coat PC collection bags used at a Canadian blood supplier, in the presence or absence of residual PCs. **Study Design/Methods**: Sets of 4 bags were used in each test ($N \geq 5$). Each set had two bags obtained after draining one apheresis and one buffy coat PC ("PC-containing" bags), and two sterile ("PC-free") bags obtained from apheresis and buffy coat collection kits. Each bag was inoculated with a 200-mL *S. epidermidis* culture in glucose-supplemented Trypticase Soy Broth, adjusted to 0.5 colony forming units/mL. Testing was done with two *S. epidermidis* strains, ST10002 (isolated from contaminated PCs) and AZ39 (isolated from human skin). Culture bags were incubated under platelet storage conditions for 7 days, emptied and rinsed. Biofilms were dislodged by sonication or examined *in situ* by scanning electron microscopy (SEM). Bacterial concentrations were determined in the dislodged solutions. Data were analyzed using a mixed model. **Results/Findings**: The incidence of bacteria adhering to the bag walls in the presence of PCs was significantly higher ($p < 0.0001$) than in PC-free bags for both manufacturers, which was confirmed by SEM. Bacterial attachment in PC-containing bags was not significantly different between culture bags containing either residual apheresis or buffy coat PCs ($p > 0.05$). By contrast, a significant increase in bacterial adherence was observed on apheresis bags compared to buffy coat containers when PC-free bags were used ($p < 0.05$). No significant difference in attachment was found between the two *S. epidermidis* strains ($p > 0.05$). **Conclusion**: Differential bacterial adherence between both types of PC-free bags is likely due to the composition and texture of the biomaterials. Notably, bacterial adherence is enhanced in PC-containing bags, independently of the type of PCs. Future efforts should be focused on reducing PC attachment of to the inner surface of the storage containers which serve as a scaffold for bacterial adhesion.

S65-030I

A Biocompatible Bactericidal Coating for Platelet Storage Containers Inspired by Nature

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Background/Case Studies: Although platelet units are screened for bacterial contaminations, cases of missed detection have been reported particularly for the strains with a slow growth rate and high tendency for adhesion to the storage bag surfaces. The hydrophobic surface of platelet bags is considered to be conducive to bacterial adhesion and biofilm formation. In this study, a biocompatible bactericidal copolymer system applicable to coating any platelet storage bag was developed and evaluated. **Study Design/Methods**: Our copolymer system consists of three main components: a hydrophilic biocompatible segment, an anchoring mussel-inspired (MI) component (dopamine moieties), and antimicrobial peptides (AMP). These AMPs are short cationic peptides with a broad-spectrum antibacterial activity. Coating of platelet bag coupons was performed by immersing them first in a dopamine.HCl solution in a phosphate buffer, pH 8.5 for 10h at room temperature, followed by immersion in the synthesized copolymer system in MOPS (3-(*N*-morpholino)propanesulfonic acid) buffer, pH 8.5 for 24 hour at r.t. For modifying whole bags, each bag was filled with the reaction solution and kept in a static condition. To evaluate these coatings, 10^6 CFU/mL of a *Staphylococcus epidermidis* strain was incubated at 37°C with the coated and control coupons for 4 hours. Bacterial adhesion and viability was evaluated by a combination of fluorescence microscopy (bacterial viability kit) and releasing the bacteria from the surfaces and determining their number in suspension. Platelet adhesion to the bag surfaces was evaluated using scanning electron microscopy (SEM) and fluorescence microscopy after 4h incubation on a platelet shaker at 37°C. **Results/Findings**: The molecular weight (70,000 Da), polydispersity (1.17), structure and the number of incorporated AMPs (4-6) and catechol moieties (25-30) per polymer chain were found by standard analytical techniques. Coated samples showed water contact angles of $47 \pm 5°$ compared to $98 \pm 4°$ control platelet bags. Total thickness of the coating was found by ellipsometry measurements to be 15.86 ± 1.60 nm on silicon samples coated in parallel with the platelet bag samples. Accessibility and distribution of the AMP molecules on the surfaces was demonstrated by a surface sensitive mass spectroscopy technique. This coating could decrease the live bacteria number on the modified surfaces to as low as 8% of the control platelet bag samples. Biocompatibility of the coating with the platelets was shown by SEM imaging. **Conclusion**: A hydrophilic copolymer system containing antimicrobial peptides and mussel inspired anchoring groups was designed and synthesized. This copolymer provides a combination of nonfouling and bactericidal activity and can be used for coating platelet storage bags under mild aqueous conditions.

S66-030I

Bacterial Testing of Platelets – Has it Prevented Transfusion-Transmitted Bacterial Infections in Australia?

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Background/Case Studies: Australia introduced bacterial contamination screening (BCS) for platelet components in April 2008, adding to previous interventions to limit bacterial contamination of blood components, including the donor questionnaire, skin disinfection and sample diversion pouches. Cases of probable transfusion transmitted bacterial infections (TTBI) declined significantly (Borosak, Transfus Med Hemother, 2011). Further data has been analyzed to assess the continued efficacy of testing in Australia. **Study Design/Methods**: Seven-day aerobic and anaerobic culture is performed using the BacTAlert system. Following an Initial Machine Positive (IMP) flag, all associated components are recalled; treating clinicians are notified if the platelet unit or associated components have been transfused. Clinicians are notified of the final culture result of additional testing. If the same organism is cultured from the initial sample and from associated

components, the outcome is 'confirmed positive.' If the same bacteria cannot be isolated from a supplementary sample, the result is termed 'indeterminate.' **Results/Findings**: Between 2010 and 2012, 1.1% of platelet donations tested IMP; since 2013 this rate has been reduced to 0.6% through improved instrument management. The annual incidence of confirmed positive/indeterminate results averaged 0.17%. Pooled platelets had a higher incidence (0.22%) compared to apheresis platelets (0.11%). The percentage of confirmed positive/indeterminate platelet units that are transfused before recall has averaged 66% since 2010. However, of the already transfused units, 95% of confirmed positive contaminants were the generally low pathogenicity skin bacteria *Propionibacterium sp.* BCS was successful in preventing the transfusion of many pathogenic micro-organisms, such as *Serratia marcescens*. From 2006 to implementation of BCS in April 2008, probable bacterial TTBIs averaged 3.4 per year; this fell to an average of 0.7 per year from BCS implementation to the end of 2015. Of the five probable TTBI reported since BCS implementation, two were from red cells from which platelets were not manufactured and were thus not subjected to BCS. The three probable TTBIs from platelets were from platelet pools that were BCS culture-negative. Two patients died from their underlying disease, whilst the three remaining patients recovered from the TTBI. **Conclusion**: The incidence of TTBI has fallen since the introduction of BCS in 2008. However from 2008 to 2015 three probable TTBIs have occurred due to false negative BCS and two probable TTBIs have occurred in red cells from which platelets were not manufactured. None of these TTBIs were fatal. BCS has lowered bacterial TTBI risk, but has not eliminated it. Options to further mitigate bacterial contamination risk, such as pathogen inactivation, are being investigated.

Patient Blood Management

S67-030J

Rapid Responses to Intravenous Vitamin K May Obviate the Need for Factor Repletion with Prothrombin Complex Concentrates (PCCs)

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Background/Case Studies: Despite the availability of newer oral direct (not ATIII-dependent) anticoagulants, many patients remain on warfarin for venous thrombo-embolism prophylaxis, ischemic stroke prophylaxis with non-valvular atrial fibrillation, and prosthetic mechanical heart valves. When these patients present with life-threatening bleeding or if there is an immediate need for an invasive procedure, vitamin K is administered intravenously (IV) together with factor repletion with 4 factor PCCs for warfarin reversal. There are other clinical situations, however, when the clinical extent of bleeding is less or the need is more urgent than immediate (arbitrarily defined as within 5 hours) . In these circumstances, 4 factor PCCs are frequently administered in the erroneous belief that an acceptable reversal of warfarin will take 6 or more hours to achieve **Study Design/Methods**: Records of patients who received IV vitamin K were retrieved from the hospital computer system over a one-year period. The dose, time of administration, pre infusion INR, post infusion INR, and the time after vitamin K infusion were recorded. Only those who had a post infusion sample collected within or at 5 hours were included. Data were analyzed by medians and the fraction of patients who achieved an INR of 2.0 or less within 5 hours. **Results/Findings**: Thirty two events were evaluable. The median pre INR was 5.9 (Range: 2.5 −14), median post INR was 2.5 (range: 1.1- 6.2), the median time of sample collection after vitamin K infusion was 4.0 hours, and the median dose 5.0 mg. 11/32, or 34%, achieved an INR of 2.0 or less within 5 hours and 3/9 of these patients achieved an INR of < 2.0 within 3 hours. Substantial reductions in the INR were observed in all patients. No correlation was seen between the dose of vitamin K ($r = -0.3$, $p = 0.1$) or surprisingly the timing of sample collection after infusion ($r = -0.2$, $p = 0.2$) and the post INR but this may be due to the small sample size (possible Type 1 error) or the short observation period. However, it was clear that the rate of decrease in the INR is very patient dependent with considerable inter-subject variation. The decrease in the INR in the early hours after vitamin K administration can be described by the equation: post INR = 12.36 - 11.5(logRT) +2.96 (logRT)^{2,} where R= rate of return of clotting factors and T = time in hours. R varies considerably between patients, and is low in patients with hepatic disease, and is the major determinant of the speed of the decrease in the INR in the early hours after IV vitamin K administration **Conclusion**: A significant number of patients will achieve urgent warfarin reversal suitable for clinical purposes without the need to use 4 factor PCCs, avoiding the cost and safety concerns associated with the use of these plasma derivatives.

S68-030J

Trial of Feedback on Blood Use

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Background/Case Studies: Few high-quality studies have examined interventions to improve physician transfusion practice. The Trial of Feedback on Blood Use (TOFU) study was designed to rigorously test the hypothesis that providing individualized physician feedback on blood use will reduce unnecessary red blood cell (RBC) transfusions after hip surgery. **Study Design/Methods**: We performed a two-arm, prospective, multicenter, cluster-randomized controlled pilot trial examining the effect of providing monthly individualized physician feedback on RBC transfusion behavior. Four participating academic hospitals were assigned using random blocks either to the Feedback arm (n=2 sites) or Control arm (n=2 sites). Baseline data on hip surgeries, pretransfusion hemoglobin (Hb) levels, and postoperative RBC transfusions were collected for 3 months at each site. All attending orthopedic surgeons at each site then received a standardized educational presentation on the previously published FOCUS trial and the recommended RBC transfusion threshold of Hb < 8 g/dL (or symptomatic anemia) for stable postoperative hip surgery patients. In the Feedback arm sites, all attending orthopedic surgeons were emailed a monthly feedback report summarizing the number of hip surgeries that they performed, the total postoperative RBC units transfused, and the total postoperative RBC units transfused at a pretransfusion Hb < 8 g/dL. Surgeon identities were anonymized in the feedback reports, but each surgeon knew which data were their own to allow comparison with colleagues' data. No feedback was provided to surgeons in the Control arm sites. RBC transfusion data was collected at each site for 12 months ("Study Period"). The primary outcome was the proportion of patients in each arm receiving a postoperative RBC transfusion with a pretransfusion Hb > 8 g/dL. **Results/Findings**: Preliminary data are reported. In the Control arm, 30/228 (13.2%) hip surgery patients were transfused postoperatively (any pretransfusion Hb) at baseline, versus 54/349 patients (15.4%) during the Study Period. In the Feedback arm, 32/196 patients (16.3%) were transfused postoperatively at baseline, versus 65/654 (9.9%) during the Study Period. The proportion of patients receiving "excess" postoperative RBC transfusions (pretransfusion Hb > 8 g/dL) decreased by 1.3% in the Control arm versus 7.1% in the Feedback arm (Table). **Conclusion**: Monthly individualized physician feedback may have caused a modest decrease in postoperative RBC transfusions at Hb levels > 8 g/dL following elective hip surgery.

TABLE. Patients Transfused at Hb > 8g/dL

Study Arm	Patients Transfused, Baseline Hb > 8 g/dL n (%)	Patients Transfused, Study Period Hb > 8 g/dL n (%)	Difference (Baseline v. Study Period)
Control	12/228 (5.3%)	14/349 (4.0%)	−1.3%
Feedback	22/198 (11.1%)	26/654 (4.0%)	−7.1%
Difference	5.8%	0%	Net difference: −5.8%

Baseline: 3-month period before educational presentation to surgeons.
Study Period: 12-month period after educational presentation.

S69-030J

A Controlled Trial of Plateletpheresis during Cardiac Surgery

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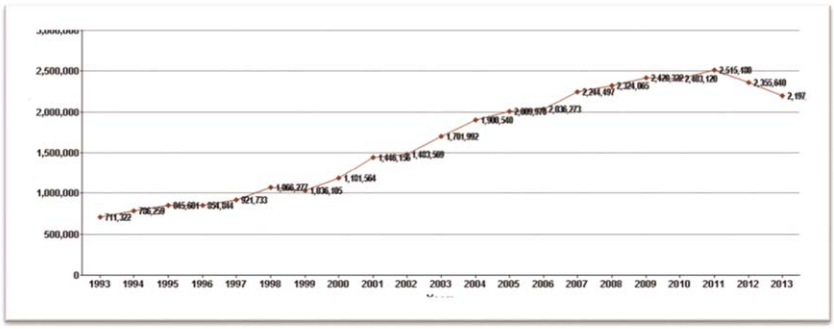
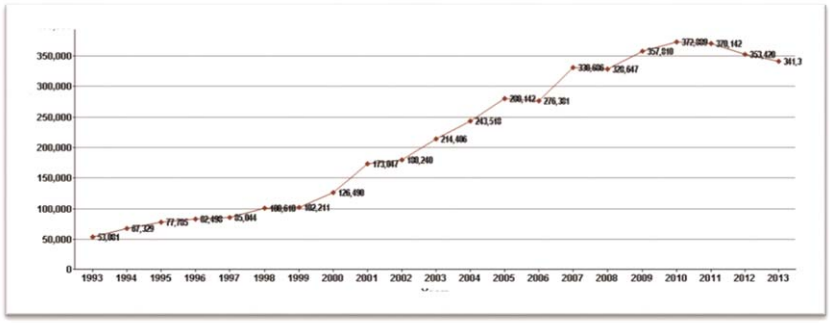
Background/Case Studies: Cardiothoracic surgery consumes up to 12% of the U.S. platelet (PLT) supply. We have previously shown that it is feasible to collect autologous PLTs by apheresis prior to surgery for post-operative reinfusion. The current study tests the hypothesis that this strategy will reduce the need for allogeneic PLT transfusion. **Study Design/Methods**: Patients in this study underwent surgery requiring cardiopulmonary bypass (CPB). They were randomized to receive either allogeneic (control,n=23) or autologous (TRIMA group,n=17) platelets. PLT apheresis was performed after induction of anesthesia. In compliance with AABB standards, autologous PLTs were maintained at 20-24 degrees C in the operating suite, and reinfused within 4 hours of collection. The decision to transfuse was made by the surgeon, who was blinded to group. Blood samples were collected into hirudin tubes at 4 times: A) at baseline prior to plateletpheresis; B) upon separation from CPB, prior to administration of PLTs; C) at end of surgery after administration of PLTs; and D) post-op day 1 (POD1). A sample from each PLT product was collected from the tubing through which it was infused. Platelet function in each sample was tested on the Multiplate instrument (DiaPharma) within 2 hours of collection, with the following agonists: TRAP (thrombin receptor agonist peptide), ADP, and COL(collagen). For testing PLT products, each sample was diluted to 100 x10^3/μL in hirudinized plasma. **Results/Findings**: After PLT collection, TRIMA patients' PLT counts decreased significantly from 187 ± 76 x10^3 (sample A) to 88 ± 36 x10^3/μL (sample B, P<0.01). After reinfusion of autologous platelets (sample C), the PLT count increased to 122 ± 64 x 10^3/μl and was 103 ± 41 x 10^3/μl the next day (sample D). Controls were 183 ± 60 x 10^3/μL (sample A), 119 ± 38 x 10^3 (sample B), 138 ± 32 x 10^3 (sample C), and 121 ± 33 x 103 (sample D). PLT counts in the TRIMA group were significantly lower than controls in samples B, but PLT reactivity was not different between the groups. Contrary to our expectations, PLT function did not decline following CBP and surgery. In fact, PLT reactivity to TRAP and COL was higher on POD1 in TRIMA and control groups. The autologous (TRIMA) PLT products had significantly better function in response to all agonists (p<0.05) than did banked PLTs. **Conclusion**: We found that only 24% of the TRIMA patients needed allogeneic PLT and only 35% needed plasma or cryo, versus 65% of the controls who received allogeneic PLTs and 59% who needed plasma or cryo. This result suggests that pre-op collection of autologous PLTs and reinfusion after cardiothoracic surgery could reduce the demand for PLT products, as well as patient exposure to allogeneic blood. Furthermore, freshly harvested autologous PLT had better function than allogeneic PLT products which had been stored for one or more days after collection.

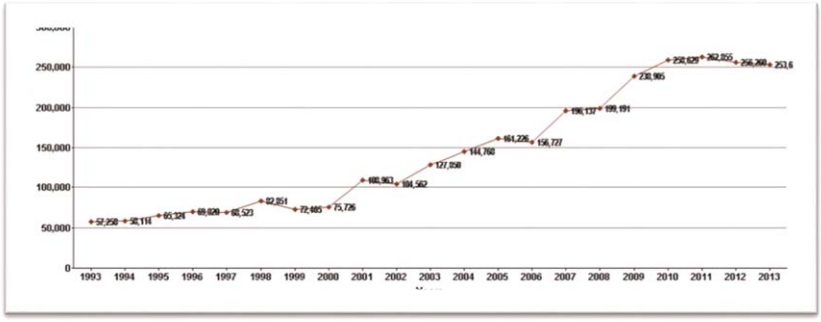
20 Years Nationwide Trends In Blood Product Utilization in US Hospitalized Patients



20 years nationwide trends in hospitalizations with reported RBC transfusions



20 years nationwide trends in hospitalizations with reported plasma transfusions



20 years nationwide trends in hospitalizations with reported platelet transfusions

S70-030J

Implementation of a Standardized Laboratory Testing, Clinical Evaluation and Transfusion Protocol for Cardiac Patients Receiving Extracorporeal Membrane Oxygenation (ECMO) is Associated with Decreased Blood Transfusions and Improved Survival

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Background/Case Studies: Extracorporeal Membrane Oxygenation (ECMO) replaces cardiac and pulmonary functions. Survival rates of 20-50% are seen among patients undergoing ECMO for cardiac indications. Bleeding is the most common complication due to coagulopathy and the need for anti-coagulation. Absence of a standardized transfusion protocol, with well-defined laboratory test and clinical evaluation, can lead to inconsistent transfusion practices. As of December 2014 we had no dedicated transfusion protocol for cardiac ECMO patients. A transfusion protocol based upon clinical findings and laboratory testing (to be presented) was developed by a multi-specialty team that included surgery, intensive care, cardiology and transfusion medicine. Transfusion practice was guided by combined laboratory value triggers and clinical indications. We evaluated the effect of this standardized protocol on clinical outcomes and overall transfusion requirements in ECMO for cardiac indications. **Study Design/Methods**: Cardiac ECMO patients $\geq$18 years old were included. Data were retrospectively collected for 12 months prior (n=30 patients) and 12 months post-implementation (n=31) of the protocol. Blood transfusions and survival were analyzed. Data from the two periods were compared using *t*-tests and Chi-square; p values of $\leq$0.05 were considered significant. **Results/Findings**: Diagnoses were similar between the two periods, and consisted of cardiomyopathy (23%), cardiogenic shock (23%), myocardial infarction (10%), left ventricular assist device recipients (10%), and other causes of cardiac failure (33%). Pre-ECMO ejection fraction was similar between the patients in the two periods (p=0.6). The number of days (mean$\pm$SD) on ECMO was not significantly different after the protocol (9.5 $\pm$ 6.4 before, to 7.9 $\pm$ 8.4 after; p=0.29). However, red cell transfusions decreased from a mean ($\pm$SD) of 28 units ($\pm$ 23) to 15 ($\pm$ 16) (p=0.009), plasma from 11 ($\pm$ 12) to 3.6 ($\pm$ 4.7) (p=0.003) and platelets from 6.8 ($\pm$ 7.4) to 2.3 ($\pm$ 2.9) (p=0.003). Most importantly and strikingly, a two-fold increase in survival was observed for the post-implementation patients (33% before to 65% after introduction of the protocol; p=0.014). **Conclusion**: The implementation of a protocol to guide transfusions by evaluating clinical findings and coagulation tests in cardiac ECMO patients was associated with striking reductions in blood transfusions and improved survival. A multi-specialty approach facilitated consistent practice amongst surgeons, intensivists, cardiologists and transfusion medicine. Reductions in transfusions may have contributed to improved survival, but this hypothesis requires investigation in randomized trials for confirmation.

S71-030J

20 Years Nationwide Trends in Blood Product Utilization: Evidence of Effectiveness of Blood Management Programs across the Nation

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Background/Case Studies: Patient blood management (PBM) programs are expanding across the United States. Multiple studies show effectiveness of PBM initiatives at individual hospital/center level. However, nationwide trends in blood utilization remain less explored. This study aims to identify trends in blood utilization in hospitalized patients over 20 years. **Study Design/Methods**: This study utilized the Nationwide Inpatient Sample (1993-2013) database for a trend analysis of inpatient blood product utilization. Using a stratified probability sample of 20% of hospitalizations, sampling weights and survey methodology were applied to generate nationally representative estimates. **Results/Findings**: From 1993 to 2011, there was steady upward trend in total number of hospitalizations reporting red blood cells (RBC), plasma, and platelet transfusions (Figure 1). However, from 2011 to 2013, there was a 12.6% decrease in hospitalizations with RBC transfusions (from 2,515,500 to 2,197,669), 7.7% decrease in hospitalizations with plasma transfusions (370,142 to 341,390) and a smaller decrease of 3.3% in hospitalizations with platelet transfusions (262,355 to 253,625). In sub-group analysis, assessing RBC utilization by age groups, hospital type and payer, there was consistent decrease in RBC utilization for all groups assessed, except for 1) pediatric age group, 2) private for-profit hospitals 3) non-teaching and 4) small bed size hospitals. **Conclusion**: These nationwide trends in RBC, plasma and platelet transfusions for hospitalized patients over 20 years show decrease in overall transfusions between 2011 to 2013 likely reflecting the effects of PBM initiatives. There is need for targeted PBM interventions for pediatrics, private for-profit hospitals, non-teaching and small bed size hospitals.

S72-030J

Very Low Rate of Serious Adverse Events Related to the Use of Intra-operative Cell Salvage

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Background/Case Studies: This study analyzed the rates of patient-related serious adverse events (SAE) associated with the use of intra-operative cell salvage (CS). **Study Design/Methods**: The electronic risk management database in a 9-hospital regional health care system was queried from January 2005 through March 2016 using search terms related to CS (autotransfusion, cell salvage, cell saver) to uncover SAEs. In addition the company supplying perfusion services to this healthcare system also maintains a patient database of all CS cases and any procedural notes associated with the cases. This database was searched from January 2005 through February 2016 to determine how many CS cases were performed in this $\sim$11 year period and as another source of SAE reports. **Results/Findings**: CS was used in 43,198 cases during the study period; 33,351 patients (77%) had CS blood returned to them. Perfusion database review revealed comments about 2,348 of these procedures. All of these comments described minor events related to the CS procedure that did not cause patient harm, such as the surgeon requested higher than normal suction pressure or insufficient quantity of shed blood recovered preventing reinfusion etc. No potential SAEs were uncovered. A review of the system-wide risk management database revealed 122 reports associated with CS. Of these, 110/122 (90%) were reports describing adverse patient events or procedural errors in which CS use was mentioned but was unrelated to the reported event. Only 12/122 (10%) of the risk management reports were directly related to CS use; 10/12 (83%) were for minor procedural events such as equipment malfunction or contamination of salvaged blood preventing return etc. Two potential SAEs were uncovered that occurred following initiation of autotransfusion. The first was a post cesarean section patient who became acutely tachycardic, diaphoretic and dyspneic. The second was a patient with postpartum hemorrhage who experienced acute dyspnea. Autotransfusion was stopped, both patients were stabilized in the operating room and were eventually discharged without further complications. Neither of these events were reported to the blood bank. It is unclear if these events were related to the use of CS or secondary to surgical causes. The overall rate of patient-related SAEs caused by CS reinfusion was between 0-2/33,351 (0% $-$0.006%). Two risk management reports described cell salvage bowl rupture during processing before reinfusion. These were not considered patient-related SAEs as no harm came to the patient although the perfusionist was exposed to the recovered blood. **Conclusion**: The use of CS appears to be safe with a very low rate of associated patient-related SAEs. Under reporting of patient related SAEs is a potential confounder and would increase the rate of adverse events.

RBC Immunohematology: Studies of Alloimmunization against RHD and Other Blood Groups

S73-040A

***RHD*weak D type 4.0* Inherited with *RHCE*ce48C* and Alloimmunization in Patients with Sickle Cell Disease (SCD)**

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Background/Case Studies: The high homology and opposite orientation of *RH* genes promote many rearrangements between them and generate a large number of *RHD* and *RHCE* variants which can be inherited together. Several studies have shown that those Rh variants in patients with SCD represent an additional risk for alloimmunization and delayed hemolytic transfusion reactions (DHTRs), but little clinical or biological evidence related to alloimmunization and DHTR are presented for all the *RH* variant alleles. It is well established that transfusion recipients with the most common weak D type 1, 2, and 3 are not at risk for forming alloanti-D when exposed to conventional RhD-positive RBCs, but there are few reports of anti-D in patients with weak D type 4.0. *RHCE*ce48C* was recently described in an African patient related to partial e antigen and involved in alloantibody formation. We report here three cases of SCD patients with *RHD*weak D type 4.0* allele linked to *RHCE*ce48C* who developed anti-D and anti-e. **Study Design/Methods**: RHD and RHCE BeadChip (Immucor, NJ, USA), were used to identify the *RH* variants in 3 SCD patients D+ and e+ with anti-D and anti-e. Serologic features of anti-D and anti-e in the patients were analyzed and the clinical significance of the antibodies was evaluated by retrospective analysis of the hemoglobin (hb) levels pre and post-transfusion and determined by change from baseline pre-transfusion hb and percentage (%) of hbS. **Results/Findings**: Among the 3 SCD patients with anti-D and anti-e, 1 patient was compound heterozygous for *RHD* and *RHCE* variants (*RHD*weak D type 4.0-RHDΨ/RHCE*ce48C-ce$^{S)}$* and 2 patients were *RHD*weak D type 4.0/RHCE*ce48C* homozygous. Serology analysis indicated that anti-D and anti-e were alloantibodies and those antibodies showed to be clinically significant as verified by a worsened anemia and/or rise in hbS when the patients were transfused with the corresponding antigens. **Conclusion**: We characterized three SCD patients with *RHD*weak D type 4.0* allele linked to *RHCE*ce48C* prone to alloimmunization and DHTR. Our results reinforce previously finding that *RHD*weak D type 4.0* allele and *RHCE*ce48C* can be involved with alloimmunization and the importance to recognize the SCD patients with RH variants in order to provide them with Rh genetically-matched RBC units.

S74-040A

A Patient with Weak D Type 3 and Anti-D Alloimmunization

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Background/Case Studies: The occurrence of anti-D in an Rh(D)-positive patient sample can be explained by a passively transferred alloantibody, active alloimmunization or an autoantibody. In patients with a negative direct antiglobulin test, the choices become more limited to an alloantibody induced by active alloimmunization in the context of a partial D or, very rarely, a weak D type 11, 15, 21, 57, but practically never a weak D type 1, 2, or 3. We describe a rare occurrence of a weak D Type 3 with D alloimmunization. **Study Design/Methods**: An 84-year-old female presented with lower gastro-intestinal bleeding attributed to diverticuli. A request was received for two units of red blood cells. The specimen typed as Group O, Rh(D) positive (3+) using an automated CAT method. The indirect antiglobulin test was weakly positive in cell #2 only;, however, a standard 11 cell panel was all negative. A ficin treated panel showed a clear pattern of anti-D with 2+ to 3+ reactivity. Two units of Group O Rh(D)-negative crossmatch-compatible red cells were transfused without incident. She had two full-term children during her reproductive years. Several previous specimens had been received from this patient: all typed as Group O Rh(D) positive with a negative indirect antiglobulin test. Single units of red blood cells had been transfused on two separate occasions within a two year period prior to the change in the indirect antiglobulin test. Further serological (serological typing/serology/phenotyping) and genotyping were performed to further investigate the observation. **Results/Findings**: Serological testing showed a negative direct antiglobulin test. Red cell phenotyping showed the patient to be positive for C (Rh2), c (Rh4), and e (Rh5), but negative for E (Rh3), with a presumed haplotype as R_1r. DNA sequencing of *RHD* exons 1-10 and flanking intron regions showed c.8G polymorphism in exon 1, indicative of *RHD*weakDtype3*. Hemizygosity for the *RHD* gene, predicted by the haplotypes, was confirmed by a semi-quantitative measurement of the *RHD: RHCE* ratio **Conclusion**: Weak D type 3 is not known to be associated with alloimmunization to RH(D) .However, this observation could be related to the sensitivity of the method employed for antibody screening and identification. As illustrated in this case, use of ficin sensitized cells was required to confirm antibody identification

S75-040A

Rh-positive Platelet Units are Associated with Low Rates of Anti-D Development in Rh-negative Male Patients

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Background/Case Studies: Because of limited platelet (PLT) inventories, Rh-positive PLTs are frequently provided to Rh-negative patients. Such units create risks for alloimmunization to non-ABO antigens, particularly Rh(D). While anti-D development can be prevented by administration of Rh immune globulin, it remains unclear whether such prophylaxis should be routinely provided after Rh-mismatched PLT infusion. With these concerns in mind, we undertook a study to assess anti-D development following Rh-mismatched PLT transfusions in an entirely male population. Our goal was to establish the rate of anti-D development associated purely with Rh-mismatched PLT transfusion in order to determine whether routine Rh immune globulin prophylaxis might be useful in our population. **Study Design/Methods**: Potential study subjects were Rh-negative men transfused with Rh-positive PLTs in 2006-2015. Further inclusion in the study required at least one follow-up antibody screen >15 days after the first Rh-positive PLT dose. Patients were excluded if they had undergone an Rh-mismatched stem cell transplant, had weak or partial D, or had anti-D detected before PLT transfusion. For included study patients, the following information was collected: age, diagnosis at time of PLT transfusion, total Rh-positive PLTs received, component type (i.e., apheresis or pre-storage pooled), total number of antibody screens after the first Rh-positive PLT, and whether anti-D was detected. **Results/Findings**: During the study period, 75.0% (1458/1946) of total PLT products administered at our facility were pre-storage pooled, while 25.0% (488/1946) were apheresis-derived components. Overall, 107 Rh-negative patients received at least one Rh-positive PLT. After application of additional inclusion/exclusion criteria, 53 patients remained for analysis. The mean age of these study subjects was 67.8 +/- 10.3 years. The majority of patients in this cohort (33/53; 62.3%) were non-immunosuppressed at the time of first PLT infusion based on clinical diagnosis. Study subjects received a range of 1-95 Rh-positive PLT units (mean = 4.7; median = 1.0) with significantly more pre-storage pooled (mean = 3.1; median = 1.0) than apheresis units (mean = 1.6; median = 0.0) administered ($p<0.0001$; Mann-Whitney U test). Patients underwent substantial follow-up testing after their first Rh-positive PLT exposure (mean = 7.5; median = 4.0 follow-up antibody screens). Anti-D was detected in only one patient (1.9%; 1/53) after receipt of a single pre-storage pooled PLT unit. **Conclusion**: The risk for D-antigen alloimmunization following Rh-mismatched PLT infusion is very low in a male, mostly non-immunosuppressed patient population. Routine use of Rh immune globulin for prophylaxis does not appear warranted for such patients.

S76-040A

A Serological Blind-Spot for Variants of Human IgG3 and IgG4 by Commonly Used Anti-Human Globulin Reagents

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Background/Case Studies: Detection of allo- and auto-antibodies to RBC antigens is the focus of immunohematology labs. With a few exceptions (e.g., ABO) most alloantibodies require the use of anti-human globulin (AHG) for detection. The anti-Ig portion of AHG focuses on characterization of IgG. However, IgG exists in 4 different subtypes (IgG1, IgG2, IgG3, and IgG4); each with different effector functions and likelihood to cause hemolysis. Since the time that AHGs were optimized for clinical use, it has now been appreciated that there is additional genetic variation within IgG subtypes (called iso-allotypes herein). To date, 29 different iso-allotypes have been described, with 7, 4, 15, and 3 iso-allotypes described for IgG1-4, respectively. Reactivity of AHG with these newly discovered Iso-allotypes has not been reported. **Study Design/Methods**: A novel monoclonal anti-KEL1 antibody (PUMA1) was isolated. The heavy and light chain variable

regions were sequenced and then cloned into expression plasmids that fused variable regions (in frame) with each of the known IgG isoallotypes. Each antibody was expressed by transfection into CHO cells. The resulting panel of antibodies was pre-incubated with KEL1+ RBCs and then subjected to testing with currently approved AHGs, by flow cytometry, solid phase systems, gel card, and wet-tube testing. **Results/Findings**: Flow cytometry demonstrated that an FDA-approved rabbit polyclonal AHG recognized each of the known human IgG isoallotypes. In contrast, an FDA-approved monoclonal AHG (Gammaclone) failed to recognize 2/15 IgG3 iso-allotypes (IgG3-03 and IgG3-13) and 3/3 IgG4 iso-allotypes (IgG4-01, 02, 03). The same IgG subtype specificity observed by flow cytometry was confirmed by solid phase, gel card, and wet-tube testing using approved diagnostic platforms. Iso-allotype specificities were only carried out by flow cytometry. **Conclusion**: These findings demonstrate a "blind spot" in alloantibody detection by a monoclonal AHG for 2 of the IgG3 isoallotypes. The non-reactivity with IgG4 is a known characteristic of this monoclonal AHG, but IgG4 iso-allotypes have not been previously reported. IgG3 is considered amongst the most clinically significant IgG subtypes, and can cause hemolysis. Should a patient have anti-RBC antibodies predominantly of an IgG3 subtype of the IgG3-03 and/or IgG3-13 variety, it is possible that a clinically significant alloantibody would be missed by current platforms. IgG-03 and IgG-13 are estimated at a frequency of 1%-3% of Caucasian and 20%-30% of African populations. The clinical significance of this laboratory finding merits further investigation. Consideration of AHG reagents ability to detect new IgG variants as they are identified may improve specificity of the testing.

S77-040A

Severe Hemolytic Disease of the Newborn Caused by an Antibody to KEAL, a New Low-Prevalence Kell Blood Group Antigen

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Background/Case Studies: A pregnant Caucasian woman (39 years old, gravida 2, para 1) with no transfusion history was hospitalized because of the Mirror Syndrome with edema, ascites, massive fetal hydrops and polyhydramnios. Her child was delivered by a Cesarean section in the 25 week of gestation with a severe anemia (3.1 g/dl) and a positive direct antiglobulin test (IgG 3+). It weighed 1,070 g and was in a critical condition with the APGAR score of 1/3/5. Though it was immediately transfused it died 9 days after delivery. The plasma of the mother was reactive with the red cells of her husband but it showed negative reactions in antibody identification panels and with multiple red cells positive for low prevalence antigens. **Study Design/Methods**: The clinical data and the serological test results suggested an antibody to a clinically significant low prevalence antigen. To determine the specificity of the antibody the family members were tested by serological and molecular methods. The antibody identification was performed in the indirect antiglobulin test in the gel technique using untreated, papain treated and DTT treated red cells. The red cells of the child's father, the father's mother and of the child's brother were cross-matched with the serum of the mother. The *KEL* gene was analyzed by exon re-sequencing and a PCR-SSP method was established for genotyping of the identified mutation. Finally the serum of the mother was tested against red blood cells heterozygous positive for the KHUL antigen. **Results/Findings**: Antibodies to following low prevalence antigens could be excluded: Wr^a, Di^a, Wu, Co^b, Yt^b, Lu14, Js^a, K17, K25, Cx, DAK, FPTT, Go^a, V, VS, Crawford, JAL, JAHK, PARG, LW^b, Ls^a, Ul^a, Tc^a, Sc2, Vw, Mg, Mi^a, Hut, Mur, Hil, Miny, He, Dantu, Mt^a, St^a, Mit, Vr, Kn^b, Vil. The serum of the mother was positive with the red cells of the child's father, the father's mother and of the child's 3 years old brother. As the reaction was negative after DTT treatment of the cells an antibody to a Kell blood group antigen was supposed. Sequencing of the father's *KEL* gene showed a heterozygous 877C>T (Arg293Trp) mutation in exon 8. The father's mother and the child's brother were also positive for the mutation defining a new low prevalence Kell blood group antigen, we named KEAL. The serum of the mother was positive with red blood cells heterozygous positive for the KHUL antigen. Screening of 11,705 blood donors for the 877C>T mutation by PCR-SSP was negative. **Conclusion**: We describe a new low prevalence Kell blood group antigen named KEAL. It is characterized by the 877C>T missense mutation in the *KEL* gene causing a single amino acid change (Arg293Trp) in the KEL protein. Antibody to KEAL caused a severe hemolytic disease of a newborn. KEAL is antithetic to the high prevalence KHUL antigen (KEL37).

S78-040A

Hyperhemolysis in Sickle Cell Patients

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Background/Case Studies: Although various pathogenic mechanisms and therapeutic options for hyperhemolysis in sickle cell disease have been proposed, standardized laboratory and treatment approaches are still lacking. Our aim was to retrospectively study immunohematologic data, hematologic laboratory parameters, treatment, and outcome of hyperhemolysis in sickle cell patients treated at our institution from 2007 through 2015. **Study Design/Methods**: Clinical information was obtained from electronic medical records. Laboratory, immunohematologic, and transfusion data were obtained from laboratory information systems. ABO/Rh typing, antibody screening and identification were performed using standard techniques. **Results/Findings**: Eight cases

TABLE. Hyperhemolysis Cases

	Patient	Previous Alloantibodies	New Antibodies	Time (Days)	Nadir Hb (g/dL)	Retic (thous/μL	LDH (U/L)	Treatment	Outcome
1[a]	40 F	C,E,K,S,Fy^a,Jk^b	none	17	5.0	622.9	555	supportive	Favorable
1[b]	42 F	C,E,K,M,S,Fy^a,Jk^b,Js^a	none	10	4.6	357.1	714	steroids, IVIG,DPO	Favorable
2	36 M	D,C,E,K,M,S,Le^b	none	8	2.1	190.6	1406	steroids, Rituximab	Favorable
3	21 M	C,E,S,Jk^b	none	6	2.9	85.5	6813	steroids, EPO	Fatal
4	19 M	C,E	none	5	5.5	141.5	1440	steroids	Favorable
5	55 F	e,C,K,$Fy^a$$Fy^b$,$Kp^a$, Lu^a,Co^b,Le^b,*	none	9	5.0	213.4	541	steroids	Favorable
6	42 F	E,K,M,Fy^a,Jk^b	none	10	5.1	175.2	683	steroids	Favorable
7	21 F	E,K,Js^b,S	none	4	4.2	335.4	699	steroids, IVIG,EPO	Favorable

Patient 1a, first episode of hyperhemolysis; Patient 1b, second episode of hyperhemolysis (2 years 8 months after the first episode);
*Antibody against unidentified low-frequency antigen;
DPO, Darbepoetin Alfa;
EPO, Epoetin Alfa;
IVIG, Intravenous immunoglobulin

were identified. One patient had hyperhemolysis twice (2 years 8 months after the first episode). All of the patients had more than one alloantibody prior to transfusion (median 5, range 2-9 alloantibodies) yet received antigen matched RBC prior to the episode. Anti-E was the most frequently identified alloantibody (6/7 patients). Laboratory findings indicated a spectrum of disease severity, with nadir hemoglobin (Hb) and absolute reticulocyte (Abs. retic) counts (mean ± SD) 4.3 ± 1.2 g/dL, range 2.1-5.5 g/dL, and 265.2 ± 171.2 thousand/μL, range 85.5 - 622.9 thousand/μL, respectively. Patient 1 required only supportive care during her first episode of hyperhemolysis, while patient 3 suffered a fatal outcome despite receiving corticosteroid and erythropoietin treatment. This may be explained by the high degree of hemolysis (LDH 6813 U/L) occurring shortly after transfusion in patient 3, and without adequate increase in red blood cell production (Abs. retic 85.5 thousand/μL). Although patients 4 and 7 also presented acutely, their hemoglobin levels and reticulocyte counts were appreciably higher than noted for patient 3. See Table for further details. **Conclusion**: The lowest reticulocyte count and highest LDH but not the lowest nadir Hb were seen in the one fatal case in our series. Further studies are needed in order to identify specific risk factors and optimal management of hyperhemolyzing sickle cell patients.

Platelet and Leukocyte Biology

S79-040B

Extracellular Vesicle Markers Associated with Mortality in Critically Ill Patients following Transfusion

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Background/Case Studies: Our group performed detailed analysis of coagulation and immune parameters in a subset of 100 subjects from the randomized, controlled clinical trial known as the Age of BLood Evaluation (ABLE) study. In ABLE 2,500 critically ill patients were randomized to receive either fresh RBC units (stored < 8 days) or standard RBC units (stored for mean 21 days). By analyzing the EV profiles of these critically ill patients, we were able to find potential predictors of mortality and MODS after transfusion. Here we present correlations between various EV markers and risk of complications in ABLE subjects. **Study Design/Methods**: Platelet poor plasma (PPP) was obtained from ICU patients before and after transfusion. PPP samples were stained with 3 panels comprising 14 different antibody markers, and flow cytometry was used to detect EVs. EV expression was evaluated both at baseline (day 0) and as a change from day 0 to day 2. A Cox regression model was used to find significant predictors of the two primary outcomes: mortality and MODS. **Results/Findings**: At baseline, high expression of CD11b, CD15, CD62p, and/or CD66b was associated with mortality ($p<0.05$) and high CD14 expression was a significant predictor of MODS ($p=0.019$). Lower CD16 and CD62L expression at baseline was associated with increased MODS risk ($p=0.032$ and $p=0.029$, respectively). A drop in CD11b and/or CD66b expression from day 0 to day 2 was associated with increased mortality ($p=0.0001$ and $p=0.007$, respectively). The drop in CD11b expression following transfusion was also associated with increased MODS risk ($p=0.0006$). **Conclusion**: Our results indicate that EVs expressing markers with known cell adhesion properties (CD11b), platelet activation (CD62p), and neutrophils (CD66b) are associated with poor prognoses in ICU patients after receiving transfusions. The absence/reduction of EVs expressing CD16 and CD62L markers were also predictive of a poor outcome. The shedding of these two receptors is known to occur with NK activation. This downregulation of CD62L and CD16, combined with the observed upregulation of known neutrophil activation markers CD11b and CD66b, has been described in patients with systemic inflammation and may help to explain why these patients fared worse after transfusion. Understanding the relationship between EV expression and patient outcome may help to identify patients at high risk of complications so that they may be monitored more closely after transfusion.

S80-040B

Anti-endothelial αvβ3 Antibodies are a Major Cause of Intracranial Bleeding in Fetal/Neonatal Alloimmune Thrombocytopenia

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Background/Case Studies: Fetal/neonatal alloimmune thrombocytopenia (FNAIT) is a severe bleeding disorder which can result in intracranial hemorrhage (ICH), leading to death or neurological sequelae. In Caucasians, maternal anti-HPA- 1a antibodies (abs) are responsible for the majority of cases. No predictive factors for ICH are available to guide prophylactic treatment during pregnancy. In this study, we investigated abs from mothers with ICH-positive FNAIT and with ICH-negative FNAIT in order to identify serological and functional differences between the groups. **Study Design/Methods**: Maternal serum samples were selected from cases diagnosed with FNAIT. Clinical data entries included neonatal brain ultrasound results, based on which the samples were assigned to the +ICH cohort (presence of ICH, n=18) or the-ICH cohort (absence of ICH, n=18). Serological studies by antigen capture assay and immunprecipitation were performed on all samples. From each cohort, 9 samples were chosen randomly to perform functional testing with endothelial cells, including adhesion to vitronectin, Caspase-Glo 3/7 assay, morphological assessment of apoptosis, production of reactive oxygen species with 2′,7′-dichlorofluorescein diacetate, and a tube formation assay using matrix gel. **Results/Findings**: In an antigen capture assay, we observed a stronger binding of +ICH abs to endothelial cell (EC)-derived αvβ3. By absorption experiments, we subsequently identified anti-HPA-1a abs of anti-αvβ3 specificity in the +ICH, but not in the -ICH cohort. Only the anti-αvβ3 subtype, but not the anti-β3 subtype, induced EC apoptosis of HPA-1a-positive ECs by caspase-3/7 activation, mediated by reactive oxygen species. In addition, only the anti-αvβ3 subtype, but not the anti-β3 subtype, interfered with EC adhesion to vitronectin and with EC tube formation. **Conclusion**: We conclude that the composition of the anti-HPA-1a antibody subtype(s) of the mother may determine whether ICH occurs. Analysis of anti-HPA-1a abs of the anti-αvβ3 subtype in maternal serum has potential in the diagnostic prediction of ICH development and may allow for modification of prophylactic treatment in FNAIT.

S81-040B

Inhibition of Effector Kinase Recruitment to the Plasma Membrane by Psoralen and Ultraviolet A Light Treatment

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Background/Case Studies: Psoralen and ultraviolet A light (PUVA) are used to kill donor pathogens in transfusion products. Recently, the Intercept pathogen inactivation method which uses amotosalen as photoactive psoralen was approved by the FDA. Besides that, PUVA can treat aberrant cell proliferation in cutaneous T-cell lymphoma, certain dermatoses and graft-versus-host disease (GvhD). Its mitostatic role by damaging nuclear DNA is well described, but PUVA also directly modulates cell behavior which is poorly understood. Because platelets are anucleate yet contain archetypical signal transduction machinery, they are ideal cells to study PUVA's DNA-independent impact on signal transduction. **Study Design/Methods**: This was investigated by western blotting of (phosphorylated) signal transduction proteins, by (tandem) mass spectrometry of phospholipids (PL) and by flow cytometry of (activated) platelet receptors. Lipid packing was measured with fluorescently labeled packing-sensitive peptides. T lymphocytes were activated with CD3/CD28 beads and interleukin-2. **Results/Findings**: Activation of integrin $\alpha_{IIb}\beta_3$ was decreased in PUVA treated platelets following dose escalations of specific PAR1 and GPVI, but not PAR4 agonists. Pleckstrin phosphorylation and calcium entry kinetics were normal by all agonists indicating phospholipase C signal transduction was not altered by PUVA.

Membrane recruitment and subsequent phosphorylation of Akt and Btk was however significantly decreased in activated PUVA platelets, suggesting defective phosphatidylinositol tris-kinase (PI3K). However, phosphorylation of inositides by PI3K was not affected in response to all platelet agonists. Mass analytical PL characterization showed that psoralens form adducts with PL in all classes, with a clear preference for reaction with unsaturated acyl side chains. Acyl (un)saturations regulate membrane packing which in turn influences binding of proteins to membranes. Therefore, peptide binding to liposomes with different packing properties were studied following PUVA. This experiment indicated that PUVA significantly increases PL packing to levels typical of liposomes with only saturated acyl chains. These data suggest that overall increased lipid packing interferes with efficient membrane-protein interaction explaining deficient recruitment of specific membrane targeted kinases. Our findings are not restricted to platelets as Akt inhibition was also found in healthy T lymphocytes treated with PUVA and in T cells from patients in a trial assessing PUVA for GvhD treatment. **Conclusion**: PUVA interferes with membrane packing by adduct formation with PL acyl chains thus contributing to indirect but specific inhibition of PI3K dependent effector kinase signal transduction in different cell types.

S82-040B

Identification of Permissible HLA Mismatches Among 19 Platelet Refractory Patients

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Background/Case Studies: Supporting highly HLA alloimmunized platelet refractory patients is difficult. All class I HLA antibodies (Abs) are not clinically significant, so some platelets expressing 'mismatched' antigens (Ags) to which patients are sensitized result in good corrected count increments (CCIs>7500). Identification of such permissible mismatched HLA Ags can expand the donor pool for these challenging patients, but requires close monitoring of CCIs with HLA-typed units, which is not always feasible. Prior studies have shown certain Ags (eg, B44 and B45) have variable expression on platelets, frequently resulting in good CCIs despite prior sensitization. We were interested in identifying other HLA Ags with similar clinical findings. **Study Design/Methods**: Records of 19 refractory patients (≥2 CCIs <7500) transfused with random, XM- and HLA-compatible units between 2/2013 and 3/2016 were reviewed. Transfusions (txn) were excluded if 1) a post-count was absent or >4 hours after issue, 2) donor HLA was not available, or 3) post-count was drawn after multiple units were transfused. Donor HLA types, when available, were obtained from the donor center database. HLA Abs were identified by LABScreen single antigen assay (Luminex, One Lambda) and classified per mean fluorescence intensity as strong (>8500), moderate (2000-8499) or weak (1000-1999). **Results/Findings**: Of 1016 platelet txns reviewed, 658 met inclusion criteria. Average txn per patient was 35 (range 5-93). All patients were highly sensitized, with mean calculated panel reactive Abs (cPRA) of 95% (range 66-100%). Abs to all HLA class I Ags except B66 were identified. For some Ags, either no mismatched units were transfused (A36, A43, A69, A74, A80, B42, B48, B54, B66, B67, B76, B77, B78, B81, B82), or all such txns resulted in CCI<7500 (B45, B65, B71 and B73; each with only 1-6 mismatched units transfused). For all other Ags, at least 1 mismatched unit resulted in CCI>7500. Analysis of HLA Ags with ≥10 mismatched txns (Table) showed on average 61% had CCI>7500 (range 32-92%), many of which were in patients with strong or moderate Abs (per Luminex assay), rather than weak ones. **Conclusion**: This study shows that quite frequently, despite the presence of HLA Ags to which patients are sensitized and have strong or moderate Abs to, good CCIs are achieved. This finding was quite common and not limited to just a few Ags. In highly HLA alloimmunized patients, it may be prudent to accept units mismatched for such Ags which have been shown to frequently result in good CCIs despite presence of strong or moderate Abs.

TABLE. HLA Ags mismatched in ≥ 10 txns

% mismatched txns with CCI>7500	HLA Ags
<50	A2, A33
50-59	A3, A23, A24, B7, B8, B35, B60
60-69	A1, A11, A25, A26, A31, A32, B44, B61
≥70	A29, A30, A68, B18, B51, B62

TABLE.

Example	XM-compatible donor	XM-incompatible donor
XM #1	**A2*** B61 **B62**	**A2** B7 B41
XM #2	**A1** B8 B44	**A1** A31 B8 B62
XM #3	A11 **A24 B60 B75**	**A24** A32 B62 B64

*HLA Ags to which patients were sensitized are underlined and bolded.

S83-040B

Unexpected Donor Compatibility in Platelet Crossmatch Testing

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Background/Case Studies: In a platelet crossmatch (XM) test which is used to identify compatible donors for patients with immune refractoriness, donor platelets are tested against patient plasma. Binding of anti-platelet antibodies (Abs) directed against class I HLA or antigens (Ags) present on donor platelets (HPA) causes positive/incompatible reactions. Thus, donors with Ags to which patients are sensitized are expected to be XM-incompatible. However, review of donor HLA types in XM tests shows inconsistencies with this theory. **Study Design/Methods**: XM was performed by Capture-P (Immucor). Patient class I HLA Ab identification was performed by LABScreen single antigen assay (Luminex®, One Lambda) and rated by mean fluorescence intensity (MFI): >8500 as strong, 2000-8500 as moderate, and 1000-2000 as weak. Seven XM tests performed in four immune refractory patients (≥2 corrected count increments, CCIs <7500) were analyzed. HLA types of the XMed donors were reviewed, when available, and correlated with patient HLA Ab specificity and XM results. **Results/Findings**: A total of 189 donors were tested in 7 XMs (39%-88% were reactive). Fifty-seven of the 189 donors were identified as XM-compatible; 33 had HLA types available. All 33 XM-compatible HLA-typed donors had at least one Ag corresponding to a moderate and/or strong patient HLA Ab: 16 moderate, 6 strong, and 11 both moderate and strong. Some XM-compatible donors expressed three or four moderate or strong mismatched Ags. In some cases, the same XM identified donors expressing a particular mismatched HLA as compatible, while another donor with the same Ag (and no other mismatched Ags) was deemed incompatible (Table). Ten of the 33 XM-compatible, HLA-typed units were transfused. CCIs were available for nine units, ranging from 6400 to 21000 (mean 12400). Only one had a CCI <7500. **Conclusion**: The lack of XM reactivity against platelets expressing HLA Ags to which patients had known strong and/or moderate Abs is puzzling. This could be a limitation of the XM test (false-negative). Perhaps a moderate or strong HLA Ab identified by Luminex® does not correspond to moderate or strong binding to platelet Ags, although this would not explain the incompatible XM results observed (Table). Further characterization of these Abs and/or expression of Ags on platelets may be helpful. The transfused XM-compatible, HLA-mismatched units had good CCIs. These findings illustrate the complexity of platelet Abs and Ags, limitations of *in vitro* testing, and the need to monitor all platelet transfusions in refractory patients to identify donors with good *in vivo* compatibility.

S84-040B

Platelet Desialylation and Immune Tolerance

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Background/Case Studies: Platelets are small anuclear cells in circulation that are known to play essential roles in haemostasis and thrombosis. However, over the years, the link between platelets and the immune system and their influence on the immune response are becoming increasingly recognized and studied. The importance of platelet clearance in the liver is an emerging phenomenon; we have demonstrated antibody-mediated platelet clearance in the liver via an Fc-independent mechanism in immune thrombocytopenia, and others have reported desialylated platelet clearance in the liver as part of platelet homeostasis and as essential in stimulating thrombopoietin generation. Given that the liver is an important immunological site, particularly in generating tolerance to exogenous antigens (e.g. oral antigens), how this platelet clearance in the liver may affect the immune system, or contribute to maintenance of peripheral tolerance

TABLE.

	Leukocyte reduction (Log10)			Platelet recovery (%)		
Driving pressure (PSI)	CD = 7 μm	CD = 8 μm	CD = 9 μm	CD = 7 μm	CD = 8 μm	CD = 9 μm
6.25	3.35 ± 0.38	2.62 ± 0.67	1.87 ± 0.44	85.4 ± 1.8	90.2 ± 2.0	91.5 ± 1.6
12.5	3.25 ± 0.51	2.39 ± 0.62	1.84 ± 0.54	84.9 ± 2.6	90.8 ± 1.6	91.6 ± 0.6
25	3.08 ± 0.40	2.16 ± 0.24	1.99 ± 0.35	80.8 ± 3.2	86.0 ± 2.9	88.6 ± 1.8

Leukocyte reduction and platelet recovery, shown as mean ±s.d. (n=5) in the devices of three CD, and under three driving pressures

has never been explored. **Study Design/Methods**: Various genetic background mice were immunized via tail-vein injections to generate antibody response. Antibody titres were measured with flow cytometry. **Results/Findings**: We found transfusion of sialidase treated (desialylated) BALB/c mouse platelets resulted in decreased antibody generation in both $\beta3^{-/-}$ and $GPIb^{-/-}$ (iso-response) and C57BL/6J (allo-response) mice, compared with non-treated platelets ($p<0.05$). Furthermore, utilizing state-of-the-art Multispectral Optoacoustic Tomography imaging, we tracked, in real-time, increased targeting of indocyanine green labeled-desialylated platelets to the liver and gut in mice following transfusion. To assess whether desialylated platelets could modulate the immune response and were not only simply less immunogenic, we pre-sensitized $\beta3^{-/-}$ mice with syngeneic BALB/c desialylated or non-desialylated platelets. Interestingly, we found upon further challenge with the same dose of allogeneic C57BL/6J WT platelets, there was a significant decreased antibody response against alloantigen $H\text{-}2K^b$ ($p<0.01$) in the mice that were pre-transfused with desialylated platelets. The suppressed antibody response was specific to platelet antigens, as there was no significant difference in response between the two groups following secondary challenge with sRBC. Immunophenotyping of spleen revealed increased $CD8^+$ Tregs with corresponding decreased T-follicular helper cells, suggesting that desialylated platelet mediated immune suppression may be acting through $CD8^+$ Tregs. **Conclusion**: Increased desialylated platelet clearance in the liver may have immunosuppressive effects against platelet specific antigens. These findings may elucidate mechanisms behind maintenance of peripheral tolerance against platelet antigens as part of normal platelet homeostasis. Additionally, these findings may be exploited as a therapeutic target to suppress alloantigen responses in transfusions or transplants.

Components and Component Processing II

S85-040C

A High-throughput Microfluidic Device for Leukoreduction of Platelet-Rich Plasma

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Background/Case Studies: Leukoreduction (LR) of platelets and other blood products substantially reduces the risk of a number of transfusion-related complications. Current LR filters operate by trapping leukocytes within the filter material, allowing continuous release of cytokines by trapped leukocytes in to the platelet product, and inducing platelet activation. To address this limitation, we utilized our group's recently-developed '*controlled incremental filtration*' approach to design a high-throughput microfluidic device that performs size-based separation of leukocytes from platelet-rich plasma (PRP). A single unit of the device (4mm×0.5mm×0.5mm) reduced the concentration of leukocytes in PRP by 1000-fold, at the volumetric throughout of >0.7 mL/min, while recovering >80% of the platelets. **Study Design/Methods**: Three versions of the leukoreduction device with critical diameter (CD) of 7, 8, and 9 μm were designed and fabricated in poly(dimethylsiloxane) by standard soft lithography. The PRP samples were obtained from whole blood donated by healthy consenting volunteers, and were driven through the device using a driving pressure of 6.25, 12.5 and 25 PSI. The platelet and leukocyte concentrations in all the input/output samples were measured with a hematology analyzer or flow cytometry. **Results/Findings**: At the driving pressure of 25 PSI, the flow rate of CD 7, 8 and 9 μm devices were 0.79, 0.97 and 1.08 mL/min, respectively. The average leukoreduction for the CD 7, 8 and 9 μm devices was 99.9%, 99.3% and 98.5% respectively (Table). As the driving pressure increased, platelet recovery decreased, which is likely due to the deformation of poly(dimethylsiloxane) under pressure (Table). As the CD increased, the devices showed progressively lower leukocyte reduction but higher platelet recovery, which could enable designing devices for applications requiring different levels of separation. **Conclusion**: This work demonstrates a high-throughput microfluidic device capable of removing more than 99.9% of leukocytes while retaining more than 80% of the platelets. By multiplexing, this device has the potential to become a manufactured product that could leukoreduce a 250mL unit of PRP in <30 minutes. Such a product could satisfy the need for leukoreduction of platelets transfused throughout the practice of medicine to millions of patients every year.

S86-040C

Characterization and Comparison of the Surface Phenotype of Refrigerated and Cryopreserved Platelets

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Background/Case Studies: Storage at room temperature limits the shelf-life of platelets to 5 days due to the risk of bacterial growth. Platelet shelf-life may be extended using alternative storage methodologies including refrigeration (2-4°C) and cryopreservation (−80°C). However, both techniques induce changes to the platelet surface phenotype, which may affect the hemostatic function and clearance rate *in vivo*. A direct comparison of the phenotypic changes induced by refrigeration and cryopreservation has not yet been reported. Thus, the aim of this study was to characterize and compare the surface receptor phenotype of room temperature, refrigerated and cryopreserved platelets. **Study Design/Methods**: Three buffy-coat derived platelets stored in 30% plasma/70% SSP+ were pooled, split and stored under the following conditions: room temperature (RT), refrigerated (4°C) or cryopreserved (−80°C with 5-6% dimethylsulfoxide). The surface phenotype of liquid-stored platelets was examined over 21 days, while cryopreserved platelets were tested immediately after thawing and resuspension in 30% plasma/70% SSP+ (n=8 in each group). The platelet surface phenotype was characterized by

TABLE. Platelet phenotypic and activation markers on Day 5 or post-thaw

Antibody	RT	4°C	Cryopreserved	p value (One-way ANOVA)
CD42a (MFI)	2603 ± 262	1992 ± 188	2042 ± 284	<0.0001
CD42b (MFI)	1838 ± 308	1322 ± 224	586 ± 284	<0.0001
CD41a (MFI)	703 ± 102	617 ± 126	364 ± 35	<0.0001
GPVI (MFI)	2778 ± 506	1765 ± 441	60 ± 16	<0.0001
CD62P (%)	3.5 ± 0.9	12.9 ± 4.4	30.1 ± 4.8	<0.0001
CD63 (%)	1.2 ± 0.7	1.5 ± 1.3	17.1 ± 2.3	<0.0001
PAC-1 (%)	1.1 ± 0.7	13.7 ± 4.7	10.6 ± 2.8	<0.0001

flow cytometry using a panel of antibodies. **Results/Findings**: Both refrigerated and cryopreserved platelets displayed a reduction in expression of GPIX (CD42a), GPIbα (CD42b), GPIIb (CD41a) and GPVI (Table) compared to room temperature storage, as determined by median fluorescent intensity (MFI). Activation marker expression, including P-selectin (CD62P), tetraspanin-30 (CD63) and integrin-αIIbβ3 (PAC-1) was increased by both refrigeration and cryopreservation, compared to room-temperature stored platelets. In general, cryopreserved platelets had a lower expression of functional glycoproteins, and a higher proportion of platelets expressing markers of activation than refrigerated platelets stored for 5 days. **Conclusion**: These results confirm that refrigeration and cryopreservation alter the external receptor phenotype of platelets, compared to conventional room-temperature stored platelets, with cryopreserved platelets displaying more dramatic changes. These changes may affect platelet function and clearance and thus clinical investigations are required to understand the value of these storage methodologies and their potential application in transfusion.

S87-040C

Characterization of Platelet Lysate Produced From Expired Platelet Components: Suitability for Expansion of Mesenchymal Stromal Cells

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Background/Case Studies: Platelet lysate is emerging as a substitute for fetal bovine serum (FBS) for expansion of human therapeutic cells, such as mesenchymal stromal cells (MSCs). Platelet lysate can potentially be produced from expired platelet components. The aim of this study was to characterize platelet lysate manufactured from either buffy-coat-derived platelets (buffy-coat lysate) or apheresis platelets (apheresis lysate). **Study Design/Methods**: Batches of platelet lysate were produced by freeze-thawing expired platelets followed by pooling of lysate from either 10 buffy-coat platelets (n=8 batches) or 12 apheresis platelets (n=8 batches). Growth factors including transforming growth factor (TGF-β1), platelet derived growth factor (PDGF)-AB, PDGF-BB, insulin growth factor (IGF)-1, endothelial growth factor (EGF), basic fibroblast growth factor (bFGF), vascular endothelial growth factor (VEGF), and hepatocyte growth factor (HGF) were measured by ELISA. The ability of platelet lysate to support the proliferation of human dermal fibroblasts was also compared to FBS using a one-way ANOVA. The phenotype of human adipose derived MSCs following culture with buffy-coat lysate was examined by flow cytometry. All data represents mean $\pm$ standard deviation. **Results/Findings**: The platelet concentration of the starting material for apheresis lysate was significantly higher than buffy-coat lysate ($1590 \pm 58 \times 10^6$ compared to $1286 \pm 54 \times 10^6$ platelets/mL; $p<0.0001$). With the exception of VEGF, all other growth factors in buffy-coat lysate were significantly lower than in apheresis lysate (Table). In comparison to 10% FBS, fibroblast proliferation was significantly higher in 10% buffy-coat lysate and both 5% and 10% apheresis lysate (all $p<0.0001$). Adipose derived MSCs cultured with buffy-coat lysate expressed CD73, CD166, CD44, CD105, and CD90 (>98% cell population) but not CD45, CD34, CD11b CD19 and HLA-DR (<0.05% cell population). **Conclusion**: Overall buffy-coat lysate contained lower levels of growth factors than apheresis lysate. However, culture with both types of lysate resulted in higher fibroblast proliferation than FBS. Adipose derived MSCs cultured with platelet lysate fulfilled the phenotypic criteria for MSCs set by the International Society for Cellular Therapy.

TABLE. Concentrations of growth factors in platelet lysates (ng/mL)

Growth factor	Buffy-coat lysate	Apheresis lysate	p-value*
TGF-β1	70.3 ± 7.4	127.7 ± 17.6	<0.0001
IGF-1	31.2 ± 4.5	113.9 ± 10.1	<0.0001
PDGF-AB	38.5 ± 5.2	54.3 ± 7.7	0.0003
PDGF-BB	12.8 ± 1.3	20.1 ± 2.2	0.0001
EGF	2.3 ± 0.1	3.6 ± 0.3	0.0001
bFGF	0.2 ± 0.0	0.3 ± 0.1	0.0025
VEGF	0.7 ± 0.1	0.8 ± 0.2	0.2713
HGF	0.6 ± 0.1	1.0 ± 0.1	0.0001

*Determined using two-tailed t-tests

S88-040C

Role for RNA Binding Proteins HuR and TTP in Platelet mRNA Degradation due to Pathogen-inactivation Treatment

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Background/Case Studies: In nucleated cells mRNA stability is regulated by the association of RNA binding proteins (BPs) to the 3' end untranslated region of an mRNA transcript. Even though platelets are anucleate, they use RNA and the ribosomal machinery derived from megakaryocytes to synthesize proteins. Unknown is how platelet mRNA levels are regulated. Pathogen inactivation treatments (PIs) use UV-light with or without a photosensitive agent to modify viral and bacterial RNA and DNA. PI also affects platelet mRNA. In this study we investigated the role of RNA BPs Human antigen R (HuR) and Tristetraprolin (TTP) on riboflavin (RF)/UV treated platelet mRNA. In mammalian cells HuR and TTP are regulated by p38 MAP kinase signaling pathway. Inhibition of p38 MAP kinase improves the platelet function after RF/UV treatment. Unknown is whether p38 MAP kinase affects platelet mRNA stability as well. **Study Design/Methods**: Three units of apheresis platelet concentrates were pooled and split into four illumination bags. One bag was kept as untreated control; the second was RF/UV treated; the third and fourth bags were spiked with 10 μM p38 MAP-kinase inhibitor SB203580 in DMSO or DMSO as vehicle control prior to RF/UV treatment. Samples were taken one hour after illumination (day 0) and on day 1, 5, 7, and 9 of storage. Total RNA amount was determined via absorbance at 260 nm. Quantitative PCR was used to determine the relative transcript amount of thrombospondin (TSP) and glyceraldehyde 3-phosphate dehydrogenase (GAPDH). Protein lysates were prepared for immunoblot analysis to quantify expression levels of RNA BPs. **Results/Findings**: Immunoblot analysis demonstrated the presence of the HuR and TTP throughout storage. The RF/UV treatment with or without inhibitor did not result in a significant change in total RNA compared to the untreated arm. In the presence of SB203580, the mRNA half-life for TSP was significantly increased to 0.92 ± 0.04 day compared to the untreated sample (0.66 ± 0.07 day; $p = 0.01$), the RF/UV treated sample (0.73 ± 0.07; $p = 0.05$) and the DMSO sample (0.79 ± 0.05; $p = 0.02$). No significant change in mRNA half-life for GAPDH was observed in the different study arms. **Conclusion**: Immunoblot results demonstrate for the first time the presence of RNA binding proteins HuR and TTP in human platelets. HuR and TTP are regulated in mammalian cells by kinases like p38 and its inhibition seems to impact mRNA levels as TSP mRNA is a known target for these RNA binding proteins. This result suggests that p38 MAP kinase might be linked to mRNA regulation via RNA binding proteins in platelets.

S89-040C

Effect of Age, Sex or Frequent Blood Donations on Donors' Ferritin Levels and Red Blood Cell Storage Stability

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Background/Case Studies: Red blood cell (RBC) donors represent a diverse population where the effect of biological variables such as age, sex or iron status on RBC storage stability is largely unknown. The purpose of this study was to further characterize the effect of such variables using various measures of hemolysis as end-point measurements of storage quality. **Study Design/Methods**: Leukocyte-reduced RBC units were donated by 13,771 enrolled donors who participated in the Red Blood Cell-Omics (RBC-Omics) study, which is part of NHLBI Recipient Epidemiology and Donor Evaluation Study-III (REDS-III). Ferritin levels (ng/mL) were determined in donors' plasma. RBCs (15 mL) were stored in transfer bags at 1-6° C for 39-42 days, after which RBCs were subjected to selected assays including percent storage hemolysis, osmotic hemolysis (Pink Test), and oxidative hemolysis using AAPH. **Results/Findings**: Increased levels of storage hemolysis were positively correlated with age in both sexes, whereas age had a minor effect on predisposition to osmotic hemolysis. Conversely, aging was correlated with

TABLE. Effect of donors' sex and age on RBC hemolysis or ferritin levels. Males: Top values; Females; Bottom values. Mean±SD

Age (years)	18-20	21-25	26-30	31-35	36-40	41-45	46-50	51-55	56-60	61-65	>65
Storage	0.36 ± 0.27	0.38 ± 0.27	0.39 ± 0.29	0.41 ± 0.31	0.41 ± 0.28	0.41 ± 0.26	0.40 ± 0.33	0.40 ± 0.26	0.41 ± 0.29	0.38 ± 0.26	0.41 ± 0.29
(%)	0.33 ± 0.21	0.34 ± 0.58	0.32 ± 0.16	0.32 ± 0.15	0.36 ± 0.42	0.34 ± 0.16	0.35 ± 0.24	0.35 ± 0.22	0.36 ± 0.23	0.35 ± 0.17	0.36 ± 0.2
Osmotic	27.8 ± 13.3	29.1 ± 13.8	30.4 ± 13.4	31.2 ± 14.1	31.3 ± 13.6	32.1 ± 14.0	32.0 ± 13.3	31.1 ± 13.6	30.5 ± 13.3	30.0 ± 12.3	29.9 ± 12.3
(%)	26.7 ± 12.6	25.5 ± 12.0	24.6 ± 12.1	25.3 ± 12.1	25.3 ± 12.4	24.9 ± 12.3	26.1 ± 12.8	26.0 ± 12.2	26.8 ± 12.2	26.7 ± 12.4	25.5 ± 11.0
Oxidative	39.7 ± 10.3	40.6 ± 10.0	39.4 ± 9.1	39.8 ± 9.6	39.4 ± 10.2	39.6 ± 10.0	39.1 ± 10.2	37.6 ± 10.0	36.2 ± 9.6	35.7 ± 9.7	33.4 ± 9.9
(%)	38.4± 8.7	38.5± 9.4	37.5 ± 9.8	37.8 ± 10.4	38.1± 9.9	38.1 ± 10.1	36.3 ± 10.1	35.5 ± 10.1	34.5 ± 9.3	32.5 ± 8.7	32.4 ± 9.5
Ferritin	69.2 ± 55.7	82.0 ± 70.7	93.2 ± 85.0	95.8 ± 101	91.3 ± 98.8	102 ± 132	74.6 ± 92.5	63.8 ± 72.4	60.3 ± 83.3	53.5 ± 72.2	41.4 ± 47.1
(ng/mL)	23.3 ± 26.2	29.4 ± 30.6	34.3 ± 37.9	35.6 ± 39.1	38.2 ± 38.1	33.8 ± 45.6	34.1 ± 40.6	38.5 ± 41.5	37.5 ± 37.8	36.7 ± 42.3	35.3 ± 44.0

increased resistance to oxidative hemolysis in both sexes (Table 1). Ferritin levels were influenced by sex and age, although no strong correlation was observed between ferritin and the three hemolytic assays. Analysis of prior donation intensity (number of donations in the past 24 months) suggested that donation of 10 or more units is associated with increased resistance to oxidative hemolysis and decreased levels of ferritin. **Conclusion**: Our findings emphasize the effect of donor's age and sex on RBC storage stability and predisposition to stress-induced hemolysis. Furthermore, the effect of prior donation on ferritin levels and predisposition to oxidative hemolysis may be explained .by iron loss, and may require further investigation to determine possible consequences on donor's health and RBC storage stability.

S90-040C

Rejuvenation of Stored Red Blood Cells Attenuates Hemolysis in a Simple Circuit Design

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Background/Case Studies: Red blood cell (RBC) hemolysis and elevated plasma free hemoglobin (PFHb) are observed during extracorporeal circuit membrane oxygenation (ECMO). The objective was to evaluate the durability of washed or rejuvenated RBCs to resist roller-pump induced hemolysis for 19.5 hours on-pump. **Study Design/Methods**: Human leukocyte reduced RBC units (n = 10) collected in CPD/AS-1 (stored at 1-6°C for 35-42 days) were subdivided and split equally by weight into aliquots ($Control_{WASH}$ and Washed or $Control_{REJ}$ and Rejuvenated Groups). Rejuvenated aliquots were processed with 25 mL rejuvesol™ Red Blood Cell Processing Solution and dry air incubated (Sarstedt SAHARA-III) for one hour at 37°C, washed (Haemonetics ACP 215), and re-suspended in saline. Control aliquots were diluted with saline to match the post-wash hematocrit of the paired rejuvenated or washed aliquot. Two identical circuits were set up with a 100 mL reservoir, 1/8 ID IV tubing, and 100 mL/minute roller pump (Watson-Marlow 120U/DV). Paired aliquots were run in parallel for 19.5 hours at 37°C in a temperature controlled environment. Complete blood counts (CELL-DYN Sapphire), PFHb (HemoCue Plasma/Low Hb), and hemolysis were analyzed. **Results/Findings**: PFHb and hemolysis increased significantly over time for all Groups. PFHb and hemolysis in the Rejuvenated Group were significantly lower than in the $Control_{REJ}$ group ($p = 0.02$, Student's t-test) (Table 1). **Conclusion**: Significantly less roller-pump induced hemolysis and PFHb accumulation were observed with rejuvenated RBCs. RBC washing alone did not significantly improve RBC resistance to hemolysis. Donor to donor variability in RBC resistance to mechanically-induced hemolysis was observed within the $Control_{WASH}$, $Control_{REJ}$, and Washed Groups. Only RBC rejuvenation prior to circulation attenuated the variability in mechanically-induced hemolysis.

TABLE. PFHb and % hemolysis for each group at the beginning and end of the circuit run.

	PFHb (g/dL)		% Hemolysis	
Group (n = 5)	(T = 0 hrs)	(T = 19.5 hrs)	(T = 0 hrs)	(T = 19.5 hrs)
$Control_{WASH}$	0.17 ± 0.01	8.06 ± 5.22	0.95 ± 0.14	51.7 ± 38.0
Washed	0.09 ± 0.02*	7.08 ± 3.94	0.53 ± 0.17*	45.9 ± 34.8
Group (n = 5)	(T = 0 hrs)	(T = 19.5 hrs)	(T = 0 hrs)	(T = 19.5 hrs)
$Control_{REJ}$	0.20 ± 0.05	7.81 ± 4.24	1.34 ± 0.68	50.4 ± 28.6
Rejuvenated	0.07 ± 0.02*	2.11 ± 0.21*	0.45 ± 0.08*	12.8 ± 1.4*

*denotes significant difference from paired group ($p < 0.05$).
rejuvesol Solution (50 mL) is FDA approved to be used as an in vitro processing solution for the rejuvenation of a unit of RBC. This protocol is for research only and is not an FDA approved method.

Donor and Therapeutic Apheresis

S91-040D

Longitudinal Assessment of Peripheral Blood counts in Highly Frequent Platelet Apheresis Donors: A 10-year Prospective Observational Study

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Background/Case Studies: The effect of intensive platelet (plt) donation on peripheral blood counts in high frequent plt donors remains open. In the present prospective study we monitored peripheral complete blood counts (CBC) in a cohort of pre-selected first time plt donors during their individual entire donation carrier (minimal requirement for donation: ≥ 200x10^9 plt/L). **Study Design/Methods**: Individual CBC was determinate before each apheresis donation, starting with the first donation and followed-up for up to 10 years. To reduce the influence of intra-individual/seasonal variations in CBC we calculate individual mean CBC/observation year based on minimal 3 donations per observation year. The study population consisted on 405 donors with median 8 (3-20) apheresis donations/observation year and a median follow-up of 3 (1-10) observation years (overall 9948 plt donations). In >90% plt donation was performed with single-arm (discontinuous) devices, resulting in the collection of mean 5.1 ± 1.4x10^11 plt/donation. **Results/Findings**: Changes in mean plt counts between first and last observation year followed a Gaussian distribution and showed a non-significant decrease in mean plt counts of −2.1 ± 25.5x10^9 plt/L (p=0.46; extremes: - 112.7 to +75.3x10^9 plt/L); in none of the donors plt counts fall below the threshold of 150x10^9 plt/L before apheresis. Spearman's correlation analysis showed a positive association between increase in mean plt counts and individual donation frequency (p=0.01), and the total number of plt collected per apheresis donation (p=0.04). Other parameters like age, sex, or the duration of the active donation career had no influence on the variation in mean plt counts (all p>0.05). Analysis of RBC counts and hemoglobin concentration [Hb] revealed no changes between the 1st donation

TABLE.

	%CD34 Pre-Apheresis		#CD34+cells/liter blood processed (X10^6/L)	
Age Decade (yrs)	Mean	Range	Mean	Range
<20 (n=8)	0.193	0.05-0.39	32.36	7.25-68.99
20-29 (n=48)	0.213	0.07-0.48	31.54	8.39-76.04
30-39 (n=16)	0.209	0.09-0.38	31.73	11.93-81.03
40-49 (n=9)	0.139	0.06-0.22	26.59	13.86-64.27
50-59 (n=9)	0.226	0.05-0.33	36.44	7.13-92.33

year and the last observation year (RBC counts: p=0.5; [Hb]:p=0.6). While individual WBC remained constant during the entire observation period (mean change: -0.6 ± 1.1x10^9 WBC/L; p=0.61), we observed a gradual decrease in mean lymphocyte counts with increased duration of the individual donation carrier (mean decrease between 1st and last observation year: -4.2 ± 0.5%; p=0.02). **Conclusion**: Our data gave no evidence for an exhaustion of the thrombopoietic system in high frequent plt apheresis donors but rather implicate a boost of the thrombopoiesis in response to intensive plt donation over prolonged time. Decrease in lymphocyte counts should be continuously monitored, although the clinical significance of the observed decrease remains speculative.

S92-040D

Do Frequent Apheresis Platelet Donors Need to be Considered for Iron Supplementation?

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Background/Case Studies: In the United States, volunteer blood donors can donate platelets by apheresis (AP) up to 24 times per year. Prior studies have revealed the potential for iron depletion in male donors without a prior history of any type of donation in the last 24 months by their third whole blood (WB) donation [Cable, *Transfusion* 2011;51:511-22; Cable, *Transfusion* 2012, 52: 702-711.) The aim of this study is to examine the combined RBC loss in AP donors from both residual blood retained in the tubing of the collection system and sample tubes and its relationship to a need for iron supplementation among AP donors. **Study Design/Methods**: The RBC losses from AP and WB donations at a large blood center in the Eastern US were examined. It was assumed that the blood of all donors had minimum hematocrit of 38%. AP are collected with the AMICUS cell separator with residual RBC loss in the collection kit of 30 mL and WB is collected in 500 mL bags. The sample tubes collected from all donors are as follows: for AP donors = three 4 mL, one 5 mL, and three 6 mL tubes and for WB donors =one 4 mL, two 5 mL, and three 6 mL tubes. **Results/Findings**: The total RBC losses associated with an AP donation are 42 mL; with a WB donation is 200.8 mL (see Table). Assuming that a donor makes the maximum # of donations in a rolling 12 month period, the 12 month cumulative RBC losses are 1,008 mL for AP donors and 1,205 mL for WB donors. By the 5th AP donation, an AP donor will sustain the same RBC loss as a donor making 1 WB donation (200.8 mL RBC losses per WB donation/42 mL losses per AP donation = 4.76 AP donations). Since a male with no prior donations of any type in the last 24 months can become iron deficient by his 3rd WB donation, a similar donor can become iron deficient by his 15th AP donation (1 WB donation RBC losses = 4.76 AP donations RBC losses; 3 WB donations RBC losses = 14.3 AP donations RBC losses or about 15 AP donations). **Conclusion**: At our blood center, frequent male AP donors making about 15 AP donations in a rolling 12 month period might need iron supplementation in the same manner that frequent male donors making 3 WB donations in a rolling 12 month period need iron supplementation to avoid both types of donors from becoming iron deficient. This finding is of significance to blood donation programs since iron deficiency leads to anemia and donor deferrals, especially considering the US the minimum hemoglobin level for all male donors will increase from 12.5 g/dL to 13.0 g/dl in May, 2016.

S93-040D

Efficacy and Safety of a New Off-line Extracorporeal Photochemotherapy Schedule in the Treatment of Patients with Graft-versus-host Disease

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Background/Case Studies: Extracorporeal photochemotherapy (ECP) is a recognized second-line treatment for patients with acute and chronic graft-versus-host disease (GVHD). However, the methodology and instrumentation used are quite variable and there is no standard schedule for ECP in the treatment of patients with GVHD. The objective of this study was to analyze the efficacy and safety of a new off-line extracorporeal photochemotherapy schedule in the treatment of patients with GVHD. **Study Design/Methods**: Patients received off-line ECP because of acute or chronic GVHD in two university hospitals. Diagnosis of acute GVHD was according to clinical and histopathological criteria and chronic GVHD by clinical assessment based on NIH criteria. The mononuclear cells (MNC) were collected using Spectra device (Terumo BCT, Lakewood, CO) after processing 1 blood volume of the patient, and collected MNCs were illuminated with UVA PIT (Med Tech Solutions, Modena, Italy). Off-line ECP for acute GVHD was administered on 2 consecutive days per week for 2 weeks, followed by 1 treatment per week for 2 weeks, then reduced to 1 treatment at 2-week interval for 1 month, and 1 treatment per month until maximum response. Off-line ECP for chronic GVHD was administered once per week for 4 weeks, followed by 1 treatment at 2-week interval for 1 month, and 1 treatment per month until maximum response. Overall response rate (ORR) in acute GVHD included patients who showed >50% improvement of organ involvement (skin, gut, or liver). ORR in chronic GVHD was assessed according to patient-reported outcomes, classified into response (clinically meaningful improvement) versus no response (no improvement or worsening). Overall survival (OS) from the start of ECP procedures was calculated. Adverse events (AE) during ECP procedures were recorded. **Results/Findings**: The population analyzed was 25 patients (14 men, 11 females) with a median age of 53 years (range: 31-73). Acute and chronic GVHD was present in 12 and 13 patients, respectively. Patients received a median number of 14 ECP procedures (range: 4-37) in a median of 4 months (range: 0.4-15). The median follow-up from the start of the ECP procedures was 7 months (range: 0.7-41). The ORR for patients with acute and chronic GVHD was 54% and 67%, respectively. OS for patients with acute GVHD and chronic GVHD was 48% at 1 year and 75% at 3 years, respectively. No AEs were recorded during any of the ECP procedures. **Conclusion**: This new off-line ECP schedule in the treatment of patients with acute and chronic GVHD was efficacious and safe.

S94-040D

RBC Alloantibody Formation Is Not Associated with RBC Age in Adult Sickle Cell Disease Patients Receiving Chronic Apheresis RBC Exchange

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TABLE. Cumulative Rolling 12 month RBC Losses

	RBC Losses/ AP Collection Kit or WB Bag mL	RBC Losses/ Sample Tubes mL	Total RBC Losses mL	Maximum # of Donations Per Year #	12 month RBC Losses mL
AP Donors	30 mL (per operator manual)	12 mL	42 mL	24	1,008 mL
WB Donors	500 ml bag volume × 0.38% hematocrit = 187.5 mL	35 ml of whole blood × 0.38 HCT = 13.30 mL	200.8 mL	6	1,205 mL

Background/Case Studies: Sickle cell disease (SCD) patients may require red blood cell (RBC) transfusions as part of therapy. RBC alloantibody formation (RBC-AF) is a potential transfusion complication that may cause hemolytic reactions and create challenges in obtaining compatible RBCs. RBC-AF rates for SCD patients receiving simple transfusion approach 5/100 units. For those receiving apheresis RBC exchange (RCE), reported rates are lower and approach 0.2/100 units. While a connection between RBC-AF and older RBC age has been suggested in simple transfusion, this idea has not been explored in RCE. We sought to ascertain the effect of RBC age on RBC-AF in SCD patients receiving chronic RCE. **Study Design/Methods**: We retrospectively analyzed SCD patients who received chronic RCE at our university apheresis center over two years. Inclusion criteria were hgb SS disease, receipt of $\geq$3 RCE, and age $\geq$18 years. All patients received leukoreduced RBCs that were, at minimum, matched for D,C,c,E,e,and K antigens. Antibody screens prior to each RCE were analyzed for RBC-AF. We obtained patient demographics, RCE data, and expiration dates of all RBC units. All unit ages were reported as 42-day maximums for consistency. Continuous variables were analyzed by Mann-Whitney test. A multivariable logistic regression model was used to evaluate effect of patient factors on RBC-AF. Cox proportional hazard models were used due to the time-dependent nature of data when assessing for new RBC-AF. We used all transfusion data from the previous 90 days for any new RBC-AF, as RBC survival and any immunologic impact was deemed negligible beyond this. Since each RCE uses multiple units, RBC age was assessed as mean unit age and oldest unit age. Statistical significance was $p<0.05$. **Results/Findings**: 22 patients had 303 RCE using 1693 RBC units; all were Black, mean age was 30.9 years, and 6/22 (27%) were female. 9 patients (41%) had $\geq$1 alloantibody prior to start of study period. RBC-AF occurred in 1 patient (4.5%); 4 new RBC alloantibodies were identified (anti-Jka, anti-Jkb, anti-S, and antibody against low-frequency antigen). RBC-AF rate was 0.23/100 units. Mean RBC age in the patient with RBC-AF was 22 ± 12 days vs. 21 ± 9 days in those without RBC-AF ($p=0.61$). Oldest RBC age in the patient with RBC-AF was 27 ± 12 days vs. 27 ± 9 days in those without RBC-AF ($p=0.98$). No factor, including RBC unit age or number of units, was associated with risk of RBC-AF ($p>0.05$ for all). **Conclusion**: RBC age was not associated with RBC-AF in adult SCD patients receiving chronic RCE. In contrast to patients receiving simple transfusions, our findings suggest that beneficial mechanisms linked with RCE, such as immune tolerance or decreased inflammation related to improved SCD control, may mitigate any potential effect of older RBC age on RBC-AF.

S95-040D

Absolute Immature Platelet Count Predicts the Clinical Outcomes of Therapeutic Plasma Exchange for Thrombotic Thrombocytopenic Purpura (TTP) Patients

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Background/Case Studies: TTP is a thrombotic microangiopathy caused by severely reduced activity of the protease ADAMTS13. It is a life-threatening diagnosis requiring prompt initiation of therapeutic plasma exchange (TPE). Although low ADAMTS13 activity is a hallmark of TTP, its value may not be immediately available. Since an array of conditions can present with microangiopathic hemolytic anemia and thrombocytopenia, prompt TTP diagnosis may be elusive. Ideally a rapid laboratory measurement that could predict the clinical outcome of TPE therapy in these patients is needed. The absolute immature platelet count (A-IPC), a real-time thrombopoietic test, has been shown to aid in the diagnosis of TTP. Here we investigate the utility of A-IPC to predict TPE outcome and response to therapy in presumed TTP patients. **Study Design/Methods**: All presumed TTP patients receiving TPE at a tertiary academic medical center from 01/01/2014 to 12/31/2015 were included in this study. Twenty-two patients were identified, and 18/22 had A-IPC measured on day of presentation. A-IPC was calculated by multiplying the immature platelet fraction (%-IPF) times the platelet count. Among these 18 patients with A-IPC measurement, 10/18 patients had confirmed TTP diagnosis with ADAMTS13 activity $<$10% and 8 patients had ADAMTS13 activity $>$10% (mean of $54.3\% \pm 5.2\%$). Platelet counts (x 10^9/L) for these two groups were 11.6 ± 1.4 and 49.1 ± 14.8, respectively. Platelet count and A-IPC changes after 3-5 TPE treatments were analyzed as an indication of outcome of TPE treatment. Correlation between A-IPC at presentation with ADAMTS13 activity and outcome of TPE treatment was also determined. **Results/Findings**: A-IPC positively correlated with ADAMTS13 activity at presentation. A-IPC (x 10^9/L) and %-IPF are 0.536 ± 0.11 and $6.36\% \pm 0.8\%$ in patients with ADAMTS13 $<$10%, and 3.58 ± 1.06 and $12.01\% \pm 2.9\%$ in those with $>$10% ADAMTS13 or normal patients respectively. All patients with ADAMTS13 $<$ 10% achieved a $>$3 fold increase of A-IPC after 3-5 TPE. A-IPC value of less than 10 x 10^9/L at presentation had 100% sensitivity, 91% specificity for predicting ADAMTS13 activity deficit. A-IPC inversely correlated with platelet count increment after 3-5 TPE treatments, which is indicative of a feedback loop and indicates positive clinical outcome. **Conclusion**: Our study shows close correlation of A-IPC and ADAMTS13 activity as well as clinical outcome of TPE in TTP patients. Because of the rapid turnaround time of A-IPC, this test may help supplement ADAMTS13 activity measurement for diagnosing TTP and predicting TPE treatment outcome at patient's presentation.

S96-040D

Utility of a Novel Genetic Assay to Confirm the Diagnosis of Complement-Mediated Thrombotic Microangiopathy

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Background/Case Studies: Improved diagnostic tests and greater understanding of the pathophysiology of thrombotic microangiopathy (TMA) have led to more rapid differentiation of various types of TMAs. Given the lack of sensitivity, high cost, and long turnaround time of current aHUS genetic assays, atypical hemolytic uremic syndrome (aHUS) remains a diagnosis of exclusion. Since April 2014, availability of "Next-Gen" aHUS genetic testing (GT) allowing rapid detection (2-5 days) of $>$230 known or suspected mutations, deletions, or polymorphisms reported as possibly associated with aHUS, including 12 of the most common mutations (sensitivity 70-75%), has enabled faster assessment of TMA cases. **Study Design/Methods**: From 4/14 to 9/15, we evaluated 95 patients (pts) with TMA. 66/95 (70%) pts had TTP (ADAMTS13 activity $<$5%), 6/95 (6%) pts had shiga-toxin ecoli (STEC) HUS, and 23/95 (24%) pts had neither (non-TTP, non-STEC TMA). TTP pts presented with (p/w) mean platelet count (plt ct) 13 x 10^9/L (5-27 x 10^9/L), LDH 2689 U/L (844-5213), creatinine (Cr) 0.8 mg/dl (0.5-2.2). 32/95 (34%) TTP pts had CNS abnormalities (abn), 5/95 (5%) had renal insufficiency (RI) (Cr $>$1.5). STEC HUS pts p/w mean plt ct 46 x 10^9/L, (36-57 x 10^9/L), LDH 545 (390-694), Cr 3.2 (2.7-4.1), with no CNS abn. Non-TTP/non-STEC TMA (TMA) pts p/w mean plt ct 61 x 10^9/L (18-153 x 10^9/L), LDH 845 (457-1336), Cr 4.1 (2.0-17.7), and ADAMTS13 of 71% (15-130%). 22/95 (23%) TMA pts had CNS abn, 71/95 (75%) had RI. **Results/Findings**: TTP pts received mean 15.6 plasma exchange (PE) treatments (txs) (5-43 txs) with 59/66 (89%) pts receiving PE taper (3X –$>$ 2X/week). 47/66 (71%) TTP pts with refractory response (or elevated ADAMTS13 antibody titer) received rituximab. STEC HUS pts received supportive care, including mean 5.2 PE txs (4-7). TMA pts received mean 6.3 PE txs (0-13). 13/23 (57%) TMA pts required hemodialysis; 5/23 (22%) pts had RI which resolved. 11/23 (48%) TMA pts with unexplained, persistent RI (and/or other thrombotic symptoms) received aHUS GT. 12/23 (52%) did not get aHUS GT and were successfully treated for associated conditions: sepsis/DIC (3 pts), SLE flare (2 pts), malignant HTN (2 pts), pre-eclampsia (2 pts); HIV TMA, gemcitabine-assoc. TMA, and scleroderma renal crisis (1 pt each). 8/11 (73%) of aHUS GT were positive (presence of CFH, CFI, MCP, thrombomodulin, or plasminogen genetic abn) or equivocal; 27% were negative. 9/11 (82%) of these TMA pts received eculizumab. **Conclusion**: While aHUS genetic assays lack the ability to "rule-out" complement-mediated TMA, these assays can assist with "ruling-in" the diagnosis. With the development of improved genetic testing (ie, increased sensitivity and speed), aHUS genetic assays may represent a "real-time" diagnostic tool enabling more rapid assessment of selected TMA cases leading to more targeted treatment.

Cellular Therapies

SP1

Development of an Antibiotic Neutralization Protocol to Improve Sterility Testing of Cord Blood Units

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Background/Case Studies: Bacterial contamination of cord blood (CB) represents a safety risk for transplantation patients. CB sterility testing at a Canadian Cord Blood Bank is performed using a 1:1 mix of CB-derived

plasma and red blood cells (RBCs). Culture bottles of an automated culture system, which lack antimicrobial neutralization properties, are used during CB sterility testing. The current process is unsuitable for CB units containing antibiotics potentially resulting in false-negative results. This study was aimed at developing an in-house method for neutralizing antibiotics in CB sterility testing samples. **Study Design/Methods**: The study was developed in three phases. In phase 1, six neutralizers including penicillinase, two ion exchange resins (resin L and resin A), a mix of lecithin and Tween 80, activated charcoal (AC), and a universal neutralizer were individually tested for their activity against penicillin or gentamycin using the model organisms *Staphylococcus epidermidis* and *Klebsiella pneumoniae,* respectively. Four tubes, each containing 3 mL of bacterial cultures adjusted to 100 colony-forming units/mL in Müller-Hinton broth were prepared to test bacterial growth, antibiotic activity, neutralizer toxicity, and neutralizer activity, respectively. Tubes were incubated overnight at 37°C under agitation. **In phase 2**, combinations of penicillinase with resin L and penicillinase with AC were tested for the simultaneous neutralization of the two antibiotics in Müller-Hinton broth as described above. **In Phase 3**, a combination of penicillinase plus resin L was used to neutralize both antibiotics in CB sterility testing samples (RBC and plasma) using an automated culture system following the manufacturer's recommendations. Bacterial growth detected in either the tubes (phases 1 and 2) or culture bottles (phase 3) was confirmed by Gram staining and colony morphology. All assays were repeated three independent times. **Results/Findings**: In Phase 1, neutralization of penicillin was achieved with penicillinase and resin A, while gentamycin was neutralized by resin L and AC. In Phase 2, the two antibiotics were simultaneously neutralized by two combinations of neutralizers, penicillinase plus resin L and penicillinase plus AC. These results were validated in Phase 3 with the effective neutralization of both antibiotics in CB sterility testing samples by adding penicillinase and resin L to the CB-derived RBC and plasma mix. **Conclusion**: A protocol for antibiotic neutralization in CB samples has been successfully developed at a Canadian Cord Blood bank. Importantly, this in-house assay applies to any CB sterility testing method and therefore is not limited to testing performed with a specific culture system.

SP2

Assessment of Preprocessing Storage Temperature on Cord Blood Potency

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Background/Case Studies: Umbilical cord blood has been proven to be an important alternative source of hematopoietic stem cells (HSCs) for transplantation. Cord blood banks are generally operated under guidelines established by national regulatory agencies, and many of them obtain an accreditation from Netcord FACT and/or AABB. Despite the standardization of cord blood banking procedures, some parameters such as the preprocessing storage temperature remain unregulated. In many cord blood banks, the cord blood units (CBUs) are kept at room temperature (RT) for up to 48 hours before volume reduction and cryopreservation. However, a recent study using a xenograft mouse model suggested that a preprocessing storage of 72 hours at RT might have deleterious effects on the HSC reconstitution capacity. The present study was undertaken to examine the effect of a preprocessing storage period of 48 hours (in agreement with regulatory guidelines for unrelated CBUs) at RT or 4°C on HSC potency in vitro, using the expression of aldehyde dehydrogenase (ALDH) in CD34+ cells as a marker of long-term repopulating cells and the classical CFU assay. **Study Design/Methods**: CBUs (n=16) were obtained from mothers who had given informed consent, divided into two smaller bags after a small aliquot of blood was taken for initial analyses, and incubated for 48 hours at 4°C or RT. Aliquots of cord blood were taken at the end of the incubation period. The CD34+ ALDH^{br} content (ADELFLUOR^{TM} assay kit) was determined by flow cytometry, and CFU assays were done using Methocult^{TM}. **Results/Findings**: The results obtained (Table 1) demonstrate that, as recently reported, the CD34+ALDH^{br} cell content in CBUs correlates well with CFUs. The results also show that the preprocessing storage temperature does not have an impact on HSC potency, as evaluated by CD34+ALDH^{br} and CFU assays. **Conclusion**: These in vitro observations suggest that the hematopoietic reconstitution potential of HSC is not affected by the preprocessing storage temperature. These observations are currently being validated in a xenograft mouse model and should help define optimal cord blood banking procedures. [1]Louis et al, Transfusion 2012;52:2401; [2]Storms et al, Blood 2005,106:95; [3]Shoulars et al, Blood, DOI 10.1182/blood-2015-08-666990

SP3

Regulatory T-cell (Treg) Graft Content in Haematopoietic Stem Cell Transplantation versus Outcome: A Systematic Review

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Background/Case Studies: Allogeneic haematopoietic stem cell transplantation (alloHSCT) can result in severe morbidity and mortality in between 30% and 50% of transplant recipients, dependent on the conditioning regimen used. The role of regulatory T cells (Tregs) on outcomes of alloHSCT is unclear. To examine the importance of allograft Tregs in reducing poor outcomes associated with alloHSCT, we have carried out a systematic review of clinical studies that report Tregs as absolute numbers and/or as a proportion of CD3+ or CD4+ T cells within the donated graft. We have sought to determine how the concentration of Tregs within the allograft impacts on a range of clinical outcomes following alloHSCT, whether there is evidence of an overall effect of Tregs on mortality, and whether any benefits are greater in some types of allograft settings than others. **Study Design/Methods**: Studies were identified from searches of major databases (MEDLINE, PubMed, Embase, CENTRAL, Web of Science CPCI-S) to October 2015. Data were extracted onto customised data extraction forms by two reviewers independently, and disagreements were resolved by consensus. The primary outcome was overall survival. Secondary outcomes included Graft-versus-Host Disease (GVHD), disease relapse, and non-relapse mortality. Random effects meta-analyses were performed using RevMan 5 and are reported as relative risk (RR) with 95% confidence interval (CI). **Results/Findings**: In studies that reported outcomes in patients stratified by Tregs (high or low absolute dose or ratio to CD3+ or CD4+), three studies (Danby et al. 2016, Delia et al. 2013, Vela-Ojeda et al. 2010) reported higher overall survival associated with high Tregs, whilst a fourth study (Wolf et al. 2007) found a higher dose of Tregs (above the mean value) associated with overall survival in patients who received myeloablative conditioning but not reduced intensity conditioning. Meta-analysis of two studies that reported survival rates and sample sizes in each subgroup (high or low Tregs) found an average 80% improvement (RR 1.80, 95% CI, 1.12 to 2.89; p=0.01) in overall survival associated with a higher absolute dose or ratio of Tregs to CD3 or CD4 cells. In six studies that reported aGVHD rates in patients stratified by high or low Tregs, meta-analysis showed an average 40% reduction in aGVHD incidence associated with high Tregs (RR 0.59, 95% CI 0.40 to 0.89; p=0.01). **Conclusion**: To our knowledge, this is first systematic review of the effect of graft Tregs on the outcomes of alloHSCT, and it provides compelling evidence for the role of graft Tregs in improving overall survival and reducing the incidence of aGVHD. The data suggest that further research to understand how to improve or select donor grafts based on the content of Tregs may yield significantly better outcomes for alloHSCT

SP4

Comparison Study between Manual and Automated Volume Reduction of Bone Marrow Products: A Single Center Experience

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Background/Case Studies: Our center has been performing volume reduction for all bone marrow products using manual method-Centrifugation

TABLE. Data from CFU assays and flow cytometry analysis of CBUs

	Initial	48 hours RT	48 hours 4°C
CD34+ALDHbr as a percent of total CD34+	64.5%	60.5%	58.7%
CFUs as a percent of total CD34+	78.6%	66.5%	69.4%

TABLE. Results Comparison between the Manual and Automated Methods

	Manual Method	Automated Method	p-Value
Number of Data (n)	62	19	
Final Product Volume (ml)	138 +/− 84 (46–428)	99 +/− 36 (46–194)	0.01
Volume Reduction Efficiency (%)	80.32 +/− 9.55 (46.63–93.74)	89.08 +/− 5.75 (71.26–93.29)	0.0006
CD34+ Cells Recovery (%)	97.05 +/− 11.70 (30.13–120.09)	95.32 +/− 10.56 (75.34–110.77)	0.6687
TNC Recovery (%)	96.80 +/− 12.15 (55.56–131.50)	86.64 +/− 7.10 (66.30–98.00)	0.0027
Viability (%)	96.07 +/− 2.71 (84.73–99.76)	98.87 +/− 0.57 (97.14–99.51)	<0.0001
Hematocrit (%)	64 +/− 14.15 (16.50–88.50)	45.75 +/− 11.92 (26–60)	<0.0001
Red Cell Contamination (ml)	85.85 +/− 53.27 (8.28–233.25)	37.14 +/− 20.98 (19.47–95.06)	<0.0001

Method. This method is labour-intensive, as product is spun once to remove red cells and then followed by a second spin to remove plasma. This method is technique-dependent, leading to huge inconsistency in red cell reduction efficiency. This study is performed to compare the manual method with the automated method using Biosafe Sepax II, which allows automated, consistent, and reproducible separation of bone marrow products in a closed and sterile environment. **Study Design/Methods**: Bone marrow processing data were collected from 2008-2012 for the manual method and 2013-2015 for the automated method. The following parameters were analyzed and compared between the two methods:
– Volume Reduction Efficiency
– CD34+ Cells Recovery
– Total Nucleated Cell (TNC) Recovery
– Viability
– Hematocrit and Residual Red Cell Contamination
Results/Findings: A total of 62 and 19 data were collected for products processed using manual and automated methods, respectively. The median volume reduction efficiency, CD34+ and TNC recovery, viability, hematocrit, and red cell contamination were 80.32% (±9.55, 46.63-93.74), 97.05% (±11.70, 30.13-120.09), 96.80% (±12.15, 55.56-131.50), 96.07% (±2.71, 84.73-99.76), 64.00% (±14.15, 16.50-88.50), and 85.85ml (±53.27, 8.28-233.25), respectively, for manual method and 89.08% (±5.75, 71.26-93.29), 95.32% (±10.56, 75.34-110.77), 86.64% (±7.10, 66.30-98.00), 98.87% (±0.57, 97.14-99.51), 45.75% (11.92, 26-60), and 37.14ml (20.98, 19.47-95.06), respectively, for automated method (see Table). **Conclusion**: The automated method has superior efficiency in terms of volume reduction (89.09% vs 80.32%), red cell reduction (37.14ml vs 85.85ml), and viable cell recovery (98.87% vs 96.07%). Both have comparable efficiency in terms of CD34 recovery (95.32% vs 97.05%). The automated method, however, has lower TNC recovery (86.64% vs 96.80%) than the manual method. The lower TNC recovery is related to lower red cell contamination, as neutrophils reside very close to or within the red cell layer in the spun products. Our data also show that the automated method appears to have a superior performance consistency than the manual method. In conclusion, the superior performance and performance consistency of the automated method make it the system of choice.

SP5

Prolonged Processing Delays of Cord Blood Units is Associated with Reduced Engraftment Activities

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Background/Case Studies: Cord blood (CB) hematopoietic stem cells (HSCs) are a curative treatment option for many patients. CB units can be stored up to 48 hrs before processing. The impact of such delays on HSC function is unclear, since most studies have used in vitro assays, which do not measure HSC activity. The main hypothesis of this work is that extended processing delays reduce the potency of post-thaw CB HSCs and contribute to slower engraftment. We set out to measure the loss of CB cells enriched in stem and progenitors and to characterize the loss in engraftment activities associated with processing delays. **Study Design/Methods**: CB units were split with one half processed immediately (baseline 8-12 hrs) and the second after a 40- to 44-hr storage period at room temperature (RT). Viability was assessed with AnnexinV/7AAD, and the frequency of CB cells with high aldehyde-dehydrogenase (ALDH) activity was monitored. Thawed CB cells were transplanted into NSG mice to track their bone marrow (BM) and platelet (Plt) engraftment activities. The Poisson statistic was used to estimate the frequency of BM and Plt engrafting cells by limiting dilution (LD) assay. **Results/Findings**: Extended storage before processing tended to reduce the yields of viable post-thaw TNC (88.7 ± 12.3% of baseline, ±SEM, p=0.28, n=3), CD45+ cells (83.2 ± 13.9%, p=0.27), and CD34+ cells (59.7 ± 32.9%, p=0.19) vs. baseline. The proportions of viable CD34+ cells and CD34+ CD45RA- HSC-enriched cells declined by 12% and 14% (p=0.15). Moreover, preliminary results suggest that the recovery of $ALDH^{bright}$ CB cells is reduced by processing delay with yields of 42.1 ± 18.5% (n=2, p=0.07) and 11.9 ± 1.3% (p=0.27) for pre-cryo and post-thaw, respectively. NSG mice were transplanted with fix or decreasing doses of post-thaw CB TNC. Generally, the mean level of hPlts in mice transplanted with CB halves stored before processing was reduced vs. baseline, although differences were not significant (e.g., 108 vs. 161 hPlts/uL at 4 weeks, p>0.05). Analysis of an LD transplantation assay done with an independent unit indicated that frequency of CB cells with short-term platelet engraftment activity was similar between both groups. However, the frequency of CB cells providing long-term hPlt engraftment (17 weeks) was reduced by 6-fold in the stored group (e.g., 0.21E-5 vs. 1.36E-5 for week 17, p<0.05). Furthermore, the frequency of long-term Scid repopulating cells (SRC) measured 21 weeks post-transplantation also tended to be reduced (0.89E-05 vs. 1.27E-05, p>0.05), resulting in a 27.5% reduction in the total number of SRC (2.5E+04 vs. 3.4E+04 per unit half). Experiments with independent units to confirm these results are ongoing. **Conclusion**: These results are consistent with the main hypothesis that extended processing delays before cryopreservation reduce CB potency and may contribute to slower engraftment.

SP6

Effect of Dilution Factor on Products after DMSO Washing Using Automated Cell Processing System: A Single Center Experience

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Background/Case Studies: Our center has been performing DMSO washing on cryopreserved products that met our washing criteria – ie, products for patients with renal dysfunction – by automated method using Biosafe Sepax II. Dilution factor for the washing procedure has been set at 1.0 time based on manufacturer recommendation. Although dilution factor of 1.0 time is recommended by the manufacturer, the CD34+ cells recovery is not satisfactory according to our release criteria of ≧70%. This study is performed to determine the feasibility of improving the procedure outcomes by manipulating the dilution factor of the washing procedure. **Study Design/Methods**: DMSO washing data were collected from 2013 - 2014 (June) for the procedure with dilution factor set at 1.0 time (DF1.0) and 2014 (July) - 2015 for procedure with dilution factor set at 1.5 times (DF1.5). The following parameters were analyzed and compared between the two:
– CD34+ Cell Recovery
– CD34+ Cell Viability
– Total Nucleated Cell (TNC) Recovery
– TNC Viability
Results/Findings: A total of 34 and 11 data were collected for DF1.0 and DF1.5, respectively. The median CD34 recovery and viability and TNC recovery and viability were 64.24% (±9.17, 49.77-83.70), 97.49% (±4.50, 79.57-100), 58.24% (±8.03, 36.83-71.47), and 71.73% (±9.16, 57.32-92.41), respectively, for DF1.0 and 73.74% (±8.16, 52.92-80.57), 90.71% (±8.52, 71.20-98.21), 62.71% (±10.54, 50.99-89.92), and 67.83% (±9.66, 57.67- 82.40), respectively, for DF1.5 (see Table). **Conclusion**: DF1.5 has superior CD34+ cell recovery (73.74% vs 64.24%) and TNC recovery (62.71% vs 58.24%) than DF1.0. Both have comparable efficiency in terms of viable TNC recovery (67.83% vs 71.73%). DF1.0, however, has superior

TABLE. Results Comparison between DF1.0 and DF1.5

	Dilution Factor		
	DF1.0	DF1.5	p-Value
Number of Data (n)	34	11	
CD34+ Cells Recovery (%)	64.24 ±9.17 (49.77-83.70)	73.74 ±8.16 (52.92-80.57)	0.0356
CD34+ Cells Viability (%)	97.49 ±4.50 (79.57-100)	90.91 ±8.52 (71.20-98.21)	0.0008
TNC Recovery (%)	58.24 ±8.03 (36.83-71.47)	62.71 ±10.54 (50.99-89.92)	0.008
TNC Viability (%)	71.73 ±9.16 (57.32-92.41)	67.83 ±9.66 (57.67-82.40)	0.27

viable CD34 recovery (97.49% vs 90.91%) than DF1.5. The lower CD34+ cell viability is probably related to the prolonged exposure of the products at room temperature due to longer procedure time. The higher the dilution factor, the greater the volume of the diluted product, therefore leading to longer procedure time. In conclusion, there are no clinical beneficial effects by increasing the dilution factor from 1.0 to 1.5 times, although statistically significant results are observed for CD34+ cells and TNC recovery as well as CD34+ cell viability. The superiority of DF1.5 in CD34 recovery is negated by the inferiority of CD34+ viable cells recovery. DF1.5 might have clinical benefit if the products can be maintained at 1-10°C throughout the washing procedure.

SP7

Temperature Fluctuations during Cryopreservation Strongly Reduce the Immunomodulatory Activity of Mesenchymal Stromal Cells

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Background/Case Studies: Mesenchymal stromal cells (MSCs) attract much interest as a cell therapy product for applications ranging from immunomodulation to regenerative medicine, and they are currently being tested in over 600 clinical trials. One of the main advantages of these cells is that there is no need for histocompatibility matching between donors and recipients. Therefore, many protocols propose the use of third-party off-the-shelf products as the most convenient source of MSCs for cell therapy applications. Although MSCs are produced under good manufacturing process (GMP), the time interval and method of transfer of cryopreserved products either from the freezer to the storage container, or from the container to the clinical site laboratory for reconstitution, are not necessary well-controlled. This creates a risk of inducing temperature fluctuations in the cryopreserved product that may affect cell functions. In the present work, we tested the impact of temperature fluctuations on the immunomodulatory potential of cryopreserved MSCs produced under GMP conditions. **Study Design/Methods**: Following cryopreservation in a controlled-rate freezer, MSC vials were separated into two groups. The first group was immediately put on dry ice, whereas the second group was left at room temperature for up to 10 minutes. Temperature monitoring was performed in one vial of each group. Cryovials from both groups were then transferred in the vapor phase of liquid nitrogen for at least 24 hours before the activity of freshly thawed MSCs was tested in an *in vitro* functional assay (inhibition of activated T-cell proliferation). Alternatively, vials stored in liquid nitrogen vapor phase were removed from the container for short periods of time and put back in the container prior for assay. **Results/Findings**: Our preliminary data show that exposure of cryopreserved vials to room temperature results in a rapid increase in temperature (about 10°C per minute) and reveals a dramatic reduction (> 50%) in the ability of MSC to inhibit activated T-cell proliferation. **Conclusion**: There is currently a debate as to whether MSC products should be used fresh or frozen. Our preliminary data reveal that exposure of cryopreserved MSCs to room temperature, even for very short periods of time, and not cryopreservation per se, negatively affects their immunomodulatory activity. This suggests that, with proper caution to never expose the product at room temperature before thawing, cryopreserved MSCs could be as effective as freshly harvested cells. We believe that our results will provide guidance for optimal banking of MSCs and will help resolve the debate on the use of fresh versus frozen MSCs.

SP8

Sterility Testing for Umbilical Cord Tissue: Contamination Rates, Effects of Processing, and Detection Sensitivity

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Background/Case Studies: Umbilical cord tissue (CT) is a significant source of mesenchymal stem cells (MSCs). While there is some guidance on processing of CT, there is considerable variation in collection, processing, storage, and quality assessment. Most protocols utilize washes in media with or without antibiotics to resolve any residual microbial contamination. The aim of this study was to investigate contamination rates of CT, the effects of processing on contamination, and the sensitivity of detection methods. **Study Design/Methods**: A total of 65 umbilical cord segments were analyzed for this study. Color and clarity of transport media were recorded. The CT segments were washed in PBS, and the veins and arteries were removed. The segments were cut into <1mm pieces, washed in PBS twice, and cryopreserved. Sterility swabs (Copan) were taken before processing and before freezing. Aerobic and anaerobic BACTEC bottles were inoculated (10ml) with transport media and post-process wash samples for each CT unit. For all positive samples, the time to detection was recorded and a sample sent for identification. Known standard positive controls were used for BACTEC bottles and swabs. Data were analyzed for pre- and post-processing sterility, media color and clarity, and method of detection (swab vs. BACTEC) using Fishers Test, ANOVA, and Tukey's HSD post-test. **Results/Findings**: Media color and clarity were not correlated with sterility ($p \geq 0.7$). Initial contamination rate was 84.6% positive detected by at least one method. BACTEC detection of sterility appeared to be more sensitive than the swab method, except for post-processing aerobic sampling: original swab vs. aerobic BACTEC, $p < 0.0001$; original swab vs. anaerobic BACTEC, $p < 0.0001$; post-processing swab vs. aerobic BACTEC, $p > 0.08$; swab vs. anaerobic BACTEC, $p < 0.0005$. There was no difference ($p = 0.27$) in the time to detection between aerobic (19-24 hrs) and anaerobic (27-41 hrs) contaminants. All positive and negative controls were correctly identified except for *C.albicans*, which had one misidentification, and *A.niger*, which had 2 of 3 no-growth results after turning positive. **Conclusion**: The clarity and color of the transport media were surprisingly not indicative of contamination. The BACTEC microbial detection system showed superior detection capabilities compared to the swab method, with the anaerobic detection appearing more sensitive. The data suggest that the CT wash steps may be sufficient to clear some contamination, but additional wash steps should be considered. The failure of proper identification of yeast and mold warrants further investigation.

TABLE.

	Swab Original	Swab Post- Process	BACTEC Aerobic Original	BACTEC Anaerobic Original	BACTEC Aerobic Post- Process	BACTEC Aerobic Post- Process
Positive	24	15	49	51	25	35
No Growth	41	50	16	14	40	30

SP9

Sterility Release Testing of Stem Cell Preparations using Dual-temperature and High-sensitivity Algorithm

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Background/Case Studies: Autologous stem cell grafts often contain antibiotics due to patients' antibiotic prophylaxis, probably resulting in false-negative results of sterility tests. **Study Design/Methods**: The comparison was performed with one buffy coat as the control matrix used as the exemplary for tissue preparations and one stem cell preparation (PBSC) using the blood culture device Bact/Alert®3D with low-temperature module (bioMérieux Nürtingen Germany). Samples were spiked twofold >10 colony-forming units (CFU) in standard iAST and iNST culture bottles for 14 days with various microbes. The PBSC was also incubated in iFA/iFN*plus* culture bottles with resorbing polymers. All aerobic bottles were incubated at 22.5°C and anaerobic bottles at 35°C. In a second analysis, exemplary microbes were incubated in the same manner, but with an additional aerobic culture bottle at 35°C, and measured with a more sensitive analysis algorithm (i-mode). **Results/Findings**: The Bact/Alert®3D-System detected all microbes appropriate to their growth behavior in buffy coat matrix in iAST and iNST. The PBSC showed a significant difference in comparison to the used culture bottles. No growth was detected in spiked bottles with *Staphylococcus aureus* (iAST), *Bacillus subtilis* (iAST/iNST), *Clostridium sporogenes* (iNST), or *Propionibacterium acnes* (iNST) compared to iFA*plus* and iFN*plus,* where a growth could be confirmed (Fig. 1). All results could be achieved independent from i-mode. The temperature comparison showed an expected slower growth at 22.5°C. **Conclusion**: Our study showed that spiked microbes grow in PBSC using iFA/iFN*plus* in contrast to iAST/iNST. Only iFA/iFN*plus* are in line with the results of the spiked buffy coat, which is recommended as a matrix by the PEI. Therefore, iFA/iFN*plus* allows a safe detection of contaminated PBSC, and we recommend the incubation at different temperatures for ATMPs for a safer microbial detection.

SP10

Efficacy and Safety of Peripheral Blood Stem Cell Collection in Low-bodyweight Children

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Background/Case Studies: Peripheral blood stem cell (PBSC) transplantation has become an ordinary procedure in children with cancer, and its use has been increasing over the time. The ease of collection and lack of need of surgical procedures are some of the many advantages that favor this practice. The aim of the study is evaluate the efficacy and safety of PBSC collection for transplantation in pediatric patients with less than 15 kilograms using a single apheresis procedure. **Study Design/Methods**: In January 2016, PBSC from two children with solid organ tumors were collected for autologous transplantation, and the goal was at least 6,0 x 10^6 CD34+ cells/kg body weight. The ages were 14 and 34 months, and they weighted 9,2 and 10,8 kilograms. Double-lumen 8 French central venous catheters were placed, and leukapheresis were performed at the eighth and ninth day of chemomobilization using a continuous flow apheresis system. The device was primed with 280 ml of ABO, Rh and Kell compatible, leukoreduced, irradiated, 64% hematocrit packed RBCs, and the anticoagulant used was ACD-A plus heparin (750 mL of ACD-A and 7,500 units of heparin), at a blood to anticoagulant ratio of 25:1. A complete blood count was determined before and after apheresis, and the patients required no transfusion. The CD34+ cell concentration in blood was counted at the beggining of apheresis in both subjects, and were 61 and 78/μL. Hypothermia was prevented with room heating; to prevent hypocalcemia, 1 mL/kg of 10% calcium gluconate was administered during the apheresis on the return line. During the collection, changes in blood pressure, oxygen saturation and heart rate were observed. The patients were under the supervision of a pediatrician who was aware of potential adverse events. **Results/Findings**: By using the formula "*Processed Blood Volume = Target CD34+/kg x Weight/Pre-apheresis blood CD34+ cell concentration x*

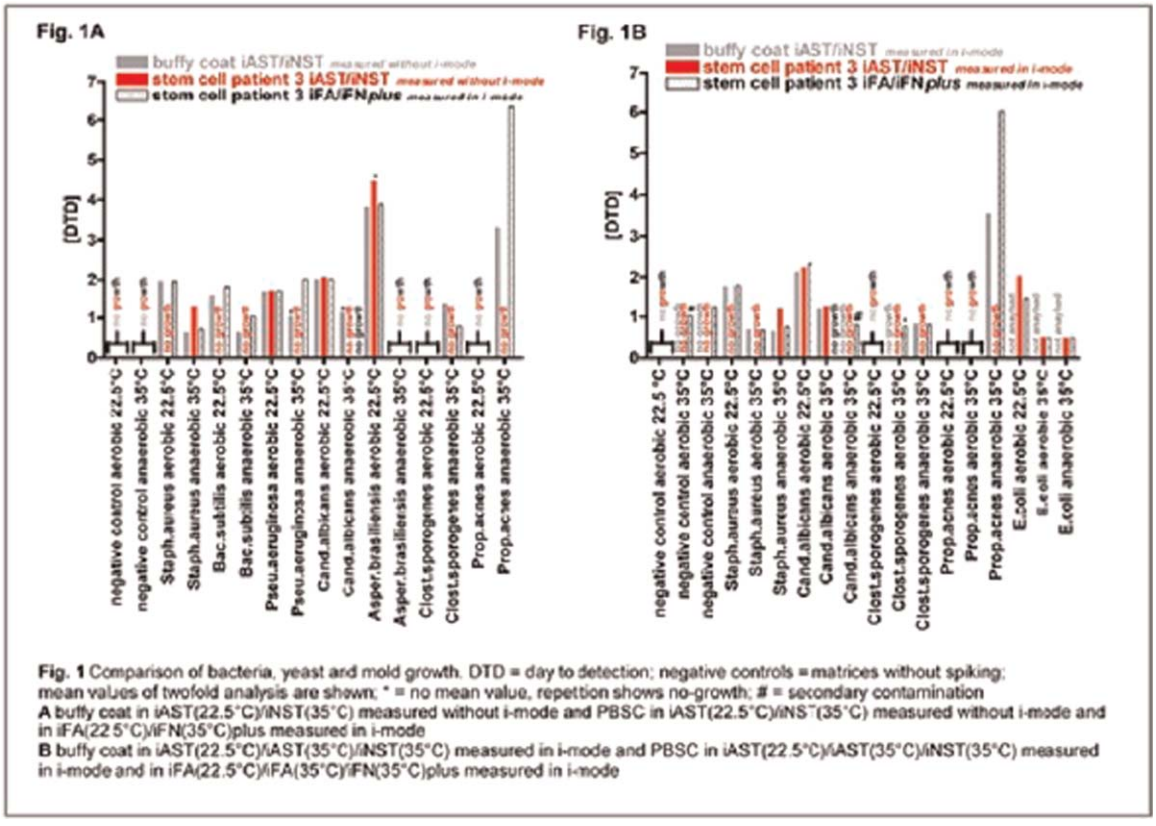

Fig. 1 Comparison of bacteria, yeast and mold growth. DTD = day to detection; negative controls = matrices without spiking; mean values of twofold analysis are shown; * = no mean value, repetition shows no-growth; # = secondary contamination
A buffy coat in iAST(22.5°C)/iNST(35°C) measured without i-mode and PBSC in iAST(22.5°C)/iNST(35°C) measured without i-mode and in iFA(22.5°C)/iFN(35°C)plus measured in i-mode
B buffy coat in iAST(22.5°C)/iAST(35°C)/iNST(35°C) measured in i-mode and PBSC in iAST(22.5°C)/iAST(35°C)/iNST(35°C) measured in i-mode and in iFA(22.5°C)/iFA(35°C)/iFN(35°C)plus measured in i-mode

Collection Efficiency", a single leukapheresis procedure was performed per patient with an average of 1,67 total blood volume processed (1,63 and 1,71), and was enough to obtain the desired number of CD34+ cells: the median number collected was 7,43 x 10^6CD34+/Kg (8,77 and 6,09). Calculations of collection efficiency were made retrospectively, and the percentage was 49,7. **Conclusion**: PBSC collection was safe and efficient. The collection in children weighing 15 kg or less represents a challenge for apheresis personnel who may not be familiar with so low body weight patients, hence operators need to modify procedures for safe collection. However, despite the potential complications that may occur (placement of vascular access, management of low extracorporeal blood volume, anticoagulant-related toxicity with metabolic and hematologic issues), remains an excellent source for harvesting hematopoietic stem cells for allogeneic and autologous transplants.

SP11

Blood CD34/White Blood Cell Count Ratio on the Day Before Apheresis is the Most Significant Predictor of Successful Peripheral Blood Stem Cell Harvest

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Background/Case Studies: Successful autologous stem cell isolation and transplantation are associated with significantly improved outcomes for many cancer patients, particularly those with hematologic malignancies. However, a substantial number of donors fail to mobilize enough peripheral blood stem cells (PBSCs) for hematopoietic stem cell transplantation. Predicting poor mobilization before harvest is important because of the development of plerixafor, a chemokine receptor CXCR4 antagonist. The aim of this study was to investigate the impact of peripheral blood CD34+ cell count on the day before harvest (pre-PBCD34+) on successful PBSC harvest. **Study Design/Methods**: We retrospectively analyzed 80 cancer patients who were autologous stem cell donors between January 2011 and April 2015 and for whom data on pre-PBCD34+ were available. PBSCs were collected after apheresis chemotherapy and G-CSF therapy with SPECTRA version 6 (Terumo BCT, Tokyo). CD34+ count was calculated with a CD34 enumeration kit (BD Biosciences, San Jose, CA). Correlation between peripheral blood CD34+ cell (PBCD34+) count and collected CD34+ cell count was calculated using linear regression and correlation analysis. Successful PBSC harvest was defined as CD34 count $> 1 \times 10^6$/kg. Various predictors of successful harvest were assessed using multivariate logistic regression analysis and a receiver operator characteristic (ROC) curve. A p-value < 0.05 was considered statistically significant. Statistical analysis was performed with JMP (SAS, Cary, NC). **Results/Findings**: Seventy-six out of 80 (95%) donors had hematologic cancer: lymphoma, 49 (61.3%); myeloma, 18 (22.5%); and leukemia, 9 (11.3%). The rest had solid tumors. Median age was 56 years, and 45 (56.3%) were male. Apheresis was successful in 65 (81.3%). We confirmed the previously reported close relationship between PBCD34+ count on harvest day and collected CD34+ cell count ($p < 0.0001$, $r = 0.92$). Multivariate analyses showed that pre-PBCD34+ and the ratio of pre-PBCD34 to white blood cell (WBC) count [pre-PBCD34(%)] was significantly associated with successful harvest of PBSCs on the next day ($p = 0.0306$ and $p < 0.0001$, respectively). ROC analysis demonstrated that pre-PBCD34(%) predicted successful harvest on the next day with higher accuracy [area under the curve (AUC), 0.93] than pre-PBCD34 (AUC, 0.81), suggesting that preBCD34(%) is the most significant predictor. According to the ROC curve, successful harvest is expected from the donors with preBCD34(%) $\geq 0.3\%$ (probability, 99%; positive predictive value, 100%). PreBCD34(%) $\leq 0.04\%$ predicts harvest failure on the next day (probability, 17%; negative predictive value, 100%). **Conclusion**: Overall, our data suggest that pre-PBCD34(%) is the most accurate predictor of successful PBSC harvest on the next day.

SP12

Red Blood Cell Depletion of Bone Marrow: What Was Old Is New Again

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Background/Case Studies: Red blood cell (RBC) depletion of bone marrow products for transplant is not a novel procedure. Published methods include both manual and automated applications. For many cellular therapy processing laboratories, RBC depletion became an archived procedure due to the increased use of hematopoietic progenitor cell, apheresis, HPC(A) products. However, recently, due in part to the increasing number of bone marrow products collected for haploidentical transplant, the need for an efficient RBC depletion method has increased. This increasing demand prompted a reexamination of the current method, sedimentation using hydroxyethyl starch (HES) with centrifugation and evaluation of a historically referenced method, sedimentation using HES with manual RBC removal. In this study, the total nucleated cell, (TNC) recovery as well as the amount of RBC reduction for each method was evaluated. **Study Design/Methods**: Mock products, containing buffy coats obtained from the local blood center and expired red blood cells, were created to execute procedure development and the subsequent process validation. The mock products were prepared to simulate bone marrow products with proportionally high TNC and RBC content, low TNC with high RBC content and smaller products with medium TNC and lower RBC content. Key points evaluated for this study, include adjustment to a target hematocrit, percent of HES added, utilization of a standard size bag and manual removal, by syringe, of the RBCs. Cells were removed by syringe in incremental fashion. The initial syringe removals were to de-bulk the product of RBCs. The subsequent syringe removal steps were performed in smaller volume increments. The acceptance criteria were total nucleated cell recovery greater or equal to 70% and RBC reduction greater or equal to 90%. **Results/Findings**: Six procedures, to include initial method development and subsequent validation, were performed to evaluate technical requirements and overall method efficiency. Average TNC recovery = 82.8% Average RBC % Reduction = 91.5% Resulting in an average RBC content = 17.9mL **Conclusion**: Historically incompatible red blood cells from bone marrow have been very difficult to remove from an allogenic graft and maintain an adequate nucleated cell dose. The historical HES method, sedimentation with centrifugation is time consuming and not as efficient at preserving TNC content. This RBC Reduction method (Initial hematocrit adjustment, Inverted bag sedimentation with HES, Increased sedimentation time and manual RBC removal) demonstrates improved TNC recovery (82.8%) compared to the TNC recovery (61%) using the historical HES method with centrifugation. Study results demonstrate this method provides a more balanced approach of RBC removal, for major ABO incompatible products, while maintaining an acceptable TNC recovery for the transplant product.

SP13

qPCR Screening for Mesenchymal Stem Cell Markers: Cadherin-11, CD73, CD90, and CD105 from Cryopreserved and Expanded Human Umbilical Cord Tissue

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Background/Case Studies: Self-renewing, non-specialized mesenchymal stem cells (MSCs) can differentiate to adipogenic, chrondrogenic, and osteogenic lineages. MSCs are applied clinically for tissue regeneration for myocardial repair and immunomodulation of graft-versus-host disease (GVHD). MSCs have been isolated primarily from bone marrow but have also been isolated from peripheral blood, umbilical cord blood, and umbilical cord tissue (UCT). To exploit the emerging therapeutic value of MSCs for future development, we show that MSCs can be expanded from cryopreserved UCT stored long-term in the vapor phase of liquid nitrogen and that cryopreserved UCT can be screened for MSC markers CD73, CD90, CD105, and CDH-11 by qPCR. **Study Design/Methods**: Donated human umbilical cord tissues were washed in PBS, sectioned into 0.25- to 0.5-cm squares, and stored in freezing media containing DMSO in the vapor phase of liquid nitrogen. After 4 and 30 weeks, aliquots and post-thawed expansions were screened for MSC marker CD73, CD90, CD105 and CDH-11 by qPCR with GAPDH as an internal standard. MSCs after expansions were confirmed by flow cytometry for the presence of CD73, CD90 and CD105 and the absence of CD34 and CD45. CDH-11 was confirmed by Western blotting. **Results/Findings**: The findings show that fold mRNA expression averaged 0.123 ± 0.019 for CD73, 0.038 ± 0.008 for CD90, 0.045 ± 0.009 for CD105 and 0.007 ± 0.003 for CDH-11 after 4 weeks in storage. After 30 weeks in storage, mRNA fold expression averaged 0.064 ± 0.008 for CD73, 0.035 ± 0.005 for CD90, 0.050 ± 0.010 for CD105 and 0.004 ± 0.002 for CDH-11. Recovery averaged 52% for CD73,

92% for CD90, 100% for CD105 and 56% for CDH-11 but was not statistically significant to indicate the compromise of frozen UCT. When non-frozen UCTs were freshly expanded for MSCs, mRNA fold expression averaged 0.060 ± 0.011 for CD73, 0.135 ± 0.039 for CD90, 0.006 ± 0.001 for CD105 and 0.159 ± 0.039 for CDH-11. When frozen UCTs were expanded for MSCs (post-thaw), mRNA fold expression averaged 0.128 ± 0.075 for CD73, 0.144 ± 0.086 for CD90, 0.009 ± 0.001 for CD105 and 0.098 ± 0.010 for CDH-11. Signal detection for MSC markers increased after in vitro expansion increased for CD73, CD90, CD105 and CDH-11, indicating that qPCR can be reliable method for surveying cryopreserved UCT stability in storage without expansion. **Conclusion**: MSC markers CD73, CD90, CD105 and CDH-11 were detected by qPCR in cryopreserved UCT and expanded MSCs. MSC expansion were confirmed by flow cytometry for MSC markers CD73, CD90 and CD105 and correlates well with mRNA expression. CDH-11 protein and mRNA expression were detected in cryopreserved UCT and MSC expansion, suggesting a potentially useful single target MSC marker for quick screening of cryopreserved UCT.

SP14

Cord Blood Processing: Comparison of Results Using Standard Manual Technique and Automated Closed Separation System

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Background/Case Studies: Umbilical cord blood (UCB) processing can be done using a manual process or an automated cell separation device. Depending on the technique, different UCB volume reduction results will be achieved, affecting the quality of the UCB unit as a graft source for hematopoietic stem cell (HSC) transplantation. The objective of this study was to compare the efficacy of the two techniques by analyzing volume, CD34, TNC counts, TNC recovery rates, and viability results. **Study Design/Methods**: From April 15 to March 16, 824 UCB units were processed at CordVida, a private cord blood bank (São Paulo, Brazil): 338 UCB units using the automated separation using the cell centrifugation device (SEPAX) and 486 UCB units using the manual technique (Pall). The total nucleated cell count (TNC) was determined pre- and post-processing and the resulting average cell recovery rate was determined. The nucleated cell viability CD45+ and CD34+ testing after processing was assessed using 7-AAD-stained samples and analyzed in a flow cytometer, while simultaneously enumerating CD34+ cells. Processing time using the automated device was approximately 35 minutes, and that using the manual technique was 1 hour. **Results/Findings**: Average TNC recovery using the manual technique was 95.30%,3.21 basis points higher than the 92.09% rate achieved using the automated technique. All units were tested for cell viability, presenting results ≥94%, consistent among all different processing techniques. No significant difference was identified in average initial volume and average **Results**:CD34/CD45 figures (see Table). The cost to process a UCB unit in Brazil using the automated device, $147, is higher than the manual technique at $94. **Conclusion**: The processing of UCB using the manual technique is a viable alternative to the automated device, as it delivers a combination of improved cell recovery rates with the same CD45/CD34 and cell viability results. The manual technique brings lower laboratory productivity if compared to the automated device. However, since the cost in Brazil of laboratory consumables used in the manual technique is so much lower than with the automated system kits, the overall cost of the manual technique is still lower. This is also partly attributable to the fact that Brazil has low labor costs relative to other countries.

SP15

Management of Delayed Thrombocytopenia after Allogeneic Hematopoietic Stem Cell Transplantation in a Ppatient with Anti-HPA-1a

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Background/Case Studies: Matching donor and recipient for HLA class I and class II haplotypes is a key part of successful hematopoietic stem cell transplantation (HSCT). Non-HLA platelet (PLT) specific antibodies are not generally considered; however, anti-HPA-1a can be a significant barrier to successful PLT engraftment with PLT-transfusion dependence and bleeding complications after HLA-matched HSCT. **Study Design/Methods**: A 58 year old female presenting with B-cell Acute Lymphoblastic Leukemia was treated with chemotherapy, developed PLT transfusion refractoriness, and was found to have anti-HPA-1a 3 months after her initial diagnosis. She was successfully transfused with HPA-1a-negative PLT. Following complete remission and full CBC recovery, she underwent HSCT from her full HLA-matched brother who was HPA-1a positive. She received a reduced intensity conditioning regimen (CR). GVHD prophylaxis consisted of tacrolimus and methotrexate. Myeloid and erythroid cell lineages engrafted around day 14 and remain robust. PLT count did not recover post-HSCT. Her course was complicated by prolonged transfusion-dependent severe thrombocytopenia (TCP) with minor hemorrhagic complications with PLT count < 5 K/mcL. Common causes of post-HSCT TCP were ruled out. Serial bone marrow biopsies, cytogenetics, and chimerism studies starting two months after HSCT showed trilineage hematopoiesis with presence of megakaryocytes, no evidence of leukemia and full-donor engraftment. **Results/Findings**: Peripheral PLT destruction was suspected. Anti-HPA-1a was persistent; the final diagnosis was TCP due to recipient-derived anti-HPA-1a. She remained HPA-1a negative PLT transfusion dependent for about 8 months post-HSCT. In order to treat her TCP, she underwent several courses of high dose corticosteroids with IVIg, weekly romiplostim for a few months, weekly rituximab for 4 weeks and tri-weekly plasmapheresis with IVIg for 2 weeks without success. Concomitantly, and while tacrolimus was tapered off, her PLT count recovered to 100 K/mcL and she became PLT transfusion independent 8 months following HSCT. Alongside, anti-HPA-1a was no longer detectable. **Conclusion**: Anti-HPA-1a hampered the success of a full matched related HSCT. Delayed PLT engraftment and severe TCP was managed by HPA-1a negative PLT transfusion, which was difficult given the scarcity of HPA-1a negative blood donors. Perhaps a myeloablative CR and/or selection of HPA-1a negative genotype HSC donors may help to prevent this serious complication. Nevertheless, efficient communication between the transfusion service and the transplant team is recommended to discuss the role of PLT antibodies in the successful outcome of HSCT and to allow the timely procurement of appropriate HPA-1a negative products.

SP16

Cord Blood Bank IT Software Solution: Stem Cell National System Solution (SCNSS)

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Background/Case Studies: A critical aspect for operating a Cord Blood Bank (CBB) is the implementation of an IT system to support all the operational activities of the bank. The Stem Cells National Systems Solution (SCNSS) provides an all-inclusive operational IT system for a Canadian CBB providing an "end to end" solution from collection to distribution of cord blood units. The system was designed and developed in-house with

TABLE.

Technique	N	Average Initial volume (mL)	Average CD34/ CD45 (x10^6/mL)	Average Initial Processing TNC count (108)	Average Post-Processing TNC(x10^8)	Average TNC Recovery (%)	Average Cell Viability (%)
Manual	486	85.83	0.29	10.43	9.94	95.30	94.59
Automated	338	88.17	0.30	11.21	10.35	92.09	94.90
Total	824	86,.9	0.30	10.75	10.11	93.98	94.72

expertise/dedicated resources for support, upgrades, customization, and enhancements. In addition, the system is supported by a high availability back-up, is self-reliant for disaster recovery and is integrated with other business areas within the organization. SCNSS has the capability to be fully electronic records compliant and is compliant to the major standards found globally such as GMP, ISO, Six Sigma, FDA Title 21 CFR Part 11 Regulation. **Study Design/Methods**: User Requirement Specifications were initiated, followed by overall system design architecture and development of specific functional system requirements. The validation process consisted of both IT integration testing and user acceptance testing for all aspects of the developed system with final approval by quality assurance staff.
Results/Findings: Quality management:

- System maintains audit log of user and system actions
- Double entry and/or 2nd person data verification required for critical fields
- Automated calculations
- Integrated tolerances that prompt to review data outside acceptable criteria
- Supplies and equipment are captured for traceability
- ISBT128 aligned system-generated labels
- Role-based authorizations restrict ability for users to only perform designated activities
- Electronic release performed by CBB Director automatically lists qualified CBUs as searchable for Canadian and International patients

Organizational Integration:

- SCNSS provides the organization with a "360" donor view enhancing customer service and records management. An individual can be a
- Blood Donor, OneMatch Registrant and/or CBU Mother.
- Integration with OneMatch eliminates the need for entry/upload of CBU information
- Interfaced with HLA laboratory system, eliminates the requirement for manual data entry
- Integration with Finance enables automated invoicing and financial postings
- Integration with electronic records repository allows for all paper-based documents to be linked directly
- Integration with Data Warehouse framework allows for data analysis
- Integration with IT support system for management of operational problem resolution

Conclusion: SCNSS has provided the end-to-end IT system for the CBB, including tracking and data capture for collection, receiving, accession, production, storage, inventory management, and distribution.

SP17

Evaluation of Direction of HLA Mismatch and KIR Ligand Mismatch in Allogeneic Hematopoietic Cell Transplant in a Single Asian Institution

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Background/Case Studies: In allogeneic Hematopoietic Stem Cell Transplant (HCT), Killer Inhibitory Receptor (KIR) ligand mismatch between donor and recipient results in Natural Killer (NK) cell alloreactivity. There is growing evidence that interaction between HLA typing and KIR molecules play a role in allogeneic HCT. Knowing HLA Class I and Class II alleles will allow extrapolation of the KIR ligand mismatching. Ligand mismatch in the graft-vs-host (GvH) direction (i.e. donor KIR ligand missing in the recipient) is proposed to increase the chance of successful marrow engraftment and also reduce the risk of relapse or graft rejection. The aim of the study is to evaluate if the direction of mismatch (GvH and host-vs-graft (HvG)) impacts marrow engraftment and transplant outcome. **Study Design/Methods**: Retrospective allogeneic HCT data from year 2006 to 2014 was analyzed. HLA typing of donors and recipients were compared to determine the presence of HLA mismatch (HLA-A3, A11, Bw4 and Cw1-8). The data of the recipient's diagnosis, direction of mismatch, conditioning regimen, marrow engraftment and transplant outcomes were collected. **Results/Findings**: A total of 241 HCT were analyzed. 8 HCT were identified to have the HLA mismatch and assumed ligand mismatch (Table 1). There were only 2 HCT with ligand mismatch in the GvH direction. One had successful engraftment with conversion while the other had graft rejection with no evidence of engraftment. For the ligand mismatch in the HvG direction, 6 HCT were identified. 3 HCT had graft rejection with no engraftment. The remaining 3 had successful engraftment in which 2 converted and 1 eventually relapsed. **Conclusion**: Due to insufficient data for ligand mismatch in the GvH direction, the study was unable to conclude if there was an increase chance of successful grafting and reduce risk of relapse or graft rejection. However, data for ligand mismatch in the HvG direction suggested that graft failure occurs more likely in non-myeloablative regimen. Successful engraftment in HvG direction was likely possible with myeloablative regimen. The more intensive conditioning regimen could have ablated the recipient NK cell, rendering them incapable of stimulating an alloreactivity against the donor graft. This might have prevented NK cell-mediated graft rejection.

SP18

In Vitro Expansion and Differentiation of Hematopoietic Stem Cells into Platelets

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Background/Case Studies: The aim: This study aimed to collect mobilized HSCs by aphaeresis and culturing the cells under effect of various growth factors cocktails to generate mature megakaryocytes and platelets. **Study Design/Methods**: Material and Methods: The present study was conducted on 10 subjects divided into: (group 1) 5 patients of liver disease with thrombocytopenia and (group 2) 5 healthy control. The culture protocol lasted for 14 days, the process of megakaryopoiesis was characterized by flow cytometry using fluorochrome-conjugated antibodies against CD61, CD34 and CD42. Mature MKs were observed as larger cells in culture using a phase contrast inverted microscope. **Results/Findings**: Results: HSCs cultured for 14 days in growth factors cocktail revealed weak expression of CD34 and positive expression of both CD61 and CD42 for both CLD and control groups compared to those before culturing. Moreover, inverted microscope study on the 14th day revealed the presence of mature MK which can be observed as larger cells in the culture. **Conclusion**: The present study revealed successful generation of MK and platelets having CD61+ve and CD42+ve surface markers from differentiation of HSCs derived from peripheral blood which is an easy accessible source with no ethical problems. This study also demonstrated that CLD doesn't affect HSCs differentiation into MK and platelets. These results together with those of previous studies constitute important implications for the development of regenerative medicine in patients suffering from thrombocytopenia.

TABLE. Ligand Mismatch HCT Cases

SN	Diagnosis	Direction of Mismatch	Conditioning Regimen	Engrafted	Transplant Outcome
1	AML	HvG	Non-Myeloablative	No	Rejection
2	Refractory AML	HvG	Non-Myeloablative	No	Rejection
3	CML	HvG	Myeloablative	Yes	Donor Conversion
4	ALL	HvG	Myeloablative	Yes	Donor Conversion
5	Relapsed Burkitt's Lymphoma	HvG	Myeloablative	Yes	Donor Conversion but relapsed on Day 101
6	ALL	HvG	Myeloablative	No	Rejection
7	AML	GvH	Non-Myeloablative	Yes	Donor Conversion
8	AML	GvH	Myeloablative	No	Rejection

SP19

Blood Group Antigen Lewis Y Plays a Role in Cytoskeleton Formation and Migration Ability in Hepatocellular Carcinoma Cells

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Background/Case Studies: Histo-blood group antigen Lewis Y (LeY) is an isomer of blood group antigen Lewis B, whose synthesis pathway is closely related to that of lewis blood group members, in which fucosyl transferases such as FUT1, FUT4, etc play significant roles. LeY is carried by various glycoproteins and glycolipids, and is demonstrated to be associated with cell recognition, adhesion as well as migration. LeY is significantly overexpressed or re-expressed in several tumor tissues and cell lines and the expression status of LeY is correlated with the tumor metastasis. In this study, we aim to found out the effect of LeY on cell motility as well as the structure of cytoskeleton in hepatocellular carcinoma cells (HCC), to shed light on the molecular mechanism LeY utilizes to regulate cell migration, which can also be referenced in the studies of the clinical roles of other carbohydrate blood antigens. **Study Design/Methods**: The migration ability and expression of LeY of two HCC cell lines SMMC-7721 and HepG2 is assayed and compared by Transwell Migration Assay as well as Wound Scratch experiment. SMMC-7721 cells transfected with siRNA against FUT1 was analyzed for LeY expression and cell migration. LeY antibody blockage experiment is also conducted to verify the role of LeY in cell motility. Immunostaining analysis is carried out on SMMC-7721 cells with FUT1 knockdown for cytoskeleton change using Phalloidin that specifically binds to F-actin. The immunostaining results are visualized using Confocal Laser Scanning Microscopy and compared with images of those transfected with negative control siRNA. **Results/Findings**: As shown by Western Blot results, relative expression level of LeY in SMMC-7721 is significantly higher than that of HepG2, which is positively correlated with their migration capacity detected by Transwell Migration Assay. LeY blockage using anti-LeY antibody significantly inhibits cell motility as demonstrated by Transwell and Wound Scratch Assay. Furthermore, FUT1 knockdown in SMMC-7721 leads to significant decrease in LeY synthesis and number of cells that migrates through transwell membrane, while stress fiber amount is markedly reduced compared to cells treated by negative control siRNA. **Conclusion**: LeY antigen has certain relationship with cell motility in HCC, probably via regulating the formation of stress fiber structure. The underlying mechanism of signal transduction may involve the glycosylation of proteins carrying the LeY antigen, which provides us with a new way to study the roles of carbohydrate blood group antigens in physiological and pathological conditions.

SP20

CD3/CD19-Depleted Natural Killer Cell Production under Good Manufacturing Practices

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TABLE. NK cell processing results

Unmanipulated MNCs	TNC count ($x10^{10}$)	2.3 ± 0.7
	% NK cells	12 ± 5
	% T cells	63 ± 8
	% B cells	10 ± 4
	% monocytes	16 ± 5
Post-column depletion	TNC count (10^9)	4.9 ± 1.4
	% NK cells	39 ± 15*
	% NK cell recovery	74 ± 15*
	Log T-cell depletion	3.5 ± 0.5*
Cytokine-activated product	% NK cells	47 ± 18
	% T cells	0.2 ± 0.3
	% B cells	0.07 ± 0.08
	% monocytes	49 ± 12
	% viability	96 ± 5
	Total NK cells infused ($x10^9$)	1.6 ± 1.1

Values reported as mean ± SD.
*Based on 25 products with post-column flow cytometry data collected prior to cytokine exposure.

Background/Case Studies: Allogeneic natural killer (NK) cell adoptive immunotherapy is a growing therapeutic option for patients with malignancy. Clinical-scale production of $CD56^+CD3^-$ NK cells using immunomagnetic microbead technology complies with good manufacturing practices (GMPs) and allows automated purification in a closed system. High level purification of NK cells using sequential CD3 depletion/CD56 selection results in significant cell loss. We present the largest report of CD3/CD19 depleted NK cells manufactured under GMP conditions for human immunotherapy trials. **Study Design/Methods**: Mononuclear cells (MNCs) collected by a 15L apheresis from non-mobilized peripheral blood were incubated with anti-CD3 and anti-CD19 ferromagnetic beads and depleted in an automated magnetic column. The NK cell enriched fraction was incubated overnight at 37°C and 5% CO_2 in X-VIVO 15 with 10% human AB serum and IL-2 1000 U/mL or IL-15 10 ng/mL. The cells were washed and resuspended in 5% human serum albumin with samples sent for lot release testing prior to infusion. A chromium release assay tested cytotoxicity. **Results/Findings**: Since 2010, 94 CD3/CD19 depleted NK cell products were manufactured in support of 8 clinical trials. Processing data is summarized in the Table. Seven products required dose adjustments to meet lot release, including 1 for total nucleated cell (TNC) count $>8x10^7$/kg and 6 for $CD3^+$ count $>3x10^5$/kg. The release specification for purity changed over time from 20% to 30% ($CD56^+CD3^-$) to a $\geq$3-fold increase in NK cells (CD3/CD19 depleted products vs apheresis MNCs). Products met lot release for viability $\geq$70% (7-aminoactinomycin D), $CD20^+$ <3%, gram stain 'no organisms seen', and endotoxin <5 EU/kg. Cytokine activation consistently increased cytotoxicity against the K562 cell line over preactivated cells. There was no difference between IL-2 (n=66) or IL-15 (n=28) incubated cells. **Conclusion**: CD3/CD19 depletion effectively minimizes T cell and B cell contamination in a single manipulation that does not compromise NK cell recovery. Cytokine-activation with IL-2 or IL-15 increases in vitro cytotoxicity compared to preactivated NK cells.

SP21

A Case Series of Intravenous Immunoglobulin-Associated Hemolysis

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Background/Case Studies: As intravenous immunoglobulin (IVIG) is widely used, there is growing awareness of IVIG-associated hemolysis from the passive transfer of immunoglobulin G (IgG) directed against red cell antigens, such as anti-A and anti-B. The aim of the study was to review the incidence and clinical features of IVIG-associated hemolysis. **Study Design/Methods**: From February 2015 to April 2016, all patients receiving IVIG at a tertiary care hospital were recorded. The samples from all laboratories after IVIG were tested for ABO grouping and direct antiglobulin test (DAT). If DAT was positive, the elution test was performed. **Results/Findings**: There were 400 IVIG administrations during the study period. Only 196 blood samples were available for the tests. Of these, 40, 34, 12 and 110 samples were blood group A, B, AB and O, respectively. Thirteen samples were tested positive for DAT. All positive results were IgG caused by passive transfer of anti-A. Three of 13 episodes with detectable anti-A had no clinical hemolysis (Table 1). Therefore, 8 patients (10 episodes) were diagnosed with IVIG-associated hemolysis. Of 10 episodes, the mean hemoglobin (Hb) before IVIG was 10.6 g/dL (range 6.8-15.5). The mean fall in Hb was 2.6 g/dL (range 0.6-5.0) and 90% had hemolysis within 24 hours. Blood transfusions were requested in 8 episodes. Patients had received a mean dose of 1.7 g/kg IVIG (range 0.5-2). Patient 3, 5, 7 and 10 received IVIG from the same batch. Most patients had blood group A. In our study, the hemolysis was treatable or self-limited and no death related to hemolysis. **Conclusion**: Clinical hemolysis is not rare after therapeutic doses of IVIG and routine monitoring of Hb should be performed. However, severe hemolysis was not found in this study suggesting that IVIG benefits outweigh the risk. Although anti-A can cause hemolysis in some patients, the majority of A or AB recipients who received the same batches of IVIG had no clinical hemolysis. Additional hemolytic factors, e.g. immune-mediated disorders, remain to be determined.

TABLE. The Patient Characteristics

Patient	Age/Sex	Blood Group	Diagnosis	Drop in Hemoglobin	Hemoglogin Before IVIG (g/dL)	Time to Onset	Blood Transfusion	Dose
1	52/M	AB RhD+	Idiopathic thrombocytopenic purpura	3.6	11.9	1 day	Yes	1 g/kg
				4.7	10.8	During IVIG infusion	Yes	2 g/kg
				4.0	9.4	During IVIG infusion	Yes	2 g/kg
2	35/F	AB RhD+	IgA nephropathy and cytomegalovirus infection	2.5	8.1	During IVIG infusion	Yes	2 g/kg
3	57/M	A RhD+	Generalized myasthenia gravis and aspiration pneumonitis	1.2	12.8	During IVIG infusion	No	2 g/kg
4	67/F	AB RhD+	Evans syndrome and			adenocarcinoma	1.4	9.6
3 days	No	1 g/kg						
5	25/M	A RhD+	Systemic lupus erythematosus	1.3	8.2	During IVIG infusion	Yes	2 g/kg
6	45/F	A RhD+	Acute myeloid leukemia	0.6*	6.8	1 day	Yes	0.5 g/kg
7	55/F	A RhD+	Diffuse cutaneous systemic sclerosis-polymyositis overlap syndromes	2.4	12.5	During IVIG infusion	Yes	2 g/kg
8	53/M	A RhD+	Drug-induced inflammatory myopathy	5.0	15.5	1 day	Yes	2 g/kg
				No	8.4	-	No	5 g/kg
9	45/M	A RhD+	Generalized myasthenia gravis	No	12.2	-	No	1 g/kg
10	53/M	A RhD+	Kidney transplant and acute on top chronic allograft dysfunction	No	9.7	-	No	1 g/kg

*Two units of red blood cells were transfused before complete blood count was done after IVIG.

SP22

HLA-A2 Homozygosis Enhances Exosome Immunogenicity and Improves T-cell Response to Dendritic Cells from Prostate Cancer Patients Without Treatment

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Background/Case Studies: Cellular immunotherapies have been adressed as supplimentary cancer treatments, especially for metastatic patients. Immunosupressor microenvironment may impair patients' dendritic cells (DCs) function leading to lower immunogenicity. Nanovesicles such exosomes (Exo) are an attractive tool for increasing immunogenicity of DCs, since they can transfer tumor antigens and induce tumor-specific T cells. Either, Exo could be generated from allogeneic sources minimizing risks associated with tumoral antigens and optimizing DCs stimulation *ex vivo*. We investigated whether HLA-A2 homozygosis could enhance immune response of allogeneic Exo (Exo-alo) and stimulate DCs from prostate cancer patients without treatment. **Study Design/Methods**: DCs of HLA-A2+ healthy donors were differentiated *in vitro* from monocytes and cultured with GM-CSF and IL-4 for 7 days. On the 5th day, DCs were pulsed with prostate specific peptide (FLTPKKLQCV), restricted to HLA-A2, and matured with IL-1, IL-6, TNF-α and PGE_2. Supernatant of DCs culture was ultracentrifuged and filtered for the isolation of Exo-alo. Exo-alo were HLA-DR+, CD86+, Hsc70+, CD63+, CD81+, CD9+ and also had the expected size and cup-shaped structures, confirmed by electron microscopy. Patient DCs were obtained from peripheral blood collection from prostate cancer patients without treatment. Immature DCs from donors and patients were sensitized with 10-20μg of Exo-alo and induced to maturation. Mature DCs were co-cultured for 5 days with allogeneic T cells, from HLA-A2(-) healthy donors in a mixed leukocyte reaction. **Results/Findings**: Homozygote Exo-alo (HLA-A2+/+) induced a 11.3 fold higher median of cell proliferation (MCP) of CD4+ and CD8+ cells when compared to heterozygote Exo-alo (HLA-A2+/-) (5.4). As well, HLA-A2+/+ Exo-alo increased the number of activated CD4+ and CD8+ T cells when compared to HLA-A2+/- Exo-alo (CD4+/CD69+: 1.7 and CD8+/CD69+: 1.5 fold increase in MCP). DC loaded with HLA-A2+/+ Exo-alo induced higher production of interleukins than heterozygote Exo-alo (IL-2 = 6.6; IL-6 = 4.1; IFN-δ = 89; TNF-α = 21 fold higher median). We found no significant differences between donor and patient DCs on CD4+ and CD8+ cell proliferation, CD69 and PD-L1 expression, IL-2, IL-6, IFN-δ and TNF-α. Also, patient DCs did not change FoxP3+ cell frequency. **Conclusion**: HLA-A2 homozygosis enhanced the effector profile of T cell response either in cell proliferation or activation. We could not identify any difference in immunological profiles from patient DCs to healthy donors DCs. Besides, increase in CD69+ cells and maintenance of FoxP3+ frequency demonstrate that Exo-alo breaks established tolerance and do not impose risks to immune homeostasis. (Financial support: FAPESP and CNPq)

SP23

A Patient with IgG/IgA Warm Autoimmune Hemolytic Anemia Treated with Eculizumab

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Background/Case Studies: Warm auto-immune hemolytic anemia (WAIHA) due soley to IgA is a rare event and usually presents as a DAT negative anemia. Reports describing successful treatment of IgA WAIHA are limited but these patients usually respond to steroids. We describe a case that exhibited both IgG and IgA autoantibodies, complement activation and severe intravascular hemolysis that was nonresponsive to standard therapy. **Study Design/Methods**: The patient was a 45 year old Caucasian female with a history of Evans Syndrome and cold agglutinin disease (CAD) first diagnosed in 2012. Treatment at that time included: steroids, azathioprine, IVIG, mycophenolate and Rituximab. She relapsed with severe AIHA in 2014 and was successfully treated with prednisone and cyclosporine. In August 2015, she again presented with severe anemia (6.4 g/dL) and thrombocytopenia (2K/μl). The patient had hemoglobinuria, marked reticulocytosis and spherocytes on the peripheral smear. During this admission, she was treated with 5 rounds of plasmapheresis, transfusion of 3 units of platelets, IVIG and other immunosuppressive drugs. In addition, from August to November she received a total of 34 phenotype matched RBCs, ie. E-, K1-, Fy(a-), Jk(a-), S-. At that time, auto-agglutination of the blood sample at 24°C and in the apheresis lines was noted and believed to be due to the previously reported cold autoagglutinin. Thus, a sample was sent for a complete serological investigation. **Results/Findings**: The initial antibody screen was negative at 4, 16 and 24°C thus excluding CAD. However, the DAT showed that the red cells were heavily coated with immunoglobulin and complement: IgG= 2+s, IgA=4+, IgM=neg, C3b/d=3+, C4b=4+. Serial blood samples were collected from 9/24/15 thru 3/7/16. During that time, the strength of both the IgG and IgA DATs decreased in response to continued aggressive immunotherapy. The IgG DAT was negative at one point; however, the reactivity with anti-C3b/d remained strongly positive (3 to 4+). Also during this period, the hemoglobin values vacillated between 3 and 11 g/dL, the LDH remained elevated (260 to 1100 U/L) and the total bilirubin only decreased to normal levels for a brief period (6.8 to 0.7 mg/dL). Because of the ongoing intravascular hemolysis and poor response to standard therapy, Eculizumab (monoclonal anti-C5) was given with good clinical results. **Conclusion**: Dimers and multimers of IgA are known to activate the alternative and lectin pathways of complement, respectively. The DAT findings of IgA, C4b and C3b/C3d on the red cells along with clinical symptoms of hemoglobinemia and hemoglobinuria suggest that the IgA was the cause of the hemolysis. Furthermore, Eculizumab may be an appropriate therapy in cases of severe refractory WAIHA when complement components are found on the red cells.

Components and Component Processing

SP24

Red Cell Concentrates from Whole Blood Stored at 4°C for 7 Days

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Background/Case Studies: During the past five years there has been an increased focus on whole blood (WB) as a therapeutic option for severely bleeding patients. Cold storage at 4°C conserves the quality of WB, including the hemostatic properties of the platelets. A pilot study was performed to investigate the feasability of manufacturing red cell concentrates from leukocyte-reduced whole blood stored at 4°C for 7 days. **Study Design/Methods**: The Imuflex® WB SP blood bag system (Terumo BCT, Lakewood, CO, USA) contains a platelet-sparing in-line whole blood filter for leukocyte reduction. This quadruple set was used for the collection and storage of whole blood for 7 days. 20 healthy volunteer blood donors gave 450 mL +/- 50 mL of whole blood to the in vitro pilot study. 10 blood bags were stored after leukofiltration (test group), while 10 bags (control group) were stored without filtration in the transfer bag same as the leukoreduced WB. After sampling and analysis on Day 0, the bags were stored horisonally at 4°C without agitation. At Day 7 the bags were tested and analyzed, before a second filtration with the Imuflex® WB RP filter to remove both leukocytes and platelets. At the same time red cell concentrates were produced with centrifugation and a manual blood press. Samples were taken and analyzed after 14, 21, 28, 35 and 42 days of storage at 4°C. **Results/Findings**: A small selection of results is presented in Table 1. **Conclusion**: Red cell concentrates after 7 days' storage as whole blood at 4°C fullfil the quality requirements outlined in the European Blood Directive. This is true both for whole blood stored without filtration and after filtration with the Imuflex® WB SP blood bag system containing a platelet-sparing filter. The double filtration was concidered a possible challenge regarding red cell damage and hemolysis, but the test group hemolysis is actually lower at all data points after filtration on Day 7. As whole blood may be used for selected clinical situations, the possiblity to produce good quality red cell concentrates after whole blood storage will help the blood bank logistics and reduce the waste related to not-transfused whole blood units.

SP25

Anaerobic storage Condition enhances GSH Levels while Maintaining Pentose Phosphate Pathway Activity

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Background/Case Studies: Stored RBCs accumulate storage lesion. While the clinical relevance of the storage lesion has not been fully elucidated, alternative strategies have been proposed to improve the quality of stored RBCs. Hypoxic/anaerobic storage of RBCs has been shown to decrease RBC hemolysis, ameliorate morphological lesions, and prevent alterations to the cytoskeletal proteome. Metabolic benefits of anaerobic storage could be partly explained by the O_2-dependent metabolic modulation, promoting release/activation of glycolytic enzymes from inhibitory binding to the N-term of band 3. However, it has been proposed that hypoxic activation of glycolysis may decrease fluxes through the Pentose Phosphate Pathway (PPP), a key pathway that regulates glutathione homeostasis by generating reducing equivalents (NADPH). **Study Design/Methods**: Leukoreduced packed RBC units in AS-3 additive solution were prepared from consenting volunteers (N=4) by apheresis. A double-RBC unit was supplemented with $^{13}C_{1,2,3}$-glucose and split 6-ways into unprocessed Control, Hyperoxic control, and Test units (4 levels of O_2). Anaerobic units were stored O_2-free, sampled O_2-free, and were assayed with UHPLC/MS. **Results/Findings**: Hypoxic storage promoted glycolysis and 2,3-DPG and ATP throughout storage in comparison to normoxic and hyperoxic controls. Tracing experiments with $^{13}C_{1,2,3}$-glucose indicated that the PPP is significantly active at lowest SO_2, despite the highest fluxes being observed in hyperoxic RBCs. Anaerobic RBCs were characterized by higher NADPH/NADP+ ratios, decreased hemolysis, lower metHb and irreversible Hb oxidation (b-His93, b-Cys94). In addition, increased total GSH, GSH synthesis as gleaned from tracing

TABLE. Characteristics of red cell concentrates made from whole blood units stored for 7 days*

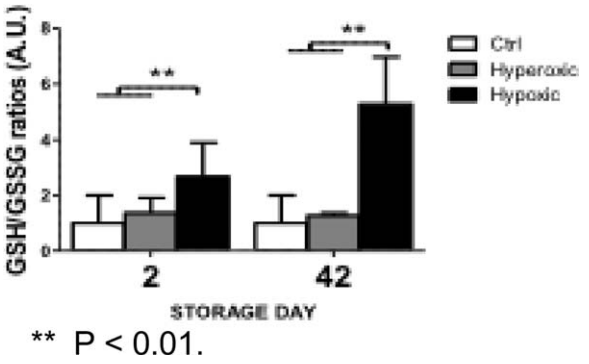
	Day 7 Before filtration	Day 7 Before filtration	Day 7 After filtration	Day 7 After filtration	Day 28	Day 28	Day 42	Day 42
Group	Control	Test	Control	Test	Control	Test	Control	Test
Hb (g/dL)	13.1	13.0	20.0	20.2	20.9	20.6	19.9	20.0
Hemolysis (%)	0.14	0.11	0.13	0.10	0.28	0.20	0.35	0.31
Potassium (mmol/L)	12.5	1.3	1.4	1.3	>40	>40	>40	>40
Glucose (mmol/L)	17.7	16.5	28.4	28.8	18.7	18.0	14.8	14.0

*All results are given as mean. p>0.05 for differences between groups for all measurements on all days.

TABLE.

GSH/GSSG	Control	Hyperoxic	Hypoxic
Day 2	1	1.35 ± 0.54	2.67 ± 1.24*
Day 42	1	1.26 ± 0.09	5.28 ± 1.70*

* $p < 0.01$.



experiments, and GSH/GSSG ratios ($p < 0.01$), and decreased supernatant urate oxidation are suggestive of decreased oxidative stress and increased total antioxidant capacity in hypoxic/anaerobic RBCs. **Conclusion**: Hypoxia ameliorates the energy and oxidative metabolic lesion in a dose-dependent fashion.

SP26

Comparison of *In Vitro* Red Cell Quality Parameters During Storage in Five Different Additive Solutions

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Background/Case Studies: Red cell concentrates (RCC) are normally stored in SAGM (saline, adenine, glucose, mannitol). During storage, *in vitro* red cell quality declines, like increased cell lysis, decreased deformability and lowered energy status. Recently, several additive solutions, designed to diminish the decline in *in vitro* quality during storage, are developed. These additive solutions allow for prolonged red cell storage. In a paired study design, *in vitro* RBC quality during storage in SAGM (control), PAGGSM (Fresenius Kabi), PAG3M (Sanquin Research), Erythrosol-4 (E-Sol4, Fenwal) and SOLX (AS-7, Haemonetics) were compared. The new solutions are mainly developed to better maintain 2,3-DPG and ATP levels during storage. High levels of 2,3-DPG allow for better oxygen release while high ATP is necessary for function and survival of RBC *in* vivo. **Study Design/Methods**: For each experiment, 5 overnight stored whole blood units were pooled and split. From 4 collection systems, SAGM was replaced by PAGGSM, PAG3M, E-Sol4 of SOLX. De whole blood units were processed according to routine procedure, into buffy-coat- depleted RCCs in additive solution, leukoreduced by filtration. RCCs were stored for 8 weeks at 2-6°C and samples for analysis of *in vitro* quality parameters. Deformability was determined with an Automated Rheoscope and Cell Analyzer (ARCA) and expressed as deformation index (DI): ratio of cell length to cell width. With DI >2.5 cells are considered deformable, cells <1.5 are considered undeformable. **Results/Findings**: Results are summarized in the table. RCC leukoreduction filtration times were increased with the alternative solutions, especially for SOLX. Haemolysis was significantly lower during storage in PAG3M and E-Sol4. RCCs in PAG3M, E-Sol4 and SOLX showed significantly higher ATP and 2,3-DPG levels compared to SAGM. In PAG3M, 2,3-DPG levels remained high during whole storage period. Storage in PAG3M, and to a lesser content in E-Sol4 and SOLX, resulted in declined RBC deformability compared to SAGM. **Conclusion**: SAGM and PAGGSM allow for storage of RBC up to 35 days. The new additive solutions allow for longer storage, with better maintenance of stability, energy status and 2,3-DPG levels. Deformability might be lesser maintained in the alternative additive solutions.

SP27

The Characterization of Extracellular Vesicles Is Influenced by Method of Detection, Blood Manufacturing Processes, and Storage Duration

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Background/Case Studies: Extracellular vesicles (EVs), including microvesicles and exosomes, are small phospholipid vesicles (≤1 μm in diameter) released by cells into body fluids such as blood, and contribute to a range of biological and pathological conditions. EVs are present in blood products, accumulate during storage, and have a potential transfusion-related immunomodulatory role. Knowledge of EVs in stored blood products is limited due to the challenges and difficulties in detecting these heterogeneous submicron-sized vesicles. The aim of this study was to assess the impact of different method to characterize EVs in differently manufactured and stored RBC products. **Study Design/Methods**: Leukoreduced packed RBC units (n=3 per group) produced from whole blood using whole blood filtration (WBF) and buffy coat (BC) methods were analyzed in triplicate. Quantification and size-profiling of EVs in RBC products were examined on day 3, 7, 21, and 42 of storage using tunable resistive plus sensing (TRPS/qNano), flow cytometer (FC), and dynamic light scatting (DLS) method. **Results/Findings**: On day 3, the qNano results indicate that WBF products have a different EVs size-profile (smaller EVs, 196 ± 15 nm) in comparison to BC products (230 ± 7 nm), ($p<0.0001$). Moreover, data from the qNano shows that the concentration of EVs < 200 nm increase throughout storage until day 21 then dramatically and significantly decrease by day 42 (BC: P=0.005, WBF: P=0.0001). These exosome concentration changes are not detectable with FC or DLS due to limitations in the resolution particles < 200 nm and/or accurately determining concentration. However, qNano and FC show that the concentration of EVs/MVs ≥ 200 nm in BC and WBF significantly increase on day 42 in comparison to day 3 ($P<0.0001$). In addition, the FC technique shows that the concentration of EVs in the WBF products is significantly higher at all of the testing points in comparison to BC products ($p<0.001$). Notably, as the DLS measures the average size of particles in suspension, an increase in the zeta-average size was observed during storage, particularly in BC units. **Conclusion**: This study shows that when compared with the qNano, FC detects only fluorescently labelled EVs ≥ 200 nm and DLS reports only the average size, not the actual size, of EVs. Furthermore, EV size and concentration in RBC products is significantly influenced by the blood manufacturing methods and storage length. As differences in the EVs Cell-of-origin between manufacturing methods is expected, the observed changes in RCC EVs characteristics with storage may represent dynamic shifts in platelet, WBC, or RBC-derived EVs populations. Overall, this study shows that not all RBC are equivalent when it comes to EV size and concentration.

TABLE.

Parameter	SAGM	PAGGSM	PAG3M	E-SOL4	SOLX
Filtration time of RCCs (min)	25 ± 4	35 ± 4	33 ± 4	41 ± 6	72 ± 26
Hemolysis (%), day 56	0.82 ± 0.11	0.66 ± 0.12	0.36 ± 0.05	0.35 ± 0.11	0.65 ± 0.13
ATP (μmol/g Hb), day 56	2.3 ± 0.1	3.0 ± 0.2	3.2 ± 0.4	3.0 ± 0.2	3.5 ± 0.4
2,3-DPG (μmol/g Hb), day 21	0.51 ± 0.24	0.64 ± 0.26	16.6 ± 6.95	2.0 ± 0.62	2.9 ± 1.57
Deformability, day 56					
DI<1.5 (%)	12	23	67	60	42
DI>2.5 (%)	70	50	16	30	42

TABLE. RBCs' physiological parameters after centrifugation

Relative centrifugal force (g)	Viability (%)	Morphological index	Diameter (μm)	Membrane potential (mV)	MCHC (%)
1	99.8 ± 0.3	17 ± 2	8.4 ± 0.8	−20 ± 2	35 ± 1
100	99.5 ± 0.4	18 ± 1	8.4 ± 1.0	−26 ± 1 *	33 ± 2
200	98.5 ± 1.4	25 ± 3 *	8.2 ± 1.5 *	−25 ± 3 *	32 ± 3
400	98.0 ± 2.2	39 ± 6 *	8.1 ± 1.0 *	−26 ± 0 *	31 ± 2
900	98.9 ± 2.1	74 ± 8 *	7.8 ± 0.8 *	−25 ± 5 *	30 ± 3 *
1500	99.2 ± 0.9	81 ± 10 *	7.4 ± 0.8 *	−26 ± 0 *	30 ± 3 *

* $p<0.05$ compared with negative non-centrifuged control (1 g).

SP28

The Poloxamer MST-188 Prevents Hemolysis in 42-day-stored, DEHP/PVC-free RBC Units

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Background/Case Studies: Use of the plasticizer di(2-ethylhexyl) phthalate (DEHP) in polyvinyl chloride (PVC) blood bags poses a potential dilemma. The presence of DEHP in blood bags has been shown to be beneficial to red cells during storage by diminishing red blood cell (RBC) hemolysis. However, decades-long concerns have been raised that DEHP use in PVC may be carcinogenic or estrogenizing. MST-188 is a poloxamer with rheological properties on the red cell membrane currently in phase 3 clinical trials in therapy of vaso-occlusive disease in sickle cell anemia. **Study Design/Methods**: We hypothesized that MST-188 may replace the plasticizer DEHP to prevent hemolysis with conservation of the biochemical and redox potential in RBCs stored for up to 42 days. Whole blood (500mL ± 10%) from 30 consenting donors, that fulfilled AABB/FDA criteria for donation, was collected and prepared using the Fenwal CPD collection set, filtered using the Fenwal RS2000 leukoreduction filter and stored in AS-1 within 8 hours of collection. Pools of two RBC suspensions from ABO identical donors were aseptically split into test storage containers (DEHP/PVC or DEHP-free/ethylene vinyl acetate -EVA-) and supplemented or not with MST-188 (0.1, 1, 5 or 7.89 mg/mL). RBC units were cold stored for up to 42 days. Hemolysis, ATP levels, osmotic fragility, deformability as assessed by ektacytometry, oxidative stress as assessed by GSSG/GSH and oxidized peroxiredoxin-2 (PRX2) levels, and phosphatidylserine (PS) exposure were analyzed on days 28 and 42 of storage. Groups were statistically compared by ANOVA test with Bonferroni correction. **Results/Findings**: As expected, RBC storage in EVA bags resulted in increased hemolysis (~4-fold) and PS exposure (~6-fold) compared with DEHP/PVC bags. MST-188 significantly prevented the increased hemolysis induced by removal of DEHP in EVA bags in a dose dependent manner by days 28 and 42 of storage (~50% reduction for the maximum concentration of MST-188, $p<0.001$). There was an inverse correlation between the concentration of MST-188 used and the hemolysis rate ($r^2=0.27$, $p<0.001$) and a direct correlation between hemolysis and PS exposure ($r^2=0.42$; $p<0.01$). Increased osmotic fragility or PS exposure of 42-day stored RBC in EVA bags was not corrected by the addition of MST-188. There were no relevant differences in the levels of oxidative stress among the groups. **Conclusion**: MST-188, in a concentration dependent fashion, is able to partly rescue the increased hemolysis and PS exposure induced by the absence of the commonly used plasticizer DEHP. The biochemical/biophysical mechanism of the favorable effect of MST-188 seems to be related to its rheological properties upon intercalation within the RBC membrane. These results provide the first evidence that the rheological agent MST-188 may be useful to replace DEHP in long-term storage of RBC.

SP29

Is There a Pre-storage Lesion in Red Blood Cells?

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Background/Case Studies: During blood bank storage, erythrocytes exhibit biophysical and biochemical changes known as "storage lesion". However, the effect of fractionation or processing for themselves has not been determined. The aim of this study was to determine the effect of centrifugation on the subpopulations and function of red blood cells (RBC). **Study Design/Methods**: Total reticulocyte counts: From 6 whole-blood donors, reticulocytes content and subtypes were determinated by flow cytometry with thiazole orange staining in whole blood, buffy coats and RBC units in AS-1, obtained following blood bank standard procedures. RBC's physiological parameters after centrifugation: Peripheral blood samples were drawn from 14 healthy volunteers. Samples were diluted (hematocrit 0.5%) in a solution containing (in mM): 140 NaCl; 5 KCl; 1 $CaCl_2$; 1 $MgCl_2$; 10 HEPES; 10 glucose; pH 7.40; 292 ± 1 mOsm/l, and centrifuged in 10 ml polypropylene tubes in a centrifuge with fixed angled rotor (45°) at 100; 200; 400; 900; or 1500 g during 10 minutes with no brake, at 20 ± 2°C. Echinocytes (morphological index), diameter (light microscopy), membrane potential (flow cytometry with $DiSBAC_2(3)$), mean corpuscular hemoglobin concentration (MCHC) (impendance cytometry) and hemoglobin release (spectrophotometry) were determined in the first 2 hours following the centrifugation. Viability was calculated as 100-hemolysis (%). Results are presented as mean±1 standard deviation. Comparisons between groups were carried out with repeated-measures ANOVA or Friedman test, and *post hoc* Dunn's test. Significance level was set at $p<0.05$. **Results/Findings**: Percentage of reticulocytes was 1.0 ± 0.4 in peripheral blood; 2.6 ± 0.8 in buffy coats; and 0.4 ± 0.1 in RBC units. Meanwhile, absolute reticulocyte count was 54 ± 19; 147 ± 55; and 27 ± 5 $x10^9$/l, respectively ($p<0.05$). **Conclusion**: After blood bank fractionation, the relative depletion of reticulocytes in RBC units represents an increase in average erythrocyte age. Moreover, simple centrifugation in the evaluated conditions, resulted in echinocyte formation, decreased diameter, membrane hyperpolarization, and decreased MCHC. These results suggest the existence of a sub-lethal damage in erythrocytes induced by processing, which has not been reported previously, and that could has been so far masked by the "storage lesion". These changes could be called "the processing lesion".

SP30

Quality of Red Cell Concentrates Irradiated Either Pre- or Post-cryopreservation

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Background/Case Studies: Cryopreservation of red cell concentrates (RCCs) can be used for long term storage of rare blood groups. Patients with rare blood types may require a bank of frozen RCCs collected from a family member. The Canadian Standards Association (CSA) indicates that irradiation is required for RCCs donated by a blood relative to reduce the incidence of graft-vs-host disease. However, there is no explicit standard in Canada that indicates if a cryopreserved RCC must then be irradiated. The following study was designed to provide guidance on whether irradiation should occur at either pre or post cryopreservation to support a patient whose medical situation would benefit by creating a sibling donated bank of cryopreserved RCCs. **Study Design/Methods**: Nine ABO Rh matched leukocyte reduced RCCs were pooled and split. The units were divided into three arms (n=3/arm); Non-Irradiated (NI), Pre-Cryopreservation Irradiation (PreC), and Post-Cryopreservation Irradiation (PostC). Units were glycerolized 3 d post collection, frozen to ≤-65°C, and deglycerolized > 24 h later using standard protocols on the COBE 2991. Gamma irradiation occurred 15 min prior to glycerolization (PreC) or 15 min post deglycerolization (PostC). Prior to treatment, units were tested for residual WBCs (rWBC), hematocrit (hct) and hemoglobin (hb). At expiry (24 h post thaw) units were tested for rWBC, hct, hb, hemolysis, extracellular K^+, MCV, RBC morphology, deformability, and recovery. **Results/Findings**: rWBC ($0.2x10^6$/RCC pre-treatment) were reduced below detectable limits in all units, regardless of the treatment group. No statistical differences were detected between

treatment groups for hct, hb, hemolysis, MCV, morphology, and recovery. At expiry, all RCCs met the CSA standards for hct ($\leq$ 0.8 L/L), hb per unit ($\geq$ 35 g/unit), and recovery ($\geq$ 80%), however none of the treatment groups met the hemolysis standard ($\leq$ 0.8%; NI: 1.13%, PreC: 1.01%, PostC: 0.97%). Extracellular K^+ was statistically higher in PreC (10.1 mmol/L) and PostC (13.9 mmol/L) when compared to NI (4.2 mmol/L; p=0.001, p=0.003). A statistical difference was also observed between PreC (p=0.510) and PostC (p=0.520) for EI_{MAX} (p=0.026). **Conclusion**: From the quality data collected in this small study, we can determine that irradiation either pre or post cryopreservation is feasible. Post cryopreservation irradiation is logistically more appealing as the RCC can be irradiated immediately prior to transfusion reducing the storage lesion due to irradiation. However, since newer closed system technologies allow for $>$ 24 h storage, distinct differences between the PreC and PostC groups may occur if prolonged storage is pursued. Further studies should be undertaken to evaluate if irradiation is required at all by evaluating WBC viability in deglycerolized RCCs.

SP31

Blood Separation and Storage with a New Gravity-Driven Device: Performance with and without Leucodepletion Filter

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Background/Case Studies: Lack of electrification during disasters or in underdeveloped areas makes preparation of red cell concentrates and plasma from whole blood donation difficult. The 3M™ Blood Separation System is a novel CE-certified, hollow-fibre based device designated for gravity-driven red blood cell separation. Aim of the present study was to compare its performance with and without integrated leucodepletion filter. **Study Design/Methods**: The blood components were investigated according to European guidelines. Blood was sampled in donation bags containing 63 ml CPD-450 stabilizer. Red cells were stored for 42 d in blood bags containing 100 ml 450-SAGM stabilizer. The net weight of donated blood as well as of red cell concentrates and plasma after separation with the 3M ™ Blood Separation System was determined. Relative haemolysis was calculated as ratio of free haemoglobin (Hb) to total Hb after complete lysis of red cells. Sterility was assayed by standard broth tests (bioMérieux, Germany). A total of n = 54 (with filter) and n = 14 (without filter) experiments were performed. Statistical analysis was performed by unpaired Student's t - test. **Results/Findings**: Mean weight of the blood units before separation was 474 $\pm$ 10 g, resulting in 219 $\pm$ 13 g (46 $\pm$ 2% of source blood weight) of red blood cell concentrate and 242 $\pm$ 47 g (51 $\pm$ 3%) of plasma when using the leucocyte filter. For experiments of the system without filter, mean weight of source blood was 514 $\pm$ 16 g, resulting in 241 $\pm$ 10 g (47 $\pm$ 1%; p=0.055) of red blood cell concentrate and 261 $\pm$ 10 g (51 $\pm$ 1%; p=0.620) of plasma. The duration of separation was 57 $\pm$ 15 min for the system including leucodepletion filter and 71 $\pm$ 12 min (p=0.001) for the system without leucodepletion. Increases in haematocrit in the red cell concentrates were 14.9 $\pm$ 1.1 and 16.3 $\pm$ 0.6% (p<0.000), resp., from 38 $\pm$ 3 and 38 $\pm$ 1% in the source blood. Immediately after separation, no significant haemolysis was detected (filter, 0.04 $\pm$ 0.02% (n =27) vs.no filter, 0.08 $\pm$ 0.02% in plasma (n =14); p<0.000). Storage of red cells for 42 d led to haemolysis of only 0.45 $\pm$ 0.16 and 0.53 $\pm$ 0.14% (n = 27 and n = 14; p=0.104), resp. Both values are well within the limits set by the European and U.S. authorities. At the end of the storage period, sterility of the red cell concentrates could always be proven for both systems (n = 37 and n = 14). **Conclusion**: The 3M ™ Blood Separation System is an easy to handle, stand-alone device which allows processing of high quality red cell concentrates and plasma from whole blood without centrifugation and automated separation. Omitting the leucodepletion filter has no negative effects on the performance of the system.

SP32

Storage of RCCs for up to 21 d Prior to Cryopreservation Using a Closed System Cell Processor Does Not Affect *in Vitro* Quality

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Background/Case Studies: We currently store RCCs for up to 14 d prior to cryopreservation. The introduction of a closed system cell processor and the recommended 7 d pre-freeze storage would present a significant logistical challenge to our blood system. The natural variability in the volume of RCCs in our national inventory presents challenges with RBC deglycerolization using a fixed centrifuge bowl on the closed system cell processor resulting in post-thaw products with variable amounts of additive solution and variable final hematocrits (Hct). We are therefore interested in the impact that the pre-freeze unit size and storage duration have on the post-thaw quality of cryopreserved RBCs. **Study Design/Methods**: Ten ABO/Rh compatible SAGM, CPD LR RCCs were pooled and split to produce 3 small (S; 256 $\pm$ 5 g), 3 medium (M; 323 $\pm$ 5 g) and 3 large (L; 390 $\pm$ 5 g) RCCs. One RCC of each size was stored for 7, 14 or 21 d. This was replicated five times to create 5 batches (n=5 per condition). Where RCC volume exceeded the deglycerolization centrifuge bowl capacity, excess cells were manually removed prior to glycerolization. A second extraction was performed to remove excess glycerol before slow freezing to ≤ -65°C. More than 72 h later, RCCs were rapidly thawed, deglycerolized, and re-suspended in AS-3. RCCs were stored 14 d post-deglycerolization and evaluated for recovery, hemoglobin (Hgb), hemolysis, Hct, ATP and extracellular K^+. **Results/Findings**: RCCs stored for 7 d before cryopreservation had more ATP than those stored for 14 d (p=0.0024) or 21 d (p=0.0029). RCCs stored 21 d had lower Hct (p=0.0335) and lower recovery (p=0.0342) than units held for 14 d. However, hemolysis was $<$ 0.8% in all RCCs and no significant differences in hemolysis or Hgb concentration were seen across storage durations. The ability of large RCCs to meet recovery target of 80% was impacted by pre-freeze volume reduction of higher volume RCCs, with large RCCs having the lowest and small RCCs having the highest recovery rates (S vs M p=0.0064, S vs. L p<0.0001, M vs L p<0.0001). However, larger units had higher Hct (S vs M p<0.0001, S vs L p< 0.0001, and M vs L p=0.0426) and Hgb (S vs M p<0.0001, S vs L p<0.0001, and M vs L p=0.0215) than smaller units. Three small RCCs (one per storage age) failed to meet the Hgb cut-off criterion of $\geq$ 35 g/unit. **Conclusion**: The RBC quality parameters measured during this evaluation suggest that RCC units can be stored for up to 21 d pre-freeze without adversely affecting quality when a 14 d post-deglycerolization expiry is used. While some units failed to meet the recovery and hemoglobin criteria, these failures can be attributed to RCC size and the volume reduction step rather than pre-freeze storage duration.

SP33

Evaluation of Select Red Blood Cell Biochemical and Coagulation Properties in Whole Blood Stored Using a Novel Anaerobic Storage Platform

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Background/Case Studies: Trauma research has explored the optimal ratio of plasma, red blood cells (RBC), and platelets yielding the best clinical outcome from massive transfusions.[1,2,3] Whole blood (WB) contains plasma, RBCs, and platelets in a 1:1:1 ratio. Studies have shown the effectiveness of RBCs preserved anaerobically.[4] **Study Design/Methods**: 8 units of whole blood collected in CPDA-1 anticoagulant (Research Blood Components Inc.), leukoreduced with platelet sparing filter (Terumo BCT). Filtered units split into conventionally stored vs anaerobically stored WB units. Anaerobic units processed with the Sorin D100 membrane oxygenator yielding anaerobic units with $\sim$ 5% SO_2 and $\sim$35mm Hg pCO_2, placed in standard PVC bags, stored in anaerobic canisters with an oxygen sorbent, filled with N_2. Control units were stored in standard PVC bags. All units stored at 1 - 6 deg sampled weekly. All assays performed using manufacturer's instruction: Hemolysis (Plasma Low, Angelfolm Sweden), ATP (DiaSys, Flacht Germany), and 2,3-DPG (Sigma-Aldrich, St. Louis, MO), activity levels for factors V, VIII, and von Willebrand Factor, Prothrombin Time (PT), activated Partial Prothrombin time (aPTT), Protein C performed using the ACL TOP® (Instrumentation Laboratory). Protein S activity: the STA-R Evolution coagulation analyzer® (Diagnostica Stago, Inc.). Thromboelastography (TEG): Haemoscope Thromboelastograph® analyzer (Haemonetics). **Results/Findings**: No difference in hemolysis detected. ATP level difference was significant at week 3:c:3.687 μmol/gHb, t: 4.300; p=0.0359. 2,3DPG was significantly higher in t at all test points, the least at week 3: c: 2.238 μmol/gHb, t:3.100; p=0.0040. TEG: no significant differences: R angle, Angle, CL30, LY30. Slight significance:week 3: K angle: c:3.463, t:4.863, p= 0.0460. Consistent difference in MA, most at week 1:c:60.975, t:53.550, p=0.0008. Significant difference in α angle at week 2:c:61.788, t:58.163, p:0.001. Significant difference in PT: day 1:c: 11.200, t:11.520, p=0.0178. Factor V: significant differences: weeks 1, 2, most: week 1:c:71.88, t:61.00, p= 0.0001, Protein S activity: significant difference in all testing, most: week 2:c:52.25, t:37.25, p=0.0019. Von Willebrand factor

significantly different weeks 2,3, week 3 most: c:55.00, t:38.86, p=0.0321. aPTT, fibrinogen, D-dimer, factor VIII, protein C, ADAMTS-13: no significant difference. **Conclusion**: Anaerobic storage of WB preserved RBC ATP and 2,3DPG more than conventional cold storage. Coagulation parameters were similar between the two methods. References: 1. Spinella PC, Perkins, JG, et al. J Trauma. 2009;66:S69-S76. 2.Borgman MA, Spinella PC, et al. J Trauma. 2007;63:805-813. 3.Sperry JL, Ochoa JB, et al. J Trauma.65:986-993,2008. 4. Dumont LJ, Yoshida T, AuBuchon JP Transfusion 2008;49:458-64.

SP34

A Simple Disposable Device for Bedside Washing of Stored Red Blood Cells

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Background/Case Studies: The suspending medium of every RBC (red blood cell) unit contains additive solution, residual plasma, platelets and leukocytes, and continually accumulates by-products of RBC metabolism and degradation (e.g. free hemoglobin, microparticles) throughout the duration of hypothermic storage. Transfusion of anything other than well-preserved RBCs serves no therapeutic purpose and may be harmful. Existing centrifugation-based methods for washing stored RBCs are too laborious and expensive for widespread use. Here we describe a simple, disposable device for washing stored RBC with saline without the use of a centrifuge. **Study Design/Methods**: RBC units (n = 15) were obtained from a regional blood center. Samples of stored RBCs were withdrawn from units and diluted with 0.9% saline to a hematocrit (Hct) of 10% to match the dilution in conventional washing procedure; 60mL of the dilute RBC sample were passed through the prototype washing device. Washed RBC product and washing waste were collected continuously at multiple extraction points along the fluidic path of the prototype washing device. The efficiency of washing was quantified by measuring volume, Hct, morphology, deformability, free hemoglobin, and total protein for both washed RBCs and washing waste. **Results/Findings**: The current prototype of the washing device operating at 5.0 mL/min produced 24.7 ± 1.3 mL of washed RBC product with Hct of 21.7 ± 0.8% and 28.3 ± 1.3 mL of washing waste with Hct of 0.7 ± 0.6%. Importantly, the prototype was able to remove ~50% of the initial volume as waste with minimal RBC loss, while operating at a practical throughput. Earlier versions of the device operating at 0.5mL/min produced washed RBC product with Hct of 36.7 ± 3.4% and washing waste with Hct of 3.4 ± 0.7%, while removing 79.7 ± 2.7% of free hemoglobin and 92.4 ± 0.04% of total protein, and improving deformability of washed RBCs by 22.03 ± 4.21%. The washing efficiency of our device was not significantly different than that performed using conventional centrifugation. **Conclusion**: Our simple, disposable device could potentially replace the use of centrifugation for washing of stored RBCs and therefore could enable bedside washing of all transfused RBCs, without altering current blood collection, storage and transfusion practices.

SP35

Effect of Liposome Treatment on the Hemostatic and Immune Profile of Stored Red Blood Cells

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Background/Case Studies: Human red blood cells (RBCs) stored in blood banks under hypothermic conditions (1-6°C), undergo a series of biochemical and biomechanical alterations, known as the "storage lesion". Liposomes have been shown to improve RBC *in vitro* quality by minimizing storage-induced membrane damage. *In vivo* studies have demonstrated that liposome-treated RBCs do not negatively affect the transfusion outcomes in an anemic rat model and result in a safe transfusion product. However, further questions remain on the effect of liposome modification of RBC membrane on potential pro-inflammatory immunohematologic activity and hemostatic responses. **Study Design/Methods**: Unilamellar liposomes were synthesized using an extrusion method to contain lipid bilayer of unsaturated phospholipids (DOPC:cholesterol, 7:3 mol%, 200 nm). Packed CPD/SAGM human RBCs (n = 6) were incubated for 1 h at 37°C with either HEPES-NaCl solution or 2 mM DOPC liposomes, and used immediately after treatment (fresh) and after 42 days of hypothermic storage to evaluate the inflammatory response. Adhesion molecules expression (VCAM-1 and E-selectin) from pre-activated (LPS-stimulated) and non-activated human umbilical vein endothelial cells (HUVECs) was measured by flow cytometry. A monocyte monolayer assay was used to evaluate immunomodulatory potential by examining erythrophagocytic responses of mononuclear cells. A mixing study in a coagulation analyzer was used to evaluate hemostatic response through clotting time (PT and aPTT). **Results/Findings**: Fresh (day 2) supernatants of control and liposome-treated RBCs induced similar expression of VCAM-1 (7.1 ± 3.6% vs. 5.2 ± 1.2%, p=0.237) and E-selectin (9.2 ± 4.9% vs. 7.3 ± 1.0%, p=0.402) in non-activated and pre-activated HUVECs (VCAM-1: 6.0 ± 3.2% vs. 5.2 ± 3.0%, p=0.653; E-selectin: 11.2 ± 1.0% vs. 15.9 ± 4.8%, p=0.083). After 42 days of storage supernatants of control and liposome-treated RBCs induced similar expression of VCAM-1and E-selectin in non-activated and pre-activated HUVECs (p>0.05). The phagocytic index was zero for both fresh and stored control and liposome-treated RBCs. PT results were comparable at day 2 (19.2 ± 0.8s vs. 19.8 ± 1.9s, p=0.471) but significantly decreased in stored supernatants from liposome-treated RBCs compared to control (16.7 ± 0.6s vs. 18.7 ± 0.6s, p=0.003). The opposite occurred for aPTT which was slightly decreased at day 2 in supernatants from liposome-treated RBCs compared to control (41.1 ± 1.2s vs. 43.0 ± 0.8s, p=0.043) but at day 42, a significant difference was no longer observed (43.9 ± 1.1s vs. 45.3 ± 1.0s, p=0.106). **Conclusion**: The membrane changes promoted by liposome treatment during storage did not negatively affect pro-inflammatory profile of stored red cells. However, supernatants showed slightly enhanced clotting response, warranting further investigations.

SP36

Analysis of Hemolysis in Stored Lipemic Red Cell Concentrates

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Background/Case Studies: Red blood cells are highly susceptible to lipid peroxidation and oxidative stress processes that occur during storage of red blood cells and contribute to hemolysis. It is described in literature that very lipemic plasmas induce increased hemolysis in red cell concentrates (RCCs) during storage. Objectives: To evaluate the degree of hemolysis in the RCCs whose plasmas had a lipemic appearance on visual inspection. **Study Design/Methods**: A total of 31 units of RCCs, leukoreduced and stored in saline-adenine-glucose-mannitol (SAG-M) for 42 days, with a mean volume of 264 ml and 12.9% from male donors were analyzed. The analysis was performed in three samples from different storage periods: Period 1 (between 1 and 5 days) Period 2 (15-20 days) and Period 3 (35-42 days). The degree of hemolysis was determined by the HemoCue Plasma/Low Hb system, using the following formula:
Hemolysis rate (%) = supernatant Hb (g/L) x (100-Hct(%))/(Total Hb (g/L)).
Total cholesterol (CHOL), triglycerides (TRIG), and high density lipoproteins cholesterol (HDL-C) were determined enzymatically following the instructions of the manufacturer, using the Dimension ®EXL analyzer (Siemens Healthcare Diagnostics.Inc.®). The study was also performed in a control group of 12 RCCs whose plasmas had a normal appearance on inspection. **Results/Findings**: The results of the lipemic units were compared with the control group. Lipemic RCCs exhibited a higher mean hemolysis rate during the first period compared to the control (difference, 0.16%); the same result was observed in Period 2. However, at the end of the storage period the difference was greater (0.28%). In the last period, some lipemic RCCs showed percentage hemolysis of more than 0.8%, which is the maximum acceptable limit of hemolysis as per the Council of Europe Guidelines. Lipid levels were different between the two groups. Total CHOL was 5.7 mg/dl higher, HDL-C 32.3 mg/dl lower, and TRIG 670.8 mg/dl higher in cases with lipemic plasma compared to the control. **Conclusion**: Although the number of samples is small, in all 3 periods of storage the degree of hemolysis was higher in the lipemic RCC group than the control. There was no significant difference in total CHOL levels between the two groups but there was in TRIG levels (p <0.001). This suggests that the cause of hemolysis is likely to be triglyceride-rich lipoproteins. Visual inspection of the RCCs in the Blood Bank routine is important in quality control, and allows the segregation of those RCCs that can potentially present hemolysis or a milky appearance due to lipemia.

SP37

Increases in Temperature within the Recommended Range Increase *in vitro* Hemolysis of Canine Red Blood Cells over 42 Days of Storage: A Pilot Study

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Background/Case Studies: According to FDA regulations (CFR 640.11), red blood cells for transfusion (RBCs) must be stored at 1-6°C, and for up to 42 days depending upon the preservative. With increasing storage time, human and canine RBCs experience *in vitro* and *in vivo* hemolysis, releasing cell-free hemoglobin (CFH) and non-transferrin bound iron (NTBI). In a canine model of sepsis and RBC transfusion, these increases in CFH and NTBI over time were associated with significantly increased mortality. Observational human studies suggest that the oldest stored units increase risks of RBC transfusion. We sought to determine in canine RBCs if increases in storage temperature within the recommended ranges affect the release of CFH and NTBI over 42 days of storage. **Study Design/Methods**: Sixteen commercially available canine universal donor RBC units, leukoreduced and collected into AS3, were randomly assigned to be stored for 42 days at a fixed temperature of 2°C (n=4), 4°C (n=4), 6°C (n=4), or at a temperature range alternating between 2 and 6°C with daily variations within that range (n=4). All bags were sampled for CFH and NTBI levels every 7 days following a sterile procedure. **Results/Findings**: All RBC units presented significant increases in the levels of CFH and NTBI during the 7 to 42-day storage interval. The progressive increase in CFH from 7 to 42 days was significantly greater in RBC units stored at 6°C compared to 4°C ($p<0.0001$), and significantly higher in RBC units stored at 4°C compared to those stored at 2°C ($p=0.04$). The increase in NTBI from 7 to 42 days was significantly higher in units stored at 6°C compared to those stored at 4°C and 2°C ($p<0.0001$ for both). CFH and NTBI levels increases during storage were not significantly different for RBCs units stored at a variable temperature between 2-6°C in comparison to 4°C (p=ns). **Conclusion**: Increasing storage temperature within the recommended range of 2 to 6°C profoundly increases the degree of *in vitro* hemolysis of canine RBCs and increases the release of CFH and NTBI. These are average values and do not indicate to what degree individual units might be susceptible to temperature variation. Variation of storage temperature within the accepted range could be an important factor compounding release of CFH and iron during RBC storage and increasing the risks associated with transfusion of older stored canine RBCs observed in the sepsis-transfusion model. Similar studies with human RBCs are in progress.

SP38

AS-7 (SOLX) Improves Quality of Stored Red Blood Cells Compared to CPD-1 and AS-1

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Background/Case Studies: During storage, several biochemical and morphological changes occur in red blood cells (RBCs). These changes are associated with increased morbidity and mortality in transfused patients. This study evaluates the role of RBC additive solutions (AS) to improve the quality of RBCs during storage. **Study Design/Methods**: Blood was collected from healthy rats (250 g, 12 mL), leukoreduced, and stored according to manufacturer instructions (4°C for 35 days). Fresh blood was collected with the same procedure and used within 1 hour after leukoreduction. Three AS were evaluated, namely Citrate, phosphate, dextrose adenine solution (CPDA-1); AS-1; and AS-7 (SOLX). Biochemical parameters measured included extracellular K+, pH, hemolysis, 2,3-diphosphoglycerate (2,3-DPG), oxygen affinity, ATP, and lactate. Mechanical properties measured included RBC deformability, RBC elongation index (EI), RBC membrane shear elastic modulus (SEM), mean corpuscular volume, viscosity, and aggregability. Storage-induced changes were measured weekly and compared to fresh blood and between AS solutions. **Results/Findings**: There were no statistical differences in biochemical or mechanical parameters at baseline and after one week of storage. However, after two weeks of storage, AS-7 preserved biochemical and mechanical properties compared to CPDA-1 and AS-1. Changes were statistically significant in most of the parameters studied after 14 days of storage (Table 1). AS-7 prevented extracellular K+ increase, reduced acidosis, showed lower cell-free Hb, preserved 2,3-DPG and ATP levels (consequently prevented the drop in P50), and reduced lactate. AS-7 also prevented the reduction of RBC deformability, preserved the EI at multiple shear stress, and also prevented the increase in membrane SEM, aggregability, and viscosity, compared to blood stored in CPDA-1 and AS-1. **Conclusion**: AS-7-stored RBCs showed reduced biochemical and mechanical changes compared to CPDA-1 and AS-1 as early as two weeks after storage. Our results confirmed previously reported in vitro changes in in vitro changes of rat RBC rheology and oxygen affinity upon storage in CPDA-1 after two weeks of storage.

SP39

Storage Solution for Rare Frozen RBCs

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Background/Case Studies: A blood center using standup LN_2 freezers to house metal canisters containing frozen RBC inventory incurred annual high costs associated with LN_2 usage, maintenance, and repair. The vast distance from the LN_2 tanks to the freezers resulted in a large volume of LN_2 loss, and the upright design caused temperature fluctuations when accessed. Tracking was also an issue, as the location of each canister was manually documented, and, when units were relocated due to temperature excursions, the urgency often resulted in tracking loss and additional time locating products would follow. Locating a unit took one hour of production time. **Study Design/Methods**: The lab recently replaced the freezers with a large LN_2 carousel freezer with accompanying software allowing easy access to RBC canisters positioned in slots on a rotating carousel. Current canister dimensions were no longer adequate for today's storage bags so custom canisters were fabricated allowing streamlined product/segment placement and decreased breakage. The carousel freezer and software system was installed and validated in Oct 2015. It's designed to release small amounts of LN_2 into copper pipes which cool the internal environment creating less frost buildup. Software allows staff access to add, remove and relocate RBC canisters into designated slots in the carousel by entering or scanning the blood ID. The system records blood ID, location, date/time, and staff tech IDs for all actions. When a product is needed, the blood ID is entered and the carousel automatically rotates to the position where the canister is located. **Results/Findings**: This has resulted in a significant reduction in LN_2 usage and making retrieving a unit 95% quicker (2.17 minutes). **Conclusion**: The decrease in LN_2 costs has established a ROI of 1.8 years.

SP40

The Antioxidant Defense System of Erythrocyte Concentrates is Increased during the First Week of Storage

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Background/Case Studies: Red blood cells (RBCs) suffer from lesions during their cold storage. They are in part due to an imbalance between antioxidant (AO) defenses and reactive oxygen species (ROS) resulting in

oxidative stress. The quality of erythrocytes concentrates (ECs) depends on the ability of RBCs to fight against lesions. Whereas the impact of ROS is in part quantified, the AO power (AOP) of ECs has been poorly reported during storage. **Study Design/Methods**: Fourteen ECs (from independent donors, 9 males, 5 females, 8 O Rh+, 5 A Rh+, 1 O Rh-) were prepared in saline-adenine-glucose-mannitol solution, leukoreduced and stored at 4°C for 42 days. AOPs were determined based on electrochemical measurements using disposable electrode strips in ECs, extracellular and intracellular medium, over a 42-day period, and compared to an ABTS-based total antioxidant capacity assay. Additionally, hematological data, microvesicles, hemolysis and extracellular uric acid were also recorded. **Results/Findings**: Hematological parameters were as previously described in the literature for RBC ex vivo aging. The AOP of ECs and extracellular samples behaved similarly and rapidly reached a maximum during the first week before a slow decay ($n = 14$), whereas AOP of the intracellular contents constantly decreased ($n = 3$). This evolution corroborates with the reported metabolism pattern exhibiting three stages. In addition, AOP values were fitted with two kinetic models to quantify the AOP evolution. **Conclusion**: AOP behaviors were recorded using a chemical and an electrochemical-based technique in ECs and the AOP showed a marked and unexpected increase during the first week of storage. The electrochemical method gives the advantage to directly monitor the AOP in EC samples (i.e. in presence of hemoglobin). These results suggest that the oxidation-reduction balance of RBCs is controlled and that RBCs are able to respond to their change of environment (i.e. RBCs in a poorer oxidative stress environment or stimulated by the blood product preparation), at least during the first few days. Knowing the origin and effect of this elevated AOP on RBCs could be beneficial for the storage quality and will have to be further studied.

SP41

Device to Assess Banked Blood Quality

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Background/Case Studies: In 2011, nearly 5 million individuals utilized 15 million units of banked blood in the United States alone. Blood shortages are expected globally due to reduced blood donation, the growing elderly population, and the increase in life expectancy. In addition, blood from different donors is not equal and thus there are differences in quality and deterioration rate. However, there is no clinical or experimental instrumentation that quantitatively assesses the biochemical and mechanical characteristics of blood before it is transfused. **Study Design/Methods**: Randomly selected RBC units collected at the San Diego Blood Bank were examined for inter-donor variability in biochemical and mechanical storage lesions over 6 weeks of storage. In vitro RBC quality was assessed by conventional biochemical and oxygen transport assays including, free Hb, K+, ATP, P50 2,3 DPG, lactate, and pH. All tests were performed once a week for 6 weeks. Deformability was measured using the cells filtration method. Cell suspension was adjusted to 10% Hct and forced through a membrane filter with 5.0μm pores and into a 1ml syringe at various flow rates. **Results/Findings**: There were no statistical differences in biochemical or mechanical parameters at baseline and after one week of storage. Changes were statistically significant between donors in most of the parameters study after 14 days of storage. Furthermore, statistically significant differences in RBC filterability (representative of the biomechanical properties of RBCs) between donors were observed as early as one week after storage ($p < 0.05$). Additionally, there was a net increase in filterability over time for RBCs of all donors, and the rate of filterability increase (i.e. deterioration rates) was different between donors ($p < 0.05$). Changes in all biochemical parameters, including K+, ATP, P50 2,3 DPG, lactate, and pH were statistically different between donors ($p < 0.05$). **Conclusion**: Current time-dependent methods of blood quality determination fail to take differences between donors in rates of deterioration for various biochemical and biophysical properties of RBCs into account. The stored blood quality diagnostic device is able to quantitatively and quickly define blood quality as demonstrated by the statistically significant differences in the biomechanical and biochemical properties between donors.

SP42

Improvement of Red Cell Quality upon Pathogen Inactivation of Whole Blood using Riboflavin/UV light by Deoxygenation

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Background/Case Studies: The application of pathogen inactivation (PI) to whole blood (WB) is hampered by its negative impact on red blood cell (RBC) quality. The generation of reactive oxidative species in RBC products contributes to increased hemolysis. The effect of oxygen (O_2) reduction either of the (WB) unit prior to the PI treatment or of the RBC units after WB treatment on the RBC quality throughout storage was evaluated. **Study Design/Methods**: Six ABO-matched WB units were pooled and split. Within three pairs, one unit was treated with riboflavin/UV light while the other was kept as untreated control. The first pair (Cntr; Cntr-PI) served as the deoxygenation controls; from the second pair (RCCdeox; PI-RCCdeox), the produced RBC units were O_2-reduced, while the WB units of the third pair (WBdeox; WBdeox-PI) were O_2-reduced prior to the PI process. In vitro RBC quality was assessed on days 2, 7, 14, 21, and 42 by measuring hemolysis development using the Harboe method, osmotic fragility reported as the NaCl concentration that produced 50% hemolysis, as well as the supernatant levels of potassium and microvesicles using a potassium electrode and flow cytometry, respectively. **Results/Findings**: Quality of RBCs derived from WB illumination was comparable to a previous study. O_2-reduction efficiency was demonstrated by hemoglobin O_2-saturation $\%sO_2$ (see table). The PI-RCCdeox units exhibited worse in vitro quality for most parameters tested compared to Cntr-PI and WBdeox-PI units throughout storage. On the other hand, hemolysis on days 21 and 42 in units Cntr-PI was significantly ($p<0.05$) higher compared to units WBdeox-PI (see table). These hemolysis data are mirrored by the number of released microvesicles, which were significantly ($p<0.05$) higher in units Cntr-PI compared to units WBdeox-PI on day 42. Potassium levels increased throughout storage, with similar levels at 42 days of 13.7 ± 1.3, 14.3 ± 0.8, and 13.9 ± 1.7 in Cntr, RCCdeox, and WBdeox units, respectively, but were significantly ($p<0.05$) higher and at similar levels in the Cntr-PI, PI-RCCdeox, and WBdeox-PI units. The osmotic fragility was similar within all units until day 21 and similar but significantly ($p<0.05$) higher in units Cntr-PI, PI-RCCdeox, and WBdeox-PI units vs. 0.46 ± 0.01 in Cntr and 0.47 ± 0.01 in RCCdeox and WBdeox units. **Conclusion**: Although the PI effectiveness for treatment of whole blood under reduced oxygen needs to be assessed, deoxygenation of RBCs may help to decrease the reduction in RBC quality caused by treatment with riboflavin/UV light.

TABLE.

study arm	Cntr-PI			PI-RCC-deox			WB-deox-PI		
storage time	day 2	day 21	day 42	day 2	day 21	day 42	day 2	day 21	day 42
s(O2) [%]	55 ±7.2	61.9 ±8.6	77.5 ±10.4	5.0 ±1.5	2.5 ± 1.2	2.6 ± 0.9	7.5 ± 1.5	3.0 ± 1.5	2.2 ± 0.7
Hemolysis [%]	0.05 ±0.02	0.44 ±0.08	1.52 ±0.27	0.11 ± 0.03	0.58 ±0.17	1.55 ±0.31	0.07 ±0.03	0.31 ±0.05	0.99 ±0.05
Microvesicles [#/1,000 beads]	497 ± 163	20,339 ±8,189	99,280 ±15,084	1,286 ± 688	22,100 ±10,445	96,684 ±14,050	474 ± 251	10,568 ±5,196	51,936 ±21,256
K+ [mM]	3.2 ± 0.4	17.2 ± 1.1	19.7 ± 1.8	3.1 ± 0.4	16.8 ± 1.0	19.9 ± 2.0	26.0 ± 0.8	16.3 ± 1.2	18.2 ± 1.8
MCF [C(NaCl)1/2 (%)]	0.46 ±0.02	0.48 ±0.03	0.52 ±0.02	0.46 ±0.01	0.46 ±0.01	0.52 ±0.01	0.45 ±0.02	0.46 ±0.02	0.52 ±0.01

SP43

Red Cell Concentrates Derived from Riboflavin/UV-Treated Whole Blood Exhibit Altered Membrane Protein Profile Compared to γ-Irradiated Red Cell Concentrates

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Background/Case Studies: Post-collection manipulations (PCM) aim to further improve product safety. However, these PCM often improve safety at a cost to product quality. Blood banks must balance product safety and quality, warranting further investigation into biochemical and biophysical changes induced by PCM. This comparative study aimed to catalogue differences in *in vitro* quality parameters and to identify changes in membrane protein profiles among standard-issue, γ-irradiated, and pathogen-inactivated (PI) red cell concentrates (RCCs). **Study Design/Methods**: Three ABO-matched whole blood (WB) units were pooled and split into three identical units. One WB unit was PI-treated with riboflavin/UV illumination prior to RCC production ($RCC^{WB\star}$). Two other WB units were produced into RCCs; one was γ-irradiated (RCC^{γ}) and the other was left untreated as control ($RCC^{\varnothing}$). Hemolysis levels were obtained by the Harboe method. Potassium (K^+) levels were measured on supernatant with a K^+ combination electrode. Mean microvesicle (MV) size was evaluated by dynamic light scattering. Osmotic fragility was determined using a series of saline dilutions, and the sodium chloride concentration that produced 50% hemolysis was reported as mean corpuscular fragility (MCF). RBC morphology was assessed using a 6-stage grading system by light microscopy. Membrane protein profiles of $RCC^{\varnothing}$, RCC^{γ}, and $RCC^{WB\star}$ were assessed on selected hemoglobin-depleted membrane fractions using a quantitative proteomics approach. Group means were compared using two-way ANOVA with repeated measures. **Results/Findings**: $RCC^{WB\star}$ exhibited significantly higher hemolysis than RCC^{γ} and $RCC^{\varnothing}$ at each time point measured ($p<0.01$). Both PCM appeared to enhance initial K^+ leakage and plateau over time, while K^+ level steadily increased in $RCC^{\varnothing}$ with time spent in storage ($p<0.01$). $RCC^{WB\star}$ MV exhibited a larger size ($p<0.01$), while RCC^{γ} and $RCC^{\varnothing}$ produced MV similar in size ($p>0.05$). MCF increased with γ-irradiation and was significantly more pronounced with PI treatment ($p<0.01$). While PI treatment led to a greater reduction in morphology score, both PCM seemed to accelerate deterioration of RBC shape compared to that of untreated control ($p<0.01$). Sixty-five unique protein groups were identified, with $RCC^{WB\star}$ exhibiting significant changes at the membrane protein level compared to RCC^{γ} and $RCC^{\varnothing}$. **Conclusion**: Overall, the *in vitro* parameters and alterations of membrane protein profiles indicated that PI treatment impacts RCC quality more severely than γ-irradiation. These results may help inform development of appropriate guidelines to ensure the safety and quality of $RCC^{WB\star}$. Moreover, the protein profiles can be used to generate mechanistic models of process-induced RBC damage, which may inform future strategies to improve RCC quality.

SP44

Whole Blood Treated with Riboflavin/UV Light: Recombination of Blood Components to Modulate the Pathogen Inactivation Impact on its Hemostatic Function

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Background/Case Studies: Pathogen inactivation (PI) has recently been extended to whole blood (WB). While the illumination of WB exhibits a negative impact on the quality of all derived blood components, it eventually might be a more efficient strategy compared to component treatment. This study evaluated the effect of riboflavin/UV light (Mirasol) on the hemostatic potential of WB using rotational thromboelastometry (ROTEM). Additionally, recombination of blood components prepared from PI-treated and untreated components was used to assess relative contributions to hemostatic function. **Study Design/Methods**: Paired ABO-matched WB units were pooled and split. One WB unit was treated with riboflavin and UV light, while the other unit was kept un-treated as a paired control. Samples were drawn 24 hours after illumination and analyzed by ROTEM after adding Kaolin and tissue plasminogen activator to standardise coagulation and fibrinolysis, respectively. For reconstitution of blood, individual blood components were prepared by differential centrifugation and combined in different ratios. In parallel to the hemostatic potential, P-selectin expression on the platelet surface and metabolic parameters were determined. **Results/Findings**: The metabolic parameter profile did not change significantly after illumination; the activation level of platelets was significantly increased after illumination (% PLTs positive for CD62P was 27.5 ± 3.2 compared to 20.9 ± 2.2 in the control WB group, $p < 0.01$). Clot-forming time (CFT) was 270 ± 69.0 sec compared to 157.6 ± 15.0 sec in the control WB group, ($p < 0.05$), and maximum clot formation (MCF) was significantly lower for the illuminated WB, 40.8 ± 4.0 mm, compared to 46.6 ± 2.2 mm in the control WB group ($p < 0.05$). The rate of the fibrin-platelet interaction (alpha value), which is primary influenced by the functionality of the platelets and the contribution of the fibrinogen, was consistent and did not change after illumination. The fibrinolysis was slightly increased in the illuminated WB but not significantly. Interestingly, platelet-poor plasma (PPP) from the illuminated WB showed two-fold increase in CFT compared to PPP of control WB group, $p < 0.01$. Reconstitution of the illuminated RBCs and platelets with control PPP in a ratio of 4:1:4 enhanced the hemostatic function of the recombined WB, and showed compatible results to the control WB mainly in CFT, alpha, and MCF. **Conclusion**: This study shows that illumination of WB has a negative impact on clot stability. However, recombining the WB after illumination and substituting the plasma in a fixed transfusion ratio of blood components could mitigate the illumination impact and replenish the shortage of functional clotting factors, which might reflect the transfusion scenario of the illuminated WB.

SP45

The Effect on Red Blood Cell Function after Riboflavin with Visible Light Treatment

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Background/Case Studies: Blood transfusion may cause adverse reactions to recipients, such as transfusion-associated graft-versus-host disease (TA-GVHD) which is often fatal and incurable. Our previous study demonstrated riboflavin with visible light treatment can inhibit lymphocyte proliferation and cytokine secretion. However, the function of red blood cells after riboflavin treatment remains to be evaluated. The aims of the present study was to investigate effect on red blood cells (RBCs) function after riboflavin with visible light (RB+L) treatment. **Study Design/Methods**: Whole blood was collected from randomly selected healthy donors and divided into two aliquots. One was stored at 4 without treatment; the other was added by riboflavin with a final concentration of 100μM and exposed to fluorescent light (centered at 420nm) from both sides by a total energy of 40J/mL. After treatment, the osmotic fragility, free hemoglobin, hemolysis as well as ATP and 2, 3-DPG levels of treated and untreated samples were assayed at once or during storage till Day 42. **Results/Findings**: The results showed that there was no difference in the osmotic fragility between RB+L treated samples and untreated ones. During storage, the average level of free hemoglobin of treated samples was higher than that of untreated ones, but the hemolysis of all samples still meet the clinical standard (<0.8%). Results of ATP and 2, 3-DPG levels showed no significant difference between RB+L treated and untreated samples. **Conclusion**: These results demonstrated RB+L treatment did not cause a significant impact on the structure and

TABLE. ATP and 2,3-DPG levels after RB+L treatment (x±std, n=4)

	0d		7d		21d		35d		42d	
	untreated	RB+L treated	untreated	RB+L treated	untreated	RB+L treated	untreated	RB+L treated	untreated	RB+L treated
ATP (mmol/g Hb)	0.14 ± 0.03	0.12 ± 0.02	0.16 ± 0.03	0.14 ± 0.02	0.10 ± 0.02	0.09 ± 0.02	0.05 ± 0.02	0.04 ± 0.02	0.02 ± 0.01	0.02 ± 0.01
2, 3-DPG (μmol/g Hb)	45.56 ± 8.62	37.66 ± 7.40	4.23 ± 7.45	3.53 ± 2.07*	0.63 ± 1.05	0.67 ± 0.78	1.19 ± 2.07	1.30 ± 2.59	0.01 ± 0.02	0.73 ± 1.18

* indicates that the level of 2,3-DPG present in treated cells is significantly higher ($p < 0.05$) than that in untreated cells.

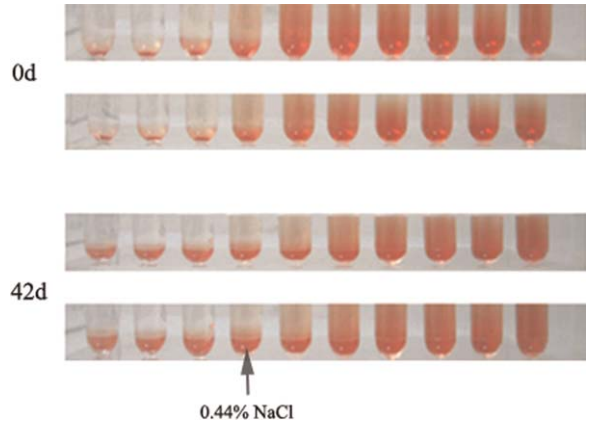

Fig. 1. Osmotic fragility assayed after RB+L treatment and on day 42 of storage.

metabolic function of red blood cells. It might be a promising method for prevention of adverse immune responses caused by WBCs.

SP46

Preserving Red Cell Function by Supplementation of Nitric Oxide from Nitric Oxide-releasing Nanoparticles during Storage

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Background/Case Studies: Human red blood cells (RBCs) can be stored for up to 42 days under controlled conditions. However, during storage, RBCs experience chemical and physical changes, altering their function when transfused. In this study, we investigate the effects of physiological amounts of nitric oxide (NO) delivered using NO-releasing nanoparticles (NOnps) on the biochemical, mechanical, metabolic, and functional changes experienced by human, hamster, and rat RBCs. **Study Design/Methods**: Blood was leukodepleted and anticoagulant with citrate, phosphate, dextrose, adenine solution (CPDA-1) and stored at 4°C. NO supplementation was given every 60 hours, at three different doses of NOnps. Plasma nitrite, nitrate, and nitrosothiol, as well as methemoglobin (metHb) in the cells increased with NOnps dose. **Results/Findings**: NO supplementation slowed down biochemical changes during storage, including: 2,3-diphosphoglycerate, pH, extracellular potassium, eryptosis, and acellular Hb. NOnps preserved RBC mechanical properties during storage, by preserving the membrane elastic module, maintaining the osmotic fragility index, cell elongation index, and corpuscular volume over 6 weeks. Additionally, NOnps preserved the enzymatic machinery that determines RBC glucose consumption. Low-dose NOnps preserved glucose-6-phosphate dehydrogenase (G6PD), hexokinase-phosphofructo kinase (HK-PFK), glyceraldehyde 3-phosphate dehydrogenase (GAPD), and pyruvate kinase (PK) activity. The NOnps also extended the capacity of RBCs to produce ATP. However, higher doses of NOnps inhibited glycolysis and depleted energy production. Transfusion of rat cells (which age faster than human cells) stored for 21 days with NOnps increased the percentage of transfused cells that survived for 24 hours from 82 ± 8% to 94 ± 4%. **Conclusion**: In conclusion, the NO released form the NOnps preserved erythrocyte functionality in all species, by delaying storage changes without oxidizing Hb and by preserving oxygen-carrying capacity.

TABLE.

Process	Antibody-positive Donors	AS-3 Aliquots Negative After Processing
Hard spin	71	20 (28.2%)
Soft spin	77	8 (10.4%)
No spin (apheresis)	1	1 (100%)
Total	149	29 (19.5%)

SP47

Analysis of Red Blood Cell Unit Product Manufacturing Techniques to Remove Donor Red Blood Cell Antibodies

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Background/Case Studies: Transfusion of blood products from donors with clinically significant red blood cell (RBC) antibodies requires additional labeling and serologic compatibility testing; due to the burden of these activities, units with antibodies are often discarded. Donor antibody screening is performed using phlebotomy samples, however, during RBC unit manufacturing, most of the plasma is removed and the remaining is diluted in additive solution (AS). We sought to determine if the manufacturing process yields RBC units without detectable red cell antibodies. The primary goal was to provide the opportunity to safely use processed RBC units that are drawn from donors with RBC antibodies for routine transfusion that are currently discarded. **Study Design/Methods**: Initial antibody detection testing of the donor EDTA sample was performed using a pooled two-cell screen test (Galileo Neo, Immucor, Norcross, GA). Antibody positive donor samples were retested along with a sample of supernatant from the processed RBC unit (AS-3, Haemonetics, Braintree, MA) created by one of two manufacturing processes: hard and soft centrifugation. The concurrent testing was performed by the same technologist. The difference between the proportions of RBC units that were found to be antibody negative following the two different processing methods was calculated by two-tailed Z-test. **Results/Findings**: Of 149 donors found to have RBC antibodies, 29 (19.5%) of the processed RBC units were negative for RBC antibodies. The hard-spun centrifugation process yielded significantly more RBC units with negative antibody screen after processing than the soft-spun process (28.2% vs 10.4%) ($p=0.006$). **Conclusion**: RBC antibodies become undetectable by a two-cell gel screening method in a significant portion of RBC units processed from donor positive whole blood collections. Use of these units with negative screen from segments would result in less product wastage. Further, directing antibody positive donor units to hard-spin manufacturing process will increase the number of usable RBC units and prevent manufacture of wasted platelet products.

SP48

Processing Buffy Coats to Enhance Lymphocyte Yield using a Semi-Automated Method

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Background/Case Studies: Lymphocytes from buffy coat preparations are in greater demand for oncology research. While manual separation can be labor-intensive, the CompoMat® G5 (Fresenius Kabi) separates the buffy coat layer from whole blood in an automated manner. **Study Design/Methods**: We validated programs to optimize the approximate sensitivity, speed, and force used in CompoMat® G5 component separation protocols for enhancing lymphocyte recovery. We collected 20 non-leukoreduced whole blood (WB) units in Fenwal Triple Blood-Packs™ and analyzed hematology samples on the COULTER® A^{c}T diff2™ (Beckman-Coulter) before and after component separation. For the separation protocol, WB units were hard spun in the Sorvall™ RC3BP Plus (Thermo Scientific) at a speed of 3800 RPM for 7 minutes and then loaded onto a CompoMat® G5 for separation of plasma and buffy coat components. The red blood cells plus additive solution remaining in the original bag were sealed off. The plasma-buffy units were hard spun again at 3800 RPM for 7 minutes and loaded onto the CompoMat® G5 to separate the plasma and buffy coat products. **Results/Findings**: On average, 44% of white blood cells (WBC) in the WB units were recovered in the buffy coats with a 5.1X factor of concentration for lymphocytes. The average total yield of WBC was $3.1X10^9$ in WB and $1.3X10^9$ in the buffy coats. Lymphocytes and monocytes had the greatest percent recovery by cell type with our protocol. See Table. CompoMat® G5 separation saves over 4 minutes of technician labor per buffy coat compared to manual processing thus allowing technicians to process multiple units at one time. **Conclusion**: Automated buffy coat processing with the CompoMat® G5 allows adequate recovery of WBCs, particularly lymphocytes and monocytes, with reduced technician labor. Improving efficiency is useful given a 546% rise in requests for buffy coats at our center from fiscal years 2014 to 2015. We are investigating further enhancements such as implementing quadruple bags to salvage currently discarded plasma and further optimizing spin settings.

TABLE.

	WBC	Lymphocytes	Monocytes	Granulocytes	Platelets
Average Number of Cells per Microliter (WB)	6,105	2,202	285	3,894	195,050
Average Number of Cells per Microliter (Buffy Coat)	23,710	11,335	1,155	11,220	976,450
Percentage Recovery	44	58	59	38	55

SP49

A New Approach to Chill and Ship Whole Blood

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Background/Case Studies: Recently, our organisation implemented the 500-mL whole blood (WB) Leukotrap RC System (Haemonetics Corp.). WB units collected with this system have to be processed within 8 hours of collection, or else they have to be rapidly chilled below 10°C. Since many of our blood drives take place at distant locations that are remote from our processing centers, WB processing within 8 hours was operationally impossible. Moreover, WB transport is subjected to difficult climatic conditions during winter and summer. The objective of this study was to develop a portable refrigeration system that is able to meet the manufacturer's recommendations for WB transport within a changing climatic environment (−35°C to 40°C) and for extended transport periods (3h to 24h). **Study Design/Methods**: A vacuum-insulated panel (VIP) box combined with commercial ice packs (Cryopak, Edison, NJ) was used in different configurations. Internal temperature profiles were measured using thermocouple probes positioned inside collection bags filled with 555 mL of 0.9% saline. These bags were warmed up to 35°C to mimic freshly collected whole blood temperature. Up to 4 bags were packed in VIP boxes and exposed to external temperatures of −35°C and 40°C for 24 hours. Temperature profiles for the different packaging methods were compared according to the cooling rate and transport time (maximal time interval where temperature was maintained between 1°C and 10°C, including an initial cooling period). The configuration presenting the best performances was validated with WB units (n=299) that weretransported by following standard operations. Residual leucocyte counts and percentage hemolysis were measured. **Results/Findings**: The best performances were obtained with one central ice pack in direct contact with collection bags. This setup was maintained in VIP boxes with a specially designed ardboard insert. Saline bags reached 10°C in 3.2 ± 0.8 hours at −35°C, while transport time was 13.4 ± 1.2 hours. At 40°C, 5.4 ± 2.6 hours were needed to reach 10°C, and transport time was 22.6 ± 1.6 hours. During validation, leukoreduced RBCs obtained using this configuration had a residual leucocyte count of 0.3 ± 0.1 X 10^6 leucocytes/bag and a percentage of hemolysis on day 42 of 0.3 ± 0.2%; these results conform to the Canadian Standards (CSA) of 5 X 10^6 leucocytes/bag and 0.8% hemolysis. **Conclusion**: In this study, we have shown a new and easy way to chill and ship WB. This reusable packing method could help blood banks to improve transport logistics between blood collection sites and processing centers by cooling and keeping WB between 1°C and 10°C for extended periods. Furthermore, WB packed in this configuration could sustain at least 13 hours of extreme temperatures (−35°C to 40°C).

SP50

Development of a Temperature-Monitoring Device to Evaluate Refrigeration Systems Used for Blood Product Distribution Applications

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Background/Case Studies: Storage and transport conditions can have major impacts on blood product quality. For example, whole blood (WB) units must reach a core temperature of between 1°C and 10°C during shipping, and this temperature must be maintained until arrival at the processing facility. Blood banks are frequently facing variable climatic conditions (T_{ext} = [−35°C to +40°C]), which represent an impressive challenge regarding temperature control, especially for blood collections taking place at locations far from the processing center. However, the development of packaging methods and quality control operations for transport boxes represents a major challenge for blood suppliers. The objective of this study was to develop a 3D-printed temperature-monitoring device (TMD) to evaluate and compare the insulation and thermal resistance performances of refrigeration systems. **Study Design/Methods**: The fully automated TMD device (10 cm x 10 cm x 10cm) includes a heat generator, an energy sink, and temperature sensors, which are capable of extrapolating thermal losses within a closed environment. The TMD uses the λ-calcus formalism and temperature measurements to evaluate cooling performances of refrigeration systems. The TMD was positioned inside insulating boxes and then used to generate heat and to measure how the almost-closed system responds. As a proof of concept, the TMD was used to compare the insulating performances (IP, C°/W) of 6 different Styrofoam boxes against their respective theoretical reference value. **Results/Findings**: The device was capable of discriminating all systems despite their similarities in shapes and compositions (IP_{B1}: theoretical: 4.32, measured: [4.6, 4.5]), IP_{B2}: 8.68 [7.7, 6.89]], IP_{C1}: 2.25 [2.2, 2.8], IP_{C2}: 4.51 [5.0, 5.1], IP_{D1}: 1.42 [1.2, 1.55], and IP_{D2}: 2.84 [2.41, 2.7]). Further experiments will increase the device's precision and repeatability. The TMD was used to measure thermal insulating performances of Vacuum-Insulated Panel (VIP) boxes used in a blood bank for WB transport and was able to discriminate defective (IP_{d1}: 9.6, IP_{d2}: 10.5 and IP_{d3}: 9.8) from functional (IP_{f1}: 16.6, IP_{f2}: 17.2) VIP systems. **Conclusion**: The TMD alpha prototype presented in this work offers a fast, simple, and reliable way to compare cooling performances between refrigeration systems and blood transport boxes, accelerating validation studies as well as the design-prototype-test cycle of new products.

SP51

Evaluation of the REVEOS Whole Blood Processing System: Quality of Red Blood Cells

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Background/Case Studies: The REVEOS automated system (TerumoBCT) can be programmed to process whole blood (WB) units into 2 or 3 blood components [red blood cells (RBCs), plasma, and interim platelet units (IPU)]. In this study, we investigated the quality of RBC units prepared with the REVEOS system and compared them to products prepared with the ATREUS system (TerumoBCT). **Study Design/Methods**: For this study, WB (450 mL) was collected into the REVEOS blood collection bag. After collection, WB bags were rapidly chilled using cooling Phase 22 packs (TCP Reliable Inc.). RBC units (n=199) were prepared and processed fresh (3-14hrs) or overnight (12-24hrs) with the REVEOS system. RBCs were suspended in SAGM, leukoreduced, and stored at 4 ± 2°C for 42 days. Assays for *in vitro* quality parameters were performed on days 2, 7, 14, 28, 35, and 42. Ten RBC units obtained with the ATREUS process were also analyzed and used as reference process. **Results/Findings**: The RBC unit volume was slightly higher, but not statistically significant, with the REVEOS process than with ATREUS (282 ± 18 mL vs. 274 ± 14 mL). RBC recovery, hemoglobin, and hematocrit met the Canadian regulatory standards with recovery $\geq$85% in all units, hemoglobin $\geq$ 35 g/units in all units, and hematocrit $\leq$ 0.80 L/L for 90% of tested units. Percentage hemolysis was below 0.8% in all units at 42 days. No RBC units exceed the limit of 5 x 10^6 leukocytes/unit, and the residual plasma volume was below the in-house limit of 55 mL. This amount of residual plasma was comparable to that found using ATREUS (21 ± 6 mL for REVEOS vs. 23 ± 5 mL for ATREUS). The levels of ATP, pO2 and pCO2, pH, glucose, lactate, sodium, and potassium, as well as the osmotic fragility index, were comparable to RBC units prepared with the ATREUS system. 2,3-DPG was the only metabolite that showed a difference between the fresh and overnight-held (6.0 ± 1.9 μmol/g Hb vs. 10.4 ± 2.0 μmol/g Hb). **Conclusion**: REVEOS WB processing system is a new technology allowing process automation as well as preparation of RBC, IPUs, and plasma units. Our results show that REVEOS RBC quality satisfies the required standards (CSA-Z902-15). Results of this study are currently used to set the parameters for the validation of the REVEOS WB processing system. Automation of WB processing with REVEOS will surely increase efficiency in our routine operations.

SP52

Non-Destructive Quality Control Testing of Red Blood Cells in a Small-volume Container

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Background/Case Studies: Regulations require that 1% of all red cell components are tested for defined quality characteristics at product expiry. Currently, quality control testing is performed by sampling in a manner which prevents the products from being available for subsequent transfusion. Blood that is collected and ultimately discarded is expensive. Reducing the number of discarded components by changing the sampling technique could lead to significant cost savings. The purpose of this project is to evaluate whether small volume containers can be used to sterily remove and store a sample for QC testing, thereby preventing the need for retention and subsequent discard of the RCC product (non-destructive testing). **Study Design/Methods**: Five SAGM leukoreduced RCCs manufactured using a top/bottom production method were pooled and then split back into two of the original RCC containers (parent units) and forty-eight 10 mL PVC/DEHP small containers. A samples was drawn from one of the parent units on days 5, 14, 21 and 43. At each time point, the full volume of the 10 mL containers were also sampled. The second parent unit was only sampled on day 43 to allow comparison with an unmanipulated unit. All samples were tested for hemoglobin, hematocrit, hemolysis, ATP, glucose, lactate and deformability. **Results/Findings**: Levels of hemoglobin (60.1 ± 1.7 g/unit vs 59.4 ± 0.5 g/unit), hematocrit (0.61 ± 0.01 L/L vs 0.60 ± 0.01 L/L), and hemolysis (0.30 ± 0.01% vs 0.30 ± 0.01%) were consistent at day 43 between the parent unit and the small volume containers. Hemolysis levels increased in the small volume containers (0.13 ± 0.02% at day 5 to 0.30 ± 0.01% on day 43) at a rate that was consistent with what was observed in the parent unit (0.18% on day 5 vs 0.29% on day 43). ATP levels, lactate, glucose, potassium and deformability were not affected by storage in a small volume container. No differences were observed between the two parent units. **Conclusion**: Here we show that samples can be drawn from RCCs and stored for up to 43 d in small volume containers, and that RCCs can be sampled at interim time points during the storage period without affecting the measured levels of hemolysis, hematocrit, hemoglobin, ATP, glucose, lactate or deformability. Non-destructive testing of blood components will reduce the number of collections for our blood system and enable other opportunities (i.e. in process quality control, lot release testing, expanded product characterization) that would enhance our quality system and lead to improvements in transfusion outcomes.

SP53

A Breakthrough in the Prevention of Transfusion Errors: ABO Typing on the Test Tube Connected Directly to the Blood Collection Bag

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Background/Case Studies: The incidence of ABO transfusion error still remains high. From 2009 to 2012 acute hemolytic reactions ABO incompatibility reported in Italy were 28, of which 4 were fatal. The error can occur at all steps of the transfusion chain and can begin at time of donation because of a donor identification error: an oversight can lead to an exchange of the Test Tube (P) destined to ABO typing of the unit. To avoid such an event, in our Blood Bank (BB) we changed our Standard Operative Procedures (SOP) and for over a year have been using a new System for Blood Collection (SBC) with a P inline, used for the ABO typing, directly connected to the collection bag (CB): thus the unambiguous association between units donated and P destined to ABO typing is ensured. **Study Design/Methods**: The SBC used (8203TT, Promedical) is a Triple Top & Bottom 450ml collection set with a P in PVC Medical Grade connected inline to the CB. The P and the CB are labeled at the time of donation. Upon arrival of the CB at the BB, the technician, after checking the correspondence of the CDM of the CB and P tags, and after the breaking of the integrated valve, fills the P directly from the CB, squeezing 2 times. Subsequently the P are detached from the CB, centrifuged at 4000 rpm, and cut at height of 75 mm with the YODA equipment that has a loading capacity of 24 P per cycle and a cutting speed of about 90" per cycle. After P are processed for ABO, Rh, Rh phenotype and unexpected antibodies (Tests) on Autovue Innova (Ortho). **Results/Findings**: To date we have performed 40,810 Tests with P. There were no technical problems with the use of P for the cut, the centrifugation and the storage at 4°C. Most important: no discrepancy was detected between the ABO typing performed with P that is printed on the label of the Validated Bag (VB), and the ABO typing performed with a segment detached from the tubing of VB before making it available for transfusion therapy, according to our final control SOP. **Conclusion**: Transfusion safety is the product of the proper implementation of all steps of the transfusion chain. It begins from the time of blood collection when you run the labeling of donated units and its accompanying samples. The SBC with P inline, is easy to use and eliminates human error of P exchange and is therefore valuable to prevent the risk of an erroneous ABO typing label on the VB. Given the flexibility of the PVC Medical Grade of P that allows high-speed centrifugation and storage at low temperature, it is desirable that in the future we can achieve a SBC in which there is also a P inline with the plasma bag that could replace the test tube accompanying the units of plasma sent to the industry for the production of plasma derivatives on which the industry performs all the serological tests.

SP54

A New, Simple Flow Cytometric Solution to Enumerate Residual Leukocytes in Leucoreduced Blood Products: A Multicenter Study

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Background/Case Studies: The BD FACSVia™ system* is a new flow cytometer featuring a compact optical design, fixed alignment, and pre-optimized detector settings for ease of use. Assisted by an intuitive user interface, daily instrument QC can be accomplished within five minutes. System software features eliminate the need for compensation and improve workflow for sample acquisition and analysis resulting in operational time savings. One of the clinical applications developed for the BD FACSVia system is the enumeration of leucocytes in leucoreduced blood products. Four centers participated in a method comparison study to compare the BD Leucocount™ (LC) assay on the BD FACSVia system with the same assay on the BD FACSCalibur™ system. Three study sites performed an inter-site reproducibility study. **Study Design/Methods**: Method comparison: De-identified leucoreduced platelet (PLT $n = 252$) and red blood cell (RBC $n = 278$) specimens were enrolled in the study. Each specimen was fluorescence labeled in four tubes using BD Leucocount™ reagent in BD Trucount™ tubes and acquired on the BD FACSVia and BD FACSCalibur instruments, respectively. Absolute counts of the residual white blood cells (rWBCs) in PLT and RBC samples were analyzed statistically. Inter-site reproducibility: BD Leucocount™ control cells with two concentration levels (High and Low) of rWBCs in PLTs and RBCs were used to evaluate the inter-site reproducibility of the BD LC assay on BD FACSVia at three sites. Duplicate stained LC control cells were acquired once per day by at least two operators at each site over 20 operational days to measure reproducibility. **Results/Findings**: Method comparison: Deming regression was performed for the rWBC absolute counts on the BD FACSVia vs the BD FACSCalibur instrument. For the PLT samples, the regression slope was 1.01 (95% CI 0.99, 1.03), regression intercept 0.09 (-0.28, 0.45), and R^2 1.00. For the RBC samples, the slope was 1.01 (0.99, 1.03), intercept 0.13 (-0.36, 0.61), and R^2 0.99. Inter-site Reproducibility: The CV% was 6.46% (95% Upper CL 7.16%) for PLT High (16.5 cells/μL), CV% 9.49% (10.52%) for PLT Low (7.3 cells/μL); CV% was 7.51% (8.32%) for RBC High (17.1 cells/μL), CV% 10.76% (11.92%) for RBC Low (6.8 cells/μL). **Conclusion**: The BD FACSVia system reported equivalent results of rWBC absolute counts in leucoreduced PLT and RBC samples compared to the predicate BD FACSCalibur system using BD LC reagent in BD Trucount tubes. The inter-site reproducibility of the BD LC assay on the novel BD FACSVia system met study specifications. The BD FACSVia system and the BD Leucocount assay form an easy to use, affordable solution that provides reliable results and simplifies the workflow for enumerating low concentrations of leucocytes in leucoreduced blood products.*Product not yet available for sale in the US.

SP55

Heterogeneity in Blood Oxygen Saturation as an Underappreciated Driver of Variance in Red Blood Cell Quality

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Background/Case Studies: Recent research focused on understanding stored RBC quality has demonstrated high variability in measures of RBC function and health across units. Studies have historically linked this high

TABLE.

Analyte	SO2 (%)		ATP (μmol/gHb)	Hemolysis (%)	metHb (%)		pH (37°C)
Days	10	42	42	42	10	42	42
Control	70	98	2.72	0.21	0.64	1.10	6.27
Hyperoxygenated	98*	99	2.39*	0.21	0.82*	1.16	6.29*

* $P < 0.05$; Average of 4.

Analyte	SO2 (%)			ATP (μmol/g			hemolysis(%)			metHb (%)			Lactate (mM)			pH (37°		
Days	10	23	42	1	21	42	1	21	42	10	23	42	10	23	42	10	23	42
Control	70±5	96±2	98±0	4.17	3.35	2.72	0.04	0.08	0.21	0.64	0.91	1.10	8.1	14.4	21.0	6.56	6.42	6.27
Hyperoxyenated	*98±0	*98±0	99±1	4.01	*2.95	*2.39	0.05	0.10	0.21	*0.82	*0.89	1.16	*7.4	*13.5	*20.1	*6.56	*6.44	*6.29

Metabolites	Day 1 Storage		Day 42 Storage	
	Pearson's correlation[1]	p-value	Pearson's correlation[1]	p-value
LysoPC 16:0	-0.878	0.002**	-0.717	0.030*
LysoPC 18:0	-0.798	0.010**	-0.818	0.007**
LysoPC 20:4	-0.448	0.227	-0.451	0.223
LysoPC 18:2	-0.301	0.432	-0.253	0.511
LysoPC 18:1	-0.628	0.070	-0.562	0.115
LysoPE 18:0	-0.545	0.129	-0.741	0.022*
LysoPE 20:4	-0.306	0.424	-0.381	0.312
LysoPE 18:2	0.061	0.876	-0.242	0.530
LysoPE 18:1	0.003	0.995	-0.274	0.476
LysoPS 18:0	0.608	0.083	-0.543	0.131
LysoPS 20:4	0.260	0.499	-0.739	0.023*

[1]Linear correlation between log concentration and donor's mean of historical 24-hour recoveries
* p≤ 0.05 and ** p≤ 0.01 by two-sided Wald test of correlation

variability to variations in processing, storage method, and age. More recently, a large number of studies have focused on differences in donor demographics, donor iron sufficiency, and genetic predisposition of the donor to poor storage, particularly through mechanisms of accelerated oxidative damage. A study was undertaken to evaluate a potential additional source of unit to unit variation in stored RBC - the role of variable oxygen saturation levels on blood quality parameters during cold storage. **Study Design/Methods**: Percent oxygen saturation ($\%SO_2$) data from 324 LR-RBC/AS-3 units used for internal and external collaborative research was included in the analysis. Whole blood units were processed into red blood cells, AS-3 added, leukocytes reduced, in compliance with AABB guidelines. LR-RBC/AS-3 products were subsequently analyzed for $\%SO_2$ levels within 3-24 hours of phlebotomy using a Blood Gas Analyzer (ABL90 FLEX Analyzer, Radiometer America). Separately, to evaluate the impact of pre-storage as well as increasing levels of $\%SO_2$ during storage, a pool-and-split study was performed. Four (4) units of LR-RBC/AS-3 were stored in PVC blood bags "as is" (Control), or with addition of O_2 to >90% (hyperoxygenated) within 8 hours of phlebotomy. The Control and Test products were periodically sampled during refrigerated storage up to 42-days and analyzed for pH, $\%sO_2$, pCO_2, MetHb, LAC, and ATP. **Results/Findings**: $\%SO_2$ levels in the LR-RBC/AS-3 were between 10 and 94%, with a mean of 48% (32.7-61.0 IQR). With weekly sampling, the %sO2 in all products increased to approximately 95%-100% in three weeks. Measured blood quality parameters including ATP, % hemolysis, methemoglobin, lactate and pH all indicate that high or increasing $\%sO_2$ levels suppressed cellular metabolism and increased cell degradation. **Conclusion**: The surprisingly high variability in starting $\%SO_2$ levels, and the effect of high oxygen saturation on red blood cell quality indicates that oxygen levels may be an important and underappreciated source of unit to unit variability in red blood cell quality.

SP56

Lysophospholipids Correlate with Historic Post-Transfusion Survival of Human RBCs

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Background/Case Studies: There is significant donor-to-donor variation in how units of RBCs store. It is unclear if known in vitro measures predict post-transfusion circulation. Importantly, no parameters have been described that can, based upon their levels at time of collection, predict post-transfusion RBC circulation after storage. Previous untargeted human and animal studies identified lipid metabolism as a pathway of interest in blood storage. **Study Design/Methods**: Nine human volunteers were identified who had previously participated in at least 2 51-Cr studies, with consistent post-transfusion 24-hr RBC recoveries. Leukoreduced RBCs were collected and were stored; each unit was sampled on days 1 and 42 of storage. Precise quantitation of a panel of 32 lipid metabolites including lysophospholipids (LysoPLs) was carried out on supernatants using a liquid chromatography- tandem mass spectrometry approach. Species of Lysophosphatidylcholine (LysoPC), Lysophosphatidylethanolamine (LysoPE), and Lysophosphatidylserine (LysoPS) were quantified using corresponding 17:1 LysoPLs as an internal standard. Pearson's correlations were calculated as using log concentration and donor's mean of historical 24-hour recoveries. **Results/Findings**: Mean historic 24-hr RBC recoveries (range: 68-92%) negatively correlated with levels of both LysoPC 16:0 ($r = -0.878$, $p = 0.002$) and 18:0 ($r = -0.798$, $p = 0.010$), as measured on day 1 of storage with a false discovery rate (FDR) of 16%. Mean historic 24-hr RBC recoveries also negatively correlated with LysoPC 16:0 ($r = -0.717$, $p = 0.030$), 18:0 ($r = -0.818$, $p = 0.007$), LysoPE 18:0 ($r = -0.741$, $p = 0.022$) and LysoPS 20:4 ($r = -0.739$, $p = 0.023$) on day 42 of storage with an FDR of 24%. Other measured LysoPLs had a range of correlations, but none of statistical significance. **Conclusion**: The current studies find a correlation of levels of LysoPLs, both at time of collection and after storage, with historic 24-hr RBC recoveries. Significant correlations were observed despite a very small number of donors and a relatively narrow overall range of historic 24-hr recoveries. However, follow up studies on more volunteers, with a pre-specified hypothesis, and using 24-hr recoveries on study units, will be required to build and evaluate a predictive model of post-transfusion RBC circulation performance.

SP57

The Effect of Pre-freeze Rejuvenation on Post-thaw Shelf Life of Red Cells

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Background/Case Studies: Processing thawed, glycerolized red cells in a functionally closed system allows for a 14 day post thaw period, if resuspended in AS3. Extension of this shelf life would further simplify the logistics of using frozen red cell concentrates (RCCs) in daily transfusion practice. The aim of this study was to investigate if increasing the energy status of 7 day old RCCs before freezing could further prolong their post thaw shelf life. **Study Design/Methods**: Leukoreduced RCCs in SAGM (n=16) were stored at 2-6°C. On day 8, four RCCs were pooled (n=4), mixed and split. From each pool, two RCCs were incubated with Rejuvesol® (Citra Labs, Braintree, MA) for 1 hr at 37°C. All RCCs were glycerolized using ACP215 (Haemonetics®, Braintree, MA) to a final concentration of 40% (w/v). The

TABLE. Total Adenylate Content (μmol/g Hb)

	SAGM		AS-3	
Day	Control	Rejuvenated	Control	Rejuvenated
0	6.5 ± 0.1	8.5 ± 0.2	6.5 ± 0.1	8.5 ± 0.6
14	6.7 ± 0.3	8.7 ± 0.3	6.6 ± 0.2	8.7 ± 0.3
28	6.3 ± 0.3	8.4 ± 0.4	6.1 ± 0.4	8.1 ± 0.4
35	5.6 ± 0.3	7.5 ± 0.3	5.4 ± 0.4	7.3 ± 0.5
42	n.d.	n.d.	4.9 ± 0.4	6.5 ± 0.5

RCCs were subsequently frozen and stored for at least two weeks at −80°C. After thawing and deglycerolization using ACP 215, from each pair (i.e. one rejuvenated and one non-rejuvenated) one unit was resuspended in SAGM (n=8) and one in AS3 (n=8). During storage at 2-6°C stability (hemolysis) and energy status (total adenylate) of the thawed RCCs were determined. **Results/Findings**: Rejuvenation increased the total adenylate content from 6.5 to 8.2 μmol/g Hb and 2,3-DPG from 1.9 to 30 μmol/g Hb. Rejuvenation did not show a negative effect on hemolysis after thawing, which stayed below 0.8% for 7 days (in SAGM) or 35 days (in AS-3). After storage for 42 days in AS3, total adenylate content in non-rejuvenated RCCs decreased to 4.9 μmol/g Hb (72% of day 1) and to 6.5 μmol/g Hb (96% of day 1) in rejuvenated RCCs. **Conclusion**: Rejuvenation resulted in a 27% increase of total adenylate. Högman et al. (Vox Sang 1985; 48:257-68) have shown a good correlation between total adenylate and *in vivo* survival, in which a total adenylate content of 82% of control warrants a 24 h recovery of at least 75%. Based on a maximum allowed hemolysis of 0.8% and a total adenylate content of >82%, thawed RCCs can thus be stored at 2-6°C for 7 days in SAGM, whereas in AS-3, thawed, prefreeze rejuvenated RCCs can be stored for 35 days.

SP58

Could Bedside RBC Rejuvenation Be a Reality?

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Background/Case Studies: Rejuvenation of red blood cell (RBC) units to restore 2,3-diphosphoglycerate (2,3-DPG) and adenosine triphosphate (ATP) lost during storage is approved by FDA. This process requires incubation with a rejuvenation solution for 1 hour at 37°C and subsequent washing in an approved cell processor making the logistics of rejuvenated RBC supply for clinical use complex for transfusion services. However, autologous cell salvage devices have previously been shown to successfully remove soluble contaminants from stored blood. The objective was to evaluate whether rejuvenated RBC units could be washed using a FDA-approved cell salvage device to remove components of the rejuvenation solution compared to standard blood bank methods. **Study Design/Methods**: Test and Control RBC (leukoreduced CPDA-1 whole blood) were rejuvenated after >35 day storage (rejuvesol™ Red Blood Cell Processing Solution) in a model operating suite using dry-heat methods. Then, RBC were pre-diluted (2000 ml) and washed with normal saline using an apheresis-design cell salvage device (CATS, Terumo BCT) with the "high quality" wash program setting (15 min. wash cycle). In a previously executed study of rejuvenated RBC, controls were incubated at 37°C for 60 minutes using the standard water bath method and washed by a standard blood bank method (2 liters of 0.9% NaCl, 0.2% Dextrose Solution using a COBE 2991, Terumo BCT). Residual hypoxanthine and inosine levels were determined using perchloric acid (PCA) extracts after washing. Inosine washout was determined from the starting volume of inosine. **Results/Findings**: Rejuvenated RBC washed using the CATS device exhibited residual hypoxanthine and inosine levels and washout rates that were comparable to RBC processed using standard blood bank method (COBE 2991) (Table 1). **Conclusion**: Dry-air incubation, coupled with cell salvage device washing appear to effectively wash rejuvenated RBC. Larger studies are needed to confirm this observation for use in a clinical setting at the point of care. Cell salvage devices are available in operating rooms and dry-heat warmers are suitable for use in that setting. This bedside process may provide clinicians another option to remove components of the rejuvenation solution compared to standard blood bank methods. Rejuvesol Solution (50 mL) is FDA approved to be used as an in vitro processing solution for the rejuvenation of a unit of RBC. This protocol is for research only and is not an FDA approved method.

SP59

RBC Rejuvenation: Dry Air versus Water Bath

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TABLE. Average ± SD Values for Rejuvenated and Washed RBCs

	Incubation Method	RBC Washing	Residual Hypoxanthine (μmol/mL)	Residual Inosine (μmol/mL)	Inosine Washout Rate
Control (n=68)	Water Bath	COBE 2991	0.59 ± 0.19	0.32 ± 0.06	97.7%
Test (n=4)	Dry Air	CATS	0.75 ± 0.06	0.12 ± 0.07	99.2%

TABLE. Avg±SD 2,3-DPG and ATP in rejuvenated and Washed RBCs (n=6)

Pre-rejuvenation (Days)	Incubation Method	Pre-RJV	D-0	D-1	D-2	D-3	D-7
Post-REJ ATP (μmol/g Hgb)							
28	H	4.4 ± 0.9	6.8 ± 0.5	8.1 ± 1.2	6.7 ± 0.3	6.7 ± 0.7*	6.0 ± 0.5
28	S	4.8 ± 0.8	7.8 ± 0.7	7.4 ± 0.8	7.0 ± 0.6	6.4 ± 0.3*	6.2 ± 0.8
35	H	4.3 ± 0.6	6.6 ± 1.8	6.8 ± 0.7	6.8 ± 0.7	6.3 ± 0.9†	5.5 ± 0.5
35	S	4.4 ± 0.5	7.7 ± 0.7	7.1 ± 0.9	7.1 ± 0.9	6.8 ± 1.0†	5.9 ± 0.7
42	H	4.0 ± 1.0	5.9 ± 1.3	6.3 ± 0.5	NT		
42	S	3.6 ± 0.5†	6.4 ± 0.1†	5.9 ± 0.2†	NT		
Post-REJ 2,3-DPG (μmol/g Hgb)							
28	H	1.5 ± 0.5	14.2 ± 1.9	12.9 ± 1.5	11.7 ± 1.4	11.4 ± 0.9*	5.8 ± 1.0
28	S	1.8 ± 1.7	15.6 ± 1.3	15.4 ± 0.6	13.3 ± 0.9	12.2 ± 1.1*	6.0 ± 1.8
35	H	0.7 ± 0.6	14.2 ± 2.0	13.8 ± 2.0	13.1 ± 2.1	11.6 ± 1.4†	5.3 ± 1.3
35	S	1.1 ± 0.5	15.9 ± 1.5	14.5 ± 1.8	13.5 ± 1.7	12.4 ± 1.9†	6.0 ± 2.0
42	H	1.1 ± 0.6	14.1 ± 1.9	14.5 ± 1.7	NT		
42	S	1.7 ± 0.9†	14.6 ± 1.8†	14.5 ± 1.2†	NT		

†n=5; *n=3; NT= Not Tested. Fresh ATP Value = ATP 4.5 ± 0.7 (μmol/g Hgb); Fresh 2,3-DPG Value = 13.3 ± 1.9 (μmol/g Hgb). Currently, dry air incubation and post-wash storage (>24 hours) are not FDA-approved for use in the United States.

Background/Case Studies: The addition of a rejuvenation solution to stored Red Blood Cells (RBC) has been shown to increase ATP and 2,3-DPG profiles to fresh levels. The objective was to compare ATP and 2,3-DPG profiles in RBC incubated with rejuvesol™ Red Blood Cell Processing Solution (rejuvesol Solution) using a water bath, Helmer (DH4), or dry air incubator, Sarstedt (Sahara III). **Study Design/Methods**: Six RBC pools, each comprised of 2 units of ABO/RH matched, CPD/AS-1 RBC (leukocyte-reduced), were sub-divided into two equal volume units each with 50 mL of rejuvesol Solution added on day 28, 35, or 42. Paired units were incubated for 60 minutes with agitation at 37°C using a Sahara III (S) or Helmer (H), washed (Haemonetics ACP 215), and stored in AS-3 at 1-6 °C for up to 7 days. Average percent (%) *in vitro* recovery and % hemolysis, average ATP, and 2,3-DPG levels were determined after storage (preRJV), after rejuvenation (postRJV), after washing (D-0), and/or during post wash storage (D-1 through D-7). ATP and 2,3-DPG results were compared to average *Fresh* values (day of collection) determined during a previous RBC rejuvenation study, n=60 (**Table 1**). **Results/Findings**: Percent (%) hemolysis was similar after incubation (H =0.5% or S=0.4%) and after post wash storage (≤0.9% on D-7). *In vitro* recovery was 94.8%. ATP was restored above the average *Fresh* value and was maintained through D-7. 2,3-DPG was restored above the average *Fresh* value and was maintained ≥5.3 μmol/g Hgb through D-7 (**Table 1**). ATP and 2,3-DPG values were slightly higher for units incubated using the dry-air method (S). **Conclusion**: ATP and 2,3-DPG were restored above average *Fresh* values when incubated with rejuvenation solution using the H or S methods. ATP was maintained through D-7 and 2,3-DPG was maintained ≥10.6 μmol/g Hgb (~80% of average *Fresh* value) through D-3.

SP60

Evaluation of Specific Gravity as an Alternative Method to Osmolality for Determining Residual Glycerol Levels in Deglycerolized RBC Products Re-suspended in AS-3

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Background/Case Studies: RBC products suspended in 40% w/v glycerol solution are frozen for up to 10 years before undergoing deglycerolization in preparation for transfusion. Quality control of deglycerolized RBC products often involves determination of the osmolality of the resulting product supernatant to ensure residual glycerol levels do not exceed 1% w/v. However, osmolality testing is not routinely performed at most blood centers. Specific gravity can be easily performed on a small, hand-held device, and may present a faster, more cost-effective method of evaluating a deglycerolized product for adequate glycerol removal. This study seeks to evaluate the use of specific gravity for approximating residual glycerol levels in products deglycerolized on the Haemonetics ACP215 Automated Cell Processor and re-suspended in AS-3. **Study Design/Methods**: Two liquid RBC products were glycerolized and deglycerolized on the Haemonetics ACP215 Automated Cell Processor in a functionally closed system to obtain supernatant solution that best reflected the final glycerol, saline, dextrose and additive solution (AS-3) present in post-deglycerolization products. Neither product was frozen between procedures, however one product was processed with 0.9% NaCl instead of glycerol solution to yield a supernatant known to be free of residual glycerol. Supernatants from both products tested for osmolality and specific gravity after glycerol was added to a final residual glycerol level approaching and exceeding 1% w/v. **Results/Findings**: Osmolality and specific gravity results for each glycerol testing level evaluated are listed in Table. Specific gravity and osmolality measurements increased as glycerol concentration increased ($R^2 = 0.93$ and 0.90, respectively). Baseline osmolality and specific gravity measurements were slightly higher for the unit prepared without glycerol, indicating some interference from an unknown concentration of glycerol in this supernatant. Specific gravity was well correlated with osmolality ($R^2 = 0.93$). **Conclusion**: The results of this study indicate specific gravity and osmolality are both reliable methods of estimating residual glycerol in deglycerolized products prepared with AS-3. Convenience and low cost make specific gravity testing an attractive method to detect unacceptably high residual glycerol levels.

SP61

Frequency of Donation Affects Red Blood Cell Product Quality

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Background/Case Studies: Measuring donor haemoglobin levels prior to whole blood (WB) donation is an essential part of blood service donor screening systems. Donors who do not meet the regulatory minimum haemoglobin concentration are deferred for their own safety. Blood services have a minimum waiting period between subsequent donations to avoid depleting donors of iron. Donor factors such as age and sex have been shown to influence donor haemoglobin levels, as well as being associated with haemolysis in stored red cell concentrates (RCCs). The goal of this project was to examine how the frequency of donation influences pre-donation haemoglobin levels and stored RCC characteristics in different donor groups. **Study Design/Methods**: Donor information (age, sex, pre-donation donor haemoglobin) was compiled for WB donors in the following categories who donated during the month of September 2014: F1: female 18-40, F2: female ≥ 60, M1: male 18-40, M2: male ≥ 60, n = 36,105. For each donor in the database, donor haemoglobin levels were compared based on donor sex, age and number of donations in the preceding 12 months. Regression analysis and analysis of group means was performed. For those donations selected for quality control testing (n = 357), post-storage RCC haemolysis, unit haemoglobin and unit haematocrit were assessed as a function of donor sex, age and frequency of donation. High intensity (HI) donors were defined as those donors who made 3 or more donations in the preceding 12 months as the average number of donations per year for our blood services was 2.1 per year. **Results/Findings**: Frequency of donation was found to have a significant influence on pre-donation donor haemoglobin levels; HI donors were found to have significantly lower pre-donation haemoglobin than low intensity (LI) donors (146.7 g/L and 143.9 g/L respectively, $p<0.0001$). The relationship between frequency of donation and pre-donation donor haemoglobin was much stronger in male donor than female donors (difference in Hb for LI and HI males: 3.9 g/L, R^2: −0.422, difference in Hb for LI and HI females: 1.5 g/L, R^2: −0.072). RCCs from HI donors exhibited decreased unit haemoglobin compared to LI donors. High donation frequency was associated with increased RCC haemolysis in female donors (female LI: 0.24%, female HI: 0.27%, $p<0.05$) and decreased haemolysis in male donors (male LI: 0.28%, male HI: 0.25%, $p<0.05$). **Conclusion**: Frequency of donation was found to influence both pre-donation donor haemoglobin levels and post-storage RCC haemolysis; both of these effects were shown to be dependent on donor age and sex. These physiological differences between donor populations, and the potential influence they have on product characteristics and donor/patient safety need to be considered when making changes donor screening criteria.

TABLE.

Estimated Glycerol Concentration (% w/v)	Standard Glycerolization Preparation		Glycerol-Free Preparation	
	Specific Gravity	Osmolality (mOsm H_2O/kg)	Specific Gravity	Osmolality (mOsm H_2O/kg)
0.0	1.008	323	1.007	295
0.5	1.009	381	1.0085	355
0.8	1.0105	418	1.0095	389
0.9	1.011	427	1.010	399
1.0	1.011	441	1.0105	413
1.1	1.0115	450	1.011	424
1.2	1.012	460	1.011	436
1.5	1.013	502	1.012	473

TABLE. Coagulation factors in plasma before and after the reconstitution of cryopreserved platelets

Coagulation factors (%)	Plasma	Plasma after platelet reconstitution	p value (paired t-test)
FV	88 ± 11	56 ± 11	p<0.0001
FVIII	108 ± 35	113 ± 37	p=0.671
FIX	114 ± 19	95 ± 16	p<0.0001

SP62

Coagulation Factor Binding to Platelets and Microparticles: Potential Mediators of the Procoagulant Activity of Cryopreserved Platelets

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Background/Case Studies: It is well established that cryopreserved platelets release microparticles and express procoagulant phospholipids; which occurs concomitantly with an increased *in vitro* procoagulant activity. As platelet and microparticle surfaces provide a catalytic site for key steps in the coagulation cascade, the aim of this project was to determine the effect of cryopreservation on the interaction between platelets, microparticles and coagulation proteins. **Study Design/Methods**: Platelets were frozen at −80°C with 5-6% DMSO, before being thawed and reconstituted in a unit of plasma. Supernatant samples were collected by centrifugation from plasma prior to platelet reconstitution and immediately after platelet thawing and reconstitution (n=12). Microparticles were removed from the supernatant by filtration using a 0.1μm syringe filter. Protein lysates were prepared from platelets and microparticles before and after thawing. Coagulation activity assays and western blotting were used to monitor changes in coagulation factors. **Results/Findings**: The coagulation factors FV and FIX were significantly reduced in the plasma supernatant following platelet thawing and reconstitution, suggesting that these coagulation factors were bound to platelets upon reconstitution and thus removed when the platelets were pelleted during supernatant preparation (Table). Supernatant FVIII remained unchanged following platelet reconstitution (Table) but was decreased upon removal of microparticles (48 ± 33%;p<0.0001), suggesting FVIII was specifically binding to microparticles generated by cryopreservation. FV was also further reduced in the microparticle-depleted supernatant (45 ± 9%;p<0.0001). In addition, the abundance of protein isoforms of FV, FVIII and FIX present in plasma, platelets and microparticles was altered by cryopreservation, when examined by western blotting. The activity of other coagulation factors (fibrinogen, factors II, VII, VIII, XI, XII, XIII) was not influenced by the reconstitution of cryopreserved platelets. **Conclusion**: These results suggest that cryopreservation alters the platelet and microparticle surface, thereby affecting the way they interact with key proteins of the coagulation cascade. This may contribute to the enhanced procoagulant profile of cryopreserved platelets. It is clinically important to understand the mechanisms of the procoagulant activity of cryopreserved platelets, in order to quantify and mitigate the risk of any potential prothrombotic complications following transfusion.

SP63

Automated Cycle for 10 Hours at 5°C and 2 Hours at 37°C Causes Significant Decrements in Platelet In Vitro Storage Properties

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Background/Case Studies: It has been previously reported that platelets (PLTs) stored under thermocycling conditions programmed to 11 hrs of 5°C and 1 hr of 37°C have improved results for a number of in vitro parameters compared to cold-stored PLTs. In this study, the in vitro properties of PLTs stored in an automated incubator with a cycle of 10 hrs at 5°C and 2 hrs at 37°C were evaluated. **Study Design/Methods**: A single Amicus apheresis PLT unit (n=7) was collected under informed consent. Following 24 hrs after collection and storage with agitation at 20-24°C, 60 mL PLT samples were aliquoted into four CLX storage bags. One bag was stored at 20-24°C (Control-RT) with continuous agitation; a second bag was continuously stored at 4-6°C without agitation (Control-CT); a third bag was held in an automated temperature cycler (11 hrs at 5°C, 1 hr at 37°C with 5 min of agitation) (TC-11); a fourth bag was stored at thermocycling conditions of 10 hrs at 5°C and 2 hrs at 37°C with 5 min of agitation (TC-10). PLTs were sampled on Days 0, 5 and 7 for 15 in vitro parameters. Data were analyzed by ANOVA with repeated measures with Bonferroni corrections. **Results/Findings**: Values of morphology score, aggregation, HSR and pH in TC-10 aliquots were less and oxygen levels and glucose consumption rate were greater than those of TC-11. Mitochondrial membrane potential (MMP) was less in TC-10 aliquots and reactive oxygen species (ROS) production was greater than those in TC-11 aliquots. Binding of CD42b was less and levels of annexin V were greater in TC-10 aliquots compared to those of TC-11. Platelet activation, as measured by binding of CD62P, was comparable between TC-10 and TC-11 PLT aliquots. **Conclusion**: During 7-day storage TC-10 PLT aliquots exhibited increased glycolysis, and diminished values for structural, functional and mitochondrial parameters. A longer warm up period (2 hours) resulted in significant PLT damage during temperature cycling.

SP64

Human Platelets Stored in an Automated Temperature Cycler Between 5°C and 37°C With a Shorter Cold Period Do Not Exhibit In Vitro Property Improvements Compared to Those of a Longer Cold-Cycling Period

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Background/Case Studies: It has been previously shown that platelets (PLTs) stored under thermocycling conditions programmed to 11 hrs at 5°C and 1 hr at 37°C have improved results for a number of in vitro parameters compared to cold-stored PLTs. In this study, the in vitro properties of PLTs stored in an automated incubator programmed to cycle for 11 hrs at 5°C and 1 hr at 37°C were compared to those of a shorter cold cycle of 5 hrs with a 1 hr 37°C warm up period. **Study Design/Methods**: A single Amicus apheresis PLT unit (n=6) was collected under informed consent. After 24 hrs of agitation at 20-24°C, PLTs were aliquoted into four 60 mL samples in CLX storage bags. One bag was stored at 20-24°C (Control-RT) with continuous

TABLE.

Day 7 Samples	pH	Glucose consumption (fmol/PLT/day)	HSR (%)	Aggregation (%)	CD42b (Mean fluorescence)	Annexin V (% positive PLTs)	Morphology (% discoid PLTs)	MMP (% JC-1 red fluoresnce)	ROS (Mean fluorescence)
Control RT	7.13 ± 0.15	0.16 ± 0.04¶	51.2 ± 11.6*	80.5 ± 23.8§	833 ± 197§	12.8 ± 6.1	57 ± 15*	63.1 ± 8.2	35.0 ± 16.3
Control CT	7.39 ± 0.08	0.07 ± 0.03*	16.2 ± 9.9	48.0 ± 19.5	705 ± 118	17.7 ± 6.3	5 ± 1	74.3 ± 6.1	88.5 ± 36.5
TC-11	7.19 ± 0.13	0.13 ± 0.03	24.3 ± 12.6	53.9 ± 16.7	666 ± 119	19.6 ± 6.8	15 ± 4	71.0 ± 5.5	53.7 ± 27.6
TC-10	6.59 ± 0.34*	0.26 ± 0.05*	10.8 ± 8.9¶	14.9 ± 5.4*	520 ± 81¶	52.0 ± 9.0*	2 ± 1¶	31.0 ± 22.9*	565 ± 428§

Values represent average ± 1 SD. *p < 0.001, §p < 0.01, and ¶p < 0.05, compared to TC-11 values.

TABLE.

Day 7 Samples	Glucose consumption (fmol/PLT/day)	pO2 (mm Hg)	pH	HSR (%)	Aggregation (%)	CD62P (% positive PLTs)	Annexin V (% positive PLTs)	Morphology (% discoid PLTs)	ROS (Mean fluorescence)
Control RT	0.16 ± 0.03	150 ± 9	7.08 ± 0.18	57.5 ± 18.5	85.2 ± 21.3	24.7 ± 9.4	12.4 ± 6.6	60 ± 16	36.8 ± 18.2
Control CT	0.06 ± 0.02	208 ± 15	7.38 ± 0.08	13.1 ± 9.6	53.5 ± 10.3	20.5 ± 18.7	18.6 ± 5.6	4 ± 1	78.9 ± 29.2
TC-11	0.11 ± 0.02	198 ± 12	7.20 ± 0.13	28.8 ± 17.0	59.7 ± 10.1	47.0 ± 13.0	17.4 ± 7.9	14 ± 3	49.2 ± 30.5
TC-5	0.16 ± 0.05*	178 ± 12*	7.06 ± 0.23	34.4 ± 13.6	58.5 ± 11.7	47.3 ± 6.7	18.0 ± 10.4	20 ± 4	54.8 ± 24.6

Values represent average ± 1 SD. *$p < 0.05$, compared to TC-11 values.

agitation; a second bag was continuously stored at 4-6°C without agitation (Control-CT); a third bag was held in an automated temperature cycler (11 hrs at 5°C, 1 hr at 37°C with 5 min of agitation) (TC-11); a fourth bag was stored under a shorter cold period of 5 hrs at 5°C and a 1 hr 37°C warm up period (TC-5), 5 min of agitation. PLTs were sampled on Days 0, 5 and 7 for 15 in vitro parameters. Data were analyzed by ANOVA with repeated measures with Bonferroni corrections. **Results/Findings**: The rate of glucose consumption was increased in TC-5 aliquots compared to those of TC-11 and was comparable with those of RT aliquots. Oxygen levels in TC-5 aliquots were less than those of TC-11 and Control-CT samples but were greater than those of Control-RT aliquots. Total PLT content was comparable between all aliquots. Aggregation, HSR, ESC, morphology score, pH levels, mitochondrial membrane potential (MMP), reactive oxygen species production (ROS) along with CD42b, CD62P and annexin V binding were all comparable between TC-11 and TC-5 aliquots. **Conclusion**: Despite better oxygen utilization, increased glucose consumption and trend towards increased morphology scores in TC-5 aliquots compared to those of TC-11, all other in vitro parameters were comparable to those of TC-11 aliquots. Introducing a shorter cold period in temperature cycling did not improve PLT in vitro properties over those obtained with a longer cold period for temperature cycling.

SP65

Increasing Plasma Concentration to 10% in Platelets Suspended in a Bicarbonate-Containing Additive Solution with 5% Plasma Better Maintains pH After a 24-hour Interruption of Agitation

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Background/Case Studies: A previous study demonstrated a significant proportion of pH failures during 7 day storage of PLT suspended in 5% plasma/95% PAS-5 following a 24 hour interruption of agitation (IA) to mimic platelet shipment between days 2 and 3. This study investigates whether increasing plasma levels to 10% improves pH control in PAS-5 suspended PLT subjected to 24 h IA. **Study Design/Methods**: A single unit of apheresis PLT was collected on the Amicus separator from consenting donors with a target yield of 4.2 x 10^{11} with concurrent plasma (n=8). Following a 1-4 hour rest period and 1 hour of agitation, aliquots were transferred into 4 CF-250 containers (Charter Medical) and PAS-5 was added to yield a 33% plasma suspension of ~180 mL. Aliquots were centrifuged at 3800 rpm for 15 min (5.5x10^7 ACE) and as much supernatant as possible was expressed. Plasma and PAS-5 was added to make four aliquots of ~60 mL; two with 5% and 10% plasma each. After a 1 h rest period, aliquots were placed on the agitator. On Day 2, one aliquot with 5% plasma and another with 10% plasma were placed in a stationary shipping container at 20-24°C for 24 ± 1 h and then returned to the agitator while the two control aliquots remained on the agitator. The primary measure, pH and an array of secondary measures were determined from aliquots on Days 2, 5 and 7. **Results/Findings**: Aliquots containing 5% plasma and subjected to the IA had a significantly lower mean pH on Day 7 compared to aliquots containing 10% plasma and subjected to IA (6.60 ± 0.48 vs. 6.96 ± 0.30, p=0.046). With an interruption of agitation, 3 of 8 aliquots containing 5% plasma had pH levels ≤ 6.2 compared to 0 of 8 aliquots containing 10% plasma on Day 7. In continuously agitated control aliquots containing 5 and 10% plasma, mean pH values were similar and pH was maintained >7.0 during 7 day storage. Additional platelet quality characteristics of the aliquots are presented in the table below. **Conclusion**: Increasing plasma concentration to 10% improves pH control during 7 day storage of PLT suspended in PAS-5 after a 24 h interruption of agitation compared to PLT suspended in 5% plasma/95% PAS-5.

SP66

Microparticles Contribute to the Adhesion of Cryopreserved Platelets to Collagen under Shear Stress

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Background/Case Studies: Cryopreservation of platelets is known to affect their *in vitro* quality and function. While cryopreserved platelets have reduced recovery post-transfusion, there is evidence that they may be more effective in reducing bleeding than conventional liquid-stored platelets. To better understand the possible mechanisms for the increased hemostatic effectiveness, the effect of cryopreservation as well as the role of microparticles (MPs) in platelet adherence to collagen under flow conditions was studied. **Study Design/Methods**: Apheresis platelet concentrates were cryopreserved by the addition of 5-6% DMSO and frozen at −80°C. Upon thawing, platelets were reconstituted in thawed fresh-frozen plasma. Pre-freeze and post-thaw samples (n=8) were flow perfused through collagen-coated micro-slide channels at 37°C at a shear rate of 250 s^{-1}. The number of adhered MPs, platelets and thrombi was determined using Image Pro 7.1. Surface markers associated with platelet adhesion and MPs were investigated by flow cytometry. Microparticles were defined as being <1μm and staining positively with CD61 and annexin-V. MP-depleted platelet samples were prepared by differential centrifugation. Non-depleted and MP-depleted post-thaw samples (n=7) were flow perfused as described above. For statistical analyses, paired t-tests were performed. **Results/Findings**: Under shear stress, the number of platelets and thrombi adhered to collagen from pre-freeze and post-

TABLE.

Assay (Day 7)	5% plasma	10% plasma	5% plasma, IA	10% plasma, IA	p*
pH (RT)	7.32 ± 0.11	7.35 ± 0.09	6.60 ± 0.48	6.96 ± 0.30	0.046
Count (PLT/μL x 10^3)	1443 ± 82	1426 ± 42	1427 ± 67	1358 ± 123	0.155
ESC (%)	12.0 ± 5.4	14.6 ± 6.6	3.8 ± 4.6	7.6 ± 3.0	0.070
MMP (JC-1, %)	80.9 ± 7.1	80.6 ± 5.9	54.3 ± 25.5	70.3 ± 13.6	0.063
Annexin V (%)	13.0 ± 4.6	13.1 ± 5.1	31.2 ± 18.5	21.0 ± 13.5	0.020
DHE (ROS, %)	26.0 ± 4.7	25.8 ± 6.1	36.5 ± 12.2	28.3 ± 6.4	0.032

*5% plasma, IA vs. 10% plasma, IA.

TABLE. Adhesion of MPs and platelets to collagen under shear stress

		Pre-freeze vs Post-thaw			Post-thaw MPs depleted		
	Category	Pre-freeze	Post-thaw	p-value	Whole	Depleted	p-value
Average number/FOV*	MPs	115 ± 54	284 ± 134	0.01	80 ± 68	17 ± 16	0.02
	Platelets	33 ± 23	96 ± 85	0.08	10 ± 3	5 ± 4	0.03
	Thrombi	1 ± 1	2 ± 3	0.2	0.1 ± 0.1	0.1 ± 0.1	0.2

*FOV = field of view; data represent mean ± SD; significance $p<0.05$.

thaw samples were not significantly different (see table), despite a significant decrease in the MFI of CD61, GPVI, CD29, CD41a and CD42b post-thaw. However, there was a significant increase in the mean number of CD61/annexin-V positive MPs, from 6.5 x 10^9/L pre-freeze to 209.8 x 10^9/L post-thaw ($p < 0.0001$), and an increase in MPs adhered to collagen post-thaw. Depletion of MPs from the post-thaw samples resulted in a significant decrease in the number of platelets and MPs adhered to collagen under shear stress (see table). **Conclusion**: Cryopreservation results in the decreased expression of platelet surface markers that mediate platelet adhesion and aggregation. MPs from cryopreserved platelets facilitate adhesion of reconstituted cryopreserved platelets under shear stress conditions. This study provides insight into the important functional role MPs may play in hemostasis when cryopreserved platelet products are transfused.

SP67

Strategies for Improving Stored Platelet Products

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Background/Case Studies: Bacterial contamination of platelet products poses a major threat to transfusion recipients and limits platelet storage at room temperature (22°C, RT) to 5 days. As a result, pathogen reduction technologies (PRT) and platelet additive solutions (PASs) have been developed. Refrigeration of platelets (4°C, 4C) also reduces the risk for bacterial contamination, but leads to aggregate formation. Currently only two apheresis and PAS systems are approved for use in the US: Trima and Isoplate (Terumo BCT) and Amicus and Intersol (Fenwal), respectively. It has been reported that platelet storage for 15 days in Intersol PAS (collected on Trima) at 4C prevents aggregate formation and shows aggregation responses superior to RT, but data with Isoplate (ISO) platelets collected on Trima has not been reported. In this study, we evaluated the state of platelets collected via Trima and stored in ISO at 4C for up to 15 days. We also examined the effects of Mirasol PRT-treatment on PAS platelets. **Study Design/Methods**: Apheresis platelet units were collected from healthy donors and divided into 65% Isoplate/35% plasma: (1) stored without agitation (ISO) and (2) stored with agitation (ISO+AG). Both platelet groups were stored at 4C and platelet quality (pH, lactate, counts), flow cytometry (phosphatidylserine (PS) exposure, CD62P), and aggregating function (ADP, collagen, epinephrine, thrombin) were assessed on Days 1, 5, 10, and 15. In a separate set of experiments, AP were collected into ISO and divided into: (1) untreated, stored at RT, (2) PRT-treated, stored at RT (RT-PRT), (3) untreated, stored at 4C, and (4) PRT-treated, stored at 4C (4C-PRT). Platelets were assessed for aggregation, platelet quality, aggregate and microparticle formation, and flow cytometry (activated GPIIb/IIIa, PS) on Days 1, 3, and 5 of storage. Data were reported as means±SEM and analyzed using one and two-way ANOVA with post-hoc Tukey test. **Results/Findings**: ISO+AG platelets showed decreased pH at Day 15 (6.7 ± 0.1) of storage compared to Day 1 (7.0 ± 0.0) whereas no difference was observed in ISO samples throughout storage. Day 15 ISO platelets showed comparable lactate levels (4.7 ± 0.1) to that of Day 10 ISO+AG (6.0 ± 0.4). Platelet counts remained stable and aggregation responses for all agonists were comparable between ISO and ISO+AG samples. Increased GPIIb/IIIa activation was observed in Day 3 RT-PRT (14 ± 5%) and Day 5 4C-PRT (22 ± 6%) compared to Day 3 RT (2 ± 0.3%) and Day 5 4C (4 ± 0.1%) controls. Aggregation response was reduced in RT-PRT while 4C-PRT retained function out to 5 days. PS was also increased in RT-PRT and 4C-PRT samples. **Conclusion**: Platelets stored at 4C in ISO without agitation retain function, metabolism, and cell counts out to 15 days of storage. Though PRT activates fibrinogen receptor and increases PS, 4C storage maintains responsiveness better than RT in PRT platelets.

SP68

Establishing a WBC Value from a Hematology Analyzer to Predict Possible Residual White Blood Cell Failures in Single-donor Platelet Products

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Background/Case Studies: Due to an increase in residual white blood cell (rWBC) monthly quality control (MQC) failures for Single-Donor Platelet products (SDP), a screening process was developed to help identify non-leukoreduced products. Although tested routinely by flow cytometry, a correlation between rWBC failures and the product WBC count from the hematology analyzer was observed. A WBC count of ≥ 0.30 x 10^3/uL was established to select products that might not meet leukoreduction standards and confirmation was performed by Flow Cytometry. This allowed us to identify non leukoreduced products that would have been missed during random MQC. Residual WBC failures continued to be observed in products that contained ≤ 0.30 x 10^3/uL, indicating the need to reevaluate the established WBC cutoff value. **Study Design/Methods**: The BD FACSCalibur was used to determine rWBC by Flow cytometry. The Sysmex hematology analyzer was used to count WBC in the SDP products. Originally, if the product WBC count was ≥ 0.30 x 10^3/uL the sample was sent for rWBC testing by Flow cytometry. After further QC failures, the cutoff for confirmatory testing was lowered to ≥ 0.10 x 10^3/uL. In August 2012 we established "Flag" to enter in our BECS for tracking of these products. **Results/Findings**: After establishing the ≥ 0.10 x 10^3/uL cut-off from the hematology analyzer, 2 years of data was evaluated. It was found that if the WBC count was between 0.10 - 0.59 x 10^3/uL, the product was often non leukoreduced. These samples were tested for rWBC by Flow cytometry and 91% were non leukoreduced. However, if the WBC count was ≥ 0.60 x 10^3/uL, 100% of the products were non leukoreduced. **Conclusion**: After implementing these guidelines, we have reduced the number of MQC failures and the possibility of releasing non leukoreduced SDPs. We were able to set a default entry for counts ≥ 0.60 x 10^3/uL and discard these products as 100% are non leukoreduced. Based on the data collected, we will evaluate if the cutoff count for 100% non leukoreduced products can be lowered to ≥ 0.25 x 10^3/uL. It is important to note that none of the units we tested had been flagged by the collection equipment for WBC counts. We think it is important for other centers to evaluate their products more proactively if they are failing rWBC MQC.

TABLE.

Flags 8/2012 - 7/2014 all products tested	Total	Passed	Fail
0.10 - 0.59 x 10^3/uL	112	10	102
>= 0.60 x 10^3/uL	75	0	75
Flags 8/2014 - 4/2016 with default for counts > 0.60	**Total**	**Pass**	**Fail**
0.10 - 0.59 x 10^3/uL	99	11	88
>= 0.60 x 10^3/uL (default count entered)	68	0	68

SP69

Storage Study of Buffy Coat Platelets in Additive Solution After Photochemical Treatment Using a Novel Triple-Storage Set

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Background/Case Studies: A novel triple-storage set is developed to pathogen reduce of double or triple products in a plasma/PAS suspension (up to $12x10^{11}$ platelets in 650 mL).
The objective of this study was to evaluate the in vitro platelet (PLT) function of INTERCEPT PLT (Cerus), processed using a set with 3 storage containers (TS) compared to a single storage container (LV) over 7 days-storage. **Study Design/Methods**: After separation with TACSI system (Terumo BCT), 3 BC platelet concentrates (PC) were pooled. This pool was split back into 2/3 and 1/3 volume units compatible with respectively TS (Test) and LV (Control) INTERCEPT sets. Test units contained about $9x10^{11}$ PLT and control units about $4,5x10^{11}$ PLT, both in 60-62% PAS. Each Test unit (target 645 mL) was connected to a TS set for addition of amotosalen, was UVA illuminated and transferred to a double Compound Adsorption Device (CAD) for agitated storage for 4 hours, and finally split into 3 PC. The same process was applied to the Control units (320 ml) using a LV set and 6 hours single CAD treatment. PLT quality was evaluated in a storage study on Day 1, 3 (not shown), 5, and 7 after donation. **Results/Findings**: Day 1 volume of Test units was 200 ± 4 mL and PLT yield was 2.55 ± 0.13 $x10^{11}$. Respectively for Control units it was 315 ± 10 mL and 4.03 ± 0.22 $x10^{11}$. Results for the storage study are shown in Table 1. PLT in both sets showed a normal metabolism with preserved HCO_3 and glucose reserves at the end of shelf life. Energy reserves were maintained with stable ATP concentration. Results for sCD62p are significantly lower in Test units than in Control units and are stable during storage. RANTES and sCD40L moderately increased with storage in both arms but results are in an acceptable range. Residual amotosalen was <0.5 μmol/L in all Control and Test units. **Conclusion**: The storage study demonstrates acceptable results for the 3 PC from the TS set and the PC from the LV set for up to 7 days of shelf life.

SP70

Quality Control of Apheresis Platelets: A BEST Collaborative Group Study to Evaluate Factors that can Influence pH Measurement

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Background/Case Studies: Blood collectors routinely monitor the pH of platelets as part of their quality control program. The pH is considered an important marker of the so-called 'storage lesion', which can result from problems during collection, processing or storage of the component. It is also suspected that some donor characteristics can increase the risk of poor platelet storage. The aim of this study is to explore these various factors by looking at a large, multinational dataset of quality control (QC) pH test results. **Study Design/Methods**: Seven (7) blood collection agencies participated in the study: Héma-Québec (HQ), Canadian Blood Services (CBS), NHS Blood and Transplant (NHSBT), Sanquin, Établissement français du sang (EFS), the Australian Red Cross Blood Service (ARCBS), and Blood Systems Inc. (BSI). For the period between September 2011 and August 2014, each center provided line-by-line information on the pH QC test results of apheresis platelets, including a unique donor identification number, donor's age, gender and body mass index (BMI), where available. Only a small fraction of components are QC tested for pH, usually around one percent. **Results/Findings**: A total of 21,671 pH measurements were included in the analysis. The distribution characteristics of pH values vary between blood centers (see table). Some of this variation can be readily explained, for example the higher mean pH observed at BSI, where pH is measured on the day of issue, compared to pH at outdate in other centers. Among donors who had two or more pH measurements ($n=3672$), there was a strong correlation between pH results ($r=0.726$; $p<0.0001$). A repeatedly low pH measurement, defined as a pH lower than the tenth percentile of the blood center distribution, was not significantly associated with donor age, gender or BMI. There was however a trend suggesting that low pH was more prevalent among donors with high or low BMI. **Conclusion**: There is considerable variation in the distribution of platelet QC pH measurements among blood centers. These variations are likely to reflect differences in collection and processing methods, timing of testing relative to collection and pH testing platforms. There is also a strong intra-donor correlation of pH measurements, suggesting that underlying donor characteristics play a role in the quality of platelets; body mass index may be one such factor.

SP71

Evaluation of the Function of Lyophilized Platelets by Thrombelastography in an *in vitro* Platelet Transfusion Model

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Background/Case Studies: Lyophilized platelets(PLTs) were considered as one of the candidate replacement for liquid conserved PLTs. In this study, an *in vitro* platelet transfusion model was established to evaluate the function of rehydrated lyophilized platelets(RLPs) by thrombelastography(TEG). **Study Design/Methods**: Blood samples from 11 patients whose TEG MA was <40 mm associated with thrombocytopenia were collected . An *in vitro*

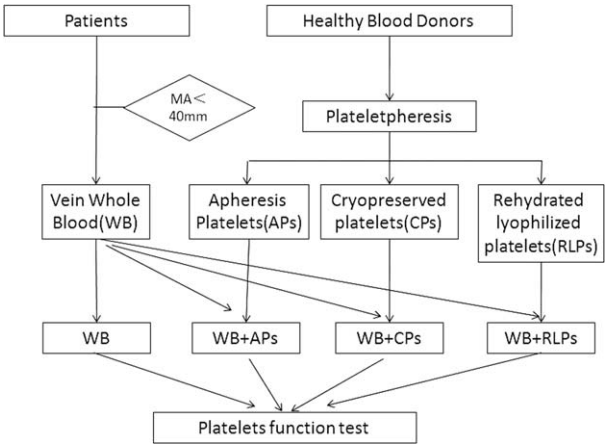
TABLE. In vitro analysis of BC PLTs (n = 6) treated with INTERCEPT and stored in plasma/SSP+

	Test units			Control units		
Variables	Day 1	Day 5	Day 7	Day 1	Day 5	Day 7
HCO_3 (mmol/L)	8.67 (0.26)†	9.25 (0.69)†	6.87 (0.61)†	8.30 (0.26)	6.95 (1.11)	4.94 (0.85)
Glucose (mmol/L)	7.02 (0.15)†	4.53 (0.36)†	2.53 (0.31)†	6.77 (0.18)	4.10 (0.47)	2.08 (0.71)
ATP (μmol/10^{11} PLTs)	4.5 (0.2)†	4.6 (0.3)	4.5 (0.4)†	4.1 (0.2)	4.5 (0.3)	4.0 (0.2)
sCD62p (ng/mL)	76.63 (10.10)†	63.59 (4.40)†	67.05 (2.92)†	84.50 (8.58)	86.80 (9.54)	95.43 (11.03)
RANTES (ng/mL)	31.09 (4.59)	33.45 (5.41)	36.16 (3.07)	34.56 (4.92)	36.04 (4.18)	39.77 (6.46)
sCD40L (ng/mL)	52.85 (9.53)	66.94 (17.72)†	64.47 (18.74)†	59.38 (6.40)	104.91 (27.28)	103.01 (17.46)

Values are expressed as Mean (Standard Deviation).
† $p<0.05$ vs control PLTs. Paired t-test.

TABLE.

Blood Center	HQ	CBS	NHSBT	EFS	SANQUIN	ARCBS	BSI
Number of individual pH measurements	1285	3243	3991	1517	894	2269	8472
Mean pH (±s.d.)	7.17 (0.25)	7.20 (0.22)	6.94 (0.28)	7.01 (0.23)	6.85 (0.18)	7.02 (0.22)	7.34 (0.31)
Lower 5th percentile	6.7	6.9	6.4	6.6	6.5	6.6	6.8
pH < 6.4; n (%)	13 (1.01)	41 (1.26)	172 (4.31)	8 (0.53)	18 (2.06)	33 (1.45)	82 (0.97)



platelet transfusion model were established by spiking those samples with one of the 3 preparations of specific donors' apheresis platelets(alternately stored at room temperature, cryopreserved, or lyophilized) to an increment equivalent to transfusion with 3x10^11 platelets. TEG test were performed to evaluate the function of incorporated platelets. The flow chart of this study design is illustrated in the figure attached. Data were analyzed with the SPSS software 17.0 for Windows version (SPSS Inc., Chicago, IL, USA).- Paired two-tailed Student *t*-test was performed when comparing the differences between two groups and $p<0.05$ was considered statistically significant. **Results/Findings**: MA enhanced significantly in the three different groups after the addition of PLTs when compared with the whole blood group(47.73 ± 5.78,46.05 ± 5.18,41.32 ± 5.76 for room temperature stored apheresis platelets(APs), cryopreserved platelets(CPs) and rehydrated lyophilized platelets(RLPs), respectively vs 35.33 ± 2.62, $p<0.01$), although the effect of RLPs was not as high as the APs and CPs MA increase ($p<0.05$). **Conclusion**: In this study, RLPs showed enhanced blood coagulation function, as well as their abilities on recovering their functions after rehydration.Our present results may represent a support for further clinical and experimental studies on RLPs.

SP72

REVEOS Whole Blood Processing System: Optimizing the Preparation of Pooled Platelet Concentrates

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Background/Case Studies: The REVEOS system (Terumo BCT) automatically separates whole blood (WB) into red blood cells (RBCs), plasma, and an interim platelet unit (IPU). After processing, 4 to 5 IPUs are manually pooled to prepare a therapeutic platelet concentrate (PC) without using additional plasma. In this study, we investigated the possibility of pooling only 4 IPUs instead of 5 to prepare PCs using the REVEOS system 3C overnight protocol. **Study Design/Methods**: WB (450 mL) was collected into the REVEOS blood collection bag. After collection, WB bags were rapidly chilled using Phase 22 packs (TCP Reliable Inc.) and stored at 20-24°C. WB was either processed with the 3C (3 components) fresh (3 to 14 hours) or the overnight (12 to 24 hours) protocol. A total of 100 and 112 IPUs were prepared by the 3C-fresh and 3C-overnight protocol, respectively. IPUs had a rest period of 1 hour prior to agitation ($>$ 8 hours for fresh-IPUs and >2 hours for overnight-IPUs). After agitation, ABO-compatible IPUs were pooled in groups of 5 IPUs (3C-fresh; $n=20$) or 4 IPUs (3C-overnight; $n=28$) without using the platelet yield indicator (PYI) given by the REVEOS device. PCs were next leukoreduced by filtration. Platelet *in vitro* parameters were measured and compared to those of products processed using the Atreus-OrbiSac system (Terumo BCT) that is currently used in our organization. **Results/Findings**: The mean volume of pools was 264 ± 5 mL and 202 ± 8 mL, respectively, for PCs made with 5 IPUs and 4 IPUs. Platelet counts were $3.3 \pm 0.5 \times 10^{11}$ PLTs (5-IPU pooling) and $2.9 \pm 0.3 \times 10^{11}$ PLT (4-IPU pooling). Platelet pools containing more than 2.4×10^{11} platelets/bag represented 100% (48 units) of the total number of pools (mean $\pm$ SD: $3.1 \pm 0.4 \times 10^{11}$ PLTs/bag;range: 2.4 to 4.2 $\times 10^{11}$ PLTs/bag). Reference PCs from the Atreus/OrbiSac system and REVEOS PCs had similar *in vitro* quality parameters, including pH, ATP, Annexin V expression, glucose, and lactate metabolism. However, platelet activation (CD62p expression) was slightly higher after separation in REVEOS CPs regardless of the protocol used ($19 \pm 5\%$ *vs.* $9 \pm 3\%$; $p_{value}<0.0001$). **Conclusion**: This study showed little qualitative differences between PCs resulting from the Atreus-OrbiSac process and those from the REVEOS process. However, using our process conditions, we show that it is possible to pool 4 IPUs prepared with the 3C-overnight protocol and to satisfy the required standards (CSA-Z902-10). Results of this study are currently used to monitor the validation of the REVEOS WB processing system in our routine operations.

SP73

Hemostatic Function of Stored Buffy Coat Platelet Concentrate in Plasma Treated with Riboflavin/UV Light and Reconstituted with Fresh-frozen Plasma

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Background/Case Studies: Pathogen-inactivation (PI) systems have been introduced to blood banking to decrease transfusion-transmitted infections (TTI). PI-treatment leads to an accelerated development of platelet storage lesion and also to decreased coagulation factor activity which might affect the hemostatic functionality of buffy coat platelet concentrate (BCPC). This study aimed to determine the effect of PI using riboflavin/UV light (Mirasol) on the hemostatic potential of BCPC produced in plasma and reconstituted with fresh frozen plasma (FFP) using rotational thromboelastometry (ROTEM). **Study Design/Methods**: Paired BCPCs produced in plasma were pooled and split. One BCPC was treated with riboflavin and UV light and the other one was kept un-treated as a paired control. Samples were drawn on days 2, 5, 7, and 9 of storage and were reconstituted for ROTEM with fresh frozen plasma to a platelet count of 100×10^9/L to mimic a transfusion scenario. In parallel, platelet activation was monitored by P-selectin expression and pH levels of these samples were determined. Six independent experiments ($n=6$) were performed. **Results/Findings**: The activation level of platelets during storage increased significantly on days 5, 7, and 9 compared to day 2 of storage (% PLTs positive for CD62P on day 9 was 77.8 ± 3.2 compared to 33.9 ± 5.2 on day 2, $p<0.01$) and was significantly higher in the illuminated BCPC ($p<0.01$) compared to the control. The pH value dropped below 6.8 ± 0.04 in the illuminated BCPCs on day 9 compared to 7.2 ± 0.03 in the control group. There was no correlation between ROTEM profile of the Mirasol treated PC and the parallel in vitro tests. BCPC reconstitution with FFP showed similar clotting time (CT) and clot forming time (CFT); after day 7 of storage the rate of the fibrin- platelet interaction decreased significantly in illuminated BCPC (alpha value was 57.6 ± 17.8 on day 9 compared to 76.3 ± 1.5 on day 7, $p<0.01$). Maximum clot formation (MCF) was significantly reduced in the illuminated BCPC compared to the control BCPC during the whole storage time (MCF was 54.1 $\pm$2.3mm compared to 59.0 ± 3.6mm in control group, $p<0.01$), but was consistent in both groups over the storage time. The fibrinolysis resistance was slightly decreased in the illuminated BCPC with a significant decrease after 7 days of storage (lysis% on day 9 was 51.6 ± 12.1 compared to 20.0 ± 1.5 in control group). **Conclusion**: This study shows that the FFP could replenish the impact of the pathogen inactivation of BCPC on coagulation factor activity, mainly on CT and CFT but not on the firmness/strength of the clot. While other in vitro tests show more deterioration of the platelet, ROTEM profiles suggest that Mirasol-treated PCs will retain their efficacy following transfusion after 7 days of storage.

SP74

Lectin Mapping Reveals Differences in Glycosylation Patterns on Platelet Proteins Following Cryopreservation and Cold Storage

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Background/Case Studies: Platelets for transfusion are conventionally stored at room temperature (20-24°C), which limits their shelf-life to between 5-7 days. Cryopreservation (−80°C) and refrigeration (4°C) of platelets has the potential to considerably extend the shelf-life, allowing greater accessibility in remote and rural environments. Although extracellular proteins on cold-stored platelets are known to undergo desialylation, which is believed to contribute to their rapid clearance upon transfusion, changes in glycosylation following platelet cryopreservation have not been studied. As such, the aim of this study

TABLE. Lectin binding in RT versus cold platelets after 5 days of storage

Lectins (MFI)	RT	Cold	p value (paired t-test)
MAA	234 ± 22	308 ± 31	0.0178
SBA	692 ± 63	887 ± 73	<0.0001
WGA	1759 ± 135	1994 ± 162	0.0003
PNA	437 ± 108	390 ± 99	0.2907

was to characterize the glycan residues exposed on conventional, refrigerated and cryopreserved platelets. **Study Design/Methods**: Using a pool-and-split design, buffy-coat derived platelets (n=8) in 30% plasma/SSP+ were stored at room temperature (RT), refrigerated (cold) or cryopreserved in 5-6% DMSO at −80°C (frozen). Platelets were sampled on day 1, 2, 5 and 9 of storage or immediately post-thaw. The exposure of specific glycan residues was assessed by flow cytometry and Western blotting using the following lectins: *Maackia amurensis* (MAA) for sialic acid, *Arachis hypogaea* (PNA) for β-galactose, *Glycine max* (SBA) for N-Acetylgalactosamine (GalNAC), and *Triticum vulgare* (WGA) for N-Acetylglucosamine (GlcNAC). **Results/Findings**: The surface binding of MAA (day 5, 9), SBA (day 2, 5, 9) and WGA (day 2, 5, 9) was significantly increased in refrigerated platelets, compared to those stored at RT (Table). In contrast, cryopreserved platelets demonstrated an approximate 2-fold reduction in the binding of all lectins, compared to the RT and cold-stored platelets. However, western blot analysis of cryopreserved platelets revealed a dramatic increase in glycosylation of specific protein isoforms migrating at 250 kDa and 75 kDa. **Conclusion**: In contrast to previous reports, desialylation and exposure of galactose residues was not observed in refrigerated platelets, although there was an increase in the exposure of GalNAC and GlcNAC residues. These differences may be due to storage in platelet additive solution, rather than plasma. Further, this study demonstrates that extracellular proteins on cryopreserved platelets undergo a generalized deglycosylation. These changes may contribute to the differences in life-span and functionality observed between platelets stored under these conditions.

SP75

Cryopreservation of Apheresis Platelets Collected using the Amicus Separator and Stored in the Collection Chamber

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Background/Case Studies: Typical preparation of cryopreserved platelets involves introduction of a DMSO containing solution to the platelet product with subsequent volume reduction via centrifugation. The excess plasma/DMSO solution is then expressed off resulting in a concentrated product ready for frozen storage. As an alternative, the Amicus Separator is capable of providing a convenient source of hyperconcentrated platelets to which a cryopreservation solution can be directly added without subsequent manipulation. This feasibility study sought to evaluate the quality of cryopreserved platelets prepared by this method. **Study Design/Methods**: Single dose platelets (n = 10) were collected from healthy subjects using the Amicus Separator. Once the subject was disconnected from the device, the procedure was terminated prior to the product transfer step and the collection chamber was isolated. Hyper-concentrated platelets were resuspended in the residual plasma contained in the collection chamber (approx. 25 mL). Cryopreservation solution (CryoStor CS10, BioLife Solutions) was added to a final DMSO concentration of 6% and the product stored at −80°C for a minimum of 1 month. For thawing, platelets were warmed in a 37°C water bath and reconstituted in PAS-5 platelet additive solution (approx. 300 mL). The platelets were transferred to a 1L PL2410 container, allowed to rest for 2 hrs, then stored at room temperature with agitation for up to 24 hrs. Platelet quality was assessed just prior to freezing, immediately post thaw, and post PAS addition at times 0, 2, 6, and 24 hrs. **Results/Findings**: In vitro parameter results are summarized in table below. Platelet yields (pre-freezing) ranged from (2.4 - 3.2) x 10^{11}. Nearly half of platelets maintained discoid morphology for up to 6 hrs post PAS addition. Consistent with previous reports, platelets were activated immediately post thaw with no significant change observed over 24 hrs. Thawed and reconstituted platelets were free of macroaggregrates. Microaggregrates, visible only by microscopy evaluation, tended to form between the 2 to 6 hr time points, and were present throughout products by 24 hrs. **Conclusion**: This study demonstrates that hyperconcentrated platelets obtained directly from the Amicus Separator can be used for the preparation of cryopreserved platelet products without the need for additional centrifugation. Further studies are required to reduce microaggregate formation at 6+ hr time points.

SP76

An Interlaboratory Comparison of Cryopreserved Platelet Quality

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Background/Case Studies: Cryopreserved platelets are now being manufactured in many centers throughout the world, in an effort to improve storage logistics and/or support military deployments. However, the collection, freezing, thawing and testing methods vary considerably between countries, making it difficult to determine whether the cryopreserved platelet components produced in each country are of similar quality. An international, multicenter study was conducted to assess the quality of platelet components manufactured at each site, with post-thaw testing performed at a single site. **Study Design/Methods**: Apheresis platelet concentrates were frozen with 5-6% DMSO at −80°C in each participating center, according to their standard protocol: Netherlands (NLD; n=10), the United States of America (USA; n=4), and Australia (AUS; n=6). The cryopreserved platelet units were then shipped to Australia, thawed at 37°C and reconstituted in a unit of thawed FFP (average volume 280 mL). *In vitro* quality parameters were examined immediately after thawing. **Results/Findings**: The post-thaw platelet concentration varied significantly between the platelets manufactured at each site (Table), due to the differences in the collection methods and starting components. The microparticle number also varied between the platelet components produced at each site, as determined by flow cytometry (CD61+/Annexin V+) and ThromboLUX measurements. These differences were related to the starting platelet concentration (NLD: 401 ± 44; USA: 318 ± 29; AUS: 485 ± 22 x 10^9/unit). Markers of platelet activation, including phosphatidylserine exposure and P-selectin expression were higher in post-thaw platelets, although the levels were comparable between each center. Similarly, platelet aggregation responses were diminished, and the extent was similar between groups. The kaolin-activated TEG responses of post-thaw platelets were also similar between the centers. **Conclusion**: These results demonstrate that although the dose of platelets and microparticles in

TABLE.

Parameter, Mean ± SD (N=10)	Pre-Freezing	Post-Thaw	Post PAS Addition (hr) 0	2	6	24
Plt Conc (x10^9/L)	4475 ± 431	4718 ± 266	789 ± 65	721 ± 51	656 ± 54	687 ± 50
MPV (fL)	7.9 ± 0.9	8.5 ± 0.7	8.9 ± 0.7	8.6 ± 0.7	8.1 ± 0.6	8.1 ± 0.5
Morphology Score (0 - 400)	338 ± 9	284 ± 21	299 ± 13	297 ± 13	284 ± 5	241 ± 19
Morphology Disc (%)	67 ± 3	47 ± 9	54 ± 4	53 ± 4	49 ± 4	35 ± 6
HSR (%)	NA	24.6 ± 8.8*	30.9 ± 9.0	37.5 ± 4.9	38.1 ± 4.2	21.1 ± 4.3
CD62p (%)	3.3 ± 5.0	45.8 ± 9.9	54.1 ± 14.0	53.2 ± 13.7	54.5 ± 15.3	51.4 ± 14.9

*N = 7

TABLE. Post-thaw parameters of platelets manufactured at each site

Parameters	NLD	USA	AUS	p-value (one way ANOVA)
Platelets (x10^9/unit)	321 ± 49	213 ± 14	422 ± 22	<0.0001
Microparticles (x10^9/unit)	78 ± 21	31 ± 7	63 ± 10	0.0007
Phosphatidylserine (%)	66 ± 7	63 ± 5	61 ± 5	0.2582
Collagen aggregation (% max)	14 ± 6	15 ± 9	19 ± 9	0.4747
TEG R time (min)	5 ± 0.4	4 ± 0.2	5 ± 0.3	0.1441

the components vary between centers, the actual platelet phenotype and function appears very similar. Despite differences in platelet collection, freezing and thawing methods, platelet cryopreservation methods in different centers are robust, and could be used interchangeably, allowing clinical data to be interpreted and applied internationally.

SP77

Functionality of Apheresis Platelets Exposed to Lower-than-standard Temperatures as Measured by Thromboelastrography

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Background/Case Studies: Platelets are stored at room temperatures (RT) between 22-24°C in agitation for a maximum of five days. If lower storage temperatures are used it is believed there is increased risk of platelet aggregation and impaired functionality. We propose that the use of cold preserved platelet products versus the RT storage platelets, would be invaluable with benefits such as shelf-life prolongation, decreased bacterial contamination. The aim of this study is to analyze platelet functionality of apheresis platelets by thromboelastography (TEG) when exposed to lower temperatures than the standard RT storage. **Study Design/Methods**: In twenty donors, the exposure of apheresis platelets for 24 hours of incubation without agitation at different temperatures (4°C, 16°C and 24°C) were compared to their controls (24°C with agitation, time 0) by TEG, analyzing the maximum amplitude (MA) that measures clot strength. Statistical analysis was performed using SAS version 9.3 with Tukey-Kramer HSD (Honestly Significant Difference) test and Paired t-test. **Results/Findings**: When comparing MA means (clot strength) of lower temperature storage (4°C and 16°C) for 24 hours, there is no significant difference when compared to the time zero control. There is a significant difference (with lower MA values) at 16°C when compared to 4°C and 24°C measurements and there is also a significant difference of the 24 hour 24°C values versus the time zero control. **Conclusion**: The TEG is an accepted and clinically useful test of hemostasis. The results show that lower temperatures do not appear to induce, at least in this in vitro study, a hypercoagulable platelet product and in fact the data points to a more prominent hypercoagulable state at RT without agitation indicated by higher MA values. Also, a reduction of the clot strength at 16°C with lower MA values is observed compared to 4°C and 24°C but is not evident when compared with control MA values. We believe this study can be used as a reference for future multi-institutional research studies with even longer platelet incubation times, with/without agitation and temperatures between 4°C and 16°C. Some donors' MA values fell below or above 2 standard deviations (SD) from the mean value even for the controls. The values outside of 2 standard deviations may represent the normal analytical variation of the TEG MA (Analytical coefficient of variation is 3 to 4%), aging of the specimen or individual differences in donors.

SP78

A 13-year Experience with the Production and Use of Pathogen-inactivated Platelets

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Background/Case Studies: The Transfusion Medicine Unit of Civic Hospital of Palermo has adopted and implemented since 2003 the production and use of Pathogen Inactivated Platelet Concentrates (PIPC) from buffy coat pool with Helinx technology (CERUS). This choice was to increase blood components safety because this technology prevents the replication of viruses with or without envelop, gram positive and gram negative bacteria, parasites and white blood cells. It has been welcomed by users. The aim of our retrospective study was to evaluate the impact of using these PIPC in our Hospital reality also in terms of safety and haemovigilance for such a long time. **Study Design/Methods**: The PIPC, inactivated with S59 Psoralen and UVA rays, have the following characteristics:

- Platelet counts in the range of 2.5-5.0x1011
- Contamination of red blood cells <4x106/ml
- Resuspension in additive solution PAS III (32-47% in plasma)
- Total Volume between 300 and 390 ml.

The clinical impact of using PIPC was evaluated by the increasing demands of PIPC by the Departments supplied by our Unit. Transfusion safety of PIPC was evaluated through the collection of haemovigilance data, related to transfusions of PIPC performed over the last 13 years in the Hospital's Departments and IsMett. **Results/Findings**: 6907 PIPC were produced in the period evaluated. Compared to the data of the last revue of 2010 there was a production implementation: going from 3157 in the first 7 years to 3750 in the following 6 years, with also an increase of the request and the use of this type of blood component. The haemovigilance data regards 6361 transfusions of PIPC, of which 62% were transfused to thrombocytopenic patients in the Oncology and Pediatric Oncology Departments, 33% to cirrhotic patients undergoing liver transplant or to cardiac patient at IsMett; the remaining 5% to patients in other Departments of our Hospital. We found 19 Adverse Events (AE), probably related to the transfusion episode, in 6361 PIPC transfusion, with a rate of 0.3%. Most AE were of grade 1 severity with chills, itching, skin rash. **Conclusion**: The implementation of the PIPC production in our Unit from 2003 to 2015 has had considerable success with all the Departments using such blood components. In fact, our haemovigilance data showed that in the first 7 years of production 2763 PIPC were transfused, in the following 6 years of production 3598 PIPC were transfused. In particular the Oncology and Haematology Departments have increased their use as they do not need to use gamma irradiation of blood components or wait for CMV negative Platelets Pools. AE for transfusion of PIPC confirm the 2010 data and are perfectly consistent with those documented for transfusions of Platelet Concentrates not Pathogen Inactivated. Our experience of 13 years has shown that the use of PIPC increases transfusion safety.

TABLE. Paired t-test results

6 Variables	N	Mean	Standard Deviation	t Value	p Value
4°C vs control	20	1.14	4.45225	1.15	0.2664
16°C vs control	20	−2.15	5.866991	−1.64	0.1177
24°C vs control	20	2.285	4.608148	2.22	0.0390
16°C vs 4°C	20	−3.29	5.66642	−2.6	0.0177
24°C vs 4°C	20	1.145	3.205994	1.6	0.1267
24°C vs 16°C	20	4.435	6.600819	3.0	0.0073

TABLE.

PGD Testing	2010	2011	2012	2013	2014	2015	Total
Total Tested	2932	1998	1518	2757	3151	4483	16839
Avg/Month	244	167	127	230	263	374	234
# Initially Reactive	12 (0.41%)	4 (0.20%)	1 (0.07%)	8 (0.29%)	11 (0.35%)	6 (0.13%)	42 (0.25%)
# Repeat Reactive	1 (0.03%)	4 (0.20%)	0	4 (0.15%)	9 (0.29%)	5 (0.11%)	23 (0.14%)
% Confirmed Positive	0	1 (0.05%)*	0	0	0	0	1

*Staph cog-neg.

SP79

Verax Pan Genera Detection (PGD) Test for Platelet Screening: A 5-year Retrospective Analysis in a High-volume Transfusion Service

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Background/Case Studies: Bacterial sepsis following platelet transfusion remains a major cause of transfusion-transmitted infections. The contamination rate is 1 in 1000 - 3000 platelet units. Sampling limitations and slow growing organisms account for infectious breakthrough. The Platelet PGD Test is a rapid immunoassay for the detection of bacteria cleared by the FDA for use as an adjunct secondary screening of bacterial contamination in platelets. There are operational concerns regarding the feasibility of applying this screening tool in a busy transfusion service. We report on our 5-year experience with use of PGD. **Study Design/Methods**: This retrospective analysis was conducted at our high-volume transfusion service(50-60,000 transfusions annually). We reviewed existing records of all platelet units screened by PGD from January, 2010 to December, 2015. All apheresis platelet units underwent routine primary screening by culture methods. Additional screening using PGD was performed on day 5 for apheresis platelets beginning February 2013. However, we switched to day 4 and 5 testing in April 2014 according to FDA draft guidance. Whole blood platelets were screened by PGD on release for transfusion. In addition, the technologists logged in the time required for testing for the purpose of calculating Full-time equivalents (FTEs). The timing started from the point of sample processing to resulting. Transfusion reaction records are reported. All patients with fever increase >1 C have units cultured. Units and patients are cultured if temperature increase is >2 C. Transfusions are administered with PDAs with alerts for reaction thresholds. **Results/Findings**: A total of 16,839 PGD tests were performed during that 5-year time period on apheresis platelet/whole blood-derived doses. If the PGD test was initially reactive, repeat testing was performed. In case of repeat reactivity, a culture was performed. 42 tests (0.25%) were initially reactive. Only 23 out of the 42 tests showed repeat reactivity (0.14%), one sample grew coagulase negative Staphylococcus. No transfusion-transmitted infections were reported over the study interval. Regarding our budgeting analysis, the annual test work load was 57,304 min/yr. Our calculated full time equivalent (FTE) required to perform this test was 0.68. **Conclusion**: The Verax PGD test is performed well in the setting of a high-volume transfusion service. There was no need for release of untested product, few products were wasted due to false-positives.

SP80

Influence of Pathogen-inactivation (PI) Technology on Platelet Production

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Background/Case Studies: With date of March 1st 2013 we introduced Intercept®(Cerus, Concord, USA) technology in our bloodbank in the western part of Austria. Responsible for about one million people, we produce about 6000 units of platelets each year. Precondition for PI was an adjustment of our platelet units to meet Cerus defined specifications. 2016, after three years of PI experience, we reviewed our production data to identify possible changes in the composition of our platelet units (numbers, volume, yield, percentage of double doses) as well as an increased use of pool platelets due to PI. **Study Design/Methods**: For two equal periods (control group: 21 months immediately before introduction of PI and test group: 21 months immediately after introduction of PI) we analyzed our produced platelet units for number, yield, percentage of double dose units as well as the number of pooled platelets. **Results/Findings**: In the control group a total of 5255 apheresis procedures were performed, 3413 in the test group. Number of pool units increased from 706 to 1952 (control versus test). Integrating pool units into apheresis procedures 5961 versus 5365 collections were performed (control versus test). 99% versus 99,4% (control vs. test) meet the minimum platelet content of $2.5*10^{11}$. Number of double dose increased from 65.2% to 69.2% (control versus test; $p< 0.001$) whereas number of single dose decreased from 28.7% to 24.5% (control versus test; $p< 0,001$). Product volume for apheresis units was slightly increased for test group (389.8mL$\pm$65.2mL versus 392.4mL$\pm$26.6mL, control versus test; $p<0,01$), platelet concentration per μL too (1464.0 ± 288.7 versus 1479.6 ± 324.6, control versus test; p=n.s.). Yield in 10^{11} was not significantly different for single dose products (4.1 ± 0.6 versus 4.0 ± 0.7, control versus test) and totally equal for double dose units (6.3 ± 0.8 for both). **Conclusion**: Adjustment of platelet units to the Intercept requirements did not influence platelet yield. Increasing the number of pool units in our production unit could decrease the number of apheresis procedures by nearly 1.500, which lead to a better utilization of our existing donor pool resulting in a better performance expressed in a significantly higher number of double dose procedures. Both measures led to decreased costs of production and helped together with discontinuation of gamma-irradiation and bacterial testing to neutralize inactivation costs.

SP81

Gamma Irradiation's Effect on Platelet Concentrates Prepared with the New REVEOS System

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Background/Case Studies: The new REVEOS system (TerumoBCT) is an integrated and automated whole blood processing platform enabling platelet concentrate (PC) production from multiple interim platelet units (IPUs) pooling. As part of a validation study to introduce this new technology while implementing an extension of the platelet storage time from 5 to 7 days, we investigated the platelet *in vitro* parameters to establish if PC quality is affected by the gamma irradiation process. Nearly half of the PCs delivered to our affiliated hospitals are gamma-irradiated (25Gy) to prevent transfusion-associated graft-versus-host disease (TA-GVHD). **Study Design/Methods**: After collection, whole blood (WB) (450 ± 45 mL; n=32) has been rapidly chilled and stored to 20-24°C with Phase 22 packs and processed overnight with the REVEOS into red blood cell units, plasma and IPUs. Eight ABO-compatible IPUs were pooled and split to obtain 2 identical PCs. One product of each pair was irradiated with 25 Gy by means of a

TABLE. In vitro comparisons of platelet markers for gamma-irradiated and non-irradiated PCs on day 7 of storage

Variable	Mean Irradiated	Mean Non-Irradiated	P
pH	7.4 ± 0.1	7.4 ± 0.01	0.55
ATP (μmol/10^{11} platelets)	5.7 ± 0.6	5.8 ± 0.6	0.91
pCO2 (mmHg)	23.0 ± 1.8	25.0 ± 3.7	0.38
pO2 (mmHg)	111.0 ± 10.4	113.5 ± 13.0	0.72
Glucose (mmol/L)	11.2 ± 0.6	10.5 ± 1.0	0.18
Lactate (mmol/L)	18.3 ± 1.0	18.9 ± 1.3	0.42
CD62p (%)	14.1 ± 3.6	13.9 ± 2.9	0.95
CD63 (%)	78.5 ± 3.7	78.9 ± 3.3	0.93
ESC (%)	21.3 ± 4.0	21.8 ± 2.9	0.85
HSR (%)	54.3 ± 8.1	58.8 ± 4.1	0.38
Annexin V (%)	2.1 ± 0.3	2.2 ± 0.3	0.70
mtDNA (ng/mL)	3.1 ± 0.6	3.3 ± 1.0	0.72

^{137}Cesium source (Gammacell 1000 Elite, Best Theratronics, Ottawa, Canada). PCs were stored at 20-24°C under continuous agitation. Control and irradiated PCs were sampled on days 2, 5, 7 and 9. Relevant PC *in vitro* quality markers including pH, extent of shape change (ESC), hypotonic shock response (HSR), activation (CD62p/CD63), membrane phosphatidylserine exposure, glucose, lactate, sodium, potassium, pO_2, pCO_2, ATP and mitochondrial DNA (mtDNA) were measured. **Results/Findings**: Platelet counts were similar in both control and irradiated PCs (2.8 ± 0.3 vs 2.9 ± 0.3 x 10^{11} PLTs) and met the minimum acceptable value of 2.4 x 10^{11} PLTs required by CSA Standards. No significant differences were observed in rheological or biochemical functions between untreated and irradiated PCs after 7 days of storage (see Table). **Conclusion**: This study shows that 25 Gy gamma-irradiation does not affect the *in vitro* quality of pooled platelet components prepared with the new REVEOS. These findings are consistent with similar international studies conducted on WB-derived and apheresis PCs.

SP82

Spotaneous Intracranial Haemorrhage in Paediatric Oncology Patients

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Background/Case Studies: Intracranial haemorrhage (ICH) is a rare but serious complication in pediatric oncology patients. ICH risk factors differ between the general population and those with cancer. In adults, several factors have been shown to increase the risk of ICH, including sepsis. Few studies have examined these risk factors in the pediatric oncology population.
Objectives:

1. Assess risk factors for the development of ICH in this population
2. Assess morbidity and mortality 48 hours and 30 days following the event

Study Design/Methods: A retrospective chart review of pediatric oncology patients treated between 1995-2014 at a tertiary care center was performed. Patients were identified from the Paediatric Oncology Group of Ontario database and the ICD-9 and ICD-10 codes for ICH. Cases of surgical or traumatic bleeding episodes were excluded. Data regarding demographics, cancer diagnosis and treatment, risk factors, clinical outcome post-ICH, laboratory data and infection criteria were collected. Infectious risk was assessed using the systemic inflammatory response syndrome (SIRS); a validated pediatric score. **Results/Findings**: 39 patients with 43 bleeding episodes were identified. The most common diagnosis was acute leukemia (21/39; 54%). 56% of bleeding episodes occurred in the setting of SIRS, with 42% being blood culture positive. 68% were preceded by suspected or proven infection. 77% required IV beta lactams and 33% were administered IV antifungals. Of those with available platelet data, 8% had counts below $10x10^9$/L, 8% were between 10-$20x10^9$/L, 44% were between 20-50 $x10^9$/L, 8% were between 50-$100x10^9$/L and 8% were $> 100x10^9$/L. At 48 hours post-ICH, outcomes included: suspension of therapy (14%), blood product transfusion (70%), ICU transfer (67%), surgical intervention (14%), and death (12%). At 30 days post-ICH, 46% remained in hospital (8% in ICU), 16% experienced neurological sequelae and an additional 3% died. **Conclusion**: This study examined risk factors for development of ICH in pediatric oncology patients. Most bleeds were preceded by a suspected or proven infection. Surprisingly, severe thrombocytopenia prior to the event was uncommon. Morbidity and mortality rates were significant but mortality rates were lower than those reported in adults. Further studies are necessary to develop a risk factor algorithm to examine the risk of ICH in pediatric oncology patients and assess the benefits of additional therapies.

SP83

Plasma Concentrate (Uber-plasma) Produced by Hemoconcentration

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Background/Case Studies: Plasma therapy is important in the management of massively bleeding patients (MBP). MBP are also frequently treated with large volumes of crystalloid solution leading to interstitial fluid overload with associated pulmonary compromise. Hemoconcentration is a strategy often applied to enhance hemostasis during cardiac surgery requiring cardiopulmonary bypass. We hypothesized that a practical method for ex-vivo concentration of large volume plasma pools could yield a therapeutic plasma product with a high proportion of procoagulant effect: free water challenge that might serve to rapidly correct coagulation status and minimize interstitial volume loading attributable to resuscitation. **Study Design/Methods**: Thawed plasma units at end of storage (day 5) were pooled in aliquots of 4. Each pool ($n = 5$) was processed by perfusion through a circuit containing an in-line hemofilter with pore size of 65 kD (Hemocor HPH 1000) to remove free water. The target for water removal was 75%. Pool volume was measured pre- and post-filtration. The following analytes were measured on pre- and post-filtration samples: albumin, activity for clotting factors II, V, VII, X. **Results/Findings**: Hemofiltration of the plasma pools to achieve the target volume reduction required 25 minutes processing. Filter performance remained intact throughout all runs. The mean concentration factor was 2.75. **Conclusion: Conclusion**: Removal of free water yields a plasma product that is intermediate in potency for factor replacement between plasma and lyophilized clotting factor concentrates. This product could be used in select patient populations, e.g., MBP patients at risk for interstitial fluid excess associated with large volume crystalloid challenge, particularly if the concentrated plasma product could be scaled for mass production.

SP84

Hemostatic Functional Analysis of a Spray-dried Plasma

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Background/Case Studies: The restoration of coagulation factors and buffering proteins in plasma is critical in the acute phase of trauma/hemorrhage. In the prehospital setting, bolstering the plasma supply by having an alternative source to standard fresh frozen plasma (FFP) would be of great benefit. A proprietary spray drying process has provided a solution to problems of plasma supply and waste. This technology can be easily adopted at blood centers with relatively mild impact on coagulation proteins. However, the shear force applied by the spray-drying process significantly reduces the number of high molecular weight vWF multimers (HMWM), accompanied by an increase in the low molecular weight multimers, leading to a net increase in vWF multimers in spray-dried plasma (SpDP). It is plausible that this trade-off compensates for the reduction of HMWM vWF and maintains platelet adhesion. This work examines the ability of SpDP to support platelet function *in vitro*. **Study Design/Methods**: Five groups of ABO-identical FFP units were pooled and split into small aliquots or full FFP units. Pooled units were spray dried without or with pretreatment (7.4 mM citric acid, SpDP/PreT). Type-matched platelets and RBCs were collected from donors on study days. SpDP/PreT was reconstituted in 2.7mM Na_2CO_3, and SpDP was reconstituted in 7.4mM citric acid (pH adjusted with Na_2CO_3) or a glycine solution. The reconstituted SpDPs and matched FFP control were evaluated on a BioFlux system for platelet adhesion to collagen under both arterial and pathological shear ($980s^{-1}$ and $4000s^{-1}$, respectively). Analyses of blood chemistry, thrombin generation, vWF:Ristocetin cofactor (Chrono-log

TABLE.

	Pre-filtration	Post-filtration	Pre-filtration Factor Content (Units)	Post-filtration Factor Content (Units)
Volume (ml)	1335	485		
Albumin (g/dL)	3.4	10.46		
Factor II (%)	79	255	1055	1236
Factor V (%)	47	186	627	902
Factor VII (%)	91	289	1214	1401
Factor X (%)	83	251	1108	1217

aggregometer), and thromboelastography (TEG) with and without RBCs/platelets were conducted. **Results/Findings**: SpDP/PreT had a lower pH (7.2 vs. 7.4 in FFP); all SpDPs had reduced bicarbonate vs. FFP control (4.1-8.1 vs. 21mM in FFP), possibly due to the loss of CO_2 during spray drying. Thrombin generation was equivalent in all samples ($p = .65$). SpDP with glycine showed similar TEG parameters to FFP; extra citrate (pre- or post-drying) caused delay in R (from 10.45 to >35min, $p < .05$) and reduction of angle (from 49.8 to <26°, $p < .01$), but had no impact on amplitude. With RBCs and platelets present, TEG differences disappeared. The vWF:Ristocetin cofactor assay showed no significant differences between FFP and SpDP ($p = .999$). Most importantly, for platelet adhesion to a collagen surface under flow, SpDP reconstituted with glycine was comparable to FFP under both arterial and pathological shear. **Conclusion**: SpDP reconstituted in glycine was comparable to FFP for all measured assays. The impact of glycine pre-treatment will be evaluated in future experiments. At present, there appear to be no hemostatic functional deficiencies in SpDP rehydrated in glycine solution despite the reduced levels of HMWM vWF.

SP85

Photochemical Treatment of Pooled Whole Blood-derived Plasma Within 19 Hours from Collection

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Background/Case Studies: The objective of this study was to evaluate the quality of plasma derived from whole blood (WB) pooled, treated with INTERCEPT, split and frozen within 19 hours from collection. **Study Design/Methods**: 5 leukodepleted plasma units from whole blood of the same ABO group are pooled and divided into two sub-units of 650 mL which are each pathogen inactivated. Both sites prepared 20 pools (5 O; 15 non-O) to obtain 120 units of PI Fresh Frozen plasma (PI-FFP). The plasma quality was evaluated before treatment (T_1) and after 2 weeks (T_2), 6 months (T_3) and 12 months (T_4) of storage below −25°C. **Results/Findings**: see Table 1 for the evolution of selected indicators of plasma quality. A moderate reduction following treatment with recoveries of 75% to 95% (68% for FVIII) and a stability during storage are observed. French requirements for FVIII and fibrinogen (≥ 0.5 IU/mL and ≥ 2 g/L in at least 70%) are met with respectively 82% and 93% after 12 months. Thrombin generation potential of plasma is adequately maintained with none of the parameters of the CAT markedly changed with treatment for the concentration of 20 pM tissue factor (TF). The kinetics of the reaction is slightly affected at the suboptimal concentration of 1 pM of TF without influence on the total amount of thrombin generated (not shown). **Conclusion**: pooled plasma derived from WB meets after PI treatment and freezing within 19h the quality standards for PI therapeutic plasma. Plasma quality markers do not reveal significant alteration due to the photochemical treatment and frozen storage. The thrombin generation capacity of plasma is preserved demonstrating its normal hemostatic potential. Access to whole blood derived plasma provides an alternate or supplementary supply to apheresis plasma.

TABLE. quality indicators of INTERCEPT treated WB derived plasma (n=40)

	Reference	T_1	T_2	T_3	T_4
Fibrinogen (g/l)	2 – 4	2.59 ± 0.23	2.23 ± 0.22[a]	2.26 ± 0.25[b]	2.33 ± 0.26[c]
Factor V (%)	70 – 130	98 ± 9	89 ± 11[a]	87 ± 10[b]	-
Factor VII (%)	70 – 130	103 ± 10	78 ± 11[a]	76 ± 10[b]	-
Factor VIII (IU/ml)	0.5-1.5	0.96 ± 0.14	0.65 ± 0.12[a]	0.63 ± 0.12[b]	0.61 ± 0.10[c]
Protein C (%)	66 – 120	120 ± 13	105 ± 11[a]	103 ± 12[b]	-
Protein S (%)	57 – 126	95 ± 8	90 ± 8[a]	92 ± 7[b]	-
alpha-2 antiplasmin (%)	80 – 120	101 ± 5	82 ± 5[a]	83 ± 7[b]	-
ADAMTS 13 (%)	50 - 150	95 ± 17	85 ± 15[a]	87 ± 17[b]	-
PT (%)	70-130	110 ± 9	90 ± 8[a]	87 ± 8[b]	-
aPTT (sec)	25 – 42	37.5 ± 3.0	41.8 ± 2.4[a]	42.2 ± 2.6[b]	-
Thrombin Generation test at 20 pM Tissue Factor	Lag time (min) 1.65 – 3.61	1.43 ± 0.27	1.39 ± 0.21[a]	1.43 ± 0.23	1.46 ± 0.26
	Peak (nM thrombin) 197 - 485	356.0 ± 27.9	356.3 ± 28.5	351.5 ± 25.7	346.5 ± 29.0[c]
	ETP (nM x min) 1,226 – 2,438	1,581.1 ± 153.7	1,662.6 ± 127.3[a]	1,636.0 ± 143.7[b]	1,608.6 ± 141.4

Two-sided paired t-Test (alpha 0.05) : a, b or c indicate a significant difference ($p<0.05$) when comparing respectively T2-T1, T3-T1 or T4-T1.

SP86

A Possibility of Precise Dose for Plasma: Plasma Proteins with Stability in Universal Pooled Plasma for Chinese Population

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Background/Case Studies: The plasma safety is gradually being resolved by pathogen tests or pathogen reduction technologies. However, besides plasma safety, another main concern about plasma is the precise dose of plasma proteins needing to be extensively studied. A great difference in plasma proteins between single FFP results in lack of precise or sufficient dose of plasma proteins in each therapeutic plasma transfusion. The blind plasma transfusion not only can't meet the prospective therapeutic efficacy after transfusion but also waste plasma to excessive infusion. **Study Design/Methods**: Based on the pooling rate of A:B:AB=6:2.5:1.5 in universal pooled plasma for Chinese population, one hundred units of single FFP (60A, 25B, 15AB) were selected to test the levels of plasma proteins including total protein (TP), albumin (Alb), Fibrinogen (Fg), Factor V (FV), Factor VIII (FVIII), Anti-III (AT-III), protein C (PC) to analyze for the difference. Different pooling protocols including pools with 20, 40, 60, 80 and 100 units were designed to optimize the minimum pooling number with a stable level of plasma proteins comparing with single FFP. The pooled plasma with the optimal minimum pooling number was used to further evaluate the optimal storage condition and period at 22 degree, 4 degree and −20 degree respectively. **Results/Findings**: There were significant differences with a wide range, the maximum fluctuation was FVIII and the minimum was TP and Alb in a more stable level, in the levels of plasma proteins among single FFP. After pooled with different pooling protocols, the mean value of plasma proteins not changed significantly compared with single FFP ($P>0.05$). However, with the pooling number increasing, the plasma proteins in a whole level tended to be stable with the reduction of standard deviation (SD). For example, the SD values of Fg with 20, 40, 60 and 80 pooling protocols was 1/1.5, 1/3.8, 1/4.7, 1/7 times than that of Fg with individuals. Comprehensive analysis showed the SD values of seven plasma proteins tended to be stable at the beginning of 40 pooling protocol comparing with 20 pooling protocol or individuals. With the prolongation of storage, the retention of plasma protein decreased. The safely storage for pooled plasma were 1 day at 22 degree with reduction of 28% for VIII, 4 day at 4 degree with reduction of 36% for VIII and 3 month at −20 degree with reduction of 52% for VIII respectively. **Conclusion**: This is the first study to evaluate the stability of plasma proteins in universal pooled plasma that possibly contribute to improve a kind of blood products with a stable level of plasma proteins and support the usage of pooled plasma for establishing precise dose to plasma proteins.

SP87

Analysis of Fresh-frozen Plasma Issued to Hospitals in a Regional Blood Center

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Background/Case Studies: The Transfusion Center provides blood components to approximately 2.7 million inhabitants and issues 13,400 fresh frozen plasma units (FFP) per year. Since 1998 plasma has been treated with methylene blue. Over the last years, measures to reduce the risk of transfusion-related acute lung injury (TRALI) were implemented. Since 2008 the plasma for transfusion has been provided by male donors (without previous transfusions), but female donors with the same requirement as male donors and who never have been pregnant, are still needed to meet the demand for group AB. The strategy should provide plasma without leukocyte antibodies (HLA class I and class II). **Aim**: To have an evaluation in relation to the issuing of FFP with the requirement established to try to prevent TRALI. **Study Design/Methods**: The number of units of FFP issued by the Transfusion Center to hospitals was analyzed by ABO group for a two year period (Jan 2014-Dec 2015) and hospital specialties were analyzed as well. **Results/Findings**: 30 hospitals received FFP, the number of units issued was from 3 units to 3,434 per year, 3 hospitals received more than 180 units per month (high-user), one of them received more than 23% group AB plasma during the year 2014; after intervention to improve the plasma use, the issue was 11% the following year. Four hospitals received from 40 to 80 units per month (intermediate user), 6 hospitals between 10-30 units and 17 hospitals less than 10 units FFP per month. In the case of very low FFP users, there is 50% demand for group AB plasma, range (0-100%), demonstrating a wide variation between blood group mixes, even in some cases of high users. This variance does not exist in red cell issues. In one hospital the bias towards AB group was in the context of the thawing of "universal"

TABLE. The blood group frequency within our population and average (minimun-maximum) of high-user hospital issues (as %)

	ABO distribution in population (%)	2014 average (min-max)	2015 average (min-max)
Group O	43	36% (31-44)	33% (31-36)
Group A	47	46% (42-58)	51% (48-55)
Group B	7	6% (3.5-9.5)	8% (6-9.5)
Group AB	3	12% (3-23)	8% (4-11)
All groups (issued units FFP)		8,867	8,984

FFP in massive hemorrhages. The main reasons for FFP transfusion were liver disease, massive hemorrhage, cardiac surgery and others surgeries. No cases of TRALI following plasma transfusions were reported. **Conclusion**: It is important to give blood group matched FFP in order to maintain inventory and moreover to ensure an adequate supply and appropriate utilization of a limited resource.

SP88

Elimination of Microparticles from Human Plasma by the THERAFLEX MB-Plasma System

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Background/Case Studies: THERAFLEX MB-Plasma treatment is used to inactivate pathogens in human plasma. It is known that methylene (MB)/light treatment influences plasma proteins and pathogens. Natural degradation products from blood cells can be found in plasma in form of microparticles. In this study, flow cytometric analysis was used to quantify such subcellular particles. The aim of the study was to investigate if the filtration steps of THERAFLEX MB-Plasma treatment (PLAS-4 and BlueFlex filtation) reduce RBC derived microparticles and whether THERAFLEX MB-Plasma treatment contributes to the formation of microparticles. **Study Design/Methods**: Pathogen inactivation was done with six plasma units using the THERAFLEX MB-Plasma system and the MacoTronic B2 illumination device. Samples were taken before and after filtrations. Flow cytometric analysis was used to detect and quantify subcellular particles in the range of 0.5 to 4 μm (according to particle size reference beads). Origin of the particles were discriminated by antibody based linage markers of the Plasmacount Kit (BD). **Results/Findings**: It could be shown that the PLAS-4 filtration procedures reduced RBC derived microparticles for >90% (sd= 5%). The formation of additional microparticles by MB/light treatment was not observed. An additional MP reduction of the BlueFlex filter could not be assessed because of the low starting counts of MPs after PLAS-4 filtration. **Conclusion**: We conclude that the PLAS-4 filtration step of THERAFLEX MB-Plasma treatment ensures the efficient reduction of RBC derived MPs in THERAFLEX MB-treated plasma that are already present in human plasma. Additional contribution of the BlueFlex filter should be investigated.

SP89

Comparison of Device Variability in Platelet-rich Plasma Procedures

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Background/Case Studies: Platelet-rich plasma (PRP) devices can often vary with operation and functionality. The Arteriocyte Magellan is a dual-spin processing system that can provide a specific volume of concentrated PRP. The Magellan uses syringe pumps and a microprocessor-controlled centrifuge to separate PRP from whole blood. The Arthrex Angel System has touch-screen options to program a specific blood volume and hematocrit in order to produce a concentrated PRP product. The Angel utilizes a volume separation chamber which will separate red blood cells, platelet-poor plasma and platelet-rich plasma. In addition to functionality differences, the post cellular counts of the PRP products are also variable. The aim of our study was to compare the final PRP product from the Angel with that from the Magellan. **Study Design/Methods**: Validation studies using one fresh whole blood (FWB) unit were performed on five devices - two Angels and three Magellans. During this validation, the devices were set up to function similarly, despite their inherent differences. The Angels and Magellans were programmed to spin 60 mL anticoagulated FWB. The devices were then programmed to yield approximately the same amount of PRP (3-4 mL). Hemoglobin (Hb), platelet (plt) count, and leukocyte (WBC) count were measured by performing a pre and post CBC on the FWB and PRP products. P values were calculated between the means of the Angel results and Magellan results to determine statistical significance. **Results/Findings**: Two studies were performed on the Angel devices and six studies were performed on the Magellan devices using FWB from one unit. The means, standard deviations, and P values of results obtained are shown in the table. **Conclusion**: When programmed to produce a similar PRP volume yield, the post platelet count is similar between the two devices with the Magellan producing higher residual hemoglobin. When both devices are programmed to spin the same amount of FWB, the P values show that the differences between all CBC measurements are statistically significant.

SP90

Serum Growth Factor and Fibronectin Concentrations in Dry Eye Patients and Healthy Blood Donors

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Background/Case Studies: Autologous serum eye drops (SEDs) are beneficial for patients suffering from dry eye syndrome due to their growth factor and fibronectin content. Patients are not always eligible to donate blood for autologous SEDs, and allogeneic SEDs from blood donors could provide an alternative. Limited studies have investigated the variability in serum growth factor concentrations from patients and healthy blood donors. Further, the minimum concentration of growth factors in SEDs to initiate corneal cell proliferation and wound healing is unknown. The aims of this study were to determine growth factor concentrations in serum from patients and healthy donors, and to investigate the ability of different serum samples to stimulate cell proliferation and wound healing. **Study Design/Methods**: Whole blood was collected from dry eye syndrome patients (n=9) and healthy blood donors (n=102) and left to clot at 2-6°C for 24 hours. Serum was prepared by centrifugation, diluted to 20% with 0.9% sodium chloride and stored at −30°C. Epidermal growth factor (EGF), platelet-derived growth factor (PDGF)-AA, PDGF-BB, transforming growth factor (TGF)-β1, TGF-β2 and fibronectin were measured using magnetic bead-based assays and ELISA. Growth factor concentrations were compared across donor age groups

TABLE.

Mean± SD	No.	FWB volume (mL)	PRP volume (mL)	Pre Hgb (g/dL)	Post Hgb (g/dL)	Pre PLT count (x10/9/L)	Post PLT count (x10/9/L)	Pre WBC count (x10/9/L)	Post WBC count (x10/9/L)
Angel - 3%	2	60	3.5 ± 0.7	13.4	0.2	196	1319 ± 137	3.4	7.8
Magellan - 30	3	30	4	13.4	4.0 ± 0.2	196	1050 ± 73	3.4	11.8 ± 1.2
P value			0.2683		0.0001		0.0588		0.0208
Angel - 3%	2	60	3.5 ± 0.7	13.4	0.2	196	1319 ± 137	3.4	7.8
Magellan - 60	3	60	10	13.4	1.1 ± 0.2	196	664 ± 57	3.4	6.4 ± 0.2
P value			0.0001		0.0091		0.0044		0.0026

TABLE. Serum growth factor and fibronectin concentrations (mean ± SD)

Growth factor	Patients	Blood donors
EGF (pg/mL)	75 ± 30	79 ± 36
PDGF-AA (pg/mL)	781 ± 226	822 ± 269
PDGF-BB (pg/mL)	4728 ± 1396	4130 ± 1607
TGF-β1 (pg/mL)	7725 ± 1533	8735 ± 2249
TGF-β2 (pg/mL)	1104 ± 255	828 ± 310
Fibronectin (μg/mL)	192 ± 46	188 ± 46

(one-way ANOVA) and gender (t-tests). Human corneal epithelial cells were incubated with serum from healthy blood donors and assessed using a CyQUANT cell proliferation assay and in a scratch wound assay. **Results/Findings**: There was a wide range in growth factor and fibronectin concentrations from patient and blood donor serum samples (Table). Serum from younger blood donors (20-29 years) had significantly higher PDGF-BB concentrations ($p=0.0149$) than older healthy donors (60-69 and 70-79 years). There were no differences in growth factor concentrations between male and female donors. There was no correlation between individual growth factor concentrations and corneal cell proliferation. However, serum samples with higher fibronectin concentration were better able to stimulate cell migration in scratch wound assays than those with low fibronectin concentration. **Conclusion**: Although serum contains many growth factors, correlation of a single factor with cell proliferation is difficult. However, fibronectin concentration does appear to influence cell migration, and may serve as a quality marker when producing eye drops from allogeneic serum.

SP91

Serum Eye Drops: A Survey of International Production Methods

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Background/Case Studies: Serum eye drops (SEDs) are used to treat dry eye syndrome and non-healing corneal lesions when other treatments fail. Despite being used for the past three decades, with many clinical studies demonstrating efficacy, there is no internationally harmonized method for producing SEDs. A survey was developed to better understand how SEDs are currently produced. **Study Design/Methods**: A 40-question survey requesting information regarding donor selection, blood collection and processing, infectious disease screening, shelf-life and regulatory requirements for the production of autologous and allogeneic SEDs was sent to blood centers and hospitals worldwide. Survey data were collected into a REDCap database via a secure web interface and subsequently analyzed using Excel. **Results/Findings**: A total of 55 responses were received. Of these, 37 responses were sufficiently complete to be included in subsequent analyses, with 21 responses from centers indicating they produce autologous or allogeneic SEDs. Collection, infectious disease screening and processing practices differ widely, according to the size of the center and their ability to collect, process and test the blood. Generally, blood centers collect larger blood volumes ($\geq$ 200 mL), whereas hospitals and medical centers typically collect $<$ 200 mL. The majority of centers (81%) screen donors for infectious diseases including Hepatitis B, Hepatitis C, HIV, HTLV and in some cases syphilis, CMV, WNV and Chagas disease. Four centers (19%) indicated they do not perform infectious disease screening. These were hospitals or medical centers that only produce autologous eye drops. Blood is allowed to clot from 0-6 h up to 3 days before centrifugation, with the majority of centers (72%) allowing up to 24 h before further processing. Serum is frequently diluted with saline or phosphate buffered saline solution before dispensing to reduce the concentration of growth factors, and the extent of dilution ranges from 20 to 50%. Only a small proportion of centers (29%) sterile filter the serum before dispensing. The volume dispensed ranges from approximately 0.5 mL to 5 mL, into vials, eye-dropper bottles or tubing segments once serum has been processed. SEDs are usually stored frozen, and the shelf-life ranges from 3-12 months. Many centers (52%) apply a post-thaw shelf-life of 24 hours, although one allows 48 hours and two allow one week. **Conclusion**: Despite divergences in methods for producing SEDs, the end result is small-volume aliquot of serum that can be stored frozen and administered by a patient at home. If more centers move from producing autologous to allogeneic SEDs, this may provide an opportunity for collection and production methods to become more standardized internationally.

SP92

Fibrinogen Content of Prepooled Cryoprecipitate: The First Step to Establishing Dosage and Pharmacoeconomic Equivalency with Fibrinogen Concentrates

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Background/Case Studies: Cryoprecipitate units (CRYO) are required to have a minimum 150 mg fibrinogen (FIB). Although recent and historical literature has determined that the average CRYO unit contains 200-250 mg FIB by using the Clauss method, some more recent publications suggest that the FIB content is as high as 400 mg, but the method used in these studies was either not specified or was the PT method, as opposed to the standard Clauss method which is preferred for most patient testing. Prepooled CRYO products are required to have minimum FIB content proportionate to the number of pooled units; however, data on the actual FIB content of these prepooled products is not readily available. In 2009, the FDA licensed a purified FIB concentrate for congenital fibrinogen deficiency opening the door to off-label clinical use. This concentrate is labeled with exact FIB content. As most CRYO is now used exclusively for FIB replacement, it is important to determine the FIB content of prepooled CRYO in order to establish dosage and pharmacoeconomic equivalency with concentrate. **Study Design/Methods**: Thawed plasma units returned to the transfusion service unsuitable for reissue were sampled following intervals of refrigeration to confirm that measured FIB content is unaffected by prolonged storage. A few were kept unrefrigerated as further controls. Thawed prepooled CRYO units that expired on the shelf or were returned unused to the transfusion service were sampled for FIB content following intervals of refrigeration and subsequent warming in a 37°C water bath. FIB content was assayed after appropriate saline dilution via the Clauss method using the STA-R Evolution® (Stago, UK). FIB content was calculated by multiplying the FIB concentration by the volume of each prepooled CRYO unit. Our hospital is supplied with pre-pooled CRYO products made from 5 separate CRYO units, so FIB content in a single CRYO unit was calculated by dividing the measured FIB content of the prepooled CRYO by five. **Results/Findings**: Twenty-eight prepooled CRYO products were tested. The mean volume of the prepooled CRYO units was 126 mL (range 95-132 mL) and the mean storage age at the time of thaw was 266 days (range 21-361 days). The mean FIB concentration of the prepooled CRYO products was 1350 mg/dl (range 1032-1980). The mean FIB content per unit of a single CRYO unit was 270 ± 44 mg. The mean calculated FIB content of our 5-unit prepooled CRYO products was therefore 1700 mg based on the mean volume. **Conclusion**: The FIB content of prepooled CRYO is consistent with recent and historical literature of single CRYO units when measured by the Clauss method. The mean FIB concentration of 1350 mg/dL may be of interest when performing pharmacoeconomic comparisons between CRYO and purified FIB concentrate.

SP93

Extending Storage of Thawed Cryoprecipitate from 4 Hours to 24 Hours at 20°C to 24°C Poses a Safety Risk to Transfusion Patients

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Background/Case Studies: Transfusion of plasma components, such as cryoprecipitate CPD, is recommended to treat patients with coagulation abnormalities or massive bleeding. Currently, thawed cryoprecipitate can only be stored at 20-24 °C for a maximum of 4 hours. However, it has been demonstrated that the activity of coagulation factors in thawed cryoprecipitate is maintained after 24 hours of storage at 20-24 °C. These results form the basis for extending the shelf life of thawed cryoprecipitate for up to 24 hours. However, it is important to demonstrate the safety of the proposed change. To that end, this study was developed to determine if bacterial growth is significantly increased in contaminated thawed cryoprecipitate when stored for up to 24 hours at 20-24 °C. **Study Design/Methods**: Groups of 3 cryoprecipitate units were used for each experiment ($N\geq5$). The three units were thawed, tested for sterility by plating onto blood agar, and then spiked with one of the following bacteria: the Gram positive *Staphylococcus epidermidis*, or the Gram negative species *Serratia liquefaciens, Pseudomonas putida*, and *Pseudomonas aeruginosa,* to a target

TABLE.

Parameter	Initial	Hypotonic washing	Isotonic washing
Discocyte + Echinocyte 1	38.1 ± 19.5%	61.0 ± 10.7%‡	56.8 ± 11.9%
Echinocyte 2 + Echinocyte 3	52.0 ± 18.7%	32.2 ± 11.4%‡	31.6 ± 13.4%
Sphero-echinocyte + Spherocyte	9.5 ± 3.4%	3.2 ± 2.8%‡	9.2 ± 3.6%
Stomatocyte	0.4 ± 0.2%	3.6 ± 0.9%†,‡	2.4 ± 1.4%
Free Hb	–	−80.4 ± 7.5%‡,*	−86.9 ± 6.5%*
PS exposure	–	−48.6 ± 20.2%†,‡,*	−1.0 ± 13.2%*
AMVN perfusion rate	–	+27.0 ± 3.4%‡,*	+25.3 ± 5.2%*

†: $p<0.05$ compared with isotopic washing, ‡: $p<0.05$ compared with initial sample, *: relative change against the initial sample.

concentration of approximately 10^2 colony forming units (CFU)/mL. Unit 1 was designated as the control (time 0 = t0), and was tested immediately after spiking for bacterial concentration. Units 2 and 3, were stored in a platelet incubator to maintain 20-24 °C for 4 hours (t4) and 24 hours (t24), respectively. Upon incubation, these units were also tested for bacterial enumeration by serial dilution and plating onto blood agar. Differences in bacterial counts between storage times were analyzed using t-test. **Results/Findings**: No differences in bacterial concentration for any of the species were observed between cryoprecipitate control units (t0) and units stored for 4 hours (t4) ($p>0.05$). When comparing bacterial concentrations between t4 and t24 cryoprecipitate units, it was found that the concentration of *S. epidermidis* was not significantly different between the two groups of units (0.0938). By contrast, when cryoprecipitate storage was prolonged to 24 hours, significant differences in bacterial concentrations were observed for the three Gram negative organisms. Titers of *P. putida, P. aeruginosa* and *S. liquefaciens,* significantly increased from approximately 10^2 CFU/mL in t4 units to approximately 10^6 CFU/mL ($p=0.0113$), 10^5 CFU/mL ($p=0.0016$) and 10^4 CFU/mL ($p=0.0032$) in t24 units, respectively. **Conclusion**: Extending the shelf life of thawed cryoprecipitate at 20-24 °C from 4 hours to 24 hours is not recommended as pathogenic Gram negative bacteria are able to proliferate under these conditions posing a significant safety risk for transfusion patients.

SP94

The Effects of Storage Temperature on Platelet Aggregation

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Background/Case Studies: The study of platelet aggregation is essential to assess in vitro platelet function by different platelet activation pathways We systematically evaluated the effects of test temperature and storage temperature on platelet aggregation using impedance aggregometry **Study Design/Methods**: Aliquots of citrated platelet rich plasma (PRP) from 15 healthy adult volunteers were stored at 37°C and 22°C and 4°C. Aliquots were subjected to impedance aggregometry in response to adenosine diphosphate, ristocetin, and arachidonic acid performed **Results/Findings**: Aggregation induced by ristocetin, and arachidonic acid was not significantly different at the test temperatures of 37°C and 22°C but was significantly impaired at 4°C. In contrast, adenosine diphosphate induced aggregation was significantly increased at 37°C and 22°C and 4°C. Hypothermia exclusively impaired collagen-induced aggregation. Storage temperature of 22°C exclusively enhanced adenosine diphosphate induced aggregation compared with storage at 37°C or4°C **Conclusion**: Our results suggest that mild hypothermic test conditions have no relevant effect, whereas profound hypothermia induces defects in adhesion, thromboxane generation, and activation.Storage temperature considerably affects the aggregation response to the agonists adenosine diphosphate but not to arachidonic acid and ristocetin. The effect of hyperthermia on platelet aggregability remains unclear. The effect of the temperature on platelet aggregation depends not only on the platelet agonist used but also on the blood storage condition.

SP95

Removal of Irreparably Damaged Cells from Stored Blood by Washing in Hypotonic Saline

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Background/Case Studies: Most blood transfusions involve units of red blood cells (RBCs) stored in an anticoagulant-preservative solution at 2-6°C for up to six weeks. A majority of RBCs in a unit are preserved well, while some RBCs progressively deteriorate and undergo the echinocytic transformation from healthy flexible bi-concave discocytes to rigid sphero-echinocytes and spherocytes. This morphological degradation involves loss of cell membrane and is therefore irreversible. Infusion of these irreparably damaged RBCs (sphero-echinocytes, spherocytes) into patients has no therapeutic purpose, and may in fact be harmful to some patients. Here we describe a simple approach to removing sphero-echinocytes and spherocytes from stored blood via selective lysis in hypotonic saline. **Study Design/Methods**: Washing was performed by mixing a sample of stored RBCs (n = 5, 6-week old units) with hypotonic (0.585%) saline at 1:4 ratio (v:v), incubating the mixture for 30 minutes, and then bringing osmolality of the sample back to within the isotonic range (290 ± 15 mmol/kg) by adding the mixture to normal (0.9%) saline at 1:9 ratio (v:v). Washed RBC samples were assayed for RBC morphology, free hemoglobin (Hb) concentration, surface phosphatidylserine (PS) exposure, and the ability of stored RBCs to perfuse an artificial microvascular network (AMVN). The results were compared to conventional isotonic washing. **Results/Findings**: Hypotonic washing of stored RBCs induced selective lysis of irreparably-damaged RBCs, while still keeping overall hemolysis acceptably low. Hypotonic washing reduced the fraction of irreparably-damaged cells (sphero-echniocytes, spherocytes) nearly 3-fold from 9.5 ± 3.4% (range: 7.0 - 15.2%) down to 3.2 ± 2.8% (range: 1.4 - 8.0%), and cut the number of PS exposing cells in half from 1.35 ± 0.80% (range: 0.48 - 2.57%) to 0.58 ± 0.25% (range: 0.28 - 1.12%). Hypotonic washing also showed an improvement in the AMVN perfusion rate, but the improvement was not significantly different from that of isotonic washing (Table). **Conclusion**: We demonstrated a simple and cost-effective washing protocol for the selective removal of irreparably damaged RBCs. Further development and implementation of this method in clinical practice could have a potentially transformative impact on the safety and efficacy of blood transfusion.

SP96

Blood Bag Constriction for Volumetric Control in Austere Environments

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Background/Case Studies: Fresh whole blood (FWB) "buddy" transfusions are a powerful tool in emergency care; however, the lack of clinically available equipment and supplies in field situations frequently leads to collection bags being under- or overfilled. Underfilling can lead to citrate toxicity or coagulopathy, while overfilling can cause coagulation within the bag or the development of symptomatic hypovolemia in the donor. While use of a scale to monitor/control collection volumes is the standard, such equipment is unavailable in scenarios where FWB transfusions are most likely. This study describes two simple, rapid controls over volumetric expansion of the collection bag: (1) the use of a cord to constrict the bag, and (2) folding/clamping the bottom of the bag. **Study Design/Methods**: A Terumo collection bag was welded to a 1 L saline bag and allowed to fill to completion via gravity. Final volume was verified with a graduated cylinder. For constriction, paracord was tied around the center of the bag at circumferences ranging from 6-7". With clamping, a locking medical hemostat secured the bag at fold lengths ranging from 1-1.5". Several units were drawn into Fenwall collection bags during training exercises of the 75th Ranger Regiment by three methods: estimating by vision/touch, constricting with 5.5" cord (required due to shape differences in the Fenwall bag), and clamping with hemostat. **Results/Findings**: With a

desired blood volume of 450mL, preliminary studies showed an optimum constriction circumference of 6" for the Terumo bag, resulting in a median saline-only mass of 440.6g (n=4, CV=2.0%) which would be equivalent to approximately 449.3mL of whole blood. Cord circumferences of 6.5" and 7" yielded 470.4g (n=3, CV=2.7%) and 498.9g (n=5, CV=4.9%), respectively. Clamping the bag with a 1.5" fold resulted in a median saline mass of 455.0g (n=3, CV=0.5%), corresponding to approximately 464.0 mL of whole blood. With an expected total mass of 585g, median collection volumes in training exercises were reported as 598.5g (eye test; n=66, CV=10.2%), 582.0g (5.5" cord; n=34, CV=6.5%), and 542.0g (hemostat; n=18, CV=8.7%). **Conclusion**: Both of these filling restriction methods illustrate the speed and consistency required to collect blood in a battlefield scenario. The use of a common cord is appealing, but some variability is inevitable with knot tying; perhaps a better alternative would be a prefabricated band or a marked zip-tie. Clamping showed the least variability in preliminary studies and was quicker to implement, but this method carries the risk of rupturing the bag (mitigated with gauze padding); these tests showed no indications of damage after clamping. An analysis of available collection bags is required to guarantee volumetric matching. With proper training, appropriate volume collection can be obtained with these methods in any environment.

SP97

Blood Component Separation of Pathogen-Reduced Whole Blood by the PRP Method Produces Acceptable Red Cells, but Platelet Yields and Function are Diminished

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Background/Case Studies: The need for pathogen reduction technology (PRT) for blood components has been demonstrated when standard blood components are unavailable and fresh whole blood (FWB) is used to treat severe bleeding. PRT has been shown to have minimal effects on hemostatic function and could conceivably prolong the utility of WB in austere conditions. This study focused on blood components processed from PRT-treated WB. The effects of storage temperature on platelet concentrates from control and PRT-treated WB were also investigated. **Study Design/Methods**: FWB was collected in CPD anticoagulant from healthy donors for control (CON) and PRT treated WB, 10 units per group. PRT was performed using riboflavin and ultraviolet light (Mirasol® System, TerumoBCT). Red blood cells (RBC), platelet concentrates (PC) and plasma for fresh frozen plasma (FFP), were isolated by sequential centrifugation. RBC were stored at 4°C, FFP at-80°C; PC were stored at 22° or 4°C. Components were assayed on days: 1, 22, 29 (RBC); ~1, ~180 (FFP); 1,3,5,10,15 (PC). Blood gases, chemistry and CBC were determined for all components. Hemostatic function was analyzed by TEG (thromboelastography); platelet integrity and function was assessed by flow cytometry, TEG, extent of shape change, hypotonic shock response, and platelet aggregometry; RBC were assessed for ATP, 2,3 diphosphoglycerate and free hemoglobin. FFP were analyzed for PT, PTT, and coagulation protein levels on the STA-R Evolution and by ELISA. Data were analyzed as repeated measures, followed by analysis of variance to assess interactions. Significance was set at $p<0.05$. **Results/Findings**: Component processing following PRT resulted in a significant drop in platelet recovery. Most PRT-PC bags fell below AABB guidelines for platelet count. PRT-PC also showed a minimal, but significant decrease in clot strength and decreased aggregometry. While PRT-PC-22 differed significantly at D1 from CON-PC-22, by D3 differences were less profound. Storage at 4°C improved platelet function for PRT-PC-4 compared to CON-PC-22 or PRT-PC-22. Apoptotic caspases 3, 7, 8 and 9 were differentially elevated at all time points in the PRT samples. In FFP analyses, PT and PTT were prolonged; factors V, VII, VIII, and XI, protein C and fibrinogen were significantly decreased following PRT treatment. While free hemoglobin was elevated two-fold at D28, all other measures were comparable for CON-RBC and PRT-RBC. **Conclusion**: Blood components isolated by the PRP method from PRT-treated WB result in PC that fail to meet AABB guidelines. FFP also shows diminished coagulation capacity. However PRT-RBC are comparable to CON-RBC. PRT-WB retains acceptable hemostatic function but alternatives to the PRP method of component separation should be explored.

SP98

Quantitative Phase Microscopy for the Assessment of Red Blood Cell Aging: Membrane Fluidity of Discocytes Decreases Non-monotonically

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Background/Case Studies: Whole-cell morphology is a robust measure of red blood cell (RBC) integrity, reflecting the myriad biochemical, structural, and functional changes that underlie the "storage lesion" of RBC. Optical interferometry is an emerging technology for the measure of membrane fluctuation, potentially providing a surrogate assay of cell stiffness. **Study Design/Methods**: Quantitative phase microscopy (QPM) uses an off-axis Mach-Zehnder interferometer to study spatial and temporal characteristics of individual cells in vitro and is frequently used for imaging red blood cells. Using high-speed imaging (1000Hz), we analyzed the nanoscale membrane fluctuations of discocytes sampled from three bags of RBCs over a period of 7 weeks at 4 degrees C. **Results/Findings**: The mean discocyte membrane fluctuation declined in each unit during storage from a range of 44.0-52.7 milliradians (mrad) with standard deviation (SD) range 5.5-12.4 at week 1 to 36.2-43.8 mrad $\pm$ 5.3-7.3 mrad at week 7. **Conclusion**: Membrane fluctuation as a result of Brownian motion declined during the storage of RBC, but not monotonically (Figure 1). These findings differ from the previously published findings of a monotonic decline in membrane fluctuation during RBC storage. A major difference in our approach was sampling from the blood bag in our case, as compared to sampling the tubing aliquot "tails" in the published work. Indeed, there is published work indicating that tails are inappropriate samples for RBC quality studies (PubMed ID 23834158). With further refinement, however, QPM can be a useful indicator of declining membrane fluidity in stored RBC.

Donor and Therapeutic Apheresis

SP99

Absolute Immature Platelet Count Improves Sensitivity and Specificity of a Clinical Prediction Sscore for Thrombotic Thrombocytopenic Purpura

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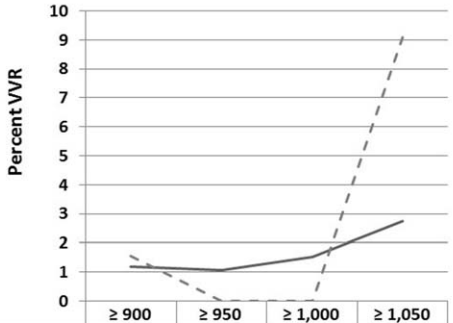
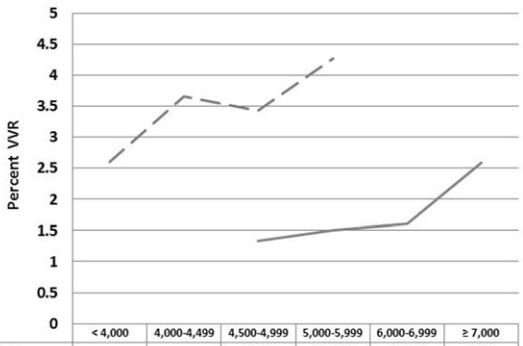
Background/Case Studies: Thrombotic thrombocytopenic purpura (TTP) is a life-threatening diagnosis requiring prompt initiation of therapeutic plasma exchange (TPE). Measurement of the absolute immature platelet count (A-IPC) has been reported to help in the diagnosis and response to therapy of ADAMTS13 deficient (idiopathic) TTP patients. The aim of this study was to determine if A-IPC could improve a previously developed clinical prediction score for TTP. **Study Design/Methods**: A retrospective chart review of 18 clinically suspected TTP cases presenting at a tertiary academic medical center between 2012 and 2013 was performed. Our patient cohort consisted of nine idiopathic TTP, two human immunodeficiency virus (HIV)-associated TTP, and seven non-TTP patients with thrombocytopenia. Multiple laboratory variables were assessed, including A-IPC, creatinine, platelet count, D-dimer, reticulocyte percentage, and indirect bilirubin. All patients were treated with daily 1-1.5 volume TPE, received type-specific plasma replacement, had ADAMTS13 activity measured, and follow-up including alternative diagnoses and response to plasma exchange were reviewed. **Results/Findings**: Six clinical variables were applied to patients according to ADAMTS13 deficiency (<10%,idiopathic TTP patients). Different scores were assigned to six variables based on the predictive power of each variable: A-IPC <5 X10E9/L, +21; platelet count>35 X10E9/L, −30; D-dimer > 2000 ng/mL, −10; Indirect bilirubin > 1.5 mg/dL, +20.5; Creatinine > 2.0 mg/dL, −11.5; Reticulocyte > 3%, +21. All idiopathic TTP patients (ADAMTS13 <10%) had a significantly decreased A-IPC and PLT count at presentation. Mean clinical prediction score in the idiopathic TTP patient cohort was 35.89 $\pm$ 22.87 while mean clinical prediction score in the non-TTP patients with thrombocytopenia cohort was −11.83 $\pm$ 11.55. With addition of A-IPC to the previously reported clinical prediction score, our clinical prediction score has 89% sensitivity, 100% specificity, and 100% positive predictive value for diagnosing idiopathic TTP patients. **Conclusion**: Our data show that A-IPC can be an important component of a clinical prediction score for TTP diagnosis. A-IPC value of less than 5 X10E9/L at presentation significantly increases the sensitivity, specificity, and positive predictive value of a previously reported TTP clinical prediction score. Our study may enable the accurate diagnosis of TTP and predict the response to plasma exchange with readily available clinical variables.



	≥ 900	≥ 950	≥ 1,000	≥ 1,050
Male n	2,026	1,034	527	545
Male VVR Rate	1.2	1.1	1.5	2.8
Female n	64	32	7	11
Female VVR Rate	1.6	0.0	0.0	9.1

Product Volume (mL)



	< 4,000	4,000-4,499	4,500-4,999	5,000-5,999	6,000-6,999	≥ 7,000
Male n			3,299	14,078	6,459	1,195
Male VVR Rate			1.3	1.5	1.6	2.6
Female n	1,802	2,321	1,487	1,216		
Female VVR Rate	2.6	3.7	3.4	4.3		

Estimated Blood Volume (mL)

SP100

Vasovagal Reactions in High-Volume Apheresis Collections – What Is the Risk?

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Background/Case Studies: The 55-year old Nadler nomogram is used to estimate apheresis donor blood volume (BV) for calculation of both the 15% extracorporeal volume limit and maximum allowable collection volume. Holme (Transfus Apher Sci 2008;39:161) demonstrated its more recent systematic overestimation as US body habitus has changed since the 1960s. Individuals with high body mass index may be at particular risk for overcollection. We analyzed vasovagal reaction (VVR) rates in Trima (Terumo BCT, Lakewood CO) procedures yielding ≥900 mL in components. **Study Design/Methods**: Procedure data from Trima's Vista™ Information System (Nov 2013 - Oct 2015) were linked with donor demographics and minor VVR records from eProgesa and proprietary hemovigilance system records of more severe onsite VVRs and offsite VVRs of any severity. Only procedures without saline replacement were analyzed (platelet/plasma/RBC or platelet/plasma collections). **Results/Findings**: Of 32,756 donations, 4,246 yielded volumes ≥900 mL (4,132 males). The table shows that collections above 1,050 mL more than doubled the VVR rate in males compared with all other volume categories. The very small number of observations in females limited significance in this and the multivariable analysis. As Nadler BV increases, the VVR rate also increases. At 7,000 mL male BV, VVRs increase trajectory (1,050 mL = 15% of 7,000 mL BV). No clear cutoff was evident for female donors, known to have higher reaction rates. Multivariable analysis was performed (not shown) factoring donor age, EBV, first-time versus repeat status, time on the instrument and collection site into a model with males whose collection was ≥13% estimated BV (removing early-terminated procedures possibly related to a reaction in progress). First-time donor and site were lesser influences on the risk of VVR which doubled at collection volumes ≥1,050 mL or BVs ≥7,000 mL. **Conclusion**: Our organization set its maximum Trima collection volume at 1,050 mL or 15% of BV, whichever is less, to enhance apheresis donor safety. Annual projections of plasma loss from this safety measure were <25 L.

SP101

Male Hemoglobin Guidelines of 13.0g/dl with a 12-week Whole Blood Interval

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Background/Case Studies: In 2012, AABB released an Association Bulletin requesting organizational guidelines to address iron deficiency in blood donors. To support this bulletin, in 2013 our program's inter-donation interval for whole blood was changed from 8-weeks to 12-weeks. Since this change, hemoglobin deferrals have decreased and there has been a decreased incidence of low ferritin within the whole blood donor population. In May 2016, FDA increased the male hemoglobin requirement from 12.5 g/dl to 13.0 g/dl to further mitigate the incidence of iron deficiency in blood donors. This evaluation looked to see if having the 12-week interval would significantly decrease male donors deferred for hemoglobin, using the 13.0 g/dl cutoff. **Study Design/Methods**: The male hemoglobin values for both 2012 (8-week interval) and 2015 (12-week interval) were compared and statistical significance for the comparison was completed with an unpaired t-test ($p<.05$). The number of male donors with new acceptable hemoglobin of 13.0g/dl was compared in both 8-week interval and 12-week interval and statistical significance was determined using a Chi-square test ($p<.05$). **Results/Findings**: During the 8-week interval period, 15422 males presented for donation, with 14097 donors (91%) having hemoglobin 13.0g/dl or higher. During the 12-week interval period, 9832 males presented for donation, with 9333 (95%) donors having hemoglobin 13.0g/dl or higher. There are a significantly lower number of male donors requiring low hemoglobin deferral with a 12-week inter-donation period. Furthermore, the average hemoglobin also was significantly increased with the 12-week inter-donation interval, moving from 14.9 g/dl to 15.2 g/dl. **Conclusion**: Implementation of a 12-week whole blood inter-donation period has attenuated the impact of the new FDA male minimum hemoglobin requirement of 13.0 g/dl on product collection.

TABLE.

	8-week interval	12-week interval	p value
Total Males Presented	15,422	9832	
Total Males Hgb ≥ 12.5 g/dl	,	9577	
Percentage deferred	4.42%	2.59%	
Total Males Hgb ≥ 13.0 g/dl	14,097	9333	<0.0001
Percentage deferred	8.59%	5.08%	
Average Hgb (g/dl)	14.9	15.2	<0.0001

SP102

Are Spectra Optia and Amicus Equally Suitable for Collection of MNCs and Their Subsets

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Background/Case Studies: The use of mononuclear cells (MNCs) as a therapy is well established and new therapeutic applications continue to emerge. Dependent on the intended use different MNC subsets are favoured, CD34+ cells for stem cell collections CD14+ and CD33+ cells for the generation of dendritic cells. CD3+ cells for donor lymphocyte infusions (DLI). Alpha beta ($\alpha\beta$) and gamma delta ($\gamma\delta$) T-cell populations are CD3 subsets and are natural killer (NK) cells. They include cytotoxic, interferon (IFN)-

TABLE. Univariate and multivariable analysis for 30-day mortality outcome

	Covariate	Hazard ratio (95% confidence interval)	p-value
Univariate analysis	Age	1.04 (1-1.09)	0.052
	Sex (Female vs. Male)	1.52 (0.36-6.37)	0.57
	Race (African American vs. Non-African American)	0.38 (0.09-1.51)	0.17
	Central nervous system involvement (Yes vs. No)	6.68 (0.82-54.32)	0.076
	Disease status (Non-initial vs. Initial episode)	7.53 (1.52-37.34)	0.013*
	Platelet normalization (>150,000/μL) within 7 days (No vs. Yes)	8.38 (1.03-68.13)	0.047*
	White blood cell count (x10^3/μL)	1.10 (0.96-1.27)	0.16
	Hematocrit (%)	0.93 (0.81, 1.08)	0.34
	Platelet count (x10^3/μL)	0.99 (0.93-1.04)	0.58
	LDH (IU/L)	1.001 (1-1.001)	0.0035*
	Creatinine (mg/dL)	1.37 (1.06-1.77)	0.016*
	HNP1-3 (ng/mL)	1.02 (1.002-1.03)	0.023*
	iC3b (μg/mL)	0.99 (0.93-1.07)	0.88
	C5-9 (μg/mL)	1.25 (0.85-1.84)	0.26
	C4d (μg/mL)	0.86 (0.57-1.29)	0.46
	Bb (μg/mL)	1.20 (0.88-1.64)	0.25
Multivariable analysis	Platelet normalization (>150,000/μL) within 7 days (No vs. Yes)	12.13 (1.26-116.69)	0.031*
	Disease status (Non-initial vs. Initial episode)	8.11 (1.34-49.29)	0.023*
	LDH (IU/L)	1.001 (1-1.001)	0.11
	Creatinine (mg/dL)	0.87 (0.61-1.24)	0.44
	HNP1-3 (ng/mL)	1.01 (0.997-1.03)	0.12

gamma-producing lymphocytes that actively respond to viral infections; $\gamma\delta$ T cells also have well-established protective roles in cancer, activated $\gamma\delta$ T cells exhibit potent anti-tumour activity. Thus collection of CD3 subsets may be substantial for future immunotherapeutic approaches for treatment of different types of cancer. In this investigation we analysed the collection properties concerning MNCs and subsets of Amicus (Fresenius) and Spectra Optia (TerumoBCT). Our aim was to identify the best suitable device for specific demands. **Study Design/Methods**: Twelve healthy volunteers (3 females and 9 males, median 44yrs, 21-56) from our routine multikomponent donor pool were recruited for MNC donation on Amicus™ (Fresenius) and Spectra Optia® (TerumoBCT) in a cross over design. They all fulfilled the requirements for blood donation. We processed 6000 ml of blood within 120 minutes. The MNC products as well as pre-and post peripheral blood samples were analyzed for cell counts and MNC subsets by FACS analysis using trucount tubes (BD Biosciences) for multi-color single-platform staining according to the technical manual. The FACSDiVa 6 software (BD Biosciences) was used for cell acquisition and data evaluation. The following MNC subsets were analyzed: CD3, CD19, CD33, CD3 $\alpha\beta$, CD3 $\gamma\delta$ CD4 $\alpha\beta$, CD8 $\alpha\beta$, CD56. Furthermore the amounts of concomitantly collected red blood cells and platelets were measured. For statistical analysis the Wilcoxon signed rank test was applied. **Results/Findings**: The procedures were well tolerated by the donors. We found no differences in pre and post values of the donors although Optia collected significantly more platelets than Amicus (mean 2.29x10^11/Optia vs 0.64x10^11/Amicus, $p<0.05$). On the other side the concomitantly collected red cell fraction was significantly higher in Amicus than in Optia (9.35ml/Amicus vs 1.66ml/Optia, $p<0.05$). The number and purity of collected MNCs and subsets was comparablel in both devices (81.8%/Amicus vs 84.6%/Optia). **Conclusion**: Both devices are equally applicable for MNC collection in general and for all tested subsets. How far the higher platelet numbers in Optia and the higher RBC volume in Amicus, respectively, may negatively influence in vitro expansion studies needs further investigation.

SP103

Predictors for 30-day Mortality in Patients with Acquired Autoimmune Thrombotic Thrombocytopenia Purpura (TTP): A Single-center Experience

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Background/Case Studies: Acquired TTP is a potentially fatal syndrome, resulting from autoantibodies against ADAMTS13. We sought to determine the association between baseline biomarkers and 30-day mortality. **Study Design/Methods**: A retrospective observational analysis was performed on all patients admitted to our institution with the clinical diagnosis of TTP and ADAMTS13 level <5% between 2006 and 2015, excluding ones without samples for further laboratory testing. Besides demographics and routine laboratory parameters, specimens were analyzed for plasma concentrations of complement activation markers and human neutrophil peptides (HNP1-3s), which are released from activated neutrophils during inflammation. These markers were correlated with a 30-day mortality outcome. **Results/Findings**: During the study period, 52 patients (28 females, 24 males; median age: 46.5 years; 36 patients with initial TTP episodes) were eligible and had frozen plasma for laboratory analysis. At baseline, the median hematocrit, platelet (PLT) count, and lactate dehydrogenase (LDH) were 25%, 14250/μL and 878.5 IU/L, respectively. Eight patients died within 30 days (median=9 days). Univariate analysis showed that disease status (non-initial vs. initial episode), whether platelet count normalized (defined as PLT count >150000/μL within 7 days), LDH, creatinine, and HNP1-3s were all associated with 30-day mortality (Table). However, multivariate analysis using covariates that had significant association with outcome from the univariate analysis revealed that only disease status and PLT normalization within 7 days were significantly associated with 30-day mortality (Table). **Conclusion**: Patients with acquired autoimmune TTP had decreased 30-day mortality outcome if they had prompt PLT normalization within 7 days and/or the disease for the first time. Larger multicenter studies should be performed to confirm these findings.

SP104

Caloric Loss Associated with Apheresis

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Background/Case Studies: A common event during and following apheresis is a sense of feeling chilled and hungry. Apheresis staff routinely supply blankets and snacks to counter these complaints. But these complaints may represent clinically significant symptoms indicating caloric loss related to apheresis and may be medically important in small patients and those undergoing large volume procedures. Caloric or heat loss associated with apheresis has not been quantitated. **Study Design/Methods**: To determine caloric loss, we monitored the temperature of 17 rhesus monkeys and the temperature and volume of the fluids withdrawn and infused during apheresis on two different apheresis devices. All temperatures were measured with Omega thermocouples and recorded at one-minute intervals during the entire apheresis procedure using a multi-lead Omega RDXL4SD recording thermometer. **Results/Findings**: Ten HPC-A collections were performed with a Fenwal CS3000 Plus device (BLOOD 87:1644, 1996) at a mean flow rate of 11 mL/min, revealing a loss in temperature between the inlet and return lines of a mean(SD) of 7.8(1.5)°C while processing 1,009(18) mL, resulting in 6,656(1,689) calories lost. Seven HPC-A collections were performed with a Spectra Optia device at a mean flow rate of 10 mL/min, revealing 9.5(0.9)°C lost between the inlet and return lines while processing

1,425(201) mL ($p<0.001$, difference in volumes processed), resulting in a loss of 11,827(1,987) calories. Although the CS3000 has an internal chamber heater and the Optia does not, the temperature loss between the two instruments was not significantly different ($p=0.10$). However, the caloric loss between the two devices was significantly different ($p<0.001$), likely due to the larger blood volume processed using the Optia vs the CS3000. Caloric content is computed by multiplying the volume of the fluid by the temperature change times the specific heat capacity of the fluid. By definition, one calorie is the amount of energy (4.2 joules) required to heat 1 mL of water 1°C; the corresponding heat capacity of blood is 3.6 joules per mL. Accordingly, a large volume at a lower temperature can contain and transfer more caloric energy (calories) than a smaller volume at a higher temperature. In an effort to control caloric loss during large volume apheresis without adding the additional extracorporeal volume of a blood warmer set, we placed a minimum of 38 cm of the return line in a 50°C water bath. With this maneuver, we were able to match the draw and return line temperatures and thereby eliminate caloric loss due to the apheresis procedure. **Conclusion**: We conclude that there is significant caloric loss associated with apheresis and warming return line fluids can alleviate this caloric loss. This maneuver may prevent symptomatic chills and hunger in subjects experiencing apheresis-associated caloric loss.

SP105

The Effect of Triple Apheresis Platelet Product Donation on Donors' Hematological Variables

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Background/Case Studies: A triple apheresis platelet (triple-PLT) product contains at least $9x10^{11}$ thrombocytes, according to national guidelines. For the donor, this loss represents nearly the 60% of the total amount of circulating platelets. Limited evidence is available regarding the hematological effects of short and long-term regular triple PLT donation. **Study Design/Methods**: Donors with at least three (3) triple-PLT donations performed over a 2-year period, were examined. Hematological variables were measured in a donor sample before each procedure, using a hematology analyzer (Abbott Cell Dyn 1800). Donors were categorized by gender, and cumulative number of triple-PLT donations and donation frequency (procedures per month) were determined. The Wilcoxon signed rank test was used to evaluate the change in hematological variables between the first and the last donation (Δ). Linear regression methods were used to evaluate effects of the number of donations and frequency, on changes in hematological variables. A significant difference was defined as a p value of less than 0.05. **Results/Findings**: In total 37 men and 5 women performed 197 triple-PLT donations. The median of procedures was 4 (IQR1-3: 3,00-5,25), with the maximum number of procedures and frequency being 18 and 1.1/month, respectively, during the analyzed period. There was no significant difference between the first and last donation for any of the hematological variables analyzed (platelets and leucocytes counts, Hb, MCV, MCH, RDW, MPV). Regression analysis found a declining trend of platelets and leukocytes counts associated with the frequency of donations, only when more than 6 donations were performed in the 2-year period. An increasing trend of Hb was found in men associated with both number of donations and frequency. The opposite was found for women, where Hb declined as number of donations and frequency were higher. The MCH showed a non-significant increasing trend in women associated with the donation frequency only. **Conclusion**: Triple-PLT donation performed in frequencies no higher than 1 procedure per month, showed no significant impact in hematological variables during the analyzed period. Certain but non-significant differences were found by gender associated with both number of donations and frequency.

SP106

The Effect of Unrelated Allogeneic Peripheral Blood Stem Cell Donor Age on Mobilization and Apheresis Collection of CD34+ Cells

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Background/Case Studies: Peripheral blood stem cells (PBSC) collected through apheresis of a related or unrelated donor continue to be an important source for allogeneic transplantation. This is highlighted by the BeTheMatch® Registry report of over 5,000 PBSC transplants occurring in 2013. The cell dose in the PBSC product is of upmost importance for engraftment, with $4x10^6$ CD34+ cells/kg of recipient weight considered the minimal number required. Higher doses are required in reduced-intensity conditioning and haploidentical transplants. A few studies have evaluated the effect of donor age on the success of mobilization. Most of them suggest higher age decreases PBSC CD34+ yields. More data is needed to elucidate this area and could provide transplant centers another evaluation criterion for the selection of an appropriate donor. **Study Design/Methods**: All PBSC donors collected from January 2013 through May 1, 2016 were retrospectively evaluated. This equated to 90 unique donors. One donor had inadequate venous access and was transferred to another facility for emergent central line placement and collection. This donor was excluded from this analysis. Data collected on the remaining 89 donors included age (in years) at time of donation, %CD34 in the donor's peripheral blood just prior to apheresis, and the total CD34+ cells collected per liter of blood processed during apheresis. **Results/Findings**: Table 1 shows the data on all 89 donors. The donors were categorized into decade age groups. For each age group, the mean and range of the %CD34 in peripheral blood and total CD34+cells/liter of blood were calculated. This data shows that none of the age groups examined have a statistically different level of %CD34 pre-apheresis or total number of CD34+cells/liter of blood processed. Data were analyzed using Unpaired T-Test. **Conclusion**: In this analysis of 89 sequential unrelated PBSC donors, there is not a statistically different level of %CD34 pre-apheresis or total number of CD34+cells/liter of blood processed when analyzed by age decade groups. This does not agree with most of the published literature on this topic, although a few published articles report this as well. Additional data is needed to verify these findings since this data set only comprised 89 donors and the preponderance of donors were in the 20-29 and 30-39 age groups. If verified, however, this could provide transplant centers with assurance that donors of a wide age range are appropriate to select for donation.

SP107

Absolute Immature Platelet Count (A-IPC) Predicts Imminent Platelet Recovery in a Thrombotic Thrombocytopenic Purpura (TTP) Patient with Coexistent Active Systemic Lupus Erythematosus (SLE) and Lymphoma

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Background/Case Studies: A-IPC reflects a real-time thrombopoietic rate that can predict platelet count recovery in TTP, in particular, in patients with additional coexistent platelet consumptive processes. Here we report on using A-IPC kinetics to predict and monitor imminent platelet recovery in a TTP patient with coexistent SLE and lymphoma. **Study Design/Methods**: A 37 year old female, under clinical management for active SLE and diffuse large B-cell lymphoma on remission, presented with acute onset of anemia and thrombocytopenia. Relevant laboratory results at presentation: platelet count 11 x 10^9/L, hemoglobin 7.1 g/dL, LDH 751 U/L, creatinine 1.18mg/dL, and haptoglobin < 8. TTP was suspected and daily therapeutic plasma exchange (TPE) was initiated in the setting of ADAMTS13 deficiency (<5%) and inhibitor of 0.9. A-IPC was obtained with daily complete blood counts as the product of the immature platelet fraction and platelet count. **Results/Findings**: Platelet counts at presentation ranged from 11-17 x 10^9/L and A-IPC of 0.6-1.1 x 10^9/L. Initiation of TPE led to rapid A-IPC production on day 2 of 2.48 x 10^9/L which continued to increase with TPE. In every instance the A-IPC increment preceded by 2-3 days corresponding changes of the platelet count. At this time flow analysis indicated patient's lymphoma could be relapsing. TPE was continued and on day 16 patient achieved platelet count of 147 x 10^9/L with corresponding A-IPC of 4.4 x 10^9/L. Of note a 3-fold ratio increase in A-IPC was obtained on day 2 of TPE. Platelet count remained over 140 x 10^9/L after 17 TPEs. Of interest, A-IPC ratio of 3 or greater was sustained for first 17 procedures (range: 4.03 - 5.08, mean: 4.53). ADAMTS13 activity increased to 8% on Day 14 of TPE. Once platelet count stabilized, A-IPC began a slower trend suggestive of normalization of a negative feedback loop driving platelet count recovery. Weekly Rituximab at 325mg/m^2 was given weekly for four cycles and alternated with TPE after her platelet count was stable at over 130 x 10^9/L. However, platelet count trended slightly lower over last course of TPE, from 132 x 10^9/L down to 110 x 10^9/L, while A-IPC remained high ranging from 2.79 to 4.14, indicative of an ongoing process which was being compensated by higher immature platelet production. TPE was discontinued on day 34, with platelet count at 110 x 10^9/L and A-IPC at 3.3. Corresponding ADAMTS13 activity was 36%. In subsequent seven months of follow up platelet counts remained stable with normalized ADAMTS13 activity. **Conclusion**: A-IPC rapidly and reliably predicts treatment response or recovery in TTP patients even in the presence of other comorbidities and should be routinely analyzed for diagnosing and monitoring TTP patients.

TABLE. Citrate Concentration (μmol.L^{-1})

Protocol		type	Pre-apheresis	Post-apheresis
Fenwal	AMICUS Bi-ponction	PLT-PLAS	797±194	1109±226
	AMICUS Uni-ponction		422±319	1545±660
	AUTOPHERESIS	PLAS	141±25	459±91
Terumo BCT	TRIMA	PLT-RCC	153±28	917±198
		PLT-PLAS	129±26	1828±685
Haemonetics	MCS+ LDP-C5	PLT-PLAS	290±188	836±210
	MCS+ C-SDP	PLT-PLAS	316±170	768±246
	PCS2	PLAS	248±128	420±107

TABLE. Citrate kinetics

Parameter	Calculations
Clearance **CL** (L/mn)	0,139
Compartment volume **V1** (L)	1,540
Compartment volume **V2** (L)	9,89
Half Life (T1/2α)	8,2 min

SP108

Citrate Concentration after Platelet and Plasmapheresis using Different Apheresis Systems

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Background/Case Studies: Little has been published on the decrease of donor citrate concentration after plasma or plateletpheresis protocols. In order to characterize the kinetics of citrate elimination, The Etablissement Français du Sang initiated a study on current platelet and plasmapheresis protocols to better understand pharmacodynamics of post-donation citrate elimination **Study Design/Methods**: The study was run in two phases. Phase I was designed to determine pre and post-apheresis citrate concentrations on 2 plasmapheresis and 6 platelet-plasmapheresis on AMICUS, TRIMA, MCS+, PCS2 and AUTOPHERESIS. For each protocol, a cohort of 20 donors (10M/10F) was selected. Citrate concentration was determined before and at the end of the collection.
Phase II focused on the two protocols giving the lower and higher post-collections citrate concentrations. 20 donors (10M/10F) were sampled at 0, 15, 30, 45, 60 and 90 mins at the end of the procedure for citrate concentration. **Results/Findings**: Mean pre-collection citrate concentration was 221μM. Mean post-collection was 420μM for plasmapheresis (Haemonetics PCS2) and 1828 μM for combined platelet/plasma collection on Trima (Terumo BCT). For phase II, mean citrate concentration at T_0 on PCS2 was 382 μM and initial concentration was recovered within 60 mins. On plateletpheresis (Trima), mean citrate concentration at T_0 was 2119 μM and initial concentration was recovered within 90 mins. A bi-compartmental pharmacodynamics best fitted the observed concentration decrease, with a mean clearance of 0.14 L/min and a mean distribution volume of 12 liters **Conclusion**: Post-apheresis citrate concentration is highly dependent on apheresis protocol. Pharmacodynamics calculation suggests a bi-compartmental model fits best the observed decrease. In all cases, this study confirms the complete elimination of the infused citrate within 90 minutes after the end of collection.

SP109

A Single-needle Off-line Extracorporal Photopheresis Pprotocol: Feasibility and Sside Effects

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Background/Case Studies: Extracorporal photopheresis (ECP) is an established second-line treatment for both graft-versus-host-disease (GVHD) after stem cell transplantation (SCT) and the bronchiolitis obliterans syndrome (BOS) after lung transplantation. A single-needle, off-line protocol was established in our center: buffy coat is collected on a cell separator, exposed to UVA light in the presence of 8-methoxypsoralen, and re-transfused. **Study Design/Methods**: We retrospectively analysed the feasibility of our protocol and the number of side effects related to 796 ECP procedures in 44 patients. **Results/Findings**: The mean age of patients was 49 years, 35% were female, and ECP was initiated 492 days (range 21-2,117) after transplantation. The mean duration of ECP was 20 weeks (range 1-93) with 18 procedures per patient (range 2-54). In the initial patient assessment, 14/44 patients were scheduled for central venous access (CVA); 4/44 had one, and 26/44 had two sufficient peripheral veins. In total, 537 procedures were performed via single-needle peripheral vein access, of which 85 (15.8%) required change of the punctured vein during the procedure. 20/548 (3.8%) were terminated early because an acceptable apheresis flow rate could not be maintained. A higher termination rate was observed in the CVA cohort (25/248=10%). The decision to cease ECP because of limited venous access was made in 5/44 patients (median week 9, range 1-26); 3/5 with CVA. Clinical side effects were observed in 18/793 procedures (2.3%) and included citrate reactions (10), vasovagal reactions (2), dyspnoea (2) hypopotassemia (2), and GI bleeds associated with low platelet counts (2). Major incidents observed in the CVA cohort included catheter-associated infections (5), fibrin obstruction requiring lysis (4), and catheter-associated thrombosis (2).Transfusion support with RBCUs or platelets was required in 10/44 patients for 28/793 procedures (3.5%). **Conclusion**: A major challenge in ECP is venous access. Single-needle, off-line protocols using peripheral veins are feasible in the majority of patients (63.6%), and most procedures are uneventful (63.4%). Occasionally, peri-procedural re-puncturing may be required. Based on our data, we conclude that 24/44 patients (54.5%) would also qualify for a peripheral dual-needle approach, but only in 308/796 (38.7%) procedures. Early termination of single-needle ECP procedures is not more frequent than in procedures with central lines. Of note, central lines put significant additional risk on patients. Central lines should only be considered for ECP if no reliable peripheral access can be established. Side effects of ECP not related to the venous access are rare and easily manageable.

SP110

Evaluating the Medical Necessity of Holiday and Weekend On-Call Apheresis Procedures at a Teaching Hospital

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Background/Case Studies: Our University Blood Center has an active apheresis service which includes 3 nurses who rotate on call duties. We have experienced significant apheresis nurse turnover (5 apheresis nurse resignations in 2.5 years). Exit interviews with the apheresis nurses revealed that the high frequency of weekend and holiday apheresis procedures was the primary reason for job dissatisfaction. The purpose of this study was to review weekend and holiday apheresis procedures for calendar year 2015 to determine if there were procedures that were not truly urgent over the weekend. **Study Design/Methods**: Weekend and holiday apheresis data was retrospectively collected and analyzed for calendar year 2015. Importantly, the clinical indication provided by primary service was assumed to be correct and not challenged. Each case was reviewed and assigned an ASFA indication category. The ASFA data was reviewed to determine if apheresis was a daily requirement for the condition, or could be performed every other day, or could be delayed until the earliest workday. **Results/Findings**: In 2015, there were 113 total holiday and weekend days evaluated, of which fifty-three days (46.9%) had one or more apheresis procedures. In total, 98 procedures were performed (2 RBC exchanges and 96 TPE or PP) on 39 unique patients. Four of 9 (44.4%) holidays and 29 of 52 (55.7%) weekends had apheresis procedures. Per ASFA 2013 guidelines, 8 procedures were category III or uncategorized, and 22 procedures which may be performed "every other day" were performed on consecutive weekend days. In total, as many as 27 weekend-holiday apheresis procedures could have been avoided, which translates to 10 weekend days which would have had no apheresis procedures. This translates to a reduction by 18.9% of holiday-weekend days worked. **Conclusion**: According to 2013 ASFA apheresis guidelines, 27.5% (27 apheresis procedures) of the weekend-holiday workload was performed under less than emergent/urgent conditions and was not "lifesaving". We have experienced significant turnover in nursing personnel and we plan to review cases proactively to see if they are urgent/emergent versus routine. This effort will likely reduce the total number of weekend procedures without compromising patient safety or outcomes. It is also likely to decrease staff turnover among our nurses.

TABLE. Total Red Cell Exchange with Depletion Procedures, n = 155

Age	18.5 years (7-36 years)
Weight	40 Kg (19 Kg-72 Kg)
Pre-procedure HCT	27%-37.6%
Red Cell depleted to HCT	24%-25%
End HCT	27%-30%
Target FCR	30%
Red cells saved	40 mL-510 mL

SP111

Efficacy and Tolerability of a Depletion-Red Cell Exchange Program with the Spectra Optia in Sickle Cell Disease Patients

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Background/Case Studies: Red Cell alloimmunization, iron overload, difficulty in finding phenotype-matched RBC, and multiple donor exposures are some of the major challenges that medical professional are confronted in treatment of chronically transfused Sickle Cell Disease (SCD) patients. Our center provides RBC exchange for scheduled patients in our chronic RBC exchange program and RBC exchange in emergency situations (acute chest syndrome, complicated pregnancy, and prior to surgery). In this study, we report our experience of automated RBC exchange in our SCD patients in whom we used Depletion-followed-by-Exchange technique. **Study Design/Methods**: We used Spectra Optia Apheresis System (TerumoBCT) for automated red cell exchange. A total of 155 RBC exchanges were performed by using the new apheresis platform. Hemodynamically stable patients with minimum HCT of 27% were selected for depletion followed by full exchange. Pre-exchange HCT ranged between 27% - 37.6% and patients weight was in range of 19 Kg - 72 Kg. Depletion volume was replaced by normal saline. Furthermore, to analyze the Red Cell volume saved in depletion-followed-by-exchange method we divided the patients in two categories, i.e., Group 1 category included patients with weight $<$ 30Kg and pre-procedure HCT $<$30%. Group 2 included patients having weight $>$ 40Kg and pre-procedure HCT $>$30%. **Results/Findings**: All procedures were completed without any complications. End HCT was left in the range of 27% - 30% or as requested by the patient's physician. Red cells saved were in the range 40mL - 510mL. **Conclusion**: Sickle cell disease patients represent a group of transfusion dependent patient population who are fraught with lifetime challenges for them, transfusion medicine and those medical professionals who care for them. We believe that minimizing Red Cell exposure to these patients can assist in lowering the risks of multi-transfusions, primarily, alloimmunization. Spectra Optia apheresis system provides an opportunity to deplete the sickle red cells followed by full exchange in SCD patients. Significant volumes of difficult-to-find phenotyped red cells can be saved in SCD patients with initial HCT of $>$30% and weighing 40kg and more. All patients tolerated the procedure well. Patients follow-up and more data needs to be collected to provide long term benefits of this methodology.

SP112

Fat Embolism Syndrome versus Thrombotic Thrombocytopenic Purpura in Patients with Sickle Cell Disease: Red Cell Exchange versus Plasma Exchange

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Background/Case Studies: Fat Embolism Syndrome (FES) is a rare complication of bone marrow necrosis in patients with sickle cell disease. The clinical triad of respiratory distress, thrombocytopenia, and petechial rash is characteristic of FES and may result in end organ dysfunction. In some patients these symptoms may mimic the clinical pentad of fever, thrombocytopenia, microangiopathic hemolytic anemia, altered mental status, and renal dysfunction associated with thrombotic thrombocytopenic purpura (TTP). It is imperative to rapidly diagnose FES to prevent further emboli, but the diagnosis can be delayed when more common diagnoses, especially TTP, are considered impeding appropriate diagnostic testing and treatment. **Study Design/Methods**: A 55 year old woman with hemoglobin SC disease had a two day history of abdominal pain followed by coma and respiratory failure. Initial findings supported non-ST segment elevation myocardial infarction, bilateral patchy opacities on thoracic CT, and normal head CT. Mild anemia (9.1 g/dL) and thrombocytopenia (126,000/uL) were noted. Her condition progressed with worsening anemia (5.5 g/dL) and thrombocytopenia (36,000/uL), fever, and elevated LDH (4214 U/L). Sickle cells, hemoglobin C crystals, shistocytes, and numerous nucleated red blood cells were present on peripheral smear. The diagnosis of TTP was highly suspected, and plasmapheresis was initiated. After five plasmapheresis procedures, her laboratory values had slightly improved, but her neurologic status remained unchanged. The ADAMTS-13 result revealed mild decrease in activity (49%; ref range $>$61%). A red cell exchange was then performed, and a brain MRI was obtained, finding hypodensities throughout the cerebral and cerebellar white matter consistent with fat microemboli, rendering the diagonsis of FES. Her post exchange hemoglobin remained stable (hemoglobin 8.9 g/dL), and two days post exchange, her platelets had increased to 177,000/uL. Unfortunately, her neurological status remained poor. **Results/Findings**: There have been 61 cases of FES reported in patients with sickle cell disease; 37 died (61%), 22 survived (36%), and two have unknown outcomes. Red cell exchange was performed on 19 patients, red cell transfusions on 19 patients, and 22 patients received supportive therapy alone. Fatal outcomes occured in 5 (26%), 11 (58%), and 20 (91%) patients, respectively. **Conclusion**: The frequency of FES is unknown in patients with bone marrow necrosis. In patients with sickle cell disease who develop acute respiratory and neurologic dysfunction, ADAMTS-13 levels and early utilization of brain MRI can provide rapid diagnosis so that aggressive and appropriate treatments can be initiated earlier.

SP113

Seasonal Variation in the Occurrence of Thrombotic Thrombocytopenic Purpura in Egypt

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Background/Case Studies: Thrombotic Thrombocytopenic Purpura (TTP) is defined by microangiopathic hemolytic anemia and thrombocytopenia with no other possible explanation. Being a rare disease, its epidemiology is still poorly understood. Limited data have been published on its seasonal trends. These data came from different regions in the US. Most of these studies point toward an increased incidence of TTP in the summer and the spring. Warm weather has been speculated for being a possible trigger in individuals who are at risk. The role of certain allergens and infections was suggested as a potential explanation for such seasonality. The aim of this study was to explore the seasonal factors that may influence the occurrence of TTP in Egypt and the Middle East, hoping this study can help better understand the epidemiology of this autoimmune disease. **Study Design/Methods**: This study included TTP patients with ADAMTS 13 activity of less than 10%, who underwent therapeutic plasma exchange from 2008 to 2016. Laboratory and demographic characteristics of patients were collected. Data on initial and relapsed episodes and month of presentation were analyzed. **Results/Findings**: Records of 37 patients with TTP were reviewed, of whom 23 (62.2%) were females. Their median age was 25 years. The overall mortality rate was 5/37 (13.5%). Their laboratory findings revealed thrombocytopenia, microangiopathic hemolytic anemia and schistocytes in the peripheral blood smear. Twenty nine patients (78.4%) were described as idiopathic and 8 (21.6%) had secondary causes including pregnancy (7 patients) and clopidogrel use (1 patient). Thirty seven patients had 39 episodes with 34 initial episodes and 5 relapses. Of the 5 relapses two occurred within two months, two occurred after 1 year, and one presented 20 years after complete remission. All episodes for both the idiopathic and secondary TTP demonstrated winter predominance, with 74.4% of all episodes presenting between November and April (29/39). Winter had significantly higher incidence for TTP (15/39 (38.5%)), compared with the summer (5/39 (12.8%) ($P=0.009$). This, However, was not significant when compared with the incidences in the spring (10/39 (25.6%)) and the fall (9/39 (23.1%)). Patients with secondary TTP had 10 episodes, with 80% of all episodes presenting between November and April. **Conclusion**: Compared to the seasonal trend in the occurrence of TTP in the US, seasonal trend in Egypt appears to be different. Our cohort of patients demonstrated winter predominance. Future studies, looking into the seasonal variation influencing the occurrence of TTP in different geographic locations may be warranted. This can help gain additional insight into the possible environmental factors involved in the occurrence of TTP, ultimately providing a better understanding for the pathophysiology of this rare disease.

SP114

The Management of Patients on Anticoagulation Therapy while Undergoing Therapeutic Plasma Exchange

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Background/Case Studies: Therapeutic plasma exchange (TPE) is used for various conditions in a heterogeneous patient population. The TPE process, during which plasma is removed, may lead to significant alterations in hemostasis. **Study Design/Methods**: AABB Apheresis Subsection members from 9 institutions discussed the management of patients receiving anticoagulation while undergoing TPE. **Results/Findings**: TPE schedules: In some institutions the clinical team provides a schedule, but in others the apheresis team decides. The discussants agreed that performing TPEs every other day rather than daily lessens the effects of TPE on clotting factors. Anticoagulation: Most institutions perform TPE for patients while on warfarin, heparin, or newer anticoagulants; several places switch patients on these medications to low molecular weight heparin, which they withhold on the day of TPE. Regarding new oral anticoagulants, one institution recommends switching to enoxaparin or dalteparin and not to administer these on the day of TPE until after the procedure. Monitoring coagulation status and replacement fluids: Most institutions perform one plasma volume TPEs. The standard replacement fluid is 5% albumin. However, if INR is $\geq$1.5 and $\leq$2, or fibrinogen is between 80 and 100 mg/dL, some physicians use 10 to 15 ml/kg of plasma for the last part of the TPE, reducing albumin by that amount (equates to about 3 units of plasma or about 1/4 of the plasma volume). If INR is $\geq$2 or fibrinogen is $<$80, some physicians use 4 units of plasma instead of albumin for the last part of the TPE (about 1/2 of the plasma volume). Other formulas used: for INR 1.5-1.7, use 1/4 of the volume as plasma; for INR 1.8-1.9, use 1/3 of the volume as plasma; for INR 2, use 1/2 of the volume as plasma (in each case, use the plasma for the last part of the TPE); for INR $>$2, use all plasma. Patients on warfarin for pulmonary embolism or atrial fibrillation may not need plasma if their baseline INR is 2 unless there is concern for bleeding. Calcium supplementation: Factors contributing to hypocalcemia during TPE include the anticoagulant usually used (citrate, which binds calcium), the additional citrate in plasma (if used), and the lack of calcium in albumin. Although some institutions do not routinely give calcium for a standard TPE, others do. Following ionized calcium levels is helpful. Calcium carbonate may be given orally before and, if needed, during TPE (e.g., 2500 mg to 3000 mg prior and 1000 mg to 1500 mg at the midpoint, if indicated), or calcium gluconate may be infused IV (e.g., depending on the patient's calcium level, 1 to 2 gm, not to be given in the same line as plasma). **Conclusion**: Patients undergoing TPE must be monitored closely and managed on an individual basis taking into account their clinical condition and the issues discussed above.

SP115

Absolute Immature Platelet Count (A-IPC) Dynamics in Adolescent Patients with Thrombotic Thrombocytopenic Purpura (TTP)

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Background/Case Studies: TTP is a thrombotic microangiopathy due to severely reduced activity of the von Willebrand factor-cleaving protease ADAMTS13. The median age for diagnosis of idiopathic TTP is 41 (range 9-78). By estimation, the incidence of TTP in children $<$18 years old is approximately 1 per 10 million per year which is 30 fold less common than in adults. The disease course and characteristics of TTP in younger patients may differ from that seen in older populations, however, they have not been well studied. Here we report our observations of A-IPC in three adolescent patients with ADAMTS13 activity $<$10%. **Study Design/Methods**: Our study cohort consisted of three adolescent patients diagnosed with idiopathic TTP (ADAMTS13 activity $<$10%) who underwent daily 1-1.5 volume therapeutic plasma exchange (TPE) with type specific plasma as replacement fluid. The ages of the patients at time of first TTP diagnosis were 16, 17 and 19 years old. One of the three patients had two relapse episodes, which required extended hospital stays. Clinical course and laboratory values for these three patients were reviewed. A-IPC was generated by multiplying the immature platelet fraction (%-IPF) times corresponding platelet count. **Results/Findings**: All three patients were female with a BMI$>$30 but otherwise previously healthy prior to initial presentation. Two were Caucasian and one was biracial. ADAMTS13 activity was 6% in one patient and $<$5% in the other two. ADAMTS13 inhibitors were identified in two patients and ADAMTS13 antibody was identified in the third patient. All three had a significantly increased %-IPF ($>$10%) and decreased A-IPC and platelet count at presentation. The A-IPC rapidly trended higher; greater than 3 fold once TPE treatment was initiated and showed a negatively regulated feedback curve once platelet counts recovered. A very high distinct A-IPC peak (10.0-19.5 x 10^9/L) suggestive of significant platelet consumption/turnover were observed in these young patients soon after start of TPE. All three patients required prolonged hospital stays. **Conclusion**: Clinical and laboratory features of TTP in these adolescent patients shared similarities, specifically high %-IPF at presentation and high A-IPC peak values during TPE treatment. This pattern differs from that previously reported for an older cohort of patients and may point to a unique disease course in this patient population, suggesting a prolonged treatment course may be needed for younger TTP patients. Additional studies are needed.

SP116

Optimization of the Spectra Optia for Apheresis of Very Small Subjects

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Background/Case Studies: Apheresis of small volume subjects requires procedure modifications related to anticoagulant, venous access, and volume management. In this study, an apheresis procedure for small volume subjects is evaluated using the Spectra Optia. **Study Design/Methods**: Three rhesus macaques, weight 6.1-8.1 kg, were studied. 100 mL of autologous blood (25mL/wk x 4 wks) was used to prime. 81 mg of aspirin was given for 2 days. Apheresis procedures were performed twice on each monkey either 1 month apart (2 monkeys) or sequentially (1 monkey). G-CSF(15μg/kg SQ) was administered for 5 consecutive days and a single dose of AMD3100 (1 mg/kg SQ) 2-3 hours prior to leukapheresis. Autologous blood was pooled, diluted 1:1 with saline, washed, and ACDA(10%v/v) added. A customized albumin option was used to prime to shorten ramp-up time. 30-35 mL of the 40-50 mL packed RBCs was initially used to prime at 10 mL/min. A closed circuit was then created between the return line and the pRBC bag and the flow rate increased to 40 mL/min until 300 mL was processed. To minimize citrate toxicity and avoid volume overload, animals received heparin 50 U/kg bolus IV followed by an ACDA solution containing heparin 5U/mL at an inlet:AC ratio of 25:1. A Collection Preference (CP) setting of 20 was selected. Procedures were terminated on the third collection. A single lumen central catheter was used for the draw and a 19g angiocatheter for the return line. CBC, chemistries, and ionized calcium (iCa) levels were monitored. After each collection, diluted CaCl (10mg/kg diluted in 2.5mL saline) was administered to the return line over 10 mins using a syringe pump. **Results/Findings**: Six apheresis procedures were performed. Inlet flow rates were 10 mL/min. Mean(SD) volume processed was 1497(202) mL per procedure (3.6(0.4) blood volumes). The baseline iCa value of 1.11(0.05) dropped to 0.82(0.07) mmol/L at procedure end. The HCT did not change (37.5(4.8) to 37.4(4.8)% ($p=0.8$)); however, platelet counts declined from 335(112) to 132(39) x$10^3/\mu$L($p=0.002$). This drop was reflected in a large number of platelets in the product, 1201(399)x$10^3/\mu$L. Product MNC content was 7.28(1.01)x10^9 . MNC collection efficiency (CE) was 60.5(10)%. Product MNC composition consisted of 9.8(0.8)x10^8 CD4$^+$, 11.6(5.2)x10^8 CD8$^+$, and 15.9(6.6)x10^8 CD20$^+$ lymphs, and 11.6(5.2)x10^8 CD14$^+$ monos. The CE for CD34+ cells was 54(30)%, with 39(22)x10^6 CD34+ cells in the product. Following immunoselection, 21(7)x10^6 CD34+ cells were isolated (94.2(4.8)% purity), yielding a transplant dose of 2.6(2.0)x10^6/kg. **Conclusion**: The use of apheresis in a pediatric setting is difficult due to small blood volumes and a high risk of adverse events. Here we identified a novel means to perform apheresis safely and effectively in small volume subjects; having numerous therapeutic applications in both human and veterinary medicine.

SP117

Recovery from Overlapping Immune Processes Leading to a Catastrophic Immune Presentation during Pregnancy can be Determined by Changes in Absolute Immature Platelet Counts (A-IPC)

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Background/Case Studies: Multiple clinical conditions lead to thrombocytopenia and differentiating among them can be challenging due to significant overlap in clinical presentation. A-IPC aids in differentiation among etiologies of thrombocytopenia, as previously shown in the setting of thrombotic thrombocytopenic purpura. Here we report the case of a pregnant woman presenting with a catastrophic immune-mediated fetal demise. **Study Design/Methods**: A 30 year old G3P0020 female with a history of systemic lupus erythematosus and anti-phospholipid antibodies presented with intrauterine fetal demise in her 19th week (third loss). Patient had thrombocytopenia (55 x 10^9/L), anemia (Hgb 8.9 g/dL), and elevated lactate dehydrogenase (422 U/L). After dilatation and evacuation (D&E) patient responded poorly to platelet and red cell transfusions and renal function deteriorated (1.89 g/dL). At this time, subtle acute mental changes led to initiation of therapeutic plasma exchange (TPE) with plasma as replacement fluid. ADAMTS13 activity testing from admission day was 60% (x2). A-IPC was calculated as the product of the immature platelet fraction and platelet count. **Results/Findings**: Platelet nadir was 13 x 10^9/L 3 days post-D&E and patient developed elevated troponins. Daily TPE led to increased platelet count of 163 x 10^9/L by day 10 that was sustained for a week. On day 13, patient was started on Eculizumab (900 mg) with pause of TPE. On day 19, platelets decreased to 55 x 10^9/L and TPE was resumed. A-IPC increased from 5.7 x 10^9/L to 6.8 x 10^9/L, indicative of a consumptive process. The patient tested positive for anti-platelet and for anti-platelet factor 4 antibodies; serotonin release assay was negative. An additional 12 TPE were performed and patient was given 2nd course of Eculizumab (900 mg) with post-TPE boost (600 mg). On day 25 she was given the first of 3 doses of cyclophosphamide (664-724 mg); A-IPC increased to 8.7 x 10^9/L on day 31. Platelet count remained around 100 x 10^9/L for almost two weeks. On day 43 platelets decreased to 73 x 10^9/L, A-IPC was 4.73 x 10^9/L and daily TPE was initiated. On day 49 patient was given first of two doses of Rituximab (325mg/m^2). A-IPC increased to 6.9 x 10^9/L which preceded platelet count return to 94 x 10^9/L. A-IPC remained at 4-5.8 x 10^9/L for ten days leading to sustained response of platelet counts. Patient was discharged on day 60; one week post-discharge patient's platelets were 174 x 10^9/L. **Conclusion**: Complex immune-mediated thrombocytopenia can be challenging to follow but testing of the A-IPC can help to elucidate sustainability of response to therapy. Further studies on the application of A-IPC kinetics may prove to be a valuable tool in the management of patients with overlapping immune processes.

SP118

Multiple Plasmapheresis Procedures: Essential in Treatment of Anti-NMDAR Encephalitis

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Background/Case Studies: Anti-N-methyl D-aspartate receptor (anti-NMDAR) encephalitis is one of the most commonly diagnosed autoimmune encephalitides. Its presentation may be severe and devastating as part of a paraneoplastic syndrome with neuropsychiatric symptoms such as seizures, dysautonomia, and dyskinesias affecting children and young adults as the major victims. Therapeutic plasma exchange (TPE) has been shown to be beneficial, but may have limited effects due to the prolonged undetectable status of the pathogenic tumor. We report a case of a patient with paraneoplastic syndrome who responded to TPE treatment after tumor removal. **Study Design/Methods**: This is a 20 year-old female with a past medical history of an ovarian cyst status post removal two years prior who presented with symptoms of agitation, psychosis, and suspected seizures. Lumbar puncture revealed clear cerebrospinal fluid (CSF) with a protein 54.3, glucose 47 and white blood cells (WBC) 311. Anti-NMDAR antibody was detected in her serum with a titer of 1:160. Abdominal magnetic resonance imaging revealed a right ovarian cystadenoma. Besides intravenous immunoglobulin and rituximab, 3 TPE procedures were performed prior to operation at an outside facility. Her mental status deteriorated immediately after ovarian tumor removal. With concern for the possible release of antibody during tumor removal and the relatively long half-life of the anti-NMDAR antibody, we performed 7 additional TPE procedures. **Results/Findings**: The patient's mental and physical status steadily improved with the increased number of TPE procedures performed. After a total of 10 TPEs, the patient became capable of participating in three hours of physical and occupational therapy daily while hospitalized. The anti-NMDAR antibody CSF titer decreased to 1:40 after five procedures. Additionally, the WBC count of the CSF decreased to 19. **Conclusion**: We encountered an uncommon case where the underlying tumor was identified shortly after clinical presentation. The combination of tumor removal and TPE proved to be invaluable in the management of anti-NMDAR encephalitis. Multiple post-operative TPE procedures may be required not only to remove additional antibodies released during the tumor removal but also to counter the long half-life of the anti-NMDAR antibody.

SP119

The Donor Factors Influencing the Amount of CD34+ Cells Collected for Peripheral Blood Stem Cell Transplantation

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Background/Case Studies: Recently, peripheral blood stem cell (PBSC) has been widely used as the stem cell source in allogeneic hematopoietic stem cell transplantation (HSCT) replacing conventional bone marrow transplantation. PBSCT has advantage in accessibility, donor complications and rapid engraftment. Under normal conditions, only less than 0.05% of the white blood cells (WBC) are CD34+ cells, so mobilization and collection of peripheral blood CD34+ cells is important. We analyzed the predicting factors affecting the total amount of peripheral blood CD34+ cells. **Study Design/Methods**: Six hundred seventy two healthy donors who under went PBSC harvest procedure at Seoul St. Mary's Hospital between 2009 and 2015 were enrolled. All donors received subcutaneous G-CSF (10 μg/kg donor body weight) for four consecutive days and PBSC harvest was performed using a commercially available apheresis system (COBE Spectra, Gambro BCT, Inc., Lakewood, CO) on the fourth day of G-CSF administration. Statistical tests (Jonckheere-Terpstra trend test, Student's T test) were used to assess the significant correlation between age, gender, body weight, number of collection and number of collected CD34+ cells. **Results/Findings**: Collected peripheral CD34+ cell numbers were decreased with increasing donor age ($p<0.05$). Peripheral CD34+ cell numbers were increased with increasing donor weight ($p<0.05$). We analyzed the gender factor and found out male donors tend to have more amount of CD34+ cells than female donors ($p<0.05$). We also analyzed whether collecting through a peripheral vein in the arm or central vein would make a difference. It was not significantly correlated with the total count of PB CD34+ cells ($p=0.45$). The Number of cell collection times had relationship with amount of CD34+ cells. The total amount of CD34+ cells collected decreased with increasing number of cell collection. **Conclusion**: The gender, body weight, age, number of collection of donors were significantly correlated with the number of PB CD34+ cells. The collection route did not affect the cell count. We suggest that investigating the donor factors is important prior to PBSC mobilization.

SP120

The Effect of a Software Upgrade on Occupancy Rate in Apheresis Schedules

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Background/Case Studies: To achieve the specified targets of plasmapheresis procedures, Sanquin contacts donors for plasmapheresis appointments which are registered in the eProgesa agenda. After a software upgrade (express software) on 65% of all apheresis equipment at collection sites in The Netherlands, procedure times have shortened with an average of 12 minutes due to a higher return speed. This promises favourable effects for the schedule planning as well as the session plan within the Blood Collection Department. The time gain can be used to schedule more procedures in the same time slot. Purpose of this study is to make use of the software to create a smart occupancy rate so more appointments can be made in the apheresis schedules without increasing waiting and passing time. The effects are measured by means of a pilot. **Study Design/Methods**: For the schedules it was important to determine the mean donation time of a standard donation procedure (600-650 mls). In order to accomplish this information, data of 108,339 plasmapheresis donations collected with apheresis equipment between Q1 and Q4 2014 were analysed. New schedules with the same opening hours and sessions per location were calculated and prepared in Excel. Then the national blood bank information system

TABLE.

	Average procedure time per donor	Agenda planning
Before software upgrade	43 minutes	0% extra procedures
After software upgrade	31 minutes	19% extra appointments; i.e., 665 extra appointments

was prepared. Historic figures showed that a surplus planning of 40% (i.e. 140% planning) was needed in order to reach a 100% target of the plasma collections. **Results/Findings**: The mean duration of a plasmapheresis donation with the new software is 31 minutes, with a standard deviation of 0.05 minutes. This shortened procedure times results in a 16%-21% increase of appointments the same time slot, with an increase average of 19%. The increase in additional appointments resulted in a nationwide increase average of 20% plasma procedures. **Conclusion**: Adjusting the apheresis schedules to the shortened apheresis donation time creates extensive opportunities to make appointments and will therefore lead to an increase of plasma procedures in the same time slot. This results in a guaranteed reach of reliable plasma targets. There has been no significant increase of donor complications. On the opposite: donors now have several choices with regard to popular appointment times, resulting in goal-oriented sessions with optimal target results. And last but not least: donors benefit from a shortened passing time.
Results:

SP121

Red Cell Exchange and RhIg Mitigate Anti-D Formation after Massive Transfusion

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Background/Case Studies: Massive Transfusion Protocol (MTP) needs may exceed Rh negative red blood cell (RBC) stocks, with transfusion of Rh pos RBCs to Rh neg patients. Red cell exchange (RCE) via apheresis and RhIg reduce anti-D formation.In this MTP case, an O Rh-neg 18 year female (F) transfused O Rh-pos RBCs is treated with RCE and RhIg. **Study Design/Methods**: Solid phase testing - RBC antibody screen (ABS), ABO/Rh determination, (NEO, Immucor, Norcross, GA, USA); Tube Method - ABO/Rh determination, RBC ABS, DAT, IAT in polyethylene glycol (PEG), antibody elution in PEG with Gamma Elu-KIT II (Immucor, Norcross, GA, USA); Light microscopy - FMH RapidScreen (Immucor, Norcross, GA, USA); RCE calculations - Cobe Spectra software v6.1 (Terumo BCT, Lakewood, CO, USA) **Results/Findings**: Post motor vehicle accident 18 year F Trauma 1 patient came to hospital A, an American College of Surgeons (ACS) Level 2 trauma center with multiple pelvic fractures and vaginal bleeding, MTP called. Patient typed O neg; antibody screen was neg. Given 16 O neg RBCs; then 8 O pos RBCs. Total hospital A transfusions: 24 RBCs, 16 FFP, 2 PLTs, 1 Cryo(5 pool). Transferred to hospital B, ACS Level 1 trauma center, and typed O pos, given 1 O neg RBC, 1 PLT and tranexamic acid. Subsequent external fixation and post-surgery care required 5 O pos RBCs, 10 FFP, 2 PLTs, 2 Cryo (5 pools). Family history of 2 relatives (1st degree) with anti-D following 1st pregnancy noted. Post accident day 2, the 167cm, 79 kg patient underwent RCE via Cobe Spectra (Terumo BCT, Lakewood, CO, USA) with 27% HCT, calculated TBV of 5135mL and using FCR of 10 a total of 17 O neg RBC units were exchanged over 3 hours, with 134 mL of calculated remaining Rh pos RBCs. RhIG at 18 μg RhIG/mL Rh Pos red cells totaling 8 (600 μg) vials was given. Hypotension (from 163/65 to 93/44 mmHg) and bradycardia (from 91 to 66 bpm) followed the 3rd RhIG vial; the remaining RhIG was administered the following day without further incident. Two PLTs were transfused for Thrombocytopenia (16 K/uL) after RCE. FMH was twice negative after RCE. Antibody screen 5 months post RCE is negative. **Conclusion**: Large volume RCE followed by IV RhIG performed to avoid anti-D formation following Rh incompatible RBCs in MTP with a strong family history of pregnancy related anti-D. No hemolysis was noted, mild hypotension and bradycardia were seen in relation to IV RhIG administration and thrombocytopenia was seen in relation to the apheresis procedure.

SP122

Therapeutic Plasma Exchange Performed in Tandem with Hemodialysis without Supplemental Calcium in the Apheresis Circuit

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Background/Case Studies: Therapeutic plasma exchange (TPE) and hemopoietic progenitor cell (HPC) collection are apheresis procedures that can safely be performed in tandem with hemodialysis. For HPC collection, it is not necessary to administer supplemental calcium during tandem procedures because ionized calcium does not fall to a statistically significant extent as the returning blood passes through the dialyzer. It is not known whether this applies to TPE, in which a mixture of blood and pharmaceutical albumin, an avid binder of plasma ionized calcium, is returned to the patient through the dialyzer. We report on 3 dialysis-dependent patients who required TPE and underwent tandem treatments without supplemental calcium in the apheresis circuit. **Study Design/Methods**: All TPE procedures processed 1 plasma volume using a COBE Spectra apheresis system with 5% albumin solution as the replacement fluid. No calcium gluconate was added to the apheresis circuit. Hemodialysis was performed concurrently with TPE without heparin in the dialysis circuit. All patients were dialyzed against a dialysis bath that included 2.5 meq/L of calcium. Plasma ionized calcium was measured at the outset, midpoint and the end of apheresis to determine whether it remained stable during the tandem procedures. **Results/Findings**: Patient information and outcome data are provided in the table. Overall, ionized calcium fell 4-12% which was statistically significant but not enough to cause hypocalcemic toxicity in any patient. **Conclusion**: Albumin is more potent at reducing plasma ionized calcium than citrate in tandem procedures, but hemodialysis is protective against hypocalcemic toxicity.

TABLE.

Days post-accident	Rh testing	RBC antibody Screen	RBC antibody identification	DAT	Eluate	FMH screen
0 (hospital A)	Neg Weak D-Neg	Neg				
0 (hospital B)	3+MF	Neg				
2 (after RCE)	Neg Weak D-Neg	Pos	Anti-D	Pos for C3d		
5						Neg
9						Neg
10	Weak micro positive	Pos	Anti-D	Pos for IgG	Anti-D	
150		Neg				

TABLE. Patient information and outcome parameters

Patient Information		Plasma Volume (mL)	Plasma Ionized Calcium (mg/dL) Start	Mid	End	Urea Reduction Ratio* (%)
Patient # 1	51 y/o ♂ with recurrent FSGS after second renal transplant	6735	5.3		5.0	75.3
Patient # 2	63 y/o ♀ with anti-GBM disease	3677	4.6	4.4	4.4	67.8
		3786	4.6	4.4	4.2	67.1
		3687	4.8	4.5	4.2	61.5
Patient # 3	53 y/o ♂ with humoral renal rejection	3597	4.4	4.2	4.1	64
	1 month post transplant for nephrosclerosis	3500	4.5	4.6	4.3	84.6
			$p = 0.024$§			

*URR = 100 x [BUN] pre − [BUN] post / [BUN] pre

§Friedman Repeated-Measures ANOVA on Ranks

SP123

Therapeutic Plasma Eexchange in Carfilzomib-induced Thrombotic Microangiopathy

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Background/Case Studies: A 60 year old male with IgA kappa plasmacytic myeloma status post multiple treatment regimens as well as auto- and allo-HCTs presented with thrombocytopenia, hemolytic anemia, schistocytosis (image 1) and renal failure. He had recently started treatment with carfilzomib, pomalidomide, and dexamethasone (CPD). His presentation was attributed to a probable drug reaction to carfilzomib (discontinued) using the Naranjo adverse drug reaction scale. **Study Design/Methods**: Eight daily therapeutic plasma exchanges were performed and pertinent laboratory parameters were trended (table 1). **Results/Findings**: At admission, urine protein was 9408 mg/24hr (reference range <150 mg/24hr) and complement levels were normal. The patient remained afebrile without neurologic alterations. Renal function improved and he was discharged. **Conclusion**: The FDA approved CPD for the treatment of patients with relapsed myeloma who have received one to three prior lines of therapy in 2015. An online FDA drug warning notes "cases of thrombotic microangiopathy, including

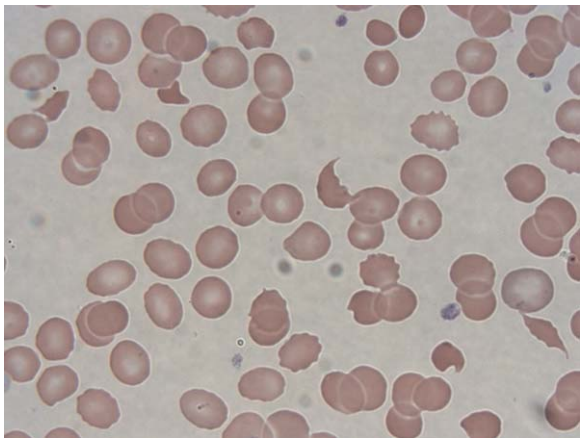

Fig. 1. Carfilzomib-induced schistocytosis (1000x total magnification)

TABLE.

Test or Procedure	3/28/2016	3/30/2016	3/31/2016	4/1/2016	4/2/2016	4/3/2016	4/4/2016	4/5/2016	4/6/2016	4/7/2016	4/8/2016	4/9/2016	4/11/2016
	Date												
Hemoglobin (reference range: 13.5 - 17.5 g/dL)	11.1	8.8	8.0	7.8	8.7	8.8	8.9	7.8	9.6	8.3	8.2	8.1	10.3
Packed red blood cell units				1				1				1	
Platelet count (reference range: 130 - 400K/mm3)	104	40	100	121	127	136	154	186	220	212	198	208	267
Apheresis platelet units		1											
Lactate dehydrogenase (reference range: 90 - 200 U/L)			458	293			198			135	152		
Serum creatinine (reference range: 0.44 - 1.27 mg/dL)		4.64	5.16	5.42	5.33	5.47	4.73	3.96	3.77	2.93	3.00	2.53	1.91
Schistocytes/hpf (500x)		26.0		43.3		35.7	30.3	16.3		16.3			6.3
ADAMTS-13 activity (reference range: >69%)		75		85									
24 hour urine output (mL)			1075	900	2500		1775	1000	1800	2050	2200		
Fresh frozen plasma transfused with exchange (mL)				3600	3600	3600	3600	3600	3600	3600	3600		

thrombotic thrombocytopenic purpura/hemolytic uremic syndrome, have been reported." The American Society for Apheresis Guidelines (2013) does not include carfilzomib-induced thrombotic microangiopathy in its indications for therapeutic plasma exchange. This is the first case known to the authors documenting a trial of therapeutic plasma exchange in carfilzomib-induced thrombotic microangiopathy and it was successful.

SP124

Management of a Sickle Cell Disease Patient with Severe Thrombocytosis

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Background/Case Studies: Sickle cell disease (SCD) is a severe genetic disorder that not only creates dysfunctional red blood cells (RBC) but can also lead to elevated platelets (PLT). Symptomatic thrombocytosis due to SCD are commonly treated indirectly by treating SCD. We report a case where both RBC exchange and plateletpheresis are utilized to treat a SCD patient with persistent thrombocytosis and its thrombotic symptoms. **Study Design/Methods**: A 33 year old man with a medical history of sickle cell disease, cerebrovascular accident, and deep venous thrombosis has had repeated admissions for possible thrombotic events and persistent thrombocytosis. During the early admissions (A-C in Table), his symptoms were managed with urgent RBC exchanges. On one admission, the patient presented with progressing altered mental status, thrombocytosis (PLT count, 1811 x 10^9/L), and head CT concerning for right frontal lobe infarct. PLT count decreased to 274 x 10^9/L after RBC exchange. **Results/Findings**: Subsequent readmissions would present with similar possible thrombotic symptoms. During admission D (Table), the patient presented with neurological symptoms (scanning speech and nystagmus) and PLT count of 2370 x 10^9/L. Brain MRI revealed areas of encephalomalacia in the right temporal and left temporal, frontal, and parietal lobes. Since a RBC exchange was done about 3 weeks prior to the event, plateletpheresis (D1) was performed aiming to prevent further thrombotic events; however, PLT count increased to 1 million in a few days after the initial post procedural count of 881 x 10^9/L. An additional RBC exchange (D2) was subsequently administered. The patient's PLT gradually recovered, and his symptoms improved. Further bone marrow biopsy and genetic testing were negative for myeloproliferative disorder. Given his clinical presentation, the patient was placed on regular outpatient RBC exchange to treat both his SCD and thrombocytosis. Follow up for the past three years revealed stable PLT counts at approximately 400 x 10^9/L with no hospital admissions to date. **Conclusion**: Thrombocytosis with concurrent SCD is most likely reactive in etiology hence plateletepheresis in this setting is usually ineffective. However, plateletpheresis may be required when severe thrombotic complications are in high risk. Long-term RBC exchange is optimal for not only treating SCD but also reducing PLT count, further decreasing the risk of vascular complications.

TABLE.

Admissions	A	B	C	D1	D2
Pre-procedure PLT count*	1811	1037	1925	2370	1712
Post-procedure PLT count*	274	347	605	881	978

*value x 10^9/L.

SP462

The Apheresis Management of Patients with Solid Organ Transplantation

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Background/Case Studies: Therapeutic apheresis (TA), including both therapeutic plasma exchange (TPE) and extracorporeal photopheresis (ECP), have been used in the treatment of rejection of solid organ allografts. The American Society for Apheresis has published guidelines on the use of TA for solid organ transplantation; however, the details of apheresis treatment are not specified. The goal of this study is to survey the practice of TA among AABB Apheresis Subsection members' institutions for the treatment of rejection of solid organ allografts. **Study Design/Methods**: A discussion forum was created among the AABB Apheresis Subsection Committee members from 6 institutions to discuss the TA management plans for patients with rejection of solid organ allografts. **Results/Findings**: Treatment plan: For acute rejection of heart allografts, 2 institutions perform at least 3 daily emergent TPEs based on the patient's hemodynamic instability regardless of the biopsy results or the presence of donor specific antibodies (DSAs). Further TPEs every other day may be given if DSAs are present. Ejection fraction and DSA levels are used as biomarkers to monitor treatment response. ECP is used mainly for the treatment of chronic rejection. For acute rejection of lung allografts, some institutions perform TPE (can be urgent if the patient needs extracorporeal support) for a total of 5 treatments every other day. Other institutions only perform ECP for rejection of lung allografts. For acute rejection of renal allografts, the urgency of TPE depends on the patient's clinical condition. Several institutions perform 3 to 5 TPEs every other day. One institution performs 4 TPEs daily followed by 3 TPEs every other day, and sometimes this cycle is repeated. DSA levels are monitored. TPE for acute rejection of liver allografts is not common; one institution performs 5 TPEs every other day within 24 hours of being consulted. Replacement fluid: All institutions agreed that 5% albumin should be the replacement fluid for TPEs unless the patient has a coagulopathy, active bleeding, is pre- or post-procedure (e.g., biopsy) and/or has fibrinogen $<$100 mg/dL or INR $\geq$1.5. In such situations, varying amounts of 5% albumin and plasma (for the last part of the exchange) generally are used as replacement fluids. **Conclusion**: There is considerable variation in TPE protocols for the treatment of solid organ rejection among institutions participating in the AABB Apheresis Subsection. Most members agree that TPE should be performed emergently for unstable patients or within 24 hours for stable patients. If TPE is performed, 5 procedures are common. The first few may be daily, and the latter ones may be every other day. DSAs may be used as biomarkers for follow-up. Unless otherwise indicated, 5% albumin is used as replacement fluid. ECP is used mainly for the treatment of chronic rejection.

Donor Recruitment, Retention, and Adverse Events

SP125

The Variation in Blood Cells Counts Before and After Blood Donation

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Background/Case Studies: The voluntary un-remunerated blood donation rate in mainland China is now only 9‰ according to the statistics by the Ministry of Health of PRC. One main reason is that people worry about the influence on health after blood donation. This study investigated donors' physiological change and the release and recovery time of reserve pool after blood donation by observing the variation in blood cells counts for different donation amount at different times before and after blood donation. **Study Design/Methods**: 63 voluntary donors of different ages were randomly chosen. They were divided into 2 groups: Group A (200ml) and Group B (400ml) with respect to the volume of blood donated. Blood routine tests were performed before, immediately after, then 1hour, 1 day and subsequently 1 week after the donation. **Results/Findings**: All the data of blood routine test were in the normal range at different times. It has been shown that for group A, the RBC and Hb counts had respectively decreased by $(0.97 \pm 0.65)\times10^{12}$/L and$(29.20 \pm 18.89)$g/L immediately after blood donation; then had respectively increased by $(0.75 \pm 0.56)\times10^{12}$/L and (22.66 ± 16.31) g/L 1hour after blood donation to immediately after donation. And for group B, the RBC and Hb counts respectively decreased immediately after donation by $(1.04 \pm 0.48)\times10^{12}$/L and (31.26 ± 14.04)g/L, while the counts at 1 hour after donation respectively increased by $(0.89 \pm 0.45)\times10^{12}$/L and (27.53 ± 14.17) g/L respective to immediately after donation. There was an obvious variation in blood cell counts before and immediately after donation, and also between immediately after donation and 1 hour, 1 day and 1 week after donation ($P<0.05$). The red blood cell and hemoglobin of two groups at 1 hour after donation can be restored to more than 93% to that before donation. **Conclusion**: Although there is decrease in blood cell counts after a donation, tissue fluid replenishes blood volume immediately and blood cells counts reach a peak at 1 hour post-donation as the reserve pool releases blood cells. The blood volume is replenished within a week of donation with no obvious difference in blood cell counts after donation in both Group A and Group B. Hence it can be deduced that blood donation is safe.

SP126

Donor Willingness to Share Protected Health Information in Cohort Health Outcomes and Genetic Studies

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Background/Case Studies: Donors' willingness to share protected health information (PHI) has been the subject of discussion and research across the globe. The advent of the Precision Medicine Initiative (PMI) in the USA, an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person, requires access to detailed individual health information. Blood donors are considered strong candidates for participating in PMI. The objective of this study was assess how likely donors would be to participate in a long-term study of changes in their health status, as well as how likely they would be willing to provide biobank specimens for genetic analysis and access to PHI in their medical records. **Study Design/Methods**: We conducted a cross-sectional, anonymous survey of blood donors at our blood center. In June and July 2014, an anonymous electronic survey was administered to blood donors in Northern California. Donors aged 18 to 65 with an email address on record who had presented to donate at least three times from January 2008 to May 2014 were eligible to participate. **Results/Findings**: A total of 10,000 survey links were emailed, 9963 were delivered, 1420 survey access clicks were registered, and 1153 surveys were completed between June 26 and July 1, 2014 for a 14.3% response rate and an 11.6% completion rate. Willingness to participate in a long-term donor health outcomes study was evident (77%) and the majority of those would be willing to provide access to their PHI (79%). Eighty six percent of respondents would contribute a blood sample for non-genetic studies and 80% would contribute a sample for genetic research. Donors with 11 to 20 lifetime donations were twice as likely to participate, 1.4 times as likely to allow PHI access and 1.5 times as likely to donate a sample for genetic research than donors with 1 to 3 lifetime donations. **Conclusion**: Donors in Northern California overwhelmingly declared their willingness to participate in long-term donor health outcomes studies that included genetic research. Although not all regions of the country are the same with respect to donor knowledge and comfort participating in large cohort studies, the survey results suggest that as persons become more familiar and comfortable with electronic health records, genetic studies, and large database-driven research (a.k.a. Big Data), donor willingness to share PHI and blood samples for both genetic and non-genetic studies should mature as well, making it easier to establish donor health cohorts.

SP127

A Telephone-based Motivational Interview Promotes Blood Donor Autonomy and is Related to Both Quicker Donor Return and a Higher Proportion of Returns

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Background/Case Studies: One source of difficulty in meeting the ongoing demand for blood products is the limited retention of relatively novice blood donors. This study examined the effect of a telephone-delivered motivational interview developed to strengthen donor autonomy (i.e., internal motivation to give) and promote enhanced donor return. **Study Design/Methods**: Recent blood donors (N=466; 60.9% Female; Mean Prior Donations = 2.3; SD = 1.7; 53.8% first-time donors) recruited from two blood centers (New York Blood Center, Hoxworth Blood Center) were randomly assigned to receive either a motivational interview call or a control call within one month of their donation. Internal motivation for giving was assessed approximately one week before and one week after the call, and blood center database records tracked donor return behavior for one year. Structural equation modeling was used to examine the effect of group (motivational interview versus control call) on donor autonomy and subsequent donation behavior. **Results/Findings**: An initial structural equation model, with days to return as the behavioral outcome, demonstrated good fit to the data (CFI =0.973, RMSEA=0.058, SRMR=0.038), and included a significant positive relationship between intervention group and donor autonomy (B = 0.062, $p<.05$) and a significant negative relationship between donor autonomy and days to return (B = −0.138, $p<.01$). An additional path was added from donor autonomy to donor return (yes/no), and a chi-square difference test revealed that this resulted in a stronger model compared to when this path was held

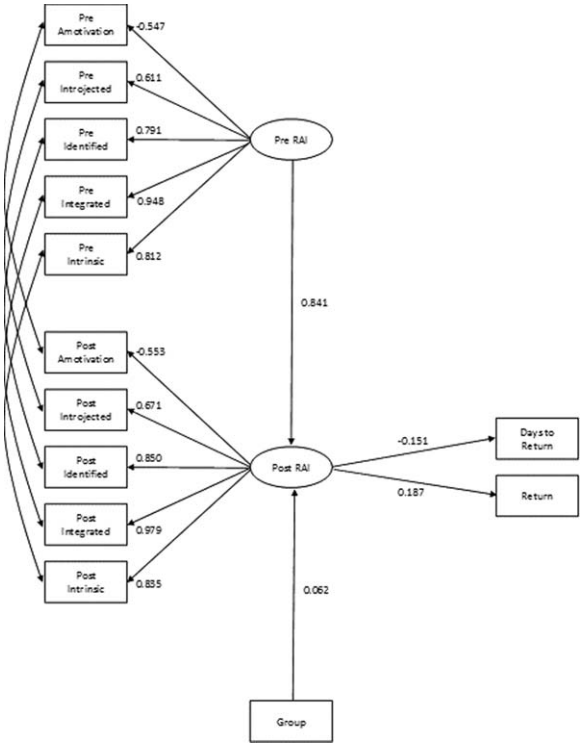

Fig. 1. Final structural equation model including donation behavior outcomes of return (yes/no) and days to return for a new donation within 1 year.

to zero (see Figure 1). **Conclusion**: A brief motivational interview enhances donor autonomy and relates to enhanced donor retention.

SP128

You're a Lifesaver: Blood Donor Feedback on Email Notification of the Specific Date on which Donor Units Were Transfused

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Background/Case Studies: Swedish blood donors (BDs) are notified via text message when their blood is transfused. This notification is not routinely performed in the United States. Such communication represents a unique way blood donation centers (BDCs) can assure BDs of the importance and impact of their blood donation. To obtain feedback about this type of communication, we surveyed BDs who had received retrospective post-donation email notifications (RPDEs) of the date(s) on which their blood was transfused. **Study Design/Methods**: In 7/2015, our hospital-based BDC initiated RPDEs to notify BDs of the date(s) on which their blood was transfused. RPDEs also provided the next eligible donation date and a link to the BDC on-line scheduler. RPDEs were manually created and sent by the BD coordinator 1-2 weeks prior to the BDs' next eligible donation date. One RPDE was sent per donation. In 3/2016, an anonymous online survey (SurveyMonkey) was emailed to 100 BDs who had received a minimum of 2 RPDEs. The BDs were asked the following questions: Do you like being told via email when your blood was used? Do you feel that being told when your blood was used makes you more likely to donate blood again? Does being told when your blood was used make you feel proud of your blood donation? Does being told when your blood was used make you want to encourage your friends to donate blood? Do you think that the BDC should continue to tell donors when their blood was used? BDs were also asked to share what they liked or disliked about being told when their blood was transfused. **Results/Findings**: The 100 BDs surveyed included 52 men and 48 women with an average age of 43 years (range 22-72 years). Nineteen were 20-29 years, 29 were 30-39 years, 15 were 40-49 years, 30 were 50-59 years, and 7 were 60-72 years. One quarter of BDs surveyed were first time donors. Fifty-nine of 100 BDs responded. All but one BD liked RPDEs. The one remaining BD had no strong feelings about notification. Three-quarters of responding BDs

felt RPDEs made them more likely to donate blood again, whereas 25% said they had no effect. Ninety-one percent of responding BD's felt that RPDEs made them feel proud of their blood donation. RPDEs inspired 78% of responding BDs to encourage friends to donate. All 59 responding BDs felt the BDC should continue to employ RPDEs. In their own words, BDs felt RPDEs made them "feel good" about their donation, created a "connection" between them and the recipient, and assured them their donation "was actually used and didn't go to waste." **Conclusion**: BDs value retrospective post-donation email notification of the date(s) on which their blood was transfused. The majority of BDs felt RPDEs made them more likely to donate again and to encourage friends to donate. BDCs should consider notifying BDs of when their blood is transfused.

SP129

Retrospective Analysis of Low Haemoglobin Levels in Female Donors in Singapore

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Background/Case Studies: In Singapore, before 1st Jul 2007, the pre-donation Haemoglobin (Hb) level was 12.0 g/dL for female. Our study in 2006 found that 35% of donors with Hb less than 12.5 g/dL had iron deficiency, the pre-donation Hb level was therefore revised to 12.5g/dL for both genders.
The current overall donor deferral rate is about 30%; low Hb accounts for close to 50% of all deferrals. The objective of the study was to analyse who were the donors at risk of low Hb and look into ways to reduce the deferral rate. **Study Design/Methods**: From 1st Jul 2014 to 30 Jun 2015, all donors who were deferred by the Singapore Blood Services due to low Hb were analysed. Both male and female donors are included in the study. The female donors were grouped into new and repeat donors and subdivided into age 16-40 years and age >40 years. They are analysed according to their Hb level (Hb <11.9 and Hb12.0 to 12.4g/dL). **Results/Findings**: During the study period, 50,244 male and 37,896 female prospective donors were included in the study. Our study showed that 29.6% of new female donors had Hb <12g/dL, and16.8% had Hb between 12.0-12.4g/dL. 27.4% of the female repeat donors had Hb<12.0g/dL but only 3.3% of them had Hb between 12.0-12.4g/dL. Most of the new female donors with low Hb were aged between 16-40 years. In comparison, only 1% of first time male donors and 4.6% of repeat male donors were deferred for low Hb. **Conclusion**: Under the WHO definition, the minimum Hb level for child bearing female should be 12.0g/dL. However, 26.3% of our first time female donors who are aged 16 to 40 years had low Hb of <12g/dL. Since the commonest cause of anaemia is iron deficiency, this strongly hints at a high prevalence of iron deficiency among the general population. It is important to improve the Hb in our blood donor as low Hb is a cause of high donation lost, leading to inadequate blood supply to meet the clinical demands. It also results in collection inefficiency, waste of donors' efforts and more resource commitment to recruit more donors. Our strategies to improve blood donors' Hb includes providing dietary advice to donors, educational pamphlets on iron intake to all donors and posters on iron deficiency anemia at all Hb testing counters. Iron supplements are given to all donors after each whole blood donation, and we also provide iron-rich refreshments. For donors who failed the Hb criteria for two consecutive visits, serum ferritin will be done to assess their iron status and hematinic supplement are given accordingly. We engage the National Health Promotion Board to improve public awareness on Iron Deficiency Anemia (IAD) through putting up educational messages about the importance of sufficient dietary intake of iron and prevention of IDA on their website. We will analyse the rate of low Hb deferral after one year to see any improvement in collection efficiency

SP130

The Impact of the New Hemoglobin Criteria for Male Donors on the Blood Supply of Singapore

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Background/Case Studies: Effective May 23, 2016, the FDA will increase the minimum acceptable hemoglobin level for male blood and platelet donors from 12.5 to 13.0 g/dl. The reason for changing the minimum hemoglobin level for male donors is to protect the donor's health and prevent iron deficiency. Our national blood center follows AABB guidelines and the current minimum hemoglobin level for both male and female donors is 12.5 g/dl. The aim of this study is to assess the impact on the number of male donors deferred and to the national blood supply if the minimum level for males is increased to 13.0 g/dl. **Study Design/Methods**: Donor records from January 1 to December 31, 2015 were reviewed to identify male blood donors who donated with hemoglobin of 12.5-12.9 g/dl. This group will represent the donors lost due to the change in hemoglobin criteria. The number of donations and blood products lost if this group of donors were deferred were estimated using the blood collection and processing data for 2015. **Results/Findings**: A total of 73,820 donors donated in 2015 of which 43,252 (59%) were males. There were 3,470 male donors who donated with haemoglobin of 12.5-12.9 g/dl which represents 8% of all male donors or 4.7% of the total donors. If this group of male donors were deferred, it will result in the loss of 4,448 whole blood donations (red cell and FFP units as well as 772 pooled platelet units). Of the lost FFP units, 326 are from group AB+ donors. This will also result in the loss of 584 platelet and 55 plasma apheresis units (7% and 8% of total donations respectively). **Conclusion**: An increase in the minimum acceptable hemoglobin level for male donors will affect the nation's blood supply and result in an estimated loss of 4% of the total whole blood units and 7% of platelet apheresis units collected. Supply of precious group AB FFP units will also be affected if the change in criteria is implemented. The actual loss of male donors and donations may be more due to the fact that deferrals are associated with higher chances of donors not returning. The authors recommend not making immediate changes to the current hemoglobin cut off for male donors. A study should be done to determine the current incidence and prevalence of iron deficiency in our local donor population before any changes are made. Data from this study will serve as the basis if there is a need to amend the current hemoglobin cutoff and donation intervals and if additional donor safety programs are required. Serum ferritin testing can be performed in selected donor groups to identify who are at risk for iron deficiency (frequent donors, young and elderly donors). An iron replacement therapy program should be implemented using low doses over extended periods as it has been shown to be well tolerated, associated with good compliance and minimal side effects.

SP131

Reasons that Donors Request a Phone Call from the Blood Bank Medical Director at a Small Community Blood Center

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Background/Case Studies: The blood bank medical director is responsible for many activities related to blood donors including donor screening, laboratory testing, and management of reactions. At our small community blood center, fiscal realities require that these services be provided on a part time contract basis. From time to time, a donor specifically requests to speak to the medical director about an issue that the staff cannot resolve. The purpose of this study is to identify and categorize the reasons donors request a call from the medical director. **Study Design/Methods**: Each request over a 5-year period was sorted and saved electronically. The reasons were tabulated using an excel spreadsheet, sorted by category, and a Pareto chart was constructed to examine the most common reasons for a donor to request to speak to the medical director. **Results/Findings**: The blood center received 178 donor requests to speak to the medical director during the study period. Any reason that only occurred once was eliminated from the data set leaving 159 request for analysis. A Pareto chart was constructed using the calls with more than 1 occurrence to identify the most common requests. The top 10 requests (including ties) by category were: reactive syphilis test results: 31 (19.5%), hepatitis B core antibody results: 21 (13.2%), HIV antibody results: 15 (9.4%), HCV antibody results: 13 (8.2%), sickle trait results: 11 (6.9%), HLA antibody results: 11 (6.9%), HTLV antibody results: 8 (5.0%), re-entry denials: 7 (4.4%), HCV/HBV NAT positive results: 5 (3.1%), CJD deferral: 4 (2.5%), Hep B surface antigen test: 4 (2.5%), and platelet donors with abnormal WBC count: 4 (2.5%). In all 23 discrete causes of phone call request were evaluated and 12 categories accounted for 84.28% of requests to speak to the medical director. The top 4 reasons accounted for 50.3% of requests. **Conclusion**: This study revealed that a majority of requests to speak to the medical director were made regarding laboratory results. Syphilis, hepatitis B core antibody, HIV antibody, and HCV antibody testing results accounted for more than half of requests (50.3%). An effort to refine donor communication in these areas may improve the understanding of results by the donors and reduce the number of phone calls made by donors and the medical director.

SP132

Repeat Ferritin Testing in Canadian Blood Donors

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Background/Case Studies: Measurement of ferritin levels followed by donor notification is a possible strategy to mitigate iron deficiency in blood donors. As part of a large donor ferritin study, we retested approximately 20% of the initial cohort of donors to determine the evolution of iron stores over time and the impact of notification for low ferritin. **Study Design/Methods**: Between July, 2014 and Dec 13, 2015, donors were informed of possible ferritin testing in the pre-donation pamphlet. Ferritin was measured on retention samples from clinics selected to represent the overall donor base (Abbott Architect). Donors with ferritin <25ug/L were sent a letter and information sheet, advising them that their ferritin level was low, they should see their MD regarding possible supplementation and refrain from donation for at least 6 months; they were not called during this period, but not coded to stop donation. Tested donors were flagged in the computer system, and if they returned to donate between Jan 7 and April 1, 2016, we attempted to retrieve the retention sample for repeat ferritin testing. At both index and return donation, only donors who passed their hemoglobin (hb) screen and successfully donated were included in the study; donors may have made several donations between the index donation and repeat testing. Donor return rates were calculated from our National Epidemiology Data Base, the minimum interdonation interval is 56 days. **Results/Findings**: 6,955 male and 5,640 female donors had initial testing done; 19% had repeat testing. 67% of males and 46% of females had normal initial ferritin levels (>25ug/L); of these, 76% of males and 71% of females returned to donate before April 1, 2016. On repeat testing, 256 of 850 males (30%) and 119 of 298 females (40%) now had ferritin <25ug/L, with an overall decrease in the mean ferritin level of 20ug/L. Conversely, on initial testing, 33% of males and 54% of females had ferritin levels <25ug/L; of these 63% of males and 50% of females returned to donate before April 1, 2016. On repeat testing, 415 of 750 males (55%) and 190 of 552 females (34%) still had ferritin <25 ug/L. There was an overall increase in the mean ferritin level of 12ug/L. **Conclusion**: Donors with normal ferritin levels who returned to donate at least once less than 2 years after index donation often had lower ferritin on repeat testing. Donors who received a letter regarding low ferritin had a lower return rate. Upon return, many were still iron deficient. There was a modest increase in ferritin levels in those who returned, passed their hb screen, and successfully donated. Simply sending donors' one letter advising them of low ferritin results often did not fully achieve the desired outcome.

SP133

Deferral Rate Reduction Using an Ultrasound Technology-based Hematocrit Measuring Device

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Background/Case Studies: Previously, donor eligibility was determined in our facility by testing capillary blood from donor candidates in the HemoCue Hb 201+ System (HC). Donor candidates with hemoglobin values at or above 12.5 g/dL were eligible for donation. We validated a new hematocrit measuring device, the UltraCrit (UC, from Separation Technology, Inc., STI) and implemented it as our test method of record in September, 2015. Four months of deferral rate data with the UC, based on a cut-off of hematocrit values less than 38% Hct, are now available for comparison with our prior method of record. **Study Design/Methods**: The UC ultrasound based system was subjected to an Instrument Qualification and System Qualification protocol developed by our Quality Assurance Department. Precision was tested on each instrument by running 20 replicates of the UltraChek Normal Control, and comparing the data to the manufacturer's specifications. Accuracy testing was performed on 20 fresh venous samples by determining the average difference generated on the UC and automated Pentra 80 hematology instruments. The four months of deferral data for both methods are based on single determinations on capillary blood samples and application of the above stated cut-off values. **Results/Findings**: The UC hematocrit measuring system met the manufacturer's specifications during the Instrument and System Qualifications; precision and accuracy testing yielded results that supported the decision to implement the UC as the method of record in our blood bank in September, 2015. The HC Hb 201+ was the method of record for all testing in January, 2015 through April, 2015. During this time, 506 candidates out of 4,012 tested had results below 12.5 g/dL, for a deferral rate of 12.6%. The monthly deferral rates ranged from a high of 14.2% in March, 2015, to a low of 10.9% in January, 2015. The data from the UC testing for the same four months of January through April, but in 2016, yielded a deferral rate of 5.6%, with 193 deferred out of 3440 tested. The variation in the monthly deferral rates for this period spanned a high of 6.5% in February, 2016 and a low of 4.3% in January, 2016. **Conclusion**: The comparison of deferral rates during a four month period since the UltraCrit was implemented to the same four months in the prior year demonstrates a significant decrease in deferral rates based on hemoglobin and hematocrit test results. We will continue to monitor our deferral rates and compare them to our historical records to determine whether this improvement is maintained.

SP134

Impact of Donor Notification of Iron Status on Select Repeat Donors' Return and Hemoglobin

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Background/Case Studies: A recent study reported little change in hemoglobin (Hb) in frequent blood donors who were informed of ferritin levels <26 ng/mL and were advised to either take an iron supplement or delay their next donation for 6 months (Transfusion Jan 26 2016 ePub). **Study Design/Methods**: Allogeneic blood donors with near-cutoff Hb values [males (M) 12.5-13.4 g/dL, females (F) 12.5-12.9 g/dL] had a serum ferritin determination. Donors with ferritin values indicating absent iron stores (AIS, <12 ng/mL) were notified by letter, counseled, and deferred from red cell-containing (RBC) donations for 24 weeks (24-wks) [notified]. Donors with low ferritin [LF, 12-19 ng/mL in F and 12-29 ng/mL in M] and donors with normal ferritin (NF) were not notified or deferred [not-notified]. We assessed return behavior and delta Hb (Δ Hb = subsequent presentation - index donation value) by gender in repeat donors (RD, ≥1 WB donation in the prior 24 months). Mean comparison test (t-test) used to compare mean Hb at subsequent presentations to mean Hb at index donations. **Results/Findings**: During a 12-month period, ferritin testing for near-cutoff Hb values on index donations was triggered in 12,140 M with mean Hb 13.1 g/dL and 31,692 F donors with mean Hb 12.7 g/dL. AIS were observed in 2,757 M (23%) and 10,323 F (33%); and LF/NF were present in 9,383 M and 21,369 F. The overall return rate of donors notified of AIS status was 71% compared to 82% in donors who received no notification. Donors were followed for at least 12 months past the expiration of the 24-wks deferral. Of notified donors, 5% returned ≤24-wks for non-RBC donations (M 12%, F 4%) and 66% returned >24-wks (M 68%, F 65%). Of returning notified donors, Δ Hb (g/dL) was higher in those returning >24-wks (M 1.6, F 0.8) than in those returning ≤24-wks (M 0.6, F 0.1), and Hb <12.5 g/dL was less frequent in donors returning >24-wks (M 3%, F 13%) than in donors returning ≤24-wks (M 7%, F 27%). Of the not-notified donors with LF/NF, 57% returned ≤24-wks (M 62%, F 54%) and 25% returned >24-wks (M 23%, F 26%). Of not-notified returning donors, Δ Hb was higher in those returning > 24-wks (M 1.3, F 0.6) than in those returning ≤24-wks (M 1.0, F 0.4), and Hb <12.5 g/dL was less frequent in donors returning >24-wks (M 4%, F 12%) than in donors returning ≤24-wks (M 5%, F 19%). Compared with index donations Hb mean, all Hb means at subsequent presentations were statistically significant ($p < 0.0001$) except that in notified F donors returning ≤ 24-wks with Hb mean of 12.8 g/dL. **Conclusion**: In repeat donors with near-cutoff Hb values, a 24-wks delay of next donation was adequate to result in a significantly positive Δ Hb in both the notified and not-notified groups.

SP135

Analysis of the Results of a Donor Reentry Test for the HCV or HIV Screening Test-positive Donors and Consideration of Improvement of Donor Reentry System

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Background/Case Studies: In Korean Red Cross, the donors showing positive screening test results of HCV or HIV have been registered in the donor deferral registry. Based on Blood management Act Enforcement Regulation of Korea, some of them can donate blood as eligible donors by passing the reentry tests with serological assay, immunoblot assay and nucleic acid test after at least 6 month. The donors showing negative results in all the test can be reentered as eligible donors. **Study Design/Methods**: We performed the reentry test for 3,367 HCV screening test positive donors and 11,964 HIV screening test positive donors from 2011 to 2015 and analyzed the results. For all the HCV screening test positive donors, serological assay, immunoblot assay and nucleic acid test were performed. For HIV screening test positive donors, after serological assay were performed for all donors, immunoblot assay was performed for donors showing negative results in serological assay and nucleic acid test was performed for donors showing negative results in immunoblot assay. **Results/Findings**: In the study period, 1,543 donors (45.8%) of HCV screening test positive donors and 7,664 donors (64.1%) of HIV screening test positive donors were reentered as eligible donors. 594 (17.6%) of HCV screening test positive donors and 539 (4.5%) of HIV screening test positive donors showed positive results in the

Blood Center		2010	2011	2012	2013	2014	% change between 2010-2014
Asian national blood service	Number of RBC distributions	3,423,025	3,479,020	3,486,060	3,467,224	3,438,608	0.46
	RBC ***transfusions***/1000 population	25.3	25.6	25.8	25.6	25.5	0.79
American blood centers, combined	Number of RBC distributions	2,500,756	2,427,921	2,410,434	2,270,677	2,079,320	-16.85
European national blood service	Number of RBC distributions	1,858,883	1,826,010	1,827,506	1,775,859	1,698,550	-8.63
	RBC ***distributions***/1000 population	34.7	34.2	32.9	31.6	30.1	-13.26
North American national blood service	Number of RBC distributions	828,822	822,749	834,908	810,333	793,761	-4.23
	RBC ***distributions***/1000 population	32.3	31.5	31.6	30.7	29.7	-8.05
Oceania national blood service	Number of RBC distributions	796,358	800,531	801,385	763,576	703,374	-11.68
	RBC ***distributions***/1000 population	36.1	35.8	35.3	33.0	29.9	-17.17
Middle Eastern national blood service	Number of RBC distributions	263,443	264,418	268,377	256,212	247,275	-6.14
	RBC ***distributions***/1000 population	34.3	33.8	33.6	31.5	29.8	-13.12
North American provinical blood service	Number of RBC distributions	234,614	239,349	245,790	246,673	230,966	-1.55
	RBC ***distributions***/1000 population	29.76	29.85	30.77	30.5	28.55	-4.07
European national blood service	Number of RBC distributions	143,512	138,391	137,210	131,883	126,040	-12.17
	RBC ***transfusions***/1000 population	32	29.3	28.8	27.2	26.7	-16.56
European national blood service	Number of RBC distributions	94,114	85,237	95,878	83,285	80,855	-14.09
	RBC ***distributions***/1000 population	41.9	38.0	42.6	36.9	35.7	-14.80

serological assay and couldn't be released. Although 2,773 (82.4%) of HCV screening test positive and 3,761 (31.4%) of HIV screening test positive donors showed negative results in the serological assay, they couldn't be released due to the results of immunoblot assay. And the results of the immunoblot assay was considered to be resulted from nonspecific reaction. There was no case of donors showing positive results only in nucleic acid test with negative results in serological assay and immunoblot assay. **Conclusion**: We thought that it is not reasonable to apply immunoblot assay to the donors showing negative results in serological assay. And it may result in loss of the qualified donors. In addition, immunoblot assay is not required as donor reentry tests for HCV or HIV screening test positive donors in the guidance of United Stats Food and Drug Administration. Therefore, we suggest that immunoblot assay would be excluded in the reentry test.

SP136

Changes in Blood Center Red Blood Cell Distributions in the Era of Patient Blood Management: The Trends for Collection (TFC) Study

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Background/Case Studies: As patient blood management (PBM) becomes more widespread, fewer red blood cell (RBC) units have been transfused. This multinational study evaluated the changes in blood center RBC distributions in an era of hospital based PBM implementation. **Study Design/Methods**: Data on number and ABO/Rh types of RBC distributions were obtained from 7 large American blood centers, and 8 national or provincial blood services (NPBS) from fiscal year (FY) 2010 through FY2014. Due to the relatively larger number of distributions and differences in ABO/Rh groups between the Japanese Red Cross and the other 7 NPBSs, Japanese data were not included in these distributions calculations. **Results/Findings**: At both the 7 American and the 7 NPBS that were analyzed, there were declines in the number of RBC distributions between FY2010 and FY2014. There was a 16.9% reduction in distributions at the 7 American blood centers, and an 8.0% reduction at the 7 analyzed NPBSs combined, excluding the Japanese Red Cross (Table). The absolute number of O negative RBC distributions decreased by 9.0% (from 233,241 units in FY2010 to 212,168 units in FY2014) at American blood centers but the proportion of the RBC distributions that were O negative increased by 9.3% during this time (from 9.3% in FY2010 to 10.2% in FY2014). The NPBSs had a 1.6% increase in the absolute number of O negative RBC distributions (from 445,331 units in FY2010 to 452,476 units in FY2014) but a 10.5% increase in the proportion of O negative distributions (from 10.6% in FY2010 to 11.7% in FY2014). The proportion of O positive RBC distributions increased at the American centers (2.9%) but was decreased at the NPBSs (1.1%) over the 5 FYs of this study, despite a 14.4%reduction in the absolute numbers of O positive distributions at the American centers and a 9.1% reduction at the NPBSs. **Conclusion**: Although overall RBC distributions have decreased over time, the proportion of distributed O units has increased substantially.

SP137

A Randomized Trial to Evaluate the Use of SMS Text Messaging, Letter and Telephone Call Reminders to Improve Return of Blood Donors with Reactive Serologic Tests

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Background/Case Studies: An important step in the completion of the donation process is notification and counseling of donors with reactive serologic screening tests. However, low return rates by these donors are common. A randomized trial to test the effectiveness of text message (SMS), letter and telephone call reminders to improve return among first-time blood donors with reactive serologic tests, failing to return following standard notification and counseling was conducted. **Study Design/Methods**: Routinely, when a donor has a reactive screening test, a letter is sent within 3 weeks asking him/her to return to the blood center for notification and sample

TABLE. Donor Recruitment Strategies

	Radio	Newspaper	Poster/ Flyer	Social Media	Website	Postcard	Hospital Newsletter	Word of Mouth
All Donors	7 (7%)	1 (1%)	12 (13%)	0 (0%)	2 (2%)	7 (7%)	32 (34%)	28 (30%)
Hospital Employees	2 (2%)	0 (0%)	4 (4%)	0 (0%)	1 (1%)	1 (1%)	30 (32%)	6 (6%)
Non-employees	5 (5%)	1 (1%)	8 (9%)	0 (0%)	1 (1%)	6 (6%)	2 (2%)	22 (23%)
First-time Donors	2 (2%)	0 (0%)	6 (6%)	0 (0%)	0 (0%)	2 (2%)	7 (7%)	7 (7%)

collection for additional tests. If the donor does not return within 3 weeks, another letter is sent asking him/her return to the blood center. Donors who do not return after these 2 contact attempts are considered non-respondents, and are the eligible population for this study. From August 2013 through July 2014, a consecutive sample of non-respondent first-time donors, who had a cell phone and resided in the metropolitan area code of São Paulo, Brazil, were randomly assigned to receive a text, a new letter or a telephone call requesting return for notification and counseling, following donation with a notifiable result at a large blood center. Return rates were measured over the subsequent 30 days. **Results/Findings**: There were 122,635 blood donations during the study period. A total of 45,485 (37.1%) donations were collected from first-time donors and 1405 (3.1%) units were discarded due to reactive screening tests. Following the first notification letter, 769 (54.7%) donors returned for notification and counseling and following a second notification letter 152 (10.8%) more donors returned. Four hundred eighty four consecutive non-returning donors (34.5% of all donors with reactive results) were randomized to receive a reminder using SMS text message (34.9%), letter (31.8%) or a telephone call (33.3%). Return following a phone call reminder was better than text (39.8% vs. 28.4%; OR=1.66; 95%CI 1.05-2.64) but not better than letter (39.8% vs. 34.4%; OR=1.32; 95%CI 0.83-2.12). Text message reminders compared to letter did not have statically different return rates (28.4% vs. 34.4%; OR=1.32; 95%CI 0.83-2.12). Older age was a predictor of higher rate of return with each year increase in age associated with a 2% increase in the odds of return (OR=1.02; 95%CI 1.01-1.04). **Conclusion**: In non-responding serologic reactive donors, telephone call led to a higher return rate than text message. The results of this study suggest that use of text message, while attractive for its simplicity, will not lead to increased donor notification success following serologic reaction marker results from blood donation in Brazil.

SP138

Effective Recruitment Strategies at a Rural Hospital-based Donor Center

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Background/Case Studies: Recruitment of new donors is especially challenging in a rural community with a small population base. To increase blood component collections, particularly apheresis platelets, several recruitment strategies were developed and implemented to reach our target donor groups. The goal of this study was to determine which recruitment methods were most effective in our community. **Study Design/Methods**: A campaign to advertise the need for platelets in the community was implemented in conjunction with a popular local grocery chain in February 2016. Several recruitment methods were employed at once: mass postcard mailings (by zip code) in the area, radio ads, a newspaper ad, posters and signs, flyer distribution, social media (Facebook, Twitter), a website ad, and posting on the hospital's daily electronic newsletter. Donors were surveyed on how they heard about the campaign and whether they were employees of the hospital or not. Repeat donations were noted as well. Data were collected and tallied for the first two months of the campaign. **Results/Findings**: Ninety-four donors presented within the two months in which data were collected. These donors donated 33 whole blood and 112 apheresis platelets. The table details the results of the donor survey. The hospital's daily electronic newsletter (34%) and word of mouth (30%) were the most frequent recruitment methods named. Thirteen percent of donors learned of the campaign via a poster or flyer. Social media and newspaper advertisements were not effective. Approximately half of these donors were hospital employees. Twenty-four (26%) were new donors. Thirty-three (35%) returned for a second donation and 13 (14%) for a third and 3 (3%) for a fourth donation. These repeat donations were for apheresis platelets. **Conclusion**: This study provided us valuable insight into the recruitment tools our population responded to. The results were surprising. The hospital's daily electronic newsletter proved the most effective method for recruiting employees. Word of mouth was most effective in reaching non-employees. Posters and flyers were somewhat effective. The social media outlets, including our website, proved to be ineffective in our donor population.

SP139

The Influence of Social Media Images on Perceptions of Blood Donor Connectedness

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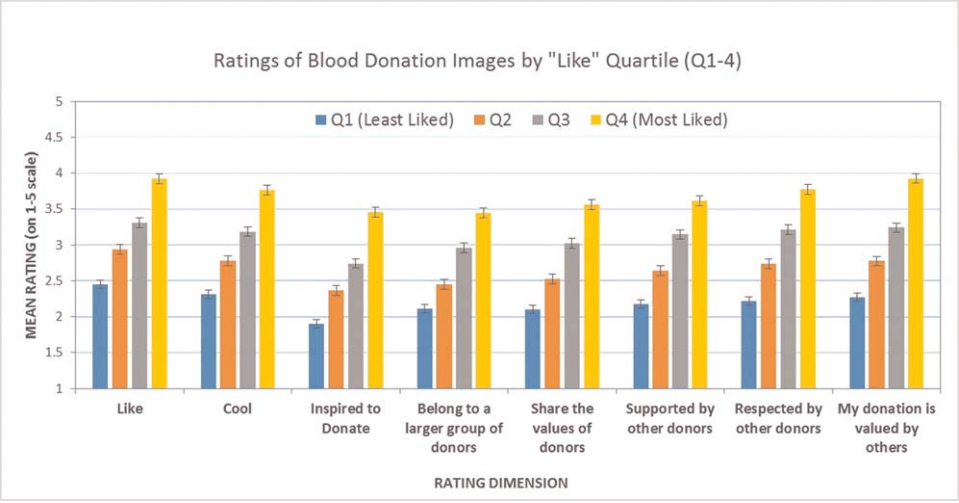

Background/Case Studies: Our goal was to identify social media images that promoted a sense of connectedness among blood donors. **Study Design/Methods**: College students (N=127; 55% women), including 42% donors and 58% non-donors, provided ratings for 82 custom-developed or donor-created images with themes of blood, blood donation, and reasons for donating blood. Using 1-5 rating scales (5 = most positive), each image was rated on eight dimensions including how much the image (1) was "liked", (2) was "cool", or (3) inspired the viewer to donate blood, and to what degree the image would make a new blood donor feel like they (4) belonged to a larger group of donors, (5) shared the values of other donors, (6) were supported by other donors, (7) were respected by other donors, and (8) were connected with other donors. **Results/Findings**: For 80 of the images (98%) the "like" ratings did not differ significantly as a function of donor status. As shown in Figure 1, when the images were divided into four groups based on their "like" ratings, ANOVAs revealed that the most liked images were also associated with the most positive responses across each of the other seven rating categories. Visual examination of the content of the most liked versus least liked images revealed a distinct preference for pictures that conveyed a sense of connection with other people or a direct contribution to the welfare of others. **Conclusion**: Images vary in the extent to which they evoke a sense of connectedness, and these differences are detected by donors and non-donors alike.

SP140

You Say It's Your Birthday: Targeted Recruitment of Whole-Blood Donors during Their Birth Month

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Background/Case Studies: Birth date is a required component of the blood donor questionnaire. In 5/2015, our hospital-based donor center implemented targeted whole blood donor recruitment during a donor's birth month. **Study Design/Methods**: Recruitment emails were sent to eligible donors who were identified by convenience sampling as having previously donated whole blood, at least once, since 4/2014. At the time they were emailed, donors were determined to be active, defined as having donated within the last 6 months, at least 6 months-lapsed, or at least 1 year-lapsed. Recruitment emails were sent at the beginning of a donor's birth month. A reminder email was sent toward the end of a donor's birth month. A unique thank you gift was offered if a donor donated during their birth month. The birthday promotion was also advertised on the hospital intranet webpage. Presenting donors were retrospectively reviewed monthly to determine "birthday donor" status. **Results/Findings**: Each month, from 5/2015 to 3/2016, an average of 59 (range 41-81) recruitment emails were sent to donor's whose birth date occurred during that month. At the time they were emailed, donors were active (41%), at least 6 months-lapsed (27%), or at least 1 year-lapsed (32%). Of these emailed donors, 16% presented for donation during their birth month. Emailed donors who presented for donation during their birth month were active (73%), at least 6 months-lapsed (17%), or at least 1 year-lapsed (10%). Of these emailed donors who presented for donation during their birth month, 10**%** were deferred. Presenting, successful birthday donors included those recruited by email (48%), as described above, and those not recruited by email (52%). Presenting, successful birthday donors who were not recruited by email included first-time donors (40%), active donors (38%), at least 6 months-lapsed donors (17%), or at least 1 year-lapsed donors (5%). **Conclusion**: Targeted recruitment of whole blood donors during their birth month was a successful recruitment technique. A donor's birthday represents another possible, positive point of contact. Anecdotally, birthday donors reported that this promotion transformed their birthday into a reminder to donate blood. Other birthday donors reported that they donated specifically to receive the unique thank you gift. Email recruitment of birthday donors was most successful with active donors. However, lapsed birthday donors did respond to email recruitment in modest numbers. Birthday donors who were not recruited by email donated serendipitously during their birth month or after seeing the birthday promotion on the hospital intranet webpage. Thus, advertising the birthday promotion to the general community was crucial to the promotion's success.

SP141

Rapid Assessment of Donor Loss Rates Associated with Past and Future Travel from Areas with Zika Virus Activity in the Donor Population

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Background/Case Studies: The accurate assessment of donor loss rates associated to travel from areas where Zika virus (ZKV) transmission is locally active is hampered by the fact that many potential donors self-defer once they learn about existing travel associated restriction policies through our community education efforts. In order to obtain timely and reliable feedback on the current and near term impact of the measures to mitigate the risk of transfusion-transmitted ZKV, we polled our donors via e-mail. **Study Design/Methods**: A sample frame of 7,216 eligible donors who gave blood (either whole blood or apheresis) between January 1 - March 14, 2016 (the date when travel restrictions were implemented) was selected for simultaneous e-mail broadcast. They were queried regarding travel to Mexico, the Caribbean or Latin America in the past six months, and separately if they had plans to travel to those areas in 2016. Responses received during the 72 hours post-broadcast were tallied. **Results/Findings**: Of the 7,216 e-mails sent, 159 (2.2%) "bounced back" (e.g. wrong e-mail address), a total of 2934 (41.3%) were opened and viewed by the intended recipients, and 1512 (21%) responded to the questions submitted. In response to the question about travel to the listed areas in the past 6 months, 119 (7.8% of respondents) said "Yes", while another 175 (11.5%) indicated they planned to visit them in 2016. **Conclusion**: While the rate of deferral of presenting blood donors due to travel to areas with active ZKV transmission in our blood collection area has been 0.2% the true impact of the implementation of new travel restrictions could not be accurately determined due to the fact that a number of donors affected do self-defer and never present to donate. The electronic survey of donors provides an additional means to gauge the potential effect of changes in donor eligibility criteria in a short period of time (it took 10 days to complete the process from conception to completion). The difference between the deferral rates for presenting donors versus those who restrain from donating and never present attest the usefulness of this approach. While the response rate was slightly more than 20%, this is within the parameters expected for the survey method utilized. Therefore, the number of responses received provide sufficient confidence on the validity of the data obtained.

SP142

The Digital Age: Reminder and Confirmation Preference in Blood Donation

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Background/Case Studies: It is documented that individuals are more likely to comply with responsibilities when reminded, and are more likely to follow through with those responsibilities when asked to confirm their commitment. Understanding modes of communication with the donor population can have significant implications in avoiding loss of follow up, improving donor experience, and ensuring appropriate use of resources and staff. The goal of this study is to determine the level of interest amongst blood donors for using appointment reminders and confirmations, and also to determine the best mode of communication by which to reach blood donors. **Study Design/Methods**: Voluntary and anonymous 20-question surveys were distributed at blood donation sites across the state from 10/29/2015 to 11/17/2015. Surveys from respondents younger than 18 years were discarded. Questions included donation frequency, preferred communications mode for scheduling, confirmation, and reminders for blood donation, and attitudes. Descriptive statistical analysis was performed using Excel. **Results/Findings**: Five hundred ninety-four surveys were received, and subdivided into frequent donors (donating 3 or more times/year; n=298) and infrequent donors(donating fewer than 3 times/year; n=194). Most respondents expressed willingness to confirm their appointments(68%) and a desire to receive reminders(61%) with a preference that communication be made through email(44%). The most widely accessible mode of communication among donors was telephone while the most frequently used mode was social media. **Conclusion**: Offering donors reminders about their appointments is a technique for increasing follow-through that is already in place and our data supports this practice. A method that is not yet used is advance confirmation, whereby donors could indicate prior to their appointments whether they still intend to attend or whether they would like to cancel. Our results show a willingness on the part of blood donors to confirm appointments. For both confirmations and reminders donors would prefer to receive their notifications by email and a day in advance of the appointments. The donor preference for email should be of value as this is much less resource intensive than the use of call centers.

SP143
Donor Guidance Program in Blood Donation
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Background/Case Studies: In Finland, Finnish Red Cross Blood Service (FRC BS) is the only provider of blood components for 5.5 million population. All blood donations are non-paid and voluntary. One of our main values is respecting the donor, and that donations are used efficiently for the benefit of patients. As blood demand in Finnish hospitals is slowly declining, it is important to adapt the number of donations accordingly and keep the ABO supply optimal. Adjusting of donor flow minimizes the risk of outdating and secures the availability of blood components. Until 2014, FRC BS encouraged donors to give blood regularly, at least 2 to 3 times per year. Since 2014, we inform each donor about the need of their ABO blood group, as we introduced an ABO blood group based customer service concept. The concept ensures coherent and reproducible communication. Donors are advised to check the red cell inventory on-line or through a smart phone application, and they are urged to donate blood when their ABO group's inventory is low or at least when FRC BS contacts them. We strengthen donors' awareness with ABO referring tokens. Since 2014, we streamlined the donation process using LEAN methods and introduced a one nurse model, where one nurse attends the donor through interview and blood donation. One nurse model gives the nurse an uninterrupted time to inform and motivate an individual donor. **Study Design/Methods**: Data from quarterly blood donor surveys Q1/2014 and Q1/2016 was used in this study, altogether 3298 datasets. We analyzed donors' awareness of red cell inventory, their feedback on nurses' blood group guidance, and donors' attitude towards receiving information on their specific ABO blood group. **Results/Findings**: Comparing results from 2016 and 2014, 43% more (39% vs 56%) responded that they checked red cell inventory before donation. Also, 64% more (16% vs 26%) reported picking up information on their ABO blood group from the staff during their visit. Of responses, 29% more (53% vs 68%) wanted FRC BS to provide information on the most beneficial time for donation. All the results were statistically significant ($p<0.05$). **Conclusion**: Blood donors want to help when their help is most needed. The donor guidance program has been effective in providing donors essential information on their ABO blood group and in giving them information, how to achieve this goal. The red cell inventory at FRC BS has improved since the program started. The combined red cell inventory target (4 to 6 days inventory) was accomplished in 54% of days in 2015 (44% in Q4/2013) and the inventory was below the minimum threshold in 5% of days (12% in Q4/2013).

SP144
We've Got An App For That! The Mobile App for Blood Donation
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Background/Case Studies: This case study analyzes six months of data in the use of the blood donation mobile application. The study quantifies the efficacy of this new tool in attracting donors and obtaining the most needed products. The mobile app gives donors the ability to schedule their own appointments on their phone or tablet. On their device, donors are presented with donation locations and the available time slots. Donors choose a time and location, confirm the appointment on the app, and receive the option for app based navigation to the donor center. They can also dial the donor center directly from the app. The app notifies donors when they're eligible to donate and encourages them to give specific blood products that are in short supply. The app also provides health and wellness information such as blood pressure, cholesterol and heart rate after a donor's first donation. This study examines another desired benefit for blood center staff to increase efficiencies through scheduling automation. The goal is for employees to spend less time answering phone calls and emails to schedule appointments and more time assisting the donors. The included administrative system allows employees to view all upcoming appointments made through the mobile application, and view the corresponding donation method (platelet, plasma, whole blood etc.) to prepare accordingly for the donor. **Study Design/Methods**: The application is analyzed through several categories: donor types, donation methods, mobile app downloads and accounts created. The donor type is broken down in four donor categories:
New (Donors that have not presented for a donation in the last 24 months.)
Lapsed (Donors who have not presented for a donation in 12 months and have donated within 24 months.)
Loyal (Donors who have presented for a donation within the last 12 months.)
Routine (Donors who have presented for a donation a five times in the 12 months prior to the agreement.) **Results/Findings: Mobile Application Statistics (10/22/15 - 4/30/16)**
Donor Type/Donors
New - 20
Lapsed - 13
Loyal - 91
Routine - 178
Total - 302
Donation Method/Donors
Plasma - 2
Platelets - 206
Double Red - 9
Whole Blood - 85
Mobile Application Downloads - 4,260
Mobile Application Accounts Created - 1,350
Conclusion: It has been found that this mobile application for donor recruitment, scheduling and management succeeds in attracting donors and platelet donations. Most notably the results show that the application led to 302 donors and 206 platelet donations. This represents a return on investment in the use of this mobile application. The application also improves internal efficiencies by automating aspects of the scheduling process. However the greatest benefits are for the donors. The mobile app offers donors the convenience of scheduling at the touch of a button while offering the element of personalization such as health and wellness information.

SP145
A Pilot Study Looking into the Effectiveness of Appointment Scheduling at the Bloodbank@Westgate Tower in Singapore
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Background/Case Studies: Like many Bloodbanks, scheduling and managing appointments and reservations are important components in the operation of an organisation. More than 85% of the appointment slots have not been fully utilized by blood donors due to various reasons. Cancelled and missed appointments equate into wasted resources if the appointment scheduling has not been fully utilized properly by blood donors. Automated reminders such as sms and maintenance of the system incurs significant costs. By applying the lean sigma method to identify the problem areas, work process improvements and enhance system efficiency enhancements can be achieved. **Aims/Objectives**: To increase the number of appointment bookings as well as appointment turn up based on appointment slots. To create a user-friendly appointment system for all blood donors and staff. To achieve a balanced blood inventory control via the appointment booking system **Study Design/Methods**: A telephone survey of 800 selected donors from the four satellite collection centres from the period April to May 2015 was conducted. These donors were interviewed via phone surveys to identify and analyse the main reasons for failure to turn up for appointment bookings. These information data were translated into Voice of Customer and Critical to Quality to analyse the reasons for not choosing appointments. **Results/Findings**: The survey results revealed that the reasons for not turning up for appointment bookings included regular donors' mentality, inaccurate data information regarding blood inventory on Donorcare website as well as unfriendly user appointment system. Based on the survey, a pilot project on appointment scheduling initiatives have been conducted from June 2015 to November 2015 at one of the satellite collection centres in the West. The Lean sigma team re-looked into the work process for re-booking and tele-recruiting at Bloodbank@ Westgate Tower. From June to November 2015, an educational tool using a simple diagram was adopted by staff to explain the benefits of appointment bookings to donors. This resulted in a total of 2208 appointment bookings. The staff monitored the appointment bookings closely with sms reminders and tele reminders. Out of 2208 appointment cases, 1311 donors turned up for their appointments. **Conclusion**: This project concluded that an educational tool explaining the benefits of appointment booking to all blood donors is essential. The positive results allowed the blood bank to relook into continued efforts to increase on-line and mobile appointment systems adoption through:

- Creating awareness for blood donation via different communication and marketing platforms.
- Continuous monitoring of blood donors' feedback for further improvements.
- Data based system for donors to book on-line to schedule their donation based on blood type requirement.

SP146

Targeting the 7%: A Strategy for Recruiting Type O Rh-negative Blood Donors

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Background/Case Studies: A process improvement team at a blood center was charged with increasing the type O Rh negative red blood cell (RBC) inventory. **Study Design/Methods**: The team utilized Six Sigma tools (Cause and Effect Matrix and Failure Modes and Effects Analysis) to identify the process inputs needing improvement. The team also conducted a focus group with type O Rh negative donors (n=12) and surveyed a random sample of donors of all types (n=286) to determine effective marketing methods and drivers for donor retention. Results from the focus group and donor surveys indicated the messaging to O Rh negative donors should include why the need for this type is high. The random donor survey reinforced the need for a compelling message to this donor group.
A five week pilot was conducted with mobile drives in one region of the blood center's service area and included post cards to O Rh negative donors prior to the blood drive as well as a Donor Alert communication piece providing:

- education about blood type needs, specifically type O Rh negative
- the meaning of 'universal donor' and the importance to the blood supply and patients
- a call to action for the donor to increase their donation frequency

The Donor Alert was distributed to blood drive coordinators to be shared with the O Rh negative donors. The donor recruitment account managers also received a list of historical O Rh negative donors from the drives and were asked to follow up with the drive coordinator regarding sharing the Donor Alert communication. The mobile collection staff used the historical donor list to compare to the appointment schedule and were asked to call any O Rh negative donors who did not have an appointment. In addition, they were asked to follow-up with the drive coordinator to contact the donor. When the O Rh negative donors presented, they were recruited to automation, if eligible. **Results/Findings**: The baseline for O Rh negative donors was 7.36% of all presenting donors. After five weeks, the presenting donor rate increased to 9.2%. The results were statistically significant, indicated by a p-value of 0.001 using the two-proportion test. The baseline for O Rh negative RBCs collected was 8.2% of all mobile red cell collections. After the five week pilot, the rate increased to 11.4%. The results were statistically significant, indicated by a p-value of 0.030 using the two proportion test. **Conclusion**: Targeted donor messaging, coupled with aggressive marketing to O Rh negative donors by donor recruitment, and supported by the collections staff can result in an increase in presenting donors and overall RBC inventory.

SP147

Projection of the Whole Blood Collection and Strategies to Maintain the Blood Supply Capacity during 2016-2030

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Background/Case Studies: Aging population is a critical issue in Taiwan. The proportion of population aged 65 and older is 12.5% in 2015, and it is expected to be 23.8% in 2030. For estimating the impact on blood supply, this study aimed to project the quantity of the whole blood collection during 2016-2030 and to evaluate the possible strategies to maintain the same capacity of the blood supply to that in 2015. **Study Design/Methods**: Age- and year-specific numbers of whole blood donors and blood units (shown as 500 mL per unit) collected during 2000-2015 were retrieved from the blood management system. The age- and year-specific population projection data were obtained from the website of Taiwan National Development Council to represent the population structure during 2016-2030. The age-specific projected quantity of the whole blood collection was estimated using the autoregressive integrated moving average model. Several strategies to maintain the same whole blood collection capacity in the projected period as that in 2015 were evaluated. All statistical analyses were conducted in R 3.1.3. **Results/Findings**: Due to the aging effect, the estimated total collected units of whole blood will decrease by 26.0%, from 1.16 million in 2015 to 0.86 million in 2030. For maintaining the same collected quantity as that in 2015 during 2016-2030, several strategies were evaluated: first, the overall donation participation rate, which is the proportion of whole blood donors in eligible population, increases from 5.93% in 2015 to 7.09% in 2030 with 0.077% annual increment; second, the average annual donation unit per donor increases from 1.14 to 1.44 with 0.02 unit annual increment; third, the proportion of the frequent donors, who annually donated 1.5 units or more, increases from 28.5% to 50.7% with 1.48% annual increment; forth, to increase participation rate as well as to increase the proportion of frequent donors. If the overall participation rate gradually increases to 6.5% or 7% in 2030, the proportion of frequent donors can be gradually increase to 32.5% or decrease to 26.7%, respectively. **Conclusion**: In the subsequent 15 years, we foresee that the quantity of the whole blood collection is dramatically decreased by one forth. The strategies proposed in this study which aimed to maintain the same collection capacity as that in 2015 would be challenging. Patient blood management will be a necessary tool to balance the supply and demand of the blood for clinical use in the future.

SP148

Concept of Donor Guidance in Donor Marketing

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Background/Case Studies: FRCBS's aim is to ensure that the storage of red blood cells corresponds to 4-6 days' requirement for all blood groups. This entails getting donors from the right ABO group to donate at the right time in the right place. For 70 years the message had been that every donor is equally important and every day is a good day to donate. The concept of donor guidance was created to support the strategic change. **Study Design/Methods**: The communication strategy was renewed in customer service, targeted marketing and mass marketing and communications. The content of all marketing channels was updated. The goal of guidance is that donors know their blood type and donate according to demand. ***Methods in targeted marketing*** Invitations (SMS, postcard, email) are used to activate donors on short term. Other targeted marketing (newsletter, letter, postcard) is used to influence donors' behavior on long term. The aim is to have better retention and donor awareness. Invitation volume, message levels and percentage by blood group is based on blood supply level and can rapidly be changed. Donors are invited and encouraged to come at the right time to the right place according to the needs of the hospitals. ***Methods in mass marketing and communication*** are print and radio ads, media, digital outdoor marketing, billboards, social media, online marketing and SEM. In all these channels blood supply is featured and donors are guided to donate in accordance with blood supply. For example real time blood barometer is used on online and outdoor marketing and every blood type has its own radio spot. Since the new strategy was implemented, donor surveys were executed regularly. We analyzed two surveys from years 2014 and 2016. **Results/Findings**: The red blood cell inventory has improved since the program started, corresponding to 4 −6 days for 92% of the time. According to the surveys in Q1/2014 39% of donors referred to the blood supply barometer before donation. In Q1/2016 the percentage was 56%. In 2014 53% of donors thought that it's important to know the blood supply, because they want to donate when they're mostly needed. In 2016 the proportion was 68%. All the changes were statistically significant ($p<0,05$). **Conclusion**: At the same time with new concept of donor guidance, organizational major changes was made (LEAN, downsizing the donor center network). It's not possible to evaluate the influence of guidance concept separate from other changes, but comprehensive remodeling of marketing, together with donor guidance in donor service, have significantly influenced blood donor behavior. Turning donors' model of thinking is a long term process. To improve the progress FRCBS develops its processes further. To support this change it's critical to introduce CRM and develop digital services, like blood group based booking, and focus on segmented marketing.

SP149

Iron Deficiency in Black Women Donors

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Background/Case Studies: Finding compatible blood among Caucasian donors for sickle cell anemia patients under red cell exchange program can be quite challenging and at time source of ethical concerns about the oversolicitation of Rh negative Caucasian donors. For this reason we launched in 2009 a program to encourage increased blood donations among black community members. We observed a good response from both men and women. But although registered black women equalled men in numbers they were deferred 15X more often than men because of low hemoglobin (Hb). Two possible explanations were considered: first a high frequency of iron deficiency among our black female donor population favoring development of anemia; second, a more important limiting impact of 12.5gm/100ml Hb criteria on blood donations for black women vs Caucasian ones. Previous population studies have indeed revealed significant Hb mean value

TABLE. Increase in Blood Donations vs Iron Deficiency

Hbgm/100ml	Donors	Donors
	Eligible	Iron-deficient ($<11\mu g/l$)
$\geq 11.5 < 12.5$	32/87 (37%)	10/32 (31%)
≥ 12.5	44/87 (52%)	9/44 (20.5%)
	Deferred	
<11.5	11	5/11 (45.5%)

differences between the two groups. **Study Design/Methods**: In order to answer those questions and eventually support a request to be made to Health Canada (H.C.) aiming at lowering the Hb qualification criteria to 11.5gm/100ml for black women we ran a study to evaluate the impact of the proposed new criteria on these donors' iron stores. **Results/Findings**: When their iron stores levels were analyzed by referring to Hb levels $\geq$12.5 vs 11.5-12.5gm/100ml, no statistically significant difference was found. H.C. has accepted the proposed changes combined with an iron supplementation program. The program was launched last August. Its framework and the qualified donation impact following its progressive implementation are presented. **Conclusion**: These results show that lowering to 11.5gm/100ml the black women Hb qualification criteria for blood donation increases their eligibility by 37%. They also revealed a high incidence of iron deficiency without anemia, which deserves iron supplementation.

SP150

Big Kaizen Event in Mobile Recruitment

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Background/Case Studies: Questions explored: What is causing inconsistencies in meeting hospital need, inability to forecast need for imports and inability to maximize use of staff in an efficient manner? A granular analysis was conducted and results indicated: mobile blood drives projected to collect $\leq$ 25 units has resulted in a substantial amount of drives not meeting projected goal. July 2014 - June 2015; of 4798 drives projected to collect $\leq$ 25 units, 1056 (22%) met target. Technically, this represents a missed opportunity of 78%. **Study Design/Methods**: Recognizing the urgency for immediate improvement, birthed the decision to conduct a Kaizen Event lead by Six Sigma Black Belts. The event focused on waste elimination, improved productivity, and sustained improvement within the mobile recruitment process. #1 - event prep; project charter depicting the problem and objective for improvement. #2; identification of event participants (mobile recruitment account managers (AM), collections). #3; roadmap - activities quantifying need for a 3 day event to produce process failure modes, root cause and determining improvements to eliminate/decrease failures. Critical variables were determined based on severity of impact. 3 core focuses were derived: Inefficiencies; AM time management and review of blood drive history. **Results/Findings**: 2 key processes were created. Creation of a process utilizing what's called "The Projection Accuracy (PA) Tool". The electronic tool assist AMs with reviewing drive history to maximize ability to project. The tool includes historical projections, units collected, deferrals, etc. dating back 3 drives for a selected group. The tool calculates number of donors needed to meet projections for previous drives as lessons learned for the AM. Post review, AMs enters the projection into the tool for the upcoming drive. Using most recent drive variables, the tool calculates presenting donors required to meet the entered projection. It is then determined if the projection is realistic based on history. AM presents a copy of the completed tool to the CP during planning meetings to review performance, ensure consensus/logic of the projection and activities needed for goal achievement. Diagrams were created to assist with process steps and AMs were trained along with role playing to address "what if" scenarios.Post implementation of improvements (8/2015-4/2016), there was a 13% (pre-22%/post-33%) increase in drives projected at $\leq$ 25 units meeting target. **Conclusion**: The inclusion of process experts from multiple departments heightened buy-in and engagement leading to greater ownership of process outputs. The core team meet weekly to continue improvement efforts learned from the Kazien Event. Robust collaboration manifested into undeniable improvement in accountability; thus improvement of drives projected at $\leq$ 25 units as well as overall projections.

SP151

Colleges' Competition on Blood Donation; an Innovative Idea of Donor Recruitment and Knowledge Dissemination Between University Students

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Background/Case Studies: Recruitment of first time donors is one of the challenges that blood banks face. Recent research suggests that educational materials may not be sufficient to motivate actual donation, despite their effect in making blood donors seeing the direct benefit of the donation. Other highlights the influence of social contexts in blood donation as crucial determinants of the donation intention. Herein, we describe our first experience in organizing a competition on blood donation between college students in our university. **Study Design/Methods**: The league was announced two weeks before the start of the competition, which took place between February 21st and April 9th 2016. The competition started with an opening ceremony under the patronage of the Dean of Student Affairs. A draw was done to divide the 9 competing colleges into 3 groups. The competition between the colleges in each group lasts for a period of 2 weeks, during which the colleges were evaluated based on different measures. These included the number of donors donating from each college, the number of donors recruited, the efforts made by the students in increasing the awareness of blood donation in the colleges and in the social media, and the student performance in different knowledge competition. Colleges qualified from the first three groups competed over one week for the league championship. The whole competition was organized and ran by the university students. Data was gathered throughout the competition and was compared with the number of donors in the same two months period in the last two years. MedCalc software (version 16.0) was used for statistical analysis. **Results/Findings**: The total number of volunteer donors during the two months period in the blood bank reached 842 donors, 604 (71.7%) of which were university students who donated as part of the competition. First time donors accounted for 55.8% of the donors. There was 52% and 41% increment in number of the total volunteer donations during the league period compared to the number of volunteer donations during the same period in 2014 and 2015 respectively. When examining the results per gender, there was a statistically significant increase in the number of male and female volunteer donors during the league period compared to the same period in 2014 and 2015 ($P< 0.0001$ for both). **Conclusion**: This initiative highlights the positive and important role of the youth in promoting blood donations, in recruiting blood donors and in the dissemination of the knowledge of blood donation. We advocate for similar initiatives in promoting blood donation in other universities and in the community.

SP152

Do Blood Donors with Vasovagal Reactions Risk Developing More Than One Reaction per Donation?

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Background/Case Studies: In recent years, studies from different countries have analysed the incidence and risk factors for immediate and delayed vasovagal reactions (VVR). To date, however, it is still not clear if donors with VVR might risk developing more than one reaction per donation. The aim of the study is to investigate if donors, who experienced VVR, develop more than one reaction per donation when compared to donors who had other reactions (OR). **Study Design/Methods**: Data was retrieved from the national IT system that manages information related to all Italian blood activities, including Haemovigilance (HV). Blood donor complications were classified following ISBT-IHN-AABB criteria. The records of 9,419,650 allogeneic whole blood and apheresis donations collected in 2012-2014, were assessed for VVR and OR. The incidence per 100,000 donations of more than one reaction other than VVR or OR per donation and their severity was evaluated. **Results/Findings**: From January 2012 to December 2014, 16,081 VVR (170.7 per 100,000 donations), and 3,815 OR (40.5 per 100,000 donations) were reported. Another reaction during the same donation was reported in 233 donors who had VVR, and in 104 donors who had OR, of which 23.6% and 59.6% respectively were citrate reactions. The incidence of more than one reaction per donation, in donors who had VVR and

OR, were respectively 2.4 and 1.1 per 100,000 donations ($p < 0.01$); of which, 0.55 per 100,000 donations were classified as moderate and 1.1 per 100,000 donations as severe. **Conclusion**: The development of more than one reaction per donation seems to be a rare event, considering also that some of them are citrate reactions and thought to be related to collection by apheresis. The Authors believe that further data and sharing experience between different countries is necessary to confirm this finding.

SP153

Self-initiated Iron Supplementation in Blood Donors: Demographics, Patterns of Use, and Motivation

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Background/Case Studies: Iron supplementation (IS) has been proposed to mitigate iron depletion in blood donors. The REDS-II RISE study in 2007-9 reported IS in 32% (M) and 52% (F) of frequent donors. The opportunity to prevent donor iron depletion using IS applies mainly to donors not already taking iron. Hence, we investigated self-reported IS use in an unselected blood donor population. **Study Design/Methods**: A survey on IS was administered to all presenting donors at our US blood center during Dec 2015. The survey asked if donors regularly took multivitamins (MV), whether the MV contained iron, or if they took a separate iron pill; how frequently they took supplements; and their reasons for IS. Donors were classified as an IS donor, Non-IS donor, or Uncertain and responses were linked to operational data via the DIN. SAS was used for statistical analysis. **Results/Findings**: Of 11540 presenting donors, 90% responded, of whom 20% reported IS. This consisted of 38% who reported MV, of whom 44% were sure it contained iron, and 6% who reported separate iron pills (including 2% reporting both). By logistic regression, female and repeat donors were about twice as likely to take iron as males and first-time donors, respectively, and donors aged 60+ four times as likely as the youngest age group (Table). Of donors reporting IS, 63% took iron daily, 18% 4-6x/week, and 17% 1-3x/week, with no gender difference but older donors much more likely to report iron daily than younger donors. IS donors cited a total of 3085 reasons for taking iron (1.5 reasons per donor). The most common reason was general health and wellness, (66% of donors), followed by donating blood (23%), avoiding deferral (10%), low hemoglobin or iron (12%), and recommended by MD (10%). **Conclusion**: While a substantial minority of blood donors take IS, the prevalence in this unselected donor population is roughly half that of frequent donors in RISE. Less than half of donors reporting IS listed a motivation specifically tied to blood donation, with a majority instead citing general health and wellness. Blood Centers could strengthen their IS programs by assessing existing donor practices and targeting education and/or recommendations to donors who would benefit from iron but are not currently taking IS.

TABLE. IS by Donor Segment

Donor Segment	Number Providing Data	% Iron Supplementation	OR (95% CI)
Male	5698	14.3	1
Female	4649	26.0	2.3 (2.1, 2.6)
17-20 years old	2219	8.0	0.4 (0.3, 0.5)
26-39 years old	1396	16.6	0.7 (0.6, 0.9)
40-49 years old	1438	20.9	1
50-59 years old	2623	23.1	1.2 (1.0, 1.4)
60 years and older	2669	26.7	1.5 (1.3, 1.7)
First-time Donors	1105	7.5	0.6 (0.5, 0.7)
Repeat Donors	9061	21.1	1
All Donors	10,347	19.6	

SP154

A National Survey on the Blood Donation Adverse Reaction In China

Y Fan[1], W An[1], X Liang[1], Q Meng[1], J Wu[1]. [1]*Dalian Blood Center, Dalian, China*

Background/Case Studies: Statistics in 2011 revealed the national blood donation number was 12.32 million in China. In recent years, there is a steady increase in the total blood collections and mobile group blood drives. Safety is the first priority of blood donor management, this study aims to investigate the rate and disposal measures of the national donation adverse reactions, and the status of drug usage in blood collection facilities. **Study Design/Methods**: The questionnaire survey was conducted in 354 blood collection facilities from all over the country, including 32 provincial blood centers and 322 regional central blood stations. Excel 2003 was used for entering the raw enumeration data from the survey forms. Data analysis was carried out using SPSS 17.0 statistical software. Descriptive data was summarized and analyzed. **Results/Findings**: A total of 201 blood collection facilities provided the effective feedback, including 23 blood centers and 178 central blood stations. The average adverse reaction rate of 201 facilities in 2014 was 0.53%. The adverse reaction rate of 23 blood centers was 0.37%, lower than that of 178 central blood stations, 0.61%. 82.43% of the blood donors with adverse reactions were the first-time donors. Both 200ml and 300ml donors had higher reaction rates than 400ml donors, details see Table. 147 (73%) blood collection facilities used drugs for disposing adverse reaction, mainly rehydration drugs. Only 12(8.16%)facilities used anti-shock drugs for severe reactions, such as Dexamethasone and Atropine. **Conclusion**: More efforts for blood collection facilities to reduce the occurrence of adverse reactions by improving collection environment, phlebotomist skills and service quality. Many mobile group donors are young and donating 200ml or 300ml for the first time, the emphasis on mobile group blood drives led to more adverse reactions. Drugs are essential for disposing adverse reactions, especially for severe reactions. To ensure donor safety, it is necessary to enhance the management of drug usage and the first aid training. Blood collection facilities should collect and report the data of donation adverse reaction in accordance with a uniform standard system, to promote the implementation of national haemovigilance program in China.

SP155

Screening for Metabolic Risk in Adolescent Blood Donors

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Background/Case Studies: The presence of cardiometabolic risk factors such as elevated blood pressure, total cholesterol and glycated hemoglobin (HbA1C) in adolescents can persist into adulthood. These risk factors are associated with increased risk for cardiovascular disease and diabetes. When more than one risk factor is present, overall risk is multiplied. There is consensus that early identification of modifiable risk factors could be beneficial in targeting interventions. High school blood drives are a unique opportunity to provide screening for cardiometabolic risk factors at low cost and minimum inconvenience to participants. **Study Design/Methods**: Participants were volunteer blood donors age 16-19 years, who donated in 2015. Systolic (SBP) and diastolic (DBP) blood pressure were measured using automated equipment (Welch Allyn, ProBP), total nonfasting cholesterol and HbA1C were determined (Beckman Coulter AU680). Abnormal results were defined as a SBP $\geq$120 mmHg and/or DBP $\geq$80 mmHg, cholesterol $\geq$170 mg/dL and HbA1c $\geq$5.7%. Donors were invited to declare their ethnicity at the time of donation. Ethnic groups were defined as African American, Asian, Caucasian, and Hispanic. **Results/Findings**: The study included

TABLE. The 2014 adverse reaction rates of 200ml, 300ml, and 400ml donors among 201 blood collection facilities in China

Collection Volume	Donation Number (Thousand)	Reaction Number (Thousand)	Reaction rate(%)	$\chi 2$	P
200ml	874.5	6.3	0.72	799.63	0.000
300ml	935.2	5.5	0.58	167.74	0.000
400ml	5151. 3	25.0	0.53		Ref.

Ref. = reference.

TABLE. Percentage of blood donors, 16-19 years old, with 1-3 risk factors (A1c, cholesterol, blood pressure) who donated in 2015 (N=37,930)

	African American		Asian		Caucasian		Hispanic	
	Female	Male	Female	Male	Female	Male	Female	Male
1 Abnormal risk factor	40.2%	45.2%	39.6%	41.7%	38.6%	47.1%	33.8%	44.5%
2 Abnormal risk factors	10.4%	13.2%	7.6%	15.6%	9.4%	11.4%	8.0%	13.7%
3 Abnormal risk factors	.3%	.4%	.3%	.5%	.1%	.2%	.1%	.2%

37,930 donors (16,704 male, 21,226 female). 9.7% were African American, 3.7% Asian, 55.3% Caucasian and 31.3% Hispanic. Only 48.2% of the entire cohort had no abnormal risk factors. A higher percentage of Males had risk factors compared to females 58.6% and 46.3% respectively. When viewed by ethnicity, 1 or more risk factors were present in 54.5% African Americans, 53% Asians, 53% Caucasians and 49% Hispanics. **Conclusion**: Blood donor screening is confirmed as an opportunity to monitor the prevalence of multiple metabolic risk factors in an ostensibly healthy subset of the population. This scrutiny does identify individuals with multiple risk factors and also reveals ethnic and gender differences.

SP156

Evaluation of Iron Stores After Red Blood Cell Donation using Zinc Protoporphyrin Analysis

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Background/Case Studies: The REDS II Donor Iron Status Study (Transfusion 2012 Apr; 52(4):702-11) showed that loss of iron stores could occur with >2 yearly red blood cell (RBC) donations despite a good pre-donation hemoglobin (HB) value. A Zinc Protoporphyrin (ZPP) point of care test would allow analysis of the extent of iron loss in RBC donors and be a surrogate to ferritin (Fer) testing. Finger stick (fs) HB was compared to venous (ven) and capillary (cap) ZPP and ven Fer levels. **Study Design/Methods**: From 12/01/15 to 03/31/16 whole blood (WB) and double red blood cell (DRBC) donors, new and repeat male (M) and female (F) ages 18-45, >45 years from 4 sites, tested for fs HB per site policy, ven and cap ZPP (Helena Laboratories, Beaumont, Texas - Protoflour Z Model#2005) and ven Fer (Beckman Coulter, Brea California, AU680) per manufactures' directions. To assess interplay of ZPP, ven Fer and gender, a linear model with gender as fix effect, ven Fer and ven Fer^2 as covariates was fitted to log transformed data (Minitab v.16, State College, PA). **Results/Findings**: 328 donors (192 M, 136 F) evaluated at 3 HB levels for subclinical iron deficiency defined as Fer levels <26 ng/mL and ZPP levels >100 umol/mol heme. F had higher ZPPs levels than M (log fs ZPP 1.736 vs. 1.692, log ven ZPP 1.697 vs. 1.645), lower HB (log 1.136 vs 1.177) and Fer (log 1.447 vs 1.628) levels. There was a highly significant relationship between ven and fs ZPP levels (R^2=0.878). The regressions coefficients for the relationship between Fer and ven ZPP were the same for both genders. The p- values were: log ven Fer <0.001, log ven Fer^2 0.004, gender 0.497, Gender*log ven Fer 0.538, Gender*log ven Fer^2 0.643 displaying a curvilinear relationship between ZPP and Fer (R^2=0.276). For donors with Fer < 26 ng/mL the regression was linear and the same for male and female (R^2 =0.21). **Conclusion**: All donor sets had subgroups with subclinical iron deficiency. The predictive value of ZPP for iron depletion was not optimal with only 27% of the variation in all ZPP levels (21% in donors with Fer of < 26 ng/mL) explained by the variation in Fer levels.

N	41	85	62
fs HB (g/dL)	12.5-12.9	13.0-13.9	>13.9
Ven Fer (ng/mL)	34.12, ±40.4, 7-243	43.46±64.51,7-451	55.64±58.96, 10-451
Ven ZPP (umol/mol heme)	58.8,±24.04,28-128	54.55±18.55,29-135	45.47±17.19, 20-168
fs ZPP (umol/mol heme)	62.77,±25.13,44-135	60.73±21.14,32-172	50.75±18.8,25-182

Data shown - Mean, SD, Range

Fig. 1. Data Shown: Mean, Standard Deviation, Range

SP157

The Association between Frequency of Blood Donation and the Occurrence of Low Birthweight, Preterm Delivery, and Stillbirth: A Retrospective Cohort Study

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Background/Case Studies: Women who donate blood on a regular basis are at high risk of becoming iron depleted. Iron-deficiency anemia increases the risk of low birthweight and possibly preterm birth. Therefore, there is a concern that regular blood donation by females might adversely impact the well-being of their offspring. This retrospective cohort study looked for an association between blood donation and adverse pregnancy outcomes. **Study Design/Methods**: The study sample included 18,483 female blood donors in their childbearing years (age 18 to 45) who delivered during the period 2001-2011 in our jurisdiction. The occurrence of low birthweight (< 2500 grams), preterm delivery (< 37 weeks of gestation) and stillbirth was ascertained by linking RBC donation frequency with birth and stillbirth registries. **Results/Findings**: The table shows associations between the frequency of donation in the 2-year period prior to pregnancy and adverse pregnancy outcomes; there was no increased risk of low birthweight or preterm birth with higher donation rates, even among women who donated ≥3 donations (average: 3.9 donations). These associations remained unchanged after adjusting for age and education level of the mother, number of prior deliveries, marital status, region of residence and year of delivery. Women who gave one red cell unit in the 2-year period before their pregnancy appeared to have a higher rate of stillbirths, however this association was not observed at higher donations rates and the test for trend was not statistically significant (p = 0.94). Low birthweight and preterm births were not

TABLE. Risk of adverse pregnancy outcomes by frequency of donation in the two-year period preceding the pregnancy among 18-45 years old female blood donors (2001-2011)

		Low birthweight		Preterm birth		Stillbirth	
Number of donations	N	n (%)	RR* (95%CI)	n (%)	RR* (95%CI)	n (%)	RR* (95%CI)
0	7641	315 (4.12)	Ref.	472 (6.18)	Ref.	17 (0.22)	Ref.
1	6349	251 (3.95)	0.96 (0.82-1.13)	377 (5.94)	0.96 (0.84-1.10)	28 (0.44)	1.98 (1.09-3.62)
2	2328	86 (3.69)	0.90 (0.71-1.13)	132 (5.67)	0.92 (0.76-1.11)	9 (0.39)	1.74 (0.78-3.89)
3+	2165	74 (3.42)	0.83 (0.65-1.06)	122 (5.64)	0.91 (0.75-1.11)	3 (0.14)	0.62 (0.18-2.12)

*Unadjusted Relative Risk

TABLE. Evolution of the TTI markers and their relationship with VBD

Year	BDr	BD in BDr	Total BD	% VBD	SYPHILIS (%)	CI (95%)Sy	CHAGAS (%)	CI (95%)Ch	HIV (%)	CI (95%)HIV
2006	8	281	10288	13	1.03	0.80-1.20	1.40	1.20-1.60	0.05	0.00-0.10
2007	12	445	10112	20	0.75	0.60-0.90	1.27	1.00-1.50	0.06	0.00-0.10
2008	14	451	9595	22	0.65	0.50-0.80	1.21	1.00-1.40	0.06	0.00-0.10
2009	21	873	9920	31	0.73	0.60-0.90	1.26	1.00-1.50	0.09	0.00-0.16
2010	41	1624	10583	35	0.79	0.60-1.00	1.11	0.90-1.30	0.07	0.00-0.12
2011	72	3509	11054	38*	0.70	0.50-0.90	0.91	0.70-1.10	0.05	0.00-0.10
2012	139	5925	11641	100	0.36	0.25-0.50	0.45	0.30-0.60	0.03	0.00-0.06
2013	214	8377	13481	100	0.27	0.20-0.40	0.51	0.40-0.60	0.02	0.00-0.05
2014	251	11074	13909	100	0.26	0.20-0.34	0.19	0.12-0.30	0.02	0.00-0.07
2015	235	11900	14336	100	0.22	0.14-0.30	0.15	0.09-0.20	0.01	0.00-0.02

* The first semester: 38%, from July to December: 100%.

more frequent among women who made $\geq$2 donations in the six-month period before their pregnancy, compared to those who did not donate during that time. **Conclusion**: Women who donate blood on a regular but moderate basis do not appear to be at higher risk of adverse pregnancy outcomes. We believe that the higher risk of stillbirth observed among women who made just one donation in the two years before their pregnancy is a spurious finding, unrelated to the donation behavior. These findings, while reassuring, will need to be replicated in different settings.

SP158

Can a 4-year Unceasing Voluntary Blood Donor Program Show a Path for the Rest of the Blood Banks?

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Background/Case Studies: It is widely known that Voluntary Blood Donation (VBD) is largely safer than Compulsory Family Blood Donation (CFBD). Also, Voluntary Repeat Blood Donation (VRBD) is safer than First Time Voluntary Blood Donation. However,even though blood collection from VBD and VRBD is recommended, and the compulsory model is banned by national regulations in this country, centralized Blood Banks (BB) have not yet achieved the 100% VBD. In the national scenario persists the CFBD (75%), and BB claim for changes in the culture that leads them to donate blood. In 2010 a BB had 35% of VBD,but CFBDstill persisted. Its authorities decided to change and chose a date to stop the CFBD. Before, they made sure to have enough stock for 15 days as well as sufficient scheduled blood drives (BDr) to supply the needs for two months. The use of educational workshops, media campaigns, including social media, promoters training, and connections with stakeholders and relatives of patients (best allies to organize BDr) buoyed the decision. **Study Design/Methods**: A retrospective 4-year and half study shows a sustained 100% VBD using tools already published. The study analyzed the Blood Donation (BD) data observing the % of VBD, the number of BDr, the number of BD's, the TTI markers and its statistical significance. The analysis of the VRBD was not possible for technical issues. **Results/Findings**: The table below shows a statistically significant decrease of Syphilis and Chagas markers in the 2012-2015 period, the N of the BD is not enough to obtain significant differences for HIV. The number of BDr and VBD increased. **Conclusion**: The BD's data show that VBD is steadily safer than a model where it coexists with CFBD. VBD significantly improves the blood safety.This study proves that it is possible to sustain VBD in a national setting where most BB endure the CFBD, and verifies that the culture for BD already exists but the limitation for donating blood lies in the blood system. This shows a path for the rest of the BB.

SP159

Consumer Attitudes toward Ddirect-to-consumer Wwellness Offerings through Blood Centers

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TABLE.

Offering	Respondents expressing interest (%)	Access offered by provider (%)
Cancer biomarker screening/ biomarker testing	92	25
Blood testing (chemistry, hematology, metabolic)	90	83
DNA testing	82	17
Chronic condition testing	75	65
Hormone testing	70	40
Anonymous data contribution	78	0

Background/Case Studies: Preventive and personalized health is an emerging ($502 billion USD) and growing (50% over next five years) market driven by consumer interest in gaining actionable information about their health. Supplemental health testing is a segment within the consumer wellness market. While many blood centers offer supplemental health testing as part of the donation process free of charge, the investigators examined whether blood donors would be attracted to an array of commercially available tests under a private payment model. **Study Design/Methods**: Blood donors and non-blood donors participated in qualitative focus groups using a standardized script (N=36), and a quantitative survey of blood donors (N=162). Key offering parameters assessed were mission fit, feasibility, and willingness to pay. Data were analyzed by an independent third party. **Results/Findings**: Results indicated the majority of donors found health testing a consistent fit with blood donation and favored supplemental health testing to gain insight into their wellness status and consequently, to a more personalized health management approach. The most desirable tests were cancer risk screening and blood tests for cholesterol levels, metabolic health, liver and kidney health, electrolytes, vitamins and minerals, fatty acids, even if already offered by a private health care provider (Table). Several offerings identified were not readily accessible through health care providers. Convenience of health testing concurrent to blood donation and the confidence entrusted to blood centers were consumer motivators that aligned with blood center objectives for ongoing donor interaction, reduced acquisition costs, and return participation. Key factors for participation included price points and reimbursement through third-party payers. Most blood donors also favored contribution of their anonymized data for purposes of clinical research and would progressively participate in a mobile app to acquire information. **Conclusion**: These data demonstrate consumer wellness offerings through health testing are synergistic with donor and non-donor interest using a private pay model that aligns with mission fit, feasibility, and willingness to pay. Further evaluation is warranted to determine price points and delivery models within the blood center setting.

TABLE.

BP Category	Measure	Donation Number 1	2	3	4	5	6
Normal	Systolic BP	109.8 (6.3)	112.1 (10.2)	112.4 (10.6)	113.2 (10.5)	113.7 (10.9)	114.4 (11.2)
	Diastolic BP	69.3 (5.6)	70.4 (7.2)	70.2 (7.4)	70.5 (7.1)	70.4 (7.5)	70.4 (7.7)
	Heart Rate	73.5 (10.8)	73.0 (10.6)	73.0 (10.6)	73.4 (10.9)	73.0 (11.0)	73.5 (10.8)
Pre-HTN	Systolic BP	126.8 (5.9)	123.4 (11.4)	123.7 (11.7)	124.3 (12.1)	124.7 (12.4)	125.1 (12.5)
	Diastolic BP	78.4 (6.1)	76.4 (7.8)	76.0 (8.0)	76.1 (8.1)	76.2 (8.3)	76.3 (8.4)
	Heart Rate	75.3 (11.3)	74.5 (10.8)	74.1 (11.1)	74.0 (10.9)	74.1 (11.2)	74.8 (11.1)
Stage I HTN	Systolic BP	144.1 (7.5)	134.7 (13.3)	134.5 (13.4)	135.0 (14.1)	134.6 (13.5)	135.1 (14.2)
	Diastolic BP	87.5 (6.8)	82.3 (8.6)	82.1 (8.2)	82.3 (8.2)	81.9 (8.7)	81.5 (8.5)
	Heart Rate	76.8 (10.8)	75.1 (10.7)	75.2 (10.6)	75.0 (11.0)	74.6 (11.1)	75.2 (11.1)
Stage II HTN	Systolic BP	165.3 (6.5)	146.0 (15.5)	143.8 (15.4)	143.5 (16.5)	143.5 (15.1)	142.1 (13.9)
	Diastolic BP	91.1 (7.2)	84.0 (8.9)	83.8 (8.5)	83.6 (9.0)	84.2 (8.0)	82.3 (9.1)
	Heart Rate	74.0 (12.5)	74.6 (12.1)	71.9 (10.4)	73.8 (13.7)	74.0 (12.5)	71.9 (11.1)

Values given as Mean (SD).

SP160

Effect of Regular Blood Donation on Blood Pressure

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Background/Case Studies: A 2016 study suggested that regular blood donation may improve hypertension (HTN) control (Transfusion 56:637). A drop in blood pressure (BP) was observed on the next presentation following a first-time-in-12-month or -ever donation in 'normotensives,' but in hypertensive subjects, the BP continued falling with 1-2 additional donations over 12 months. We expanded this observation beyond the study's 292 donors. **Study Design/Methods**: First-time donors (FTDs) with a successful whole blood (WB) draw in 2010 were followed through December 2014. BPs and heart rates (HRs) from donors with 6 successive, successful WB donations were analyzed. Summary statistics are presented from pre-donation systolic (SBP) and diastolic BPs (DBP) stratified by visit order and index BP category (normotensive BPs are below the following JNC 7-defined values: pre-HTN - SBP 120-139 mmHg and/or DBP 80-89; stage I HTN - SBP 140-159 and/or DBP 90-99; stage II HTN - SBP $\geq$160 and/or DBP $\geq$100). **Results/Findings**: There was a significant drop in SBP/DBP from the first to second presentation for all donors except normotensives whose pressures minimally increased thereafter, but remained in the normotensive range. Pre-hypertensive SBPs slowly increased over time. The DBP remained stable on presentations 2 through 6 for all donors. There were no consistent changes in HR, though pre- and stage I-hypertensives tended toward lower HRs after their initial donation. **Conclusion**: The disparate SBP/DBP response from first to second donation in normotensive vs. other donors may represent an enhanced effect of anxiety in individuals with (pre-)HTN, described in the cardiovascular literature. The 'expected' decrease in HR as acclimatization occurs was not seen in the small number of those with stage II HTN. A small but significant increase in SBP over $<$5 years in those without overt HTN may be age-related. These data certainly suggest that annual to slightly more frequent WB donation has no salutary effect on BP. More intensive donation may however, affect BP differently.

SP161

Bacterial Contamination Screening and Donor Follow-up in Australia: Clinical Outcomes and Spectrum of Asymptomatic Donor Bacteraemia

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Background/Case Studies: Universal pre-release bacterial contamination screening (BCS) of platelets with BacTAlert automated culture system forms part of the risk reduction strategy employed by the Australian Red Cross Blood Service (ARCBS) to decrease the risk of transfusion transmitted bacterial infection. The main purpose of this testing is to ensure blood component safety for recipients. In addition, BCS is effectively blood culture on blood donors and a positive result may have significant implications for donor health. While testing is deployed under a manufacturing framework, clinical interpretation and review are essential, and donor follow-up should be conducted in a clinically relevant timeframe. **Study Design/Methods**: In Australia, all platelet units are sampled at 24 hours post manufacture, after incubation at room temperature. Each platelet is inoculated into one aerobic and one anaerobic culture bottle and cultured for 7 days. Donor follow up is initiated when a microbial species is cultured and identified. ARCBS has established a framework for donor follow up which includes provision of clinical information sheets and recommendations to a donor's GP for further investigation. A review of the outcomes for donors associated with positive BCS results was conducted for the period 2012-2015. **Results/Findings**: Of the more than 950 positive BCS results over the review period, a total of 39 bacterial isolates were considered to represent possible donor bacteraemia. The 127 donors associated with these isolates were followed up. Two cases of donor endocarditis were identified, one caused by *Enterococcus faecalis* and the other by *Granulicatella adiacens*. The remaining donors reported good health, and thus had asymptomatic bacteraemia with organisms such as *Salmonella sp., Campylobacter sp.* and *Streptococcus pneumoniae*, which are frequently associated with a pathological state. The overwhelming majority of the BCS results were bacteria commonly recovered from the skin, and thought to represent product contamination by residual bacteria at the phlebotomy site post skin disinfection. Donors from this group who were followed up reported good health. **Conclusion**: While the majority of the positive BCS results represent residual bacteria at the phlebotomy site after skin disinfection, some BCS results can have significant donor health implications. A robust framework that includes medical microbiologist oversight, good communications between the laboratory testing staff and medical service team, timely follow up of donors by ARCBS medical staff and presentation of BCS results to treating clinicians with clinically relevant interpretation are required to ensure the best possible outcomes for the blood donor.

SP162

A European Survey of Donor Deferral for Allergy: Rationale and Initial Results of a Two-time Survey in 36 Countries

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Background/Case Studies: A survey on Allergy and consideration of blood establishments (BEs) for donor/donation acceptance or deferral criteria was conducted under the aegis of the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) of the Council of Europe. The initial purpose of the survey was to evaluate practices in different countries/BEs regarding mitigation of any risk related to allergy both in donors and recipients of the donated components; the secondary purpose was to draft a recommendation to be submitted to the CD-P-TS if needed. **Study Design/Methods**: A survey was prepared and disseminated to representatives of CD-P-TS members states and observers, and other BEs in the Mediterranean region who are neither members nor observers to the CD-P-TS but have implemented French, Belgian, Dutch or German regulatory requirements applied to BEs. It consisted of two consecutive questionnaires. Responses to the first questionnaire indicated that the questions posed were not precise enough as left room for interpretation and the same BE attitude could be quoted differently by respondents. The second questionnaire was presented as a diagram, with decision tree pathways to be circled by responders. **Results/Findings**: The questionnaire was sent to 43 BE representatives with, to date 25 responses from 31 CD-P-TS members, 6 from

6 CD-P-TS observers, and 4 from 6 Mediterranean observers (81.39% success rate). Among the 35 replies recorded, based on responses, we were able to stratify into 6 groups: No policy (3/35; all non CD-P-TS members); donor deferral when documented severe allergy only (22/35); donor deferral when symptomatic allergy (9/35); donor deferral when any type of allergy being reported (3/35); donor deferral when local allergy to anaesthetics, disinfectants or drug being reported (6/35); donor not excluded (1/35) for allergy issues. The rationale behind the policy in most BEs is to protect both donors (26/35 recorded answers) and blood recipients (27/35) even thought the concern of antigen or antibody transfer in the recipient is not consensual (respectively 17/35 and 23/35 admit the transfer). **Conclusion**: Donor deferral policies with respect to history of allergy in the donor are not well understood and no consistent attitude is taken even in countries with a declared specific policy. Further investigation by direct telephone or e-mail contact with group member representatives will help refine replies. The final analysis of the survey will provide data to consider proposals for amendment to the recommendations for acceptance of donors with a history of allergy in the Guide on preparation, use and quality assurance of blood components published by the Council of Europe.

SP163

The Impact of Hemoglobin Cutoff Levels on the Iron Status of Male Donors in South Africa

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Background/Case Studies: The Blood Transfusion Services (BTS) of South Africa (SA) currently apply different hemoglobin (Hb) cut-off levels when assessing male donors. Service A uses qualitative Hb measurement and a cut-off of 12.5 g/dl. Service B uses quantitative Hb measurement and a cut-off of 13.5 g/dl. A recent study to assess the iron status of SA donors provided an opportunity to assess the impact of these different Hb cut-off levels on the iron stores of male donors in SA. **Study Design/Methods**: We performed a cross sectional study among blood donors in SA. Each operational area in the two BTS were allocated 2 days during which enrolment occurred. Using consecutive sampling, specimens were collected from all eligible whole blood donors. Specimens only were collected from donors deferred for low Hb who consented to participate in the study. Each donor had a full blood count, serum-ferritin, iron and transferrin saturation performed. The locally determined normal reference range of 20-250 μg/l for s-ferritin were used in the analysis of the male donors. **Results/Findings**: In total 4412 donors were included in the original study of which 2323 (53%) were male. Of the male donors, 2106 were from Service A and 217 were from Service B. Service A deferred 26 (1%) of its donors. None of the donors from Service B were deferred. In total, 411 (20%) of the male donors of Service A had a ferritin level below 20 μg/l compared to the 15 (7%) of Service B (p-value $<$0.005). Of the 37 donors of Service A with an Hb$<$12.5g/dl and a ferritin level $<$20 μg/l only 17 (40%) were deferred. Service B had no donors with Hb$<$12 g/dl and a ferritin level $<$20 μg/l. An additional 104 of Service B's donors had an Hb between 12.4 and 13.4 g/dl and a ferritin level below 20 μg/l while service B had only 2 such donors. Similarly, Service A had 269 (14%) donors with Hb $>$13.4 but with ferritin levels below 20 μg/l compared to the 13 (6%) of Service B. **Conclusion**: Iron depletion and deficiency are more common among the male donors of Service A compared to Service B. Service A deferred only 26 (1%) of their donors. An additional 117 (6%) of Service A's donors who were allowed to donate had iron deficiency anaemia with a further 269 (13%) of its donors displaying iron depletion. This compared to the 2 (1%) donors from Service B who had been allowed to donate while displaying iron deficiency anaemia and the 13 (6%) with iron depletion. The use of the lower Hb cut-off by Service A significantly increased the risk of iron depletion and deficiency among its male donors.

TABLE. Hb distribution by ferritin level and deferral status

	Ferritin μg/l N(%)			Deferral N(%)
Hb g/dl	$<$20	$>=$20	Missing	Yes
Service A (2106)	411 (20)	1662 (79)	33 (2)	26 (1)
$<$12.5	37 (88)	4 (10)	1 (2)	17 (40)
12.5-13.4	104 (74)	35 (25)	2 (1)	7 (5)
$>=$13.5	269 (14)	1617 (84)	30 (2)	2 (0)
missing	1 (0)	6 (0)	0 (0)	0 (0)
Service B (217)	15 (7)	201 (93)	1 (0)	0 (0)
$<$12.5	0 (0)	0 (0)	0 (0)	0 (0)
12.5-13.4	2 (29)	5 (71)	0 (0)	0 (0)
$>=$13.5	13 (6)	196 (93)	1 (0)	0 (0)
missing	0 (0)	0 (0)	0 (0)	0 (0)

SP164

Vasovagal Reaction Rates Differ between Apheresis Plasma Donations and Whole-blood Donations

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Background/Case Studies: Whole blood and apheresis plasma donations are generally safe, however a variety of complications related to the collection process exist. Donors experiencing complications during collection are less likely to make repeat donations. The objective of this study was to compare the rate of vasovagal reactions (VVR) amongst apheresis plasma donations and whole blood donations. **Study Design/Methods**: Complications related to the collection process are registered in the donation data base (ProSang, Databyrån AB, Stockholm, Sweden). Both plasma donations and whole blood donations are supervised by the same collections staff. Both female and male plasma donors donate 700 ml of plasma using the Haemonetics PCS2 device if their body weight $>$70 kg and 600 ml if their body weight is between 60 and 70 kg. Donation data from 1st January 2014 until data were extracted 12th April 2016 were included in the data base. Data on VVRs were analyzed for both apheresis plasma and whole blood donations. **Results/Findings**: For whole blood donors the overall VVR rate was 0.3% (89/28,488); there was no difference in the VVR rate between male (0.3%) and female (0.3%) whole blood donors (p=0.98). However, for apheresis plasma donors the overall VVR rate was significantly higher (168/17,779, 1.0%; p$<$0.0001 compared to the VVR rate for whole blood donors); the VVR rate differed significantly between male (0.7%) and female donors (1.4%, p$<$0.0001) as shown in the table. **Conclusion**: Although overall quite low, the VVR rate amongst apheresis plasma donors was significantly higher than amongst whole blood donors, and between male and female apheresis plasma donors. Unfortunately the information in the donation data base is not detailed enough to give a possible explanation for these differences. These results indicate an urgent need for closer monitoring, and more detailed studies, of apheresis plasma donations.

TABLE. VVR for plasma donors

	Female			Male		
Age	# VVR	VVR%	Total	# VVR	VVR%	Total
17-19	1	0.6%	154	1	0.7%	146
20-29	26	1.4%	1900	39	1.4%	2789
30-39	12	1.2%	984	13	0.5%	2370
40-49	20	1.4%	1426	16	0.7%	2370
50-59	21	1.8%	1149	10	0.4%	2323
60-67	6	1.0%	577	3	0.2%	1591
Total	86	1.4%	6190	82	0.7%	11,589

SP165

The Deferral of Men Who Have Sex with Men: The South African Experience

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Background/Case Studies: The South African National Blood Service (SANBS) collects approximately 800 000 donations annually in a country with one of the highest prevalence of HIV in the world. Selection of voluntary donors at low risk of transfusion transmissible infections is central in maintaining a safe blood supply. Despite a prevalence of 18% in the South African (SA) adult population and 29% in antenatal surveys, SANBS has maintained an HIV prevalence of 0.22% among its donors. SA has progressive policies regarding MSM and is one of the few countries in the world and

the only one in Africa that allows same sex marriage. The proportion of MSM in SA is 1%-3% with an estimated HIV prevalence of 13%-49%. In 2014 SANBS lifted its 6-month deferral on MSM donors appling the same risk assessment as for heterosexual donors. **Study Design/Methods**: The rationale for lifting the deferral on MSM was based on public health and epidemiological considerations. In many developed countries HIV is more prevalent among MSM than in the general population. In developing countries, including SA, the main driver of HIV transmission is heterosexual intercourse. The prevalence of HIV in the general adult population ranges from 5.1%-28.8% in males and 17.4%-36% in females. A peak prevalence of 28.8% (95% CI: 26.9%-36.8%) is observed in males aged 35-39 years. In females the peak prevalence of 36% is observed in the age group 30-34 years (95%CI: 30.9%-41.4%). In MSM the HIV prevalence is estimated at 13%-49%. SANBS does not have any race or gender based deferrals. The fact that blood is collected from heterosexual males and females of all age groups, irrespective of the described HIV prevalence justified the rationale for lifting the deferral on SA MSM. Continuing to collect blood from males aged 35 - 39 years and females aged 30-34 years whose HIV prevalence are 28.85 and 36% respectively while deferring MSM was considered unfair or inappropriate discrimination. **Results/Findings**: There has not been any significant increase in HIV prevalence among the SANBS blood donor population since the lifting of the ban in 2014. The HIV prevalence has remained at 0.22%. A recent study done among SANBS donors demonstrated that MSM constituted about 1% of the donor population with an observed HIV prevalence of 0%. **Conclusion**: The 0% prevalence of HIV in the study of SA MSM donors supports the continuation of the practice of non-deferral of this group. The study had limitations as the sample of 109 MSM was smaller than the calculated sample size of 146 which may have resulted in underrepresentation of MSM. This may be due to non-disclosure of MSM as homosexuality still attracts significant stigma in SA, but may also reflect the relative recent lifting of the MSM-based deferral. The small number of reported MSM in the study on HIV prevalence among MSM donors necessitates ongoing surveillance.

SP166

Increase in Donor Iron Stores is Associated with Increased Interdonation Interval and Decrease in Total Prior Whole-blood Donations

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Background/Case Studies: Frequent blood donations results in decreased/absent iron stores in donors with normal hemoglobin(Hb) levels. Based on the ferrtin levels in a subset of our whole blood (WB) donors, we increased inter-donation interval from 8-12 weeks in May 2013. Ferritin levels were measured in a group of donors before and after increasing the inter-donation interval. We present our findings of changes in donor iron stores after change in inter-donation interval. **Study Design/Methods**: Ferritin levels (Nr: Female= >11 ng/ml, Male= 24 ng/l) were measured in 91 WB donors from Aug-Dec 2012 with 6 months (Ferritin >11-<24ng/ml) or −12 months (Ferritin ≤11ng/ml) deferral in those with low levels. After acheiveing normal ferritin,donors were allowed to donate WB once every 12 weeks. Inter-donation interval was increased from 8 to 12 weeks in May 2013 for all donors at our center. Ferritin levels in these donors were reassesed from Jun-Sep 2014. Donation history in the prioir 24 months, predonation hemogolbin, red meat intake, smoking, vitamin or iron supplements was assesed. Data was analyzed using the Wilcoxon rank sum test and Kruskal-Wallis test, as appropriate, with significance defined as p-value < 0.05. **Results/Findings**: 22/91 donors were deferred in 2012 for low ferritin, 12 (5 females and 7 males) months and rest for six months (all males). Of these donors, six were deferred again in 2014. These donors donated average 9 whole blood units in prior two years in 2012 and average 6 WB units in prior two years in 2014. Overall, ferritin levels increased in these donors after the increase in inter-donation interval. This increase was overall seen in deferred donors (Average ferritin: 2012: 12.5ng/ml and 2014: 40ng/ml) as compared to non-deferred donors (Average ferritin: 2012: 37ng/ml, 2014: 32ng/ml). Decrease ferritin in non-deferred donors is due to deferral of 18 donors that had normal but low ferrtin levels in 2012 and contimued to donate regularly. Along with the increased inter-donation interval, the number of prior whole blood donations corealted with the increase donor iron stores. Pre-donation hemoglobin, food intake or vitamin supplementation had no effect on the iron stores. **Conclusion**: In our study we find that increasing inter-donation interval with likely limiting the total number of whole blood donations in prior two year period results in increased donor iron stores.

TABLE.

	8-week interdonation interval	12-week interdonation interval
Ferritin Average ng/ml	31	33
Ferritin Range ng/ml	6-154	4-197
Hemoglobin Average ng/dl	14.5	14.6
Hemoglobin Range ng/dl	12.5-17.4	12.5-17.4
Average whole blood (WB) donations in prior 2 years	7.2	6.9
Range of WB donations in prior 2 years	1-13	2-7

SP167

Impact of Implementing a New Donor Hemovigilance System on Rates of Adverse Effects of Blood Donation

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Background/Case Studies: After publication of a new set of standard definitions by a joint working group of the International Society of Blood Transfusion (ISBT), the International Haemovigilance Network (IHN) and AABB, we revised and enhanced our donor hemovigilance process. **Study Design/Methods**: Only moderate and severe adverse donation events (AE) were to be reported by the blood center (BC) personnel and calls from donors reporting AEs were also recorded before implementing changes. New system was implemented in two phases: 1) addition of a question to our newly implemented electronic donor health questionnaire (eDHQ) inquiring about AE at last donation in May 2015 and 2) development of a donor AE management manual including ISBT-IHN-AABB definitions; a new reporting form and enhancement of database in October 2015. All severities of AEs had to be reported since phase 2. Rates are per 100 donations and eDHQ AEs that matched AEs reported on a form were excluded. **Results/Findings**: An average of 86 AEs per month was reported before our new reporting system. Phase 1 increased reporting to 211 per month. Phase 2 increased reporting to 1499 AEs per month, a 17.4-fold increase compared to old system. Rates per 100 donations for the 6-month period following phase 2 are presented in table. Vasovagal reactions (VVR) with no loss of consciousness (LOC) were almost 3-fold higher and VVR with LOC 2-fold higher in female donors. In addition there were 2381 citrate reactions (99.5% mild) for a rate of 10.46 per 100 apheresis donations. **Conclusion**: Implementation of a direct question to donors on AEs at last donation significantly increases the number of reports (a 2.5 fold increase in our study). Reporting of all AEs is important to better estimate the true rate of AEs after a blood donation. More sensitive data will help evaluate implementation of preventive measures, like more systematic water consumption and tensing muscle exercises that we intend to implement.

TABLE.

	FEMALE		MALE		TOTAL	
	N	RATE*	N	RATE	N	RATE
Acute nerve injury	15	0.03	9	0.01	24	0.02
Delayed nerve injury	5	0.01	6	0.01	11	0.01
Painful arm	99	0.18	69	0.09	168	0.12
Ecchymosis/ hematoma	189	0.34	276	0.35	465	0.35
Arterial puncture	2	0.00	5	0.01	7	0.01
Local allergic	116	0.21	76	0.10	192	0.14
Delayed bleeding	19	0.03	39	0.05	58	0.04
Thrombophlebitis	1	0.00	1	0.00	2	0.00
VVR-no LOC	3495	6.24	1793	2.28	5288	3.93
VVR-LOC	200	0.36	129	0.16	329	0.24
Other	6	0.01	4	0.01	10	0.01
TOTAL	4147	7.41	2407	30.6	6554	4.87

SP168
Comparison of a Noninvasive and an Invasive Device for Hemoglobin Screening in Prospective Blood Donors
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Background/Case Studies: Noninvasive hemoglobin testing represents an advance in technology on point of care testing. Hemoglobin screening is required prior donation, and capillary methods with finger stick are quite common. The finger stick process is sometimes painful with exposure of blood borne pathogens. Non-invasive hemoglobin devices are now available and can measure hemoglobin with no need of a drop of blood. The aim of this project was to compare a Non-invasive device pulse co-oximetry method called Pronto, manufactured by a company called Masimo International compared to Hemocue, manufactured by Hemocue which requires a capillary finger stick method. **Study Design/Methods**: Participants acceptance criteria for this study included to be between 18 and 65 years old with no history of hematological disorders.A signed consent form and a explanation of the study was given priorly the screening. Hemoglobin levels were measured in duplicate using Hemocue and the Pronto. Hemoglobin levels were compared using paired t-test by comparing the means and *p* values. **Results/Findings**: In average, the hemoglobin of the participants (N=50), was 14.16 ± 0.67 for Hemocue and 14.36 ± 1.13 for the non-invasive device Pronto, with p value < 0.05.Females, (N=37) had an average hemoglobin of 13.73 ± 1.06 for Hemocue and 14.19 ± 1.11 for the non-invasive device Pronto, with p value $= 0.05$. Males average hemoglobin was 15.39 ± 0.799 for Hemocue and 14.85 ± 0.99 for the Pronto, p value < 0.05. In overall, both methods had 92% of agreement, with 8% of the participants being accepted with one method and deferred with another method. All participants with discrepant results were female. **Conclusion**: Statiscally, there was no difference between the Hemocue and the Non-invasive method, Pronto in the overall population. However, it is recommended that Donor centers perform a detailed study when considering non-invasive technologies, with special consideration of the percentage of false positives that could harm donors with low hemoglobin, specially young females donors.

SP169
Interventions to Reduce Vasovagal Reactions in Blood Ddonors: A Systematic Review and Meta-analysis
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Background/Case Studies: Vasovagal reactions (VVRs) in blood donors have significant implications for the welfare of donors, donor retention and the management of donor sessions **Study Design/Methods**: Randomised trials were identified from searches of electronic databases to March 2015. Primary outcomes were donor syncope and donor return for donation. Secondary outcomes included rate and severity of mild/moderate VVRs. Data were pooled using random effects meta-analyses. **Results/Findings**: Five trials (12042 participants) of pre-donation water, eight trials (3500 participants) of applied muscle tension (AMT) and one trial each of AMT and water, caffeine, audio-visual distraction and/or social support were identified. In donors receiving pre-donation water, the relative risk (RR) of VVRs compared with controls was 0,79 [95%CI 0,70, 0,89; P<0,0001]; the mean difference (MD) in severity of VVRs (measured by Blood Donation Reactions Inventory (BDRI) score) was −0,32 (95%CI −0,51, −0,12; P<0,0001). Excluding trials with a high risk of selection bias, the RR for VVRs was 0,70 (95% CI 0,45, 1,11; P=0,13). In donors who received AMT, there was no difference in the risk of chair recline in response to donor distress from controls (RR 0,76, 95%CI 0,53, 1,10; P=0,15), although the MD in BDRI score was −0,07 (95%CI −0,11, −0,03, P=0,0005). **Conclusion**: Current evidence on interventions to prevent or reduce VVRs in blood donors is limited and does not provide strong support for the administration of pre-donation water or AMT during donation. Further large trials are required to reliably evaluate the effect of these and other interventions in the prevention of VVRs.

SP170
Evaluating the Incidence of Human Immunodeficiency Virus-positive Cases in Blood Donors in Taiwan, 2000-2015
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Background/Case Studies: In Taiwan, human immunodeficiency virus (HIV) positive cases were found to be higher in blood donors of the voluntary blood donation programs than those in general population in the 1970s and 1980s. After the implementation of prevention strategies, e.g. health education, screening, pre-donation interview, fewer HIV cases were identified in blood donors than those in general population. This study aimed to evaluate the efforts of donor selection and screening to decrease the risk of blood transfusion related HIV infection in our blood donor program. **Study Design/Methods**: We collected the number of newly reported HIV cases aged 17-65 between 2000-2015 from the surveillance system of Taiwan CDC; and collected number of cases reported by blood centers from the blood management information system. Test results of nucleic acid test (NAT), anti-HIV and HIV Western blot were used to confirm an HIV infection. The age-standardized HIV incidence rate and 95% confidence intervals (95% CI) of blood donors and general population were calculated. **Results/Findings**: Newly identified HIV cases in general population increased annually in 2000-2015, and a sharp increase was observed during 2005-2008 because there was an epidemic among the intravenous drug abusers, thus the Harm Reduction and Methadone replacement Program has initiated in Taiwan since 2005. After deducting HIV cases who are drug users (they are not possible to be a blood donor), number of new cases in general population were gradually increasing from 490 to 2,162 in 2000-2015, and number of those identified by blood centers remained stable. The proportion of new cases identified from the blood centers were declined from 11.8% to 2.7%. In 2000, the age-standardized incidence rates were 3.26 per 100,000 (95% CI: 2.97-3.55) in general population, 5.64 per 100,000 (95% CI: 1.23-10.04) in first-time donors and 4.68 per 100,000 (95% CI: 3.08-6.27) in repeat donors. However, in 2015, the age-standardized incidence rates are 15.63 per 100,000 (95% CI: 14.97-16.29) in general population, 15.27 per 100,000 (95% CI: 5.42-25.12) in first-time donors and 4.38 per 100,000 (95% CI: 3.04-5.73) in repeat donors, indicating that the current strategies have prevented significantly newly identified HIV cases from donating blood in repeat donors, but not in first-time donors. **Conclusion**: Decreasing proportion of the new HIV cases identified by blood centers and much lower HIV incidence rate in repeat donors were observed in recent years. However, the first time donors have a same incidence rate as the general population do. An advanced strategy to educate, interview, and screen first-time donors are needed.

Patient Blood Management

SP171
Role of Intravenous Iron in Avoiding Allogenic Transfusion
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Background/Case Studies: Iron Deficiency Anaemia (IDA) is a very common situation however surely underdiagnosed**.** It can impair aerobic performance leading to symptoms that will decrease quality of life (QoL). IDA has multifactorial origins. Dealing with anaemia can reduce blood transfusion, prevent complications and risks of allogenic transfusion, potentially saving many euros/year. We report the use of intravenous ferric carboximaltose, FeCar(iv), in IDA due to blood loss (Gynecological Diseases, Rendue-Osller Sindrome, Intestinal Angiodysplasias, Duodenal and Gastric Ulcers), malabsorption (Inflamatory Bowel Disease-IBD), pregnancy and cancer related anaemia. **Study Design/Methods**: Data were collected, retrospectively, between 2014-2015. A total of 168 patients with IDA in different stages and with multiple diagnoses were treated with FeCar(iv). Baseline values for hemoglobin (Hb), hematocrit (Htc), ferritin and transferrin saturation (TSAT) were collected and the same parameters were evaluated 4 weeks after FeCar(iv) - 15mg/kg, maximum 1000mg/week. **Results/Findings**: Haematologic values before and after FeCar(iv) in patients with IDA.(n=168) **Note**: 4 cases of drug related adverse events were reported (1 allergic reaction - flush and 3 gastrointestinal symptoms) **Conclusion**: Treatment with FeCar(iv) increase Hb with improvement of functional capacity and QoL (in a short time periode) and substancial cost saving potential. No patient was transfused in this period.

TABLE. Haematologic values before and after FeCar(iv) with IDA

	Hb (g/dL) before/after	Hct (%) before/after	Ferritin (ng/mL) before/after	TSAT (%) before/after	FeCar(iv) (mg) (medium dose)	Adverse events
Blood loss (n=64)	10.4/12.4	32.2/37.5	117/311	11/25	992	2 GI symptoms
Malignancies (n=37)	10.7/13.0	32.7/37.0	82/330	10/24	964	1 GI symptom
Malabsorption (n=29)	10.9/12.8	33.0/36.8	64/295	9/29	1013	1 allergic reaction (flush)
Chronic diseases (n=18)	10.1/13.2	33/41	36/211	6/26	1024	0
Obesity/sleeve (n=7)	10.7/12.5	33/38	28/260	8/28	1015	0
Hepatic cirrhosis (n=6)	10.3/12.3	31/37	59/254	9/26	1030	0
Hepatitis C (n=4)	11.7/13.3	34/39	84/399	11/26	1155	0
Pregnancy (n=3)	10.5/12	33/36	54/260	8/26	910	0

Hb = hemoglobin; Hct = hematocrit; TSAT = transferrin saturation; GI = gastrointestinal.

SP172

A Novel Approach to Fat Removal while Maintaining Blood Quality in a Discontinuous Autotransfusion Device: Concept and Evaluation

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Background/Case Studies: Fat observed during blood salvage in orthopedic or cardiac surgery can pose a risk of fat embolism and brain vessel microembolism, and should be eliminated before transfusion. Due to its light density, fat is trapped in the separation chamber of both discontinuous and continuous autotransfusion systems. Latham bowl based systems have been reported to achieve significantly lower fat removal than that seen in continuous systems. Therefore, a special fat reduction program was developed and evaluated for the new generation Cell Saver ELITE. **Study Design/Methods**: In an experimental study ABO-matched blood from fresh donations was adjusted to a hematocrit (Hct) of 10% and 1.25% fat from human fat tissue added. This blood was processed with the cell salvage device CS ELITE in a newly developed fat removal program in bowls of three sizes. Volumetric quantification of fat was performed after centrifugation of blood samples in Pasteur pipettes. The program was also evaluated for Hct, RBC recovery, and constituent washouts. **Results/Findings**: The tested fat reduction program is based on volume displacement, where a portion of blood is temporarily removed from the separation chamber. This displacement allows fat trapped in the core of the bowl to be displaced to the outer chamber of the bowl where it can easily be removed to the waste. Reducing the fluid volume in the bowl increases the air volume in the bowl which pushes fat past the packed RBC layer as bowl is re-spun. As blood is returned to the bowl and wash solution is introduced, the fat is simply pushed out to waste. Using this new program, high fat reduction rates were achieved (See Table) with all three bowls. Fat removal increased from 77.4 ±5.1% to an average of 96.6 ±1.7%. At the same time, high RBC recovery, Hct and washouts were maintained, not significantly different than the CS ELITE default program mode. **Conclusion**: Based on observations using a transparent centrifugation system, a hypothesis is presented to explain the accumulation of fat in the centrifuge bowl, both in spinning and stopped configurations. Modifications in process parameters and sequence resulted in the development of a dedicated fat removal program. This novel program significantly improves fat removal by the Latham bowl based autotransfusion device CS ELITE, thus yielding results equivalent to the continuous autotransfusion system (CATS).

SP173

Introduction of Thromboelastometry at a Tertiary Care Hospital: Three Months' Experience

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Background/Case Studies: Whole-blood functional clotting tests have become an important tool for the real time diagnosis of coagulopathy and transfusion therapy guidance in patients with major bleeding. This report details the initial use of TEM at a large regional tertiary care hospital. **Study Design/Methods**: The TEM analyzers were managed by the blood bank. The hospital's clinical staff was trained to order TEM to guide blood product resuscitation exclusively in acutely bleeding patients. Data were extracted from TEM requisition forms, TEM result forms and blood bank database. Transfusion of blood products for each patient was enumerated for the calendar day of first TEM and the following day. All TEM tests requested during the first three months following TEM implementation were included. **Results/Findings**: A total of 136 TEM tests were performed on 87 patients (57 males) (see table). Sixty-two (71%) patients only had a single TEM performed. Only 57/136 (42%) TEM tests on 35/87 (40%) patients, demonstrated evidence of coagulopathy. Amongst the other 52/87 (60%) patients for which all TEM results fell within the normal range, 33/52 (63%) received transfusion: These patients received a median of 2 red blood cell units (range 0-27), a median of 0 plasma units (range 0-22), and a median of 0 pooled platelet doses (range 0-10). Amongst the 35/87 (40%) patients with abnormal TEM - of which 34/35 (97%) had at least one TEM demonstrating prolonged clot time/clot formation time - 30/35 (86%; p=0.03 compared to rate of transfusion in patients with normal TEM) received a transfusion: These patients received a median of 4 RBC units (range 0-44), a median of 3 plasma units (0-40), and a median of 1 pooled platelet dose (range 0-15). The median number of total blood products (3.5 vs. 9) and median number of plasma units (0 vs. 3) transfused to patients with abnormal TEM was significantly higher than for patients with normal TEM (p=0.03 and p=0.02, respectively). **Conclusion**: TEM results indicating coagulopathy was associated with significantly higher rates of both administering a transfusion (86% vs. 63%) and use of all blood products and plasma units per patient. The high rate (28%) of un-transfused patients and high level (60%) of patients with normal TEM results may be due to patients experiencing acute surgical bleeding not correctable by blood product administration, or it could indicate inappropriate TEM ordering. As the institutional experience with TEM increases, the ordering precision will likely increase too.

TABLE.

	Bowl size		
Quality parameter	225mL	125mL	70mL
Hematocrit (%)	57.0 ±2.1	51.4 ±2.6	50.5 ±0.5
RBC recovery rate (%)	94.5 ±0.8	92.1 ±1.8	90.8 ±1.3
Fat elimination rate (%)	99.6 ±0.3	97.0 ±2.1	93.2 ±2.8
Albumin washout (%)	99.4 ±0.02	99.9 ±0.10	99.5 ±0.02

			Requests for TEM testing		
Patient age (years)	No. of patients	No. of TEM tests	ICU N = 92	Surgical N = 22	Medical N = 22
Unknown	3	3	1	1	1
<30	3	3	1	2	0
30-69	42	78	54	15	9
≥ 70	39	52	36	4	12

SP174

Impact of Rotational Thromboelastometry on Blood Use and Patient Outcome in High-Risk Orthotopic Liver Transplantation

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Background/Case Studies: Hemostatic control during orthotopic liver transplantations (OLTs) remains a challenge. Rotational thromboelastometry (ROTEM), a device evaluating whole blood hemostasis, was shown in some studies to reduce blood use in cardiac surgeries and traumas. It remains unclear whether similar reductions in blood use are seen in high-risk OLTs. We seek to determine if use of ROTEM (recently implemented at our hospital) reduces blood use and improves patient outcomes in OLTs as compared with OLTs performed with conventional coagulation tests alone. **Study Design/Methods**: Peri-operative OLT blood use was evaluated during three 6-month periods: 1) Pre-ROTEM (conventional coagulation tests only), 2) Interim-ROTEM (conventional coagulation tests plus ROTEM available during regular hrs only), and 3) Post-ROTEM (conventional coagulation tests plus ROTEM available 24/7). Blood use and patient/donor factors were obtained via chart review and transplant database. Outcomes and baseline characteristics between study periods were compared using unadjusted negative binomial regression and Chi-squared/Fisher's exact/Kruskal-Wallis tests. **Results/Findings**: During study period (May 2014-Nov 2015), we enrolled 226 OLT patients: 72 from pre-ROTEM, 81 from interim-ROTEM, and 73 from post-ROTEM period. Median MELD score was 37 [IQR 32-41]. The study periods were not significantly different with respect to recipient factors (age, gender, MELD score, Karnofsky score, encephalopathy grade, prior shunts, mass lesions, portal hypertension, variceal hemorrhages, >1 week hospitalization within last month, pretransplant hospitalization time, retransplantation history) and donor factors (age, gender, heart beating vs non-beating donor, organ ischemia time). There was a significant increase in cryoprecipitate usage during interim-ROTEM (incidence rate ratio (IRR)[95% CI]: 1.43 [1.04, 1.97])/post-ROTEM (IRR: 2.21 [1.61, 3.03]), as compared with pre-ROTEM ($P<0.001$) period. There is a non-significant trend towards decreased FFP usage during interim-ROTEM (IRR: 0.74 [0.56, 0.98])/post-ROTEM (IRR: 0.83 [0.62, 1.12]) as compared with pre-ROTEM period. RBC and platelet usage were similar between periods. A non-significant trend towards decreased post-operative length of stay (LOS) was observed during interim-ROTEM (IRR: 0.79 [0.624, 0.996])/post-ROTEM (IRR: 0.84 [0.66, 1.07]) periods, from median of 31.8 days (Pre) to 27.0 days (Post). There were no significant differences in post-operative exploratory laparotomy rates, all-cause mortality, and re-admission rates between periods. **Conclusion**: Addition of ROTEM for hemostasis management during high-risk OLTs appears to increase cryoprecipitate transfusions without significantly reducing use of other blood products. A non-significant trend toward reduced post-operative LOS was observed.

SP175

Massive Transfusion, Shed Blood Re-Infusion, and Thromboelastography to Successfully Manage Severe Coagulopathy during Orthotopic Liver Transplantation

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Background/Case Studies: Patients with end-stage liver disease (ESLD) pose a blood management challenge due to their limited ability to produce coagulation factors. Orthotopic liver transplantation (OLT) can be associated with substantial perioperative hemorrhage. In these patients, multiple approaches may be required to control bleeding. We present two patients who underwent OLT and who had successful management of unexpected massive bleeding. **Study Design/Methods**: The medical records of two patients with ESLD who required activation of the massive transfusion protocol (MTP) intra-operatively during OLT at our hospital in 2015. Laboratory and blood transfusion data were analyzed. **Results/Findings**: Two male patients, ages 58 and 65 years, underwent OLT. Both patients demonstrated severe coagulopathies as a consequence of their advanced liver disease. The preoperative INR values were 2.78 and 2.02 respectively. The estimated operative blood loss (EBL) was 7,000 ml in the first patient, who during a 48-hour perioperative period required transfusion of 29 units of red blood cells (RBCs), 35 units of plasma, 12 apheresis platelet units, and 20 units of cryoprecipitate. The RBC: FP: PLT ratio was 0.8:1:1.6. The EBL was 15,000 ml in the second patient, who during a 48 hour perioperative period required transfusion of 68 units of RBCs 59 units of plasma, 14 apheresis platelet units and 55 units of cryoprecipitate in the RBC: FP: PLT ratio 1.1:1:1.2. In the first patient 7,800 ml of collected shed blood was reinfused intraoperatively versus 3,900 ml in the second. In both patients venovenous bypass was performed. Thromboelastography (TEG) demonstrated fibrinolysis in both patients. Subsequent TEG also demonstrated resolution of fibrinolysis in the second patient. Both patients were discharged to home with good transplant organ function. **Conclusion**: Massive bleeding due to severe coagulopathy is challenging to manage during OLT. Activation of the MTP and shed blood collection and reinfusion were effective blood management strategies for these two patients when severe coagulopathy was encountered during OLT.

SP176

Transfusion Requirements for Patients on Venoarterial and Venovenous Extracorporeal Membrane Oxygenation (ECMO)

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Background/Case Studies: Venoarterial (VA) or venovenous (VV) extracorporeal membrane oxygenation (ECMO) is increasingly utilized to support selected critically ill adult patients. Patients on ECMO are almost universally transfused; however, evidence based recommendations for blood management are lacking. This study was conducted to better understand blood component usage by ECMO patients. **Study Design/Methods**: A single-center, retrospective analysis of ECMO patients was performed between 2012 and 2015. Clinical outcomes and laboratory data were analyzed. Data were analyzed using Microsoft Excel software and are presented as the mean (median, range) unless specified. **Results/Findings**: A total of 65 patients were studied, 49 (76% male) on VA and 16 (62% male) on VV ECMO. The mean ages were 51 and 40 years for VA and VV ECMO respectively. The mean numbers of days on ECMO was higher with VV ECMO compared to VA ECMO: 9.94 (5, 2-30) days versus 5.41 (10, 1-17) days. All patients were received at least one transfusion. Average blood use was higher with VA than VV ECMO. Total blood use in patients while on VA ECMO was 32.80 (23, 1-205) units red blood cell (RBC), 15.02 (10, 0-131) units apheresis platelets, 18.53 (8, 0-212) units plasma, and 1.90 (0, 0-28) pools of cryoprecipitate. Total blood use in patients while on VV ECMO was 17.81 (14, 2-48) units RBC, 8.31 (3, 0-44) units apheresis platelets, 4.50 (3.5, 0-21) units plasma, and 1.19 (0, 0-14) pools of cryoprecipitate. Due to the wide range of days patients were supported on ECMO, blood use data were further analyzed for use per day of ECMO. Blood use per day of VA ECMO was 5.47 (4.40, 0.33-40.33) units RBC, 2.85 (2.00, 0-23.50) units apheresis platelets, 2.41 (1.50, 0-10.00) units plasma, and 10.62 (0, 0-14.00) pools of cryoprecipitate and per day of VV ECMO was 2.18 (1.61, 0.50-6.60) units RBC, 0.92 (0.60, 0-4.89) units apheresis platelets, 0.47 (0.36, 0-1.62) units plasma, and 0.06 (0, 0-0.47) pools of cryoprecipitate. Overall survival was similar between the two groups, with 28 (57%) of VA ECMO and 10 (62%) of VV ECMO patients surviving ECMO. Patients surviving to hospital discharge were: 22 (45%) of those patients who were supported on VA ECMO and 9 (56%) who were supported on VV ECMO. **Conclusion**: This cohort of adult patients supported on ECMO demonstrated significant blood component utilization. Blood usage varied between the patients who were support on ECMO. Further analysis of patient factors, laboratory studies of hemostasis, and the development of ECMO specific transfusion guidelines may help to optimize blood management for these patients.

TABLE.

Group	CPBmin.	BleedingmL	Withouttransf.	Withtransf.	x RBCs	x FFP	x PLTs	TXA	F I Conc.
A=37 PTS	80	325	5 (13.5%)	32 (86.5%)	2.8u	0.9u	2.7u	15 PTS (40%)	10 PTS (27%)
B=39 PTS	90	262	5 (13%)	35 (87%)	2.9u	0.05u	0.2u	10 PTS (25%)	13 PTS (33%)

SP177

Patient Blood Management Program Assessment in Cardiovacular Surgery

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Background/Case Studies: Cardiovascular surgery (CVS) requires a significant blood transfusion support and consequently patients (PTS) are at risk of adverse events associated with allogenic transfusion. Patient blood management (PBM) consists of a number of evidence-based measures taken by a multidisciplinary team in order to optimize patient care. Purpose: The present retrospective study analyses the effect of implementing PBM criteria on blood transfusion therapy during CVS. **Study Design/Methods**: The 76 first-time CVS PTS with a cardiopulmonary bypass (CBP) were allotted to either Group A or B. Group A (pre-PBM): 37 PTS with a coronary disease diagnosis treated between Jan. 2013 and July 2014, before our Institution incorporated a PBM protocol. 29 PTS underwent myocardial revascularization surgery (MRS); 7 had a valve replacement (VR) and 1 underwent both procedures, MRS + VR. Group B (post-PBM): 39 PTS treated between Aug. 2014 and March 2016 by the same professional team as Group A. 24 underwent MRS; 11 had a VR and 4 were subject to both treatment, MRS + VR. Patients' admittance was programmed and routine pre-surgical studies were complied with. Pre-surgical hemostasis control was made by conventional coagulogram (CC) in both groups and by CC with Fibrinogen (F1) dosage by Clauss method and platelet count during perisurgical period. Group B control also included rotational thromboelastometry (TEM) with activators (ROTEM). Hemostasis monitoring was performed in both groups at pump exit and in the ICU until parameters were normal and/or bleeding stopped. Group B also underwent a TEM study during CBP. Both Groups were administered antifibrinolytic agents: Tranexamic acid (TXA), (Arotran)(average dose) and F1 (Haemocomplettan-Behring), (average dose 4g). Statistical analysis used: Statistic 7.0 **Results/Findings**: FFP: 95% consumption difference (IC 95%:1.7 a 2.8 - $p<0.01$). PLT: 93% consumption difference (IC 95% 4 a 9.5 - $p<0.001$). **Conclusion**: Implementation of PBM criteria in CVS patients significantly reduced risk and FFP (95%) and PLT (93%), while it increased blood components stock, usually scarce, in other patients. Greater efforts will be necessary to reduce RBC consumption. The PBM implementation meant our institution managed to reduce costs and legal contingencies and improved its position in the accreditation process.

Results:

SP178

Patient Blood Management for Paediatric Patients Undergoing Cardiac Bypass Surgery

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Background/Case Studies: In 2013, our hospital's blood management program was extended to include paediatric cardiac surgical patients undergoing bypass surgery. Candidates were referred to the Patient Blood Management (PBM) Clinic upon identification by the surgical team for dietary counselling, oral iron therapy, and discussion of transfusion options. Baseline blood work including CBC, reticulocyte count and ferritin level were measured. The transfusion rates of the patients undergoing cardiopulmonary bypass surgery in this program were examined. **Study Design/Methods**: The patients were grouped by weight because children <12 kg had their bypass pump primed with blood and were automatically transfused. Data collection started April 1, 2012 with the first 60 patients in each group ≥ 12 kg and <12 kg. In 2013 data were collected from April 1 to December 31 (n=186) but patients did not start being seen in Clinic until the end of April when the referral process from the surgeons' offices became more efficient. Data from all patients undergoing cardiac pump surgery were collected in 2014 (n=272) and 2015 (n=223) for the full calendar year. Units of blood transfused and length of stay (LOS) were analyzed. **Results/Findings**: Patients <12 kg transfused decreased slightly from 100% (60) in 2012 to 96% (116/121) in 2015 when some surgeries were started with clear prime instead of blood even though the pre-op haemoglobin levels were similar to previous years. Patients ≥ 12 kg transfused showed a downward trend from 55% (33/60) in 2012 to 50% (51/102) in 2015 with similar pre-op haemoglobins. Average discharge haemoglobin remained unchanged in children <12 kg (range 122-123 g/L) and ≥ 12 kg (range 109-117 g/L). Average pre-op ferritin showed no change in the <12 kg group (range 53-83 μg/L) or in the ≥ 12 kg group (range 43-48 μg/L). The average number of units transfused per patient increased from 0.8 in 2012 to 1.5 in 2015 for children ≥ 12 kg and remained essentially the same at 2 for those children <12 kg. The LOS was shorter for those patients who were not transfused compared to those patients transfused for both groups of children. **Conclusion**: There was little change over the four years when the data for haemoglobin, ferritin, units transfused and LOS were examined. It is difficult to gauge impact when cases of different complexities are bundled together and the proportion of complex cases varies from year to year. The highest transfusion rate in children ≥ 12 kg in 2015 may be related to the fact that fewer cardiac cases were scheduled and the majority of cases going for surgery were complex or urgent. In future studies data collection will be expanded to include diagnosis and bypass time so our efforts can be directed to those children with more complex cases that require transfusion.

SP179

Patient Blood Management (PBM) for Jehovah's Witness Pediatric Patients Undergoing Cardiac Bypass Surgery

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Background/Case Studies: Pediatric patients undergoing cardiopulmonary bypass surgery are frequently transfused. Children less than 12kg in weight require blood prime for the bypass circuit and are always transfused. Jehovah's Witnesses are opposed to transfusion. Here we describe the management of 3 JW children requiring cardiac surgery. **Study Design/Methods**: Patient 1 was seen in our cardiac program at $2\frac{1}{2}$ years after a heart murmur was detected on routine check-up. Echocardiogram showed a large secundum atrial septal defect with right ventricular dilatation. Patient 2 was a full-term baby with a murmur detected after birth. He had a large perimembranous ventricular septal defect with left to right shunt and signs of pulmonary overcirculation. Patient 3 was a full-term infant found to have Trisomy 21 and pulmonary hypertension at birth. Investigations revealed a large perimembranous VSD and biventricular hypertrophy. **Results/Findings**: All 3 patients were referred to our PBM program in preparation for cardiac surgery. Patient 1 was started on oral iron supplementation (Fe) at 6 mg/kg 5 months prior to surgery. After 1 month, her hemoglobin (Hb) was 130g/L, ferritin 31mg/L. She was started on erythropoietin (epo) and received a total of 60,000 units (10,000 units x 6). Her highest Hb was 156g/L. She underwent surgery at 17.6kg with pre-op Hb of 143g/L. Bypass time was 18 minutes. Post-op Hb was 91g/L and discharge Hb was 107g/L. Patient 2 was small and failed to thrive. His type of defect is usually repaired at 4 to 6 months of age, but his surgery was deferred because of parents' wish to avoid transfusion. He was put on a high calorie diet, Fe 2mg/kg from 4 months of age, increased to 6 mg/kg 6 months prior to surgery. His initial Hb was 118g/L, ferritin 38mg/L. He received epo 600 units x 10 doses. His highest Hb was 150g/L. He underwent surgery at 21 months and 8.5kg, with pre-op Hb 139g/L. Bypass time was 64 minutes. Post-op Hb was 69g/L. He received epo 30,000 units post-op. Discharge Hb was 81g/L. Patient 3 was started on Fe at 2 mg/kg and increased to 6 mg/kg at 6 months prior to surgery. Her

initial hemoglobin was 107g/L, ferritin 21mg/L. She received epo 4000 units x 17 doses. Her highest Hb was 151g/L 2 days pre-op. She underwent surgery at 9 months and 8.9kg. Bypass time was 69 minutes. Post-op Hb was 83g/L. She received epo 30,000 units post-op. Discharge Hb was 95g/L. These 3 patients did not receive any blood product except albumin for bypass prime. **Conclusion**: For JW patients needing cardiopulmonary bypass surgery, PBM includes high calorie diet, oral iron supplementation and erythropoietin administration at 700 units/kg twice weekly. When patients reach 8kg body weight and Hb of 150g/L, surgery is scheduled. These strategies have enabled 3 JW children needing cardiac surgery to avoid transfusion.

SP180

Intraoperative Antifibrinolytics not Associated with Decreased Intraoperative Blood Loss During Major Cardiac Surgery

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Background/Case Studies: The importance of limiting blood loss during surgery has a well-known benefit for patients and hospitals alike. There are a wide range of complications associated with intraoperative blood loss and associated hypotension in addition to the risks associated with blood product transfusions. These possible complications range from end organ damage, transfusion reactions and infections. In addition to avoiding patient complications, limiting intraoperative transfusions aids in limiting the increasing cost of blood products for hospitals. The goal of this study is to examine the relationship between the use of intraoperative antifibrinolytics and intraoperative blood loss during major cardiac surgery. This is important as the use of antifibrinolytics is becoming more widespread as a measure to reduce intraoperative blood loss during major cardiac surgeries. **Study Design/Methods**: Forty-four patients undergoing major cardiac surgery at a teaching hospital were included in the study; surgeries included both coronary artery bypass and valve repair procedures. The study population was separated into two groups based on whether they received intraoperative antifibrinolytics (both tranexamic acid and aminocaproic acid) or not. 31/44 patients were given antifibrinolytics while 13/44 were not. The study used intraoperative decrease in hemoglobin concentration as well as intraoperative estimated blood loss as two different measures of blood loss within the two populations. For the comparison of intraoperative decrease in hemoglobin, 16 patients were excluded who received RBC units intraoperatively. Student t-test was used for the statistical analysis. **Results/Findings**: When comparing the groups who received intraoperative antifibrinolytic medications with those who did not, there was no statistical difference between intraoperative estimated blood loss or intraoperative decrease in hemoglobin concentration. 16 patients who were excluded, were high risk for bleeding and RBC transfusion. 12 patients (75%) received intraoperative antifibrinolytics and 4 patients (25%) did not. **Conclusion**: The results of the study do not support the belief that intraoperative antifibrinolytics aid in reducing intraoperative blood loss during major cardiac surgery. However, the small size of the population and internal variability between each patient likely contributed to the lack of statistical significance. It would be important to look further into the relationship between antifibrinolytics and intraoperative blood loss with a larger population and with elimination of confounding variables.

SP181

Active Patient Blood Management by Transfusion Services Reduces Hospital Blood Use

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Background/Case Studies: Over 13,000,000 units of red blood cells (RBCs) are transfused in the United States per year. Numerous studies have demonstrated that restrictive transfusion thresholds (transfusing for a hemoglobin < 7 mg/dL) do not contribute to higher rates of morbidity and mortality. Liberal transfusions may increase the risk for complications and death in trauma patients, the critically ill, and in other hospitalized patients. Another benefit of restrictive transfusion is decreased hospital expenses. The purpose of this study was to determine if focused blood management by transfusion services improves adherence to hospital-approved transfusion guidelines. **Study Design/Methods**: All inpatient blood product usage and admission data between January 1st, 2014, and December 31st, 2015, was included in this study. The active patient blood management program was implemented in December 2014. Interventions to influence practice included restrictive transfusion guidelines, targeted education, new computerized physician order entry requesting the transfusion indication, and intensive utilization review by the transfusion service. Transfusions that did not reflect hospital guidelines were documented, and the ordering physicians received a letter from the transfusion practice committee. **Results/Findings**: A total of 18,404 and 15,444 products were transfused in 2014 and 2015, respectively. While admissions were similar between both years, the number of transfusions was reduced in 2015 following implementation of the blood management program (Table). As a result, over a million dollars in acquisition costs was saved in one year with a change in practice that encouraged restrictive transfusions, single unit transfusion of RBCs and platelets, appropriate dosage of plasma, and post-transfusion laboratory monitoring. **Conclusion**: The known risks of liberal transfusion and the increasing costs of healthcare make active blood product utilization efforts more attractive by reducing risk to the patient and saving money for the hospital. This study shows that significant changes can be implemented in a short period of time that improve blood transfusion practices.

SP182

Improved Compliance with Transfusion Guidelines in Hematology by Implementation of Electronic Blood Ordering with Clinical Decision Support

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Background/Case Studies: Hematology patients receive more transfusions than any other patient group. National audits in the UK, including hematology, show 20% or more inappropriate use of blood components which puts patients at unnecessary risk and wastes a costly resource. We implemented an electronic rules-based blood ordering clinical decision

TABLE.

	Financial Year		
	13/14	14/15	15/16
Hematology Inpatients	1063	876	868
Hematology Ward Bed Days	8605	8555	8965
Average Number of Red Cell Transfusions/month	165	123	135
Average Number of Platelet Transfusions/month	118	94	105

TABLE. Total number of inpatient transfusions from 2014 to 2015

	2014	2015	Actual difference (%)	Acquisition cost difference
Admissions	13,347	13,437	↑ 90 (0.7%)	
Red blood cells	11,147	9,588	↓ 1,559 (14.0%)	$369,483
Platelets	4,080	2,945	↓ 1,135 (27.8%)	$676,460
Plasma	3,177	2,911	↓ 266 (8.4%)	$18,620
Total	18,404	15,444		$1,064,563

support system (CDSS) in hematology inpatients in April 2013. It provides the most recent blood results to clinicians when orders are made, and alerts them to inappropriate orders. This was combined with electronic prescribing in October 2014 as a single process. **Study Design/Methods**: Every transfusion was audited for compliance with local guidelines, and all non-compliant transfusions were reviewed at a monthly meeting with the clinicians ordering the transfusions. Costs of transfusions were based on costings provided in the NICE blood transfusion guideline (2015). In order to assess the effect of this supervision and feedback on the ongoing compliance with guidelines of the Foundation Year 2 doctors (FY2s) who had rotated from the hematology ward, orders placed by these doctors in their new placements were audited for compliance with local guidelines for transfusion. This was compared with the compliance of orders from a similar number of junior doctors who had not been exposed to supervision and feedback. **Results/Findings**: Compliance with red cell (RCC) transfusion guidelines increased from 41% in April 2014 to 94% in March 2015, and compliance with platelet (PLT) transfusion guidelines increased from 76% to 98%. In April 2014, the number of single unit RCC orders was 0/87 (0%), but after 12 months this rose to 54/87 (62%), and has been sustained at this level since. Analysis of orders placed by FY2s that had rotated on to other specialties showed that 122 orders had been placed by 12 doctors who had demonstrated improved compliance with guidelines whilst on the hematology ward. Of these 108 (88.5%) orders were deemed to be compliant with local guidelines compared to 91/128 orders (71.1%) placed by a comparable group of doctors who had not received feedback about their transfusion practice on the hematology ward. **Conclusion**: There were savings of $170,000 associated with reduced RCC and PLT transfusions between the financial years ending 2014 and 2015; the costs of adding the module to the electronic patient record and providing training and feedback were much less. The improved practice and savings can be at least partly attributed to the implementation of CDSS and regular feedback to clinicians.

SP183

Patient Blood Management: The Impact of Local, Regional, and National Initiatives on Blood Usage

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Background/Case Studies: Patient Blood Management (PBM) is an evidence-based multidisciplinary approach to optimising the care of patients who might need a blood transfusion. The objective of a PBM program is to improve patient outcomes and to reduce unnecessary transfusion. As many different initiatives fall under the auspices of a PBM program, this study was undertaken to evaluate the impact of guidelines and education on red blood cell (RBC) utilization in a regional transfusion service. **Study Design/Methods**: In this regional transfusion service of around 1.3 million inhabitants, PBM initiatives have been in place since 1999. The initiatives, which based on guidelines and education, were listed in the chronological order of their implementation and compared to the corresponding yearly national and regional RBC utilization rates through the end of 2015. **Results/Findings**: From 1999 until 2007 the main PBM initiatives in this region consisted of recognizing that the transfusion rate in this region was high and authoring several articles for a national medical journal that described the problem. During this 8 year period the annual regional RBC transfusion rate varied from 54.6-65.3/1000 population (pop); the national annual rate ranged from 61.6-65.7/1000 pop. New national guidelines that recommended a more restrictive transfusion strategy were implemented in 2007, and the regional PBM program began in earnest in 2009-2010. Targeted meetings with specific hospital services with high RBC transfusion rates occurred to educate them about appropriate transfusion practice and follow up sessions with many of these services occurred a year later to review their progress in reducing RBC transfusions. By the end of 2013, when the large blood transfusing specialties had been educated, the regional RBC transfusion rate declined to 48.7/1000 pop. At this time the national rate was 47.9/1000 pop. In 2014 and 2015 nursing and physician education, including an electronic learning program, continued and new national transfusion guidelines were published emphasizing restrictive transfusion thresholds. By the end of 2015 the regional RBC transfusion rate dropped to 39.4/1000 pop and the national rate fell to 38.4/1000 pop. **Conclusion**: This study is notable in that the majority of the PBM initiatives that were implemented regionally and nationally were based on education and enforcement of the national guidelines. Even though the initiatives listed in this study do not cover all aspects of PBM, these findings indicate that education alone can be an effective and durable method of reducing unnecessary transfusions. The RBC transfusion rates remain relatively high indicating that education alone is unlikely to be sufficient in achieving the low RBC transfusion rates noted in other western countries.

SP184

Retrospective Email Notification of Inappropriate Plasma Transfusions: A Performance Improvement Study

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Background/Case Studies: One third of plasma transfusions are administered for mild coagulation abnormalities in non-bleeding patients to reduce presumed bleeding risk. Patients with INR values of 1.3 to 1.9 manifest normal clotting in vivo and are not at increased risk for bleeding. Additionally, plasma should be dosed to achieve 30% of plasma factor levels, requiring an average dose of 15 mL/kg plasma. Plasma transfusions are notoriously underdosed, with patients most commonly receiving 2 units of plasma. These unnecessary plasma transfusions not only delay patient treatment and waste precious resources, but they place the patient at risk for transfusion reactions and transfusion transmitted diseases. To improve plasma transfusion practices, plasma orders were retrospectively reviewed for appropriateness and physicians were notified by email of inappropriate orders. **Study Design/Methods**: Plasma orders from an urban, 200-bed, community hospital were retrospectively reviewed monthly from 7/2015-4/2016. If the plasma transfusion order was considered inappropriate, a feedback email was sent to the ordering physician the month after the transfusion. Inappropriate orders were defined as being underdosed based on patient weight and/or a pretransfusion INR$<$2. The correct plasma dose was calculated using (15 mL/kg)/250mL. Plasma orders 9 months prior to the initiation of email notification were collected as a baseline. Collected data included the ordering physician's name, patient weight, admitting diagnosis, pretranfusion INR, number of plasma units ordered, and indications for transfusion (warfarin reversal, massive transfusion, congenital factor deficiency, and acquired factor deficiency). All plasma transfusions ordered for massive transfusion, congenital factor deficiency, or for intraoperative use were excluded. **Results/Findings**: A total of 90 plasma orders were reviewed after monthly feedback was initiated and compared to baseline plasma ordering practices (Figure 1). Plasma was most commonly ordered in doses of 2 or 4 units, and on average, patients received 8.8 mL/kg and 7.7 mL/kg of plasma before and after feedback initiation, respectively. **Conclusion**: Retrospective email feedback did not improve plasma utilization. Similar to previous studies, approximately one third of plasma transfusions before and after the intervention were for an INR$<$2. Physicians also ordered insufficient plasma doses that were not weight based. Alternative strategies to improve transfusion practices need to be explored and may include hospital-based policies, educational sessions, or real-time notifications via the computer ordering system.

TABLE. Plasma Orders Before and After Feedback

	Total Plasma Orders	INR $<$ 2	INR $\geq$ 2	Correct Dose Ordered	Incorrect Dose Ordered
Before Feedback (11/2014-7/2015)	115	43 (37%)	72 (63%)	22 (19%)	93 (81%)
After Feedback (8/2015-4/2016)	90	30 (33%)	60 (67%)	10 (11%)	80 (89%)

SP185

Effectiveness of Provider Education in Reduction of Inappropriate Red Blood Cell Transfusion

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Background/Case Studies: RBC transfusion is one of the top five overuses in the American medical system. Not only are RBC units costly and in limited supply, but their use is associated with increased morbidity and mortality in a dose dependent fashion. A lack of clinician training about blood products often leads to a disconnect between clinical and blood bank staff, sometimes even resulting in adversarial situations during specific clinical scenarios. Utilizing clinical provider education through our patient blood management program may help us reduce inappropriate transfusions and the costs and risks associated with them. **Study Design/Methods**: Inappropriate RBC transfusions since 2014 have been tracked monthly by three metric parameters: RBC orders with pre-transfusion hemoglobin level $>$ 8 g/dL, post-transfusion hemoglobin level $>$ 10 g/dL, and non-emergent "blanket" 2-unit RBC orders. Our analysis focused on adult, non-emergent inpatient orders; thus transfusions involved with massive transfusion protocols, outpatients, and NICU patients were excluded from this analysis. In addition, patients with active bleeding or acute coronary insufficiency were also excluded from the 2-unit RBC order analysis. **Results/Findings**: In all of 2014, our institution completed 5932 RBC transfusion orders. Of those, 987 (16.64%) had a pre-transfusion hemoglobin $>$ 8 g/dL, 832 (14.03%) had a post-transfusion hemoglobin $>$ 10 g/dL, and 2685 (45.26%) were non-emergent 2-unit orders. From that point, provider education via both group presentations and individual communications has been periodically provided, with a special emphasis on the importance of adhering to appropriate AABB transfusion guidelines. In the first quarter of 2016, 1469 RBC orders were completed. Of those, 141 had a pre-transfusion hemoglobin $>$ 8 g/dL (9.60%), 90 had a post-transfusion hemoglobin $>$ 10 g/dL (6.13%), and 297 were non-emergent 2-unit orders (20.22%). **Conclusion**: Our data demonstrates a significant decrease in inappropriate RBC transfusions (42% drop for pre-transfusion hemoglobin $>$ 8 g/dL, 56% drop for post-transfusion hemoglobin $>$ 10 g/dL, and 55% drop for non-emergent 2-unit orders). In 2014, 1819 transfusions were given to patients whose pre- and/or post-transfusion hemoglobin levels were too high; simple provider education has reduced that overall number by almost 50%, which could have prevented the risks and expenditures of 800 to 900 units of RBCs in 2014. Furthermore, reducing 2-unit orders by more than 50% could have saved an additional 1300 to 1400 units in 2014. This study clearly demonstrates great potential for thorough provider education to be the driving force behind reducing unnecessary RBC transfusions, and should be encouraged as a first-line measure to improve appropriate-use metrics.

SP186

Simple Notification to Surgeons of Anemia in Patients Undergoing Elective Pocedures may not be Effective in Avoiding Allogeneic Transfusion

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Background/Case Studies: An important aspect of patient blood management is to correct preoperative anemia, where possible, since anemia is the most important determinant of perioperative red cell transfusion in elective surgery. Patients scheduled for elective procedures will have a preadmission sample (PAT) collected in advance of surgery, commonly for a type and screen and blood counts. Obtaining the hemoglobin level in such patients can be relatively easy, providing an opportunity to inform the surgeon if preoperative anemia is present with the potential for correction and avoidance of perioperative transfusion **Study Design/Methods**: Since 2014, all patients for whom a PAT specimen was received were checked for the presence of preoperative anemia in the associated specimen sent for a blood count. Those patients in whom the PAT specimen showed a hemoglobin of 11 g/dL or less had a letter sent to their surgeons explaining that this preoperative anemia could result in an allogeneic red cell transfusion and advising the diagnosis of the cause of the anemia and preoperative correction. Letters were sent when there was at least one week available prior to surgery. Data were tabulated by number of PAT specimens, numbers of letters sent, whether a perioperative red cell transfusion occurred and the discharge hemoglobin, if performed. **Results/Findings**: A total of 853 specimens were received over a 27 month period. For these 853 patients, the preoperative hemoglobin was 13.4 ± 1.7 g/dL and the discharge hemoglobin 11.0 ± 1.7 g/dL (mean $\pm$ 1SD) . Overall 73/853 (8.5%) were transfused perioperatively. The cohort was subcategorized into patients who got letters and were subsequently transfused or not transfused and the patients who did not get letters and who were either transfused or not transfused. These data are shown in the table. 18/50 or 34% of the patients with preoperative anemia were transfused despite letters having been sent to all as opposed to 55/803 or 7% of the non-anemic patients. The non-anemic patients were likely transfused partly because of a slightly lower (but not anemic) hemoglobin (see Table) and partly because of greater intraoperative bleeding. **Conclusion**: A large percent of the preoperatively identified anemia patients were transfused indicating that simple notification, in itself, may not be effective and requires an additional intervention in order to be successful in avoiding allogeneic transfusion.

SP187

The Cumulative Impact of Prospective Auditing on Decreasing Single-Donor Platelet (SDP) Usage

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Background/Case Studies: While SDPs represent a small percentage of units transfused, they are a major cost. In 2Q10 we introduced new transfusion (TXN) triggers in the hospital's computer order entry system and initiated prospective auditing of all orders. All platelet orders including a numeric platelet count (PLTC) as a part of the TXN trigger were prospectively audited, and SDPs were not issued if the most recent PLTC did not satisfy the selected trigger. A post-TXN PLTC was required prior to the release of a second unit in a non-rapidly bleeding patient. In 2011 we first evaluated the impact of the changes and noted that a many orders were placed using "other" as the TXN trigger. At the end of 2Q13 prospective auditing was expanded to include the free texted reason provided when placing an order using "other." In 3Q2015 "other" TXN trigger was removed. In 2016 we sought to evaluate the cumulative impact and financial benefit of auditing on SDP usage. **Study Design/Methods**: The number and cost of SDPs transfused over time was compared. The impact of different auditing interventions was assessed. For ease of analysis, the cost of a unit of SDPs was fixed at $530. The results were analyzed using the Student's T-test and Z-test. **Results/Findings**: Prior to auditing 555.9 SDPs were transfused per quarter (TPQ). Auditing against the selected TXN trigger resulted in 450 SDPs TPQ. Consistent auditing of "other" further reduced usage to 363.7 TPQ. Removal of "other," yielded 287.5 TQP in 4Q15-1Q16. Prospective auditing to the PLTC significantly decreased usage by 105.2 units per quarter (T-test, p-value 0.041) and reduced spending by $55,230 per quarter. The addition of "other" orders further decreased usage by 87 units per quarter and resulted in saving $45,675 per quarter. Although the removal of "other" did not significantly reduce usage, it did save an additional $17,333. The cumulative impact of all interventions saved an average of $142,252 per quarter. The transfusion of fewer SDPs without an accompanying reduction in purchases led the outdate rate to rise from 16.9% in 2012 to 28.9% in 2015. **Conclusion**: The cumulative value of prospective auditing of platelet orders yielded a statistically significant reduction in SDP TXN (Z-test, p-value 0.006). Each additional intervention decreased the mean number of SDPs

TABLE. Preoperative and discharge hemoglobins in the different categories*

	n	PAT Hb (g/dL)	Discharge Hb (g/dL)
Letter sent, transfused	18	9.5 ± 1.1	9.2 ± 1.2
Letter sent, not transfused	32	10.3 ± 0.8	9.5 ± 1.0
No letter sent, transfused	55	12.4 ± 1.9	9.6 ± 1.3
No letter sent, not transfused	748	13.7 ± 1.4	11.3 ± 1.6

* Data are mean $\pm$ 1SD.

TABLE. Impact of Interventions on SDP Transfusions Per Quarter

	Pre-prospective Auditing (1Q07-1Q10)	After Initiation of Prospective Auditing to Numeric Triggers (2Q10-3Q12)	After Initiation of Prospective Auditing to Numeric Triggers and Consistent Special Attention to Auditing of Reason Given with\"Other\" Trigger (3Q13-1Q14)	After Initiation of Prospective Auditing to Numeric Trigger and Inconsistent Auditing of Reason Given with\"Other\" Trigger (2Q14-3Q15)	After Removal of\"Other\" Trigger (4Q15-1Q16)
Quarterly Mean SDP Units Transfused	555.9	450.7	363.7	323.8	287.5
Quartely Mean Reduction of SDP Usage Following Implementation of a change Designed to Reduce Usage		105.2	87	39.9	36.3
Mean SDP Spending per Quarter ($530 per SDP)	$294,627	$238,871	$192,761	$171,614	$152,375
Mean Additional SDP Savings per Quarter		$55,756	$46,110	$21,147	$17,333
					$142,252

TPQ and saved money. Prospective auditing of SDP orders saved the transfusion service approximately $2.8M over the course of 5 years. The cost of increasing the outdate rate by 11.6% however reduced the overall savings.

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Impact of Restrictive Transfusion Guidelines on Red Blood Cell Transfusion Incidence

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Background/Case Studies: Current consensus Red Blood Cell (RBC) transfusion guideline recommends restrictive over liberal transfusions and a single unit transfusion, in the absence of acute hemorrhage. Our study analyzes the impact of implementation of an evidence based transfusion guideline by comparing Pre-guideline implementation (Pre-GI) to Post-guideline implementation (Post-GI) data. **Study Design/Methods**: In 01/2014, at a tertiary care center, a restrictive RBC transfusion guideline was implemented and indications updated in the electronic health record (EHR) for providers to choose an indication when ordering. A retrospective-prospective observational study focused on RBC transfusion practice change was then conducted. Data from 03/2013 was compared to 03/2014 from randomly selected patients with one of eight disease categories (malignancy, cardiac, chronic illness, infection, orthopedics, resuscitated-trauma and vascular). RBC transfusion for hemoglobin(Hgb) level >8gm/dL in cardiac and post-operative patients and Hgb >7gm/dL in all other patients as well as transfusions of more than one unit, in the absence of hemorrhage were considered excess/unnecessary. Patient demographics, transfusion indication, pre-transfusion Hgb level, total number and excess transfused unit data were retrieved from EHR. **Results/Findings**: The mean age of patients was significantly higher in the Post-GI period (67-years) than Pre-GI (60-years), *P=0.00*. For all disease categories, with the exception of cardiac and resuscitated-trauma, more patients were transfused in the Post-GI, n=157(79.3%), than Pre-GI, n=133(67.2%) period. However, in the Pre-GI period more cardiac, n=41(20.7%), and resuscitated-trauma patients, n=24(12.1%), were transfused than Post-GI period, n=29(14.7%) and n=12(6.1%), respectively. The mean pre-transfusion Hgb level significantly reduced in the Post-GI period (from 8.01gm/dL to 7.8gm/dL), *P=0.002*. Although not significant, the incidence of excess transfused units also reduced in the Post-GI (66%) from Pre-GI (70%), *P=0.30*. **Conclusion**: The study highlights the impact of guideline implementation on RBC transfusion ordering practices, as shown by a significant decline in pre-transfusion Hgb threshold. There were more cardiac and resuscitated-trauma patients transfused in the Pre-GI period. Although not demonstrated in this study the next step would be to demonstrate those patients would not have qualified for RBC transfusions if current guideline was applied. In summary, this observational study shows that implementation of an evidence based restrictive guideline is an effective initial step in reducing RBC transfusion incidence. Continued education on appropriate transfusions, could further curtail excess/unnecessary RBC transfusions with potential long term benefit of improved patient outcome and reduced hospital cost.

SP189

Blood Management in Perioperative Patients

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Background/Case Studies: Preoperative blood management ensures adequate product inventory for patients for whom intraoperative transfusion is anticipated. Physically reserving blood for patients who qualify for electronic crossmatch (ECM) is creating waste in our blood supply. The ECM should be utilized in eligible patients by making blood available the day of surgery upon request ("on-demand crossmatch"). Having more control of our blood supply will lead to a more efficient practice and improved patient outcomes without compromising care. **Study Design/Methods**: The Joint Commission on Accreditation of Healthcare (TJC) requires that blood products be available prior to the start of surgery on cases with expected blood loss requiring transfusion. If crossmatched RBCs are requested on elective cases, they are currently made available 24 hours prior to surgery. Blood is reserved for up to 72 hours postsurgery. For a patient to qualify for ECM, there has to be at least 2 valid blood bank specimens on file (one being an in-dated sample). The patient must not have a clinically significant antibody and the antibody screen on the current sample must be negative. If a second sample cannot be obtained for ABO confirmation, the patient cannot qualify for ECM. Patients with clinically significant antibodies will be restricted to a full crossmatch method with anti-globulin phase. Data was retrospectively collected for one month (August 2015) with focus on requests for blood products from scheduled surgeries most associated with transfusion including cardiac, orthopedic, vascular, neurosurgical, OB/GYN, transplant, urology, and thoracic surgery. **Results/Findings**: Physicians requested a total of 562 RBCs for 178 patients. Out of 178 patients, 148 qualified for ECM (84%), 22 patients required immediate-spin (IS) (saline) crossmatch (12%), and 7 patients required full crossmatch with anti-globulin phase (4%). Out of 562 reserved units, 466 were ECM (83%), 82 were IS crossmatch (14.5%), and 14 were full crossmatch (2.5%). The operating room requested 466 total units be available in the room prior to the case. ECM units accounted for 96% of 466 total units, with only 2.8% IS, and 1.2% full crossmatch. Only 88 units were transfused during surgery with the remaining 344 units returned to the blood bank. The ratio of transfused units vs. ordered was high, with 1:5 transfused to requested ratio. **Conclusion**: A significant number of requests were for patients that qualified for ECM. A low number of patients were transfused in the operating room, leaving a high number of reserved units that were not transfused. The clinical team should be aware that if a patient qualifies for ECM, blood can be made readily available the day of

surgery upon request in a timely manner without compromising patient care. Educational efforts between the Transfusion Service and Anesthesia will be coordinated to address this matter.

SP190

Optimizing Iron Chelation Therapy with Deferasirox in Patients with Non-Transfusion-Dependent Thalassemia: 1-Year Results from the Phase 4, Open-Label THETIS Study

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Background/Case Studies: Efficacy and safety of iron chelation with deferasirox (DFX; Exjade) 5 and 10 mg/kg/day (escalated to max 20 mg/kg/day) in patients (pts) with non-transfusion-dependent thalassemia was established in the THALASSA study (Taher et al. *Blood*. 2012;120:970-997). THETIS was designed to investigate a broader pt population (including non-transfusion-dependent congenital anemias) and to evaluate early escalation with higher DFX doses (max 30 mg/kg/day) according to baseline liver iron concentration (BL LIC). **Study Design/Methods**: Pts aged $\geq$10 years with iron overload (LIC $\geq$5 mg Fe/g dry weight [dw] and serum ferritin [SF] $\geq$300 ng/mL) were enrolled. Exclusion criteria included blood transfusions within 6 months of study enrollment or anticipated regular transfusions (unplanned transfusions allowed); HbS/β thalassemia; active hepatitis B/C; cirrhosis; or history of clinically relevant ocular and/or auditory toxicity. All pts started DFX at 10 mg/kg/day. At week (wk) 4, DFX was increased according to BL LIC. At wk 24, DFX was adjusted further: LIC $>$15: +5 to 10 mg/kg/day, max 30 mg/kg/day; LIC $>$7 to $\leq$15: +5 mg/kg/day, max 20 mg/kg/day; LIC $\geq$3 to $\leq$7: maintain dose. If LIC $<$3 or SF $<$300, therapy was held and restarted at the previously effective dose when LIC $\geq$5 and SF $\geq$300 (max 10 mg/kg/day). Primary efficacy endpoint was absolute change in LIC from BL to wk 52. **Results/Findings**: 134 pts were enrolled: 69 β thalassemia intermedia, 40 α thalassemia (HbH), 24 HbE/β thalassemia, and 1 congenital dyserythropoietic anemia. Mean daily DFX dose$\pm$SD over 1 year (considering dose adjustments) was 14.70 $\pm$ 5.48 mg/kg/day. Mean LIC$\pm$SD decreased significantly from 15.13 $\pm$ 10.72 mg Fe/g dw at BL to 8.46 $\pm$ 6.25 mg Fe/g dw at wk 52 (absolute change $-$6.68 $\pm$ 7.02 mg Fe/g dw [95% CI, $-$7.91, $-$5.45]; P<0.0001). The last assessment showed an absolute decrease in LIC of $\geq$3 mg Fe/g dw in 86 (64.2%) pts and a $\geq$30% relative reduction in LIC in 81 (60.4%) pts. Reduction in LIC was greater in pts with higher BL LIC; these pts received a higher than average dose. Median SF decreased from 1001 ng/mL at BL to 669 ng/mL at wk 52; 112 (83.6%) pts completed 1 year. Adverse events regardless of causality were reported in 97 (72.4%) pts and were unrelated to the average dose. **Conclusion**: DFX 10 mg/kg/day (escalated to max 30 mg/kg/day) resulted in a significant and clinically relevant reduction in iron overload and a similar safety profile as THALASSA. Early dose escalation at wk 4 and further adjustment of DFX at wk 24 allowed for optimization of chelation in heavily iron-overloaded pts with non-transfusion-dependent anemias.

SP191

Elimination of Predeposit Autologous Donation for Joint Replacement Surgery: Two Case Studies

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Background/Case Studies: The practice of predeposit autologous blood (PAD) transfusion for elective joint replacements surgery has declined over the last ten years. Two factors have significantly impacted PAD use: the potential to correct presurgical anemia, and allowing lower hemoglobin values as postoperative transfusion triggers. Additionally, when PAD is available there is a bias to transfuse the product at higher hemoglobin values. The cost associated with PAD was a significant factor in determining the continuation of the PAD program. Overall it was considered that the practice of PAD added little or nothing to patient safety and a plan was developed to eliminate PAD transfusions in elective orthopedic joint replacement surgery. **Study Design/Methods**: An educational and engagement program was initiated in early 2010. The educational aspect was presenting orthopedic surgeons with data regarding the questionable clinical value of PAD and the need to transfuse postoperative patients not based on hemoglobin alone. The engagement aspect was to contact the prescribing physician when a unit of autologous (or allogeneic) red cells was prescribed and the pretransfusion hemoglobin value was 9 g/dL or greater. Data were collected regarding the volume of PAD red cells during the period before and after initiation of the education and engagement program. Associated acquisition costs were tabulated as well as allogeneic transfusion rates to ensure that any decrease in autologous red cells was not associated with an increase in allogeneic transfusion. **Results/Findings**: The results are shown in Table 1. As is evident, a dramatic reduction in PAD transfusions was achieved most noticeably in the first few years. There was no evidence of an increase in allogeneic transfusions Substantial cost savings were achieved. By 2014, the PAD program was essentially eliminated with a gross savings of $326,700 annually. **Conclusion**: Through concerted effort, a deliberate reduction in PAD can result in a significant reduction in cost without any apparent increase in allogeneic transfusion.

SP192

The Effects of a Data-driven Maximum Surgical Blood-ordering Schedule on Preoperative Blood-ordering Practices

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Background/Case Studies: The maximum surgical blood-ordering schedule (MSBOS) is a document that provides guidelines for the extent of preoperative pretransfusion testing by procedure. Historically, this document was created by developing a consensus between the blood bank and the various surgical specialties. Recently, a mechanism whereby the actual number of RBCs transfused during each case was captured and utilized to create a data driven MSBOS (dMSBOS). The aim of this study was to compare blood ordering and utilization figures before and after the introduction of the dMSBOS using the crossmatch:transfusion (C:T) ratio, a measure of how often crossmatched RBCs are actually transfused. **Study Design/Methods**: The dMSBOS was created by analyzing the number of RBCs that were transfused during a variety of surgical procedures over a 12 month period. Any surgical procedure where $\leq$5% of the patients received at least 1 RBC unit was listed in the new dMSBOS as not requiring any pretransfusion testing. The extent of pre-transfusion testing for procedures where between $>$5-

TABLE. Reduction of PAD Transfusions: Two Case Studies

	Hospital A				Hospital B			
Year	Autologous Units Received	Acquisition Costs	% Transfusion Reduction from baseline (2009)	Total Allogeneic Transfusions	Autologous Units Received	Acquisition Costs	% Transfusion Reduction from baseline (2009)	Total Allogeneic Transfusions
2009	989	$267,030	---	14,573	221	$59,670	---	8,493
2010	692	$186,840	30.03%	14,445	215	$58,050	27.15%	7,774
2011	221	$59,670	77.65%	15,586	171	$46,170	22.62%	6,992
2012	92	$24,840	90.69%	14,788	69	$18,630	68.78%	6,319
2013	85	$22,950	91.41%	14,242	4	$1,080	98.19%	6,019
2014	54	$14,580	94.54%	13,696	3	$810	98.64%	5,744
2015	5	$1,350	99.49%	13,402	0	$0	100%	4,719

TABLE.

	Arterial Oxygen Pressure (n=32)				Capillary Oxygen Saturation (n=78)			
Time (Hours)	Hgb (g/dL)	% Change	PaO2 (mmHg)	% Change	Hgb (g/dL)	% Change	SpO2 (%)	% Change
−12	7 ± 0.9	-	108 ± 47	-	7.5 ± 1.1	-	96.2 ± 11.4	-
0	7.4 ± 0.9	−3.6%	106 ± 32	6.2%	6.8 ± 0.6	−9%	96.8 ± 2.6	−2%
+12	9.1 ± 1.7*	15%	94 ± 39	−7.3%	8 ± 1.1*	6.6%	96.4 ± 2.6	−7%
+24	9.1 ± 1.4*	15%	86 ± 19*	−19.4%	8.1 ± 1*	8.8%	96.3 ± 2.5*	−8%

Data is presented in Mean±SD.
Time "0" is the closest time to RBC Transfusion.
*P value <0.05 (t-test) in comparison to time of RBC transfusion (i.e, time "0").

≤25% of the patients were transfused was listed as type and screen only, and the procedures where >25% of the patients were transfused were listed as crossmatch for the median number of units transfused during that procedure. The C:T ratios at 8 hospitals in a regional healthcare system and that for 13 different surgical subspecialties at these hospitals were compared between the 12 month period before the dMSBOS was introduced, and then again for 7 months after its introduction. **Results/Findings**: In the dMSBOS, a type and screen was recommended for 11% of the 3428 listed surgical procedures and crossmatched RBCs were recommended in only 4%. The overall C:T ratio for all 8 hospitals combined did not change significantly after the introduction of the dMSBOS (from 3.34 to 3.32; p=0.53). There were also no significant reductions in the overall C:T ratios any of the individual hospitals after dMSBOS implementation (mean reduction 0.18; 95% CI [0.01-0.36]). Of the 13 surgical specialties analyzed, 9 had a reduction in C:T ratio after dMSBOS implementation although no decrease was statistically significant (mean reduction 0.46; 95% CI [0.01-0.91]). However, following the introduction of dMSBOS, the number of type & screens and type & crossmatches ordered preoperatively decreased by 5.2% (p = 0.11) and 5.3% (p = 0.11), respectively. **Conclusion**: These data suggest that a dMSBOS does not impact the C:T ratio. Potential reasons may be the surgical team's lack of awareness of its implementation or failing to heed the dMSBOS' recommendations. Campaigns to increase the profile of the dMSBOS and more rigorous enforcement of its recommendations by the blood bank staff are being planned.

SP193

Effect of Red Blood Cell Transfusion on the Partial Pressure of Oxygen in Arterial Blood and Peripheral Capillary Oxygen Saturation

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Background/Case Studies: Partial Pressure of Oxygen (PaO_2) is a measurement of O_2 concentration in arterial blood. Peripheral Capillary Oxygen Saturation (SpO_2) is an indirect measure of oxygen bound to hemoglobin (Hgb). The variable affinity of Hgb for O_2 can impact its release to the patient's tissues. Red blood cell (RBC) transfusion is used to treat anemia with the intent to improve O_2 delivery. We evaluated the effect of RBC transfusion on PaO_2 and SpO_2. **Study Design/Methods**: Data on 110 consecutive RBC orders were reviewed retrospectively for patients monitored by arterial PaO_2 (n=32) or cutaneous SpO_2 (n=78). RBC transfusions meeting our medical center's guidelines for correction of Hgb levels were included. Patients with active bleeding or undergoing procedures were excluded. Changes in Hgb, PaO_2, and SpO_2 values from 12 hours before transfusion were analyzed, both during and up to 24 hours after transfusion. Only one RBC transfusion event per patient was included. Patient's condition following transfusion was evaluated from the medical record for significant changes. **Results/Findings**: Improvement of Hgb levels was the primary indication for transfusion. The major primary diagnoses were cardiac disorders (43%), malignancy (18%), respiratory failure (12%), and other (27%). The average PaO_2, SpO_2, and Hgb concentrations are shown (Table). While significant improvement of Hgb levels was seen immediately after RBC transfusion and throughout the 24 hour observation period, both PaO_2 and SpO_2 values showed substantial decreases that continued throughout the 24 hour period. **Conclusion**: During storage RBCs undergo significant alterations, including depletion of 2,3-diphosphoglecerate (DPG), adenosine triphosphate (ATP), and loss of glutathione (GSH). DPG depletion increases RBC affinity for O_2 and decreases its delivery capacity. Despite the markedly improved Hgb levels after RBC transfusion, the changes observed here in PaO_2 and SpO_2 are the opposite of those desired, raising doubt as to whether RBC transfusion provides acutely improved O_2 delivery.

SP194

Fresh-frozen Plasma Usage In 6 Secondary Care Hospitals

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Background/Case Studies: The indications for fresh frozen plasma (FFP) are limited to replacement of coagulation factors in the management of major bleeding, plasmapheresis and reversal of vitamin K antagonist therapy when prothrombin complex concentrate (PCC) is not available. Plasma products do carry some risk in the form of transfusion reactions (TRALI, TACO and allergy) and infections. The general recommended dose of plasma is 10-15mL/kg (i.e., approximately three to five units in most adults). Clinical practice often deviates from these recommended guidelines witch potentially carries a risk to the patient without a clinical benefit. There are no established patient blood management (PBM) programs in Norway and this study serves to give additional information about current practice to be used as a template in further PBM work. **Study Design/Methods**: Medical records for all FFP transfusions in 6 secondary care hospitals were reviewed between 1.1.15-31.6.15. Records were scrutinized for indications, number of units given, ordering department, age, relevant laboratory data like INR pre- and post-transfusion and use of adjuvant therapy in the form of vitamin K or PCC. **Results/Findings**: In total 212 patients were transfused. Two patients who received 77 and 1 unit(s) of FFP respectively due to plasma exchange were not analyzed. In all, 566 units FFP were transfused to 210 patients. The FFP dose ranged from 1 to 17 units (mean 2,7units). The most common amount transfused was 2 units (42,9%). Only 1 unit was given in 26,7% of the cases. The age of the patients was: 14 to 98 years (mean 72 years). Transfusions were given to surgical patients in 70,5% and to medical patients in 29,5%. Pre- and post-transfusion INR value was found in 59,5% and 44,8% of the patients respectively. The indications for plasma transfusions were massive transfusion protocol due to traumatic bleeding: 13,3%. Bleeding with the use of vitamin K - antagonist: 30,5%. Sepsis: 3,8%. Dialysis: 1%.Other uncategorized bleeding (e.g. gastrointestinal bleeding and postoperative bleeding): 51,4%. Vitamin K was given in 40,6% of bleedings associated with the use of vitamin K- antagonists. **Conclusion**: Aside from massive transfusion most FFP units were given on questionable indications. It seems as if the dosage of FFP frequently was not properly considered, but mainly dosed in one or two units. The usage of vitamin K was much smaller than wanted in patients with vitamin K-associated bleedings. Further studies and work is needed in the format of PBM to optimize the use of FFP.

Pediatric Transfusion Medicine

SP195

Thromboelastography Utilization in Pediatric Patients with Liver Disease Undergoing Interventional Procedures

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Background/Case Studies: Prior to an interventional procedure, routine coagulation testing (RCT) which includes PT/INR and PTT is performed to assess the risk of bleeding. Current interventional radiology guidelines recommend that an elevated INR should be corrected to less than 1.5 prior to procedures. However, an INR captures only one aspect of hemostasis. There is growing evidence that RCTs may not be adequate in assessing a

patient's true risk of bleeding. Thromboelastography (TEG) is a functional assay that assesses the interaction of clotting mechanisms by measuring clot formation, stabilization and dissolution. In situations where RCTs are elevated, a normal TEG can provide reassurance that a required interventional procedure is safe to perform without transfusions. **Study Design/Methods**: Recent pediatric interventional radiology patients were cross referenced with TEG orders. Each patient was reviewed and two were identified to have liver disease and abnormal RCTs. **Results/Findings**: Two patients with abnormal RCTs had TEG performed which showed values consistent with normal hemostasis. Patient # 1 was admitted with drug reaction with eosinophilia and systemic syndrome (DRESS). During her hospitalization, she developed acute hepatitis and a liver biopsy was needed. On the day prior to the biopsy, RCTs showed an elevated INR 1.7, PT 19.4 sec, and aPTT 41 sec. A TEG was normal (R 6.2 min, K 1.2 min, Alpha 71.8 degrees, and MA 63.1 mm) and the biopsy was performed without issues. Patient #2 has a history of systemic lupus erythematosus and was admitted with direct hyperbilirubinemia. Initial labs showed INR 2.1, PT 23.8 sec and aPTT 60.5 sec. TEG showed R 4.7 min, K 2.3 min, Alpha 59.9 degrees, and MA 49 mm. The unremarkable findings of this TEG allowed interventional radiology to perform the procedure without transfusing fresh frozen plasma (FFP) to correct the INR. There were no bleeding complications in either patient. **Conclusion**: Historically, patients with abnormal RCTs are considered high risk for bleeding and receive FFP prior to the procedure. Patients with acute liver disease are at a high risk for coagulation abnormalities due to multiple causes, one of which is decreased synthesis of clotting and inhibitor proteins. Abnormal R times would suggest a delay in fibrin formation, which can be associated with decreased proteins and a predisposition to bleeding. This was not observed in either of these patients. In this case series, we have shown that despite RCT abnormalities, TEG provided reassurance on the patient's hemostatic balance allowing necessary procedures to be performed without blood product transfusion. TEG has the potential to better define a patient's risk of bleeding and to reduce unnecessary transfusions. In the future, more studies are needed to correlate TEG with a patient's risk of bleeding.

SP196

Blood Utilization Review: A Vital Initial Step in a Pediatric Blood Management Program

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Background/Case Studies: Patient blood management (PBM) is a collaborative approach to optimize and often alleviate the need for a transfusion. In an era where red blood cell (RBC) transfusion is the most common inpatient procedure performed and adverse effects of transfusion are being increasingly defined, providing and adhering to evidence-based transfusion guidelines is a priority. The data to define transfusion triggers in pediatric patients is population specific and often underutilized. Multidisciplinary blood utilization review (BUR) is one aspect of PBM that can provide an avenue for education and evaluation while optimizing transfusions in academic pediatrics. We report a single-center experience employing multidisciplinary BUR through the Transfusion Committee (TC). **Study Design/Methods**: With the aid of the institution's Quality Improvement Services (QIS), a systematic component-based review is performed retrospectively. An initial monthly "components transfused" report is generated. The week with highest transfusion volume is selected for analysis. Component specific algorithms developed and approved by the TC initially define "acceptable" versus "unacceptable" transfusions. Episodes that "fall out" of the algorithm are sent to QIS for second review. The analyst utilizes clinical information within the electronic medical record to determine the transfusions therapeutic utility. If the transfusion "fails" second tier review, a letter is sent to the ordering physician requesting justification. Each component is audited on a monthly basis (plasma, apheresis platelets, RBCs, and cryoprecipitate) to insure that all are reviewed at least three times/year. These statistics are presented quarterly to the TC for evaluation and approval. **Results/Findings**: A 5 year examination of BUR was performed. Per year a median 10.2% of transfusions were reviewed (range 8.8% - 10.9%). Each year the median % meeting primary review was 80.5% (range 79 - 82%). The component consistently "failing" initial review was apheresis platelets. Yearly 100% of transfusions met secondary review. Overall the institution had increasing "patient days" (97,867 in 2010 to 116,879 in 2015) with a 1% decrease (12.4% to 11.4%) in transfusions per patient days (12,190 in 2010 to 13,414 in 2015). **Conclusion**: The decreasing trend in transfusions/patient days suggests BUR success. We find the TC provides the most practical and transparent multidisciplinary venue to review blood use. QIS involvement provides legitimacy to the process and has identified key departmental stakeholders and champions. With a solid foundation in BUR, our next PBM steps are external benchmarking with comparable pediatric hospitals as well as incorporating real-time electronic decision support for transfusions.

SP197

Splitting Blood Products for Pediatric Patients to Reduce Intraoperative Red Blood Cell Wastage

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Background/Case Studies: This study aims to determine if ordering packed red blood cells for patients undergoing surgery in the form of split units decreases blood product wastage in the operating room. Forecasting data shows that blood demand may soon outpace supply and new strategies are required to ensure an adequate blood supply for our patients. Along with supply shortages cost remains an important concern. Currently the cost for collection and processing a unit of blood is $419 Canadian Dollars. The cost of splitting a unit of blood is $21 and therefore significant cost savings are possible if half the unit is re-circulated into the blood supply. Only one other study has reported on splitting units in pediatric surgery patients and demonstrated a decrease in donor exposure but not red cell wastage. **Study Design/Methods**: A four month prospective observational study was carried out to determine if ordering red cells as two split units would decrease blood product wastage in the operating room. For two months anesthesiologists who transfused patients intra-operatively filled out data on volume transfused and wasted, patient hemoglobin, and qualitative data on reasons for transfusion. After two months education was undertaken with operating room nursing and anesthesia on ordering split units. Anesthesiologists were allowed to order split units for any patient they deemed suitable, regardless of size or type of surgery. Data was again collected for a further two months. Cardiac and liver transplant patients were excluded. **Results/Findings**: Data was collected on 32 patients before and 29 patients after educational intervention. The primary outcome was volume of blood wasted per patient. Secondary outcomes included volume transfused, donor exposure, and cost savings per patient. Median wastage prior to the intervention was 67 mL per patient. Educational interventions and the use of split units did not result in a statistically significant decrease in red cell wastage (Table 1). Changes in transfusion volume and donor exposure were also not statistically significant. However this change in ordering practice did result in substantial cost savings of $41.53 dollars per patient. This was due to split units being re-circulated by blood bank to other patients within the hospital and occurred with all the unused split units. **Conclusion**: Ordering split units does not significantly decrease red blood cell wastage or donor exposure in non-cardiac pediatric patients. However it is a cost effective strategy of blood product management in the operating room.

TABLE. Transfusion Statistics Before and After Initiating Split Units

	Before Split Unit Intervention (n = 32)	After Split Unit Intervention (n = 29)	P-value
RBC volume transfused (mL)*	200.5 [75 - 307.5]	200 [110 - 269]	0.902
Total RBC volume wasted (mL)	67 [0 - 141.5]	0 [0 - 53]	0.175
Donor exposure (units)	1 [1 - 1.5]	1 [1 - 1]	0.394

*Data are median [IQR].

SP198

Outcome of ABO-incompatible Pediatric Liver Transplant

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Background/Case Studies: Over the past few decades the number of major ABO incompatible (ABOi) liver transplants are on the rise due to increasing evidence suggesting ABOi grafts are an acceptable alternative and can be as successful as ABO compatible ones. The best protocol for

TABLE.

Age	Gender	Reason for Transplantation	Recipient/Donor ABO Group	IsoT Prior to Transplant	Latest IsoT
5 mo	male	cryptogenic cirrhosis	O+/A+	not available	anti A <1
7 mo	male	carbamoyl phosphate synthetase 1 deficiency	O-/B+	anti B 8	anti B <1
7 mo	female	cryptogenic cirrhosis	O+/A+	anti A 64	anti A 1
8 mo	male	biliary atresia	O+/A+	anti A 8	anti A <1
8 mo	female	biliary atresia	O+/A+	anti A 512	anti A 1
9 mo	female	biliary atresia	O+/B-	anti B 16	anti B <1
11 mo	male	biliary atresia	O+/A+	anti A 2	anti A <1
19 mo	female	biliary atresia	A-/AB-	anti B 2	anti B <1
9 yo	male	cryptogenic acute liver failure	A+/B+	anti B 32	anti B 2

major ABOi liver transplants in pediatric patients is still being debated. The objective of this study is to evaluate pediatric cadaveric major ABOi liver transplant cases with variable age range at time of transplant for antibody mediated rejection (AMR) complications and percent survival undergoing the same ABOi protocol. **Study Design/Methods**: This retrospective cohort study from a single center hospital between January, 2010 and January, 2016 included all major ABOi transplants cases that had a follow up period 6 months or greater. All relevant antibody titers, liver function tests, lab reports, and documented encounters were evaluated for patient status and AMR. AMR as evidenced by elevated relevant antibody titers in conjunction with worsening liver function and confirmed liver biopsy. All patients with an isohemagglutinin titer (IsoT) check prior to transplant with relevant titers $\leq$16 were treated with standard steroids and tacrolimus therapy. Those $\geq$32 underwent plasmapheresis either pre- or intra-operatively and continued for 6 procedures post-transplant daily starting on postoperative day 1. **Results/Findings**: Ten major ABOi pediatric cadaveric liver transplant cases with age range between 5 months to 9 years old at time of transplant were found in this study but one was excluded as its adverse outcomes were not ABOi related. All 9 patients survived. Most had improved lab values supporting normal graft function. Only one had a liver biopsy which showed acute cholangitis and endothelial injury secondary to AMR. **Conclusion**: Major ABOi cadaveric liver transplants can have a high rate of patient survival in pediatric patients when using an ABOi protocol that involves using plasmapheresis when IsoT is $\geq$32 prior to transplantation.

SP199

Product Quality Control for Reconstituted Blood for Neonatal Exchange Transfusion

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Background/Case Studies: Neonatal exchange transfusion (NET) is a manual whole blood exchange procedure indicated for severe hyperbilirubinemia. The replacement fluid for NET may be a mixture of packed red blood cells (PRBC) and fresh frozen plasma (FFP) to create a blood product often referred to as Reconstituted Blood. Reconstituted Blood preparation methods (e.g. identifying low storage age PRBC, washing, and irradiation) and quality control methods (e.g. product HCT and Potassium testing) impacts preparation time, acceptance of the product by clinicians, and NET start time. To evaluate quality control methods, we performed a pilot analysis of hematology and chemistry testing platforms on Reconstituted Blood. **Study Design/Methods**: Reconstituted blood was prepared from 2 storage day old PRBC. After reconstitution, samples were taken following gentle mixing by 180 degree rocking of the blood bag 20 times, followed by 5 ml waste and test samples withdrawal. Samples were tested with: Sysmex XE-5000 Automated Hematology System, Sysmex Corp; EPOC Reader and Host Blood Analysis System, Alere North America; Vitros 4600 and 5600 Chemistry System, Ortho Clinical Diagnostics; GEM Premier 3000 Blood Gas Analyzer and IL 682 Co-Oximeter System, Instrumentation Laboratory. Twenty-four samples were tested on each instrument at the following intervals: Pre-reconstitution, 1 hour, 2 hour, 3 hour, 4 hour, and 18-24 hours. Data was analyzed in Microsoft Excel 2010 and Graphpad Prism Version 6 for Windows. **Results/Findings**: Pooled time point analysis demonstrates differences in sodium, potassium, and glucose measurements with different analyzers (ANOVA, $p<0.05$). No difference was found in pH and hematocrit. (ANOVA, $p>.05$) Data presented in Table 1. **Conclusion**: Rapid preparation and quality control for Reconstituted Blood is required for NET to minimize risk for kernicterus, often classified as a "sentinel" or "never" event for neonatal care hospital quality metrics. This pilot data suggests there maybe analyzer dependent differences in clinically relevant electrolyte measurements such as potassium. Current and future work is focused on detailed time-point analysis and effect of preparation methodology on hematological and electrolyte parameters of Reconstituted Blood.

SP200

Suspected Mild Hemolytic Disease of the Newborn Associated with Anti-Do[a]

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Background/Case Studies: Anti-Do[a] is rarely found as a single specificity and has been implicated in hemolytic transfusion reactions. However, the presence of maternal anti-Do[a] is often considered clinically insignificant for hemolytic disease of the fetus and newborn (HDFN). We report a case of maternal anti-Do[a] that was suspicious for clinical manifestations of mild HDFN. Case: A 3-day old full-term, B Positive, female infant was admitted with hyperbilirubinemia (total bilirubin (TBili) 18.6 mg/dL; normal 0.1-11.0), low hemoglobin (Hgb 13.8 g/dL; normal 15.0-24.0), and positive (1+) DAT. Patient's mother (gravida 2, para 2), also B Positive, had a negative antibody screen in her first trimester and no complications during pregnancy. There were no complications at delivery and no development of hematoma or

TABLE.

	HCT (%)	pH	K+ (meq/L)	Na+ (meq/L)	Glucose (mg/dL)
EPOC	43.1 $\pm$ 2.4	7.0 $\pm$ 0.1	6.1 $\pm$ 0.4	127.3 $\pm$ 0.5	390.4 $\pm$ 7
GEM 3000	44.9 $\pm$ 0.9	6.9 $\pm$ 0.1	8.3 $\pm$ 0.8	142.7 $\pm$ 1	362 $\pm$ 5
Vitros			7.7 $\pm$ 0.4	152.7 $\pm$ 0.7	408.9 $\pm$ 8
n	42	42	64	64	57
p	>.05	>.05	<.05	<.05	<.05

caput in the infant. Family history included a full term sibling who required phototherapy for hyperbilirubinemia. Antibody detection studies (PEG IAT) of the baby's acid eluate and plasma, as well as the mother's plasma, showed an unidentified antibody reacting weak + to 1+ at IAT with the same reagent cells. Infant's hyperbilirubinemia was managed with triple phototherapy including BiliBlanket and no transfusion was required. She was discharged 24 hours later with TBili 12.4 mg/dL and Hgb 13.0 g/dL. Despite use of BiliBlanket at home, the baby's TBili rebounded to 15.1 mg/dL five days post discharge. Peripheral smear showed mild spherocytes and moderate burr cells, acanthocytes, and tear drop cells. Her Hgb was relatively stable until age 13 days when it declined to 11.1 g/dL. One month later, TBili was still abnormal but improved to 10-11 mg/dL and her Hgb stabilized at 9.4 g/dL. It was felt breastfeeding and physiologic anemia of the newborn partially explained the continued abnormal lab values. Because of the infant's hyperbilirubinemia and anemia shortly after birth, additional samples from the parents were sent for antibody identification and molecular testing. **Study Design/Methods**: Serologic testing included routine saline and PEG IAT by tube methods. Acid elution performed using Immucor Gamma ELU-KIT II, and molecular testing with DNA isolated from WBCs utilizing TaqMan chemistry with real time PCR on a Roche Light Cycler. **Results/Findings**: Antibody identification performed on mother's serum revealed Anti-Do^a with titer of 4 using Do(a+b+) cells. The mother's serum tested against the father's ABO compatible red cells was reactive. Red Cell Genotyping showed the mother's predicted phenotype as Do(a-b+), father as Do(a+b+) and infant as Do(a+b+). **Conclusion**: Maternal Anti-Do^a is rare, and previously published cases report only a positive DAT in affected infants, without clinical indications of HDFN. To our knowledge, this is the first reported case that demonstrates both clinical and serological evidence of HDFN due to anti-Do^a.

SP201

Fetal Neonatal Alloimmune Thrombocytopenia: A Case of Multiple Maternal Alloantibodies

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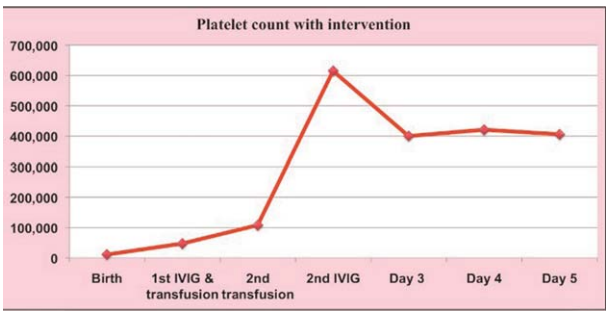
Background/Case Studies: Fetal neonatal alloimmune thrombocytopenia (FNAIT) is caused by maternal alloantibodies directed toward paternally-derived antigens on fetal platelets. The most commonly implicated alloantigen is human platelet antigen (HPA)−1a, accounting for 80% of confirmed cases. **Study Design/Methods**: We report a rare case of FNAIT caused by maternal platelet specific antibodies to HPA-1a, HPA-3b and HPA-5b. **Results/Findings**: Initial head US showed Grade IV intraventricular hemorrhage. The neonate's platelet count increased from 11,000/mL to 47,000/mL after administration of the first platelet transfusion and IVIG. An additional 15mL/kg platelet transfusion was given, which increased platelets to 107,000/mL and rose further to 615,000/mL after second dose of IVIG. Subsequent platelet count remained stable in the 400,000/mL range. No new bleeding detected on follow-up head ultrasounds. Workup was negative for any factor VIII, IX, XIII deficiency or von Willebrand disease. Paternal platelet antigen typing was positive for HPA-1a, HPA-3b and HPA-5b. Maternal antigen typing was negative for all three antigens, and she had alloantibodies to these antigens. **Conclusion**: This is a rare case of a mother missing 3 different platelet antigens, and with antibodies to all 3 causing severe thrombocytopenia and intraventicular hemorrhage in the neonate. While current studies focus on identifying only HPA-1a antibodies for FNAIT screening, this case adds to the growing literature of HPA polymorphisms that may be seen. Further studies are needed to investigate the role and risk stratification involved with the presence of multiple maternal alloantibodies.



SP202

Ceftriaxone-induced Drug Reaction Mimicking an Acute Splenic Sequestration Crisis in a Patient with Hemoglobin SC Disease

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Background/Case Studies: Ceftriaxone-induced immune hemolytic anemia (CIIHA) is a rare, but severe form of drug reaction, which appears to disproportionately affect those with sickle cell disease and other hemoglobinopathies. **Study Design/Methods**: We report a case of a 9 year-old African-American girl with hemoglobin SC disease, who became unresponsive and tachycardic within 15 minutes after receiving a single intravenous dose of ceftriaxione in the outpatient hematology clinic for fever. **Results/Findings**: The patient's hemoglobin dropped precipitously from 9.3 mg/dL to 2.3 mg/dl one hour later (resuscitation sample). Red cell clumps, but notably no visible hemolysis, were observed in the post reaction sample. The urine was tinged by red cells, without apparent hemoglobinuria. She became dyspneic with visible pallor, reduced oxygen saturation, hypotension, and progressed to cardiac arrest despite intense treatment efforts. The initial coagulation assays were normal. Serum haptoglobin and lactate dehydrogenase were not ordered. After resuscitation and return of circulation, she developed multiorgan failure and disseminated intravascular coagulation requiring massive transfusion. She died the following day from evolving cerebral edema and was declared brain dead. Serologic testing disclosed a positive direct antiglobulin test with polyspecific antibody, anti-C3, and anti-C3d, but negative with anti-IgG. Acid elution of her red blood cells showed ceftriaxone-dependent red cell antibodies. Her serum was also positive for drug-dependent red cell antibodies. Review of her prior admission documented treatment with ceftriaxone. Autopsy disclosed marked splenic enlargement (3x normal), acute congestion of the sinusoids, and sickled red blood cells. Red blood cell sickling was limited to the spleen and liver, and neither sickling, thrombi nor agglutination was observed in vasculature of other organs. Autopsy findings included sequelae of cardiac arrest and multiorgan hypoxic-ischemic injury. The autopsy findings are consistent with the abrupt drop in hemoglobin being at least partly due to rapid sequestration of antibody-coated red blood cells within the reticuloendothelial system as opposed to intravascular hemolysis. This conclusion correlates with the dramatic red cell agglutination without visible hemolysis in the post resuscitation sample. It is indeterminate whether sickled red blood cells were selectively sequestered by the liver and spleen, or whether sickling occurred after the cells were sequestered due to low oxygen tension. **Conclusion**: To our knowledge, this is the first reported case with clinical-pathologic findings suggesting that CIIHA triggered an event similar to acute splenic sequestration crisis.

Platelet and Leukocyte Biology

SP203

Gene Expression Profiling Reveals Key Mitochondrial Gene Changes in Stored Platelets

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Background/Case Studies: As of June 2015 the FDA has approved an alternative procedure under 21 CFR 640.120 that allows for storage of apheresis platelets at refrigerator temperature (4°C) without agitation for up to 3 days for use in the resuscitation of actively bleeding patients. We previously observed increased levels of mitochondrial-associated reactive oxygen species (ROS) during 22°C (RT) storage compared to 4°C-stored platelets. Understanding underlying mechanisms responsible for enhanced hemostatic function at 4°C will be critical for such improvements in platelet transfusion. We hypothesized that 4°C platelets display better mitochondrial respiratory function compared to standard 5-day RT platelets and that mitochondrial gene expression differences between RT and 4°C -stored platelets will correlate with mitochondrial function. **Study Design/Methods**: Apheresis platelets in plasma (AP) or PAS collected from healthy donors were stored at RT or 4°C. Testing was performed on Days 1, 5, 10 and 15. Mitochondrial respiration, maximal oxygen utilization, and individual mitochondrial complex-dependent respiration were assessed with high-resolution respirometry. Total RNA was extracted from AP and PAS at Days 1 (BL), 5, 10, and 15 from RT and 4°C-stored platelets. RNA quality was examined

using gel electrophoresis and platelet mitochondrial gene expression analysis was evaluated. **Results/Findings**: Mitochondrial respiration was lower in platelets stored at 4°C (AP and PAS) compared to RT (Day 5= −57%±0.3; $P < 0.05$), demonstrating that refrigeration slows metabolism. Additionally, maximal mitochondrial oxygen utilization (electron transport system capacity) was better preserved in platelets stored at 4°C. Mitochondrial gene expression studies revealed distinct differences in expression profiles for 4°C versus RT-stored platelets when normalized to BL measures. Storage at 4°C resulted in significantly greater preservation of gene products starting at Day 5 ($P<0.05$). In contrast, RT samples resulted in a marked decrease or loss of gene expression when compared to BL levels ($P<0.05$). The observed mitochondrial preservation at 4°C was enhanced with storage in PAS out to Day 15. **Conclusion**: Platelet mitochondrial respiratory function decreased in RT-stored platelets, but the impairment was attenuated by 4°C storage. Gene expression profiling of mitochondrial-related genes revealed that distinct differences exist in key mitochondrial genes between the storage conditions. This work illustrates that 4°C storage of platelets preserved and enhanced critical mitochondrial genes compared to RT that was further enhanced with PAS. This finding combined with improved mitochondrial respiratory measures and reduced ROS demonstrates a significant improvement in current efforts to mitigate platelet dysfunction.

SP204

Dysregulation of Platelet Function and Morphology in the Setting of α-synuclein Deficiency

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Background/Case Studies: Alpha-synuclein is an important mediator in the pathology of synucleinopathies such as Parkinson's disease. Of note, α-synuclein expression has also been detected in the bone marrow, and erythrocytes and platelets in peripheral blood. However, its physiological role in the hematopoietic system is not known. Recent reports indicate that α-synuclein deficiency profoundly affects the maturation of lymphocytes, immunoglobulin production and class switching suggesting that α-synuclein is paramount to a mature immune response. Furthermore, α-synuclein deficiency is associated with mild anemia and a slightly smaller platelet size. This study aimed to begin analyzing the potential ultrastructural changes of α-synuclein deficiency and physiological role in platelets using α-synuclein knockout (KO) mice. **Study Design/Methods**: KO mice and age and sex-matched (8-10 weeks old) wild type (WT) mice were used for these experiments. The expression of CD62P on platelets before and after thrombin treatment was determined using flow cytometry. Separately, platelets from peripheral blood samples of KO and WT mice were analyzed using transmission electron microscopy (EM). In addition, peripheral blood smears, automated platelet counts, and mean platelet volumes (MPV) were obtained; additionally, platelet clumps (PC) per 10 high power fields (HPF x 40) were counted in each smear. **Results/Findings**: Mean platelet counts between the two groups were not statically different (mean, 616.9 x 10^9/L in WT vs. 648 x 10^9/L in KO). The MPV, however, was lower in KO group (mean, 4.16 fL in WT vs. 3.93 fL in KO, $p=0.02$). The mean manual count of PC per 10 HPF was higher in KO group but did not reach statistical significance (mean, 34.2 ± 19.9 in WT vs. 19.6 ± 11.9 in KO, $p=0.55$). CD62P expression in the absence of stimulation was higher in α-synuclein KO platelets compared to WT platelets (10.3 ± 5.9 in WT vs. 26.7 ± 12.3 in KO); which increased after thrombin stimulation (19.5 ± 14.0 in WT vs. 45.8 ± 11.1 in KO). EM analysis showed markedly abnormal platelet morphology characterized by extensive degranulation and fragmentation in KO mice. **Conclusion**: Our results show that absence of α-synuclein is associated with changes in platelet morphology and function manifested as decreased MPV, increased CD62 expression, greater tendency for platelet clumping, and extensive platelet degranulation and fragmentation. Decrease in MPV could be attributed to faster degranulation and fragmentation of circulating platelets as identified by EM. Our data suggests a crucial role of α-synuclein in platelet physiology. Further studies are needed to elucidate α-synuclein's physiological role.

SP205

Simultaneous Genotyping of Human Platelet Antigen by Polymerase Chain Reaction Sequence-based Typing

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Background/Case Studies: The distribution of human platelet antigens (HPA) vary between different populations. Genotyping for HPA systems is required in the investigation of patients with suspected HPA antibodies and for the provision of compatible blood products from HPA-typed donors. However, HPAs have more than 50 alleles, which make large-scale investigations in populations and acquisition of matched platelet units difficult. In this study, an improved PCR sequence-based typing (PCR-SBT) method combined with a high-throughput DNA sequencer for simultaneous genotyping HPA-1 to 28w systems was established. **Study Design/Methods**: The specific primers for HPA-1 to 28w were designed and the PCR amplification conditions were optimized. Amplification products were purified by enzyme digestion and sequenced.10 reference samples from the 17th and 18th Platelet Immunology Workshop of the International Society of Blood Transfusion(ISBT) were genotyped for HPA-1 to 28w with this PCR-SBT method and the methods previously reported. **Results/Findings**: According to the permutation and combination, a total of 18 pairs of specific primers were designed and verified to amplify nucleotide fragments including each HPA polymorphism. The nucleotide positions of these primers were more than 50 base pairs (bp) distant from HPA polymorphisms and all known single nucleotide polymorphisms (SNPs) sites in HPA genes. The amplification products ranged from 200 to 800 bp and contained variant nucleotides for HPA-1 to 28w. If two HPA nucleotide polymorphism positions were close to each other and located in the same exon of the glycoprotein gene, only one pair of primers was designed to amplify the adjacent HPA systems together.18 pairs of primers were divided into 6 groups by adding different 3 pairs of "heads" the sequence of which were the same as those of sequencing primers. All PCR amplification conditions were identical. All of the sequencing reactions were finished only with 3 pairs of sequencing primers. 10 reference samples were used for the HPA-1 to 28w analysis by the PCR-SBT and obtained 100% correct genotypes in these samples. **Conclusion**: The PCR-SBT method greatly reduces the workload. It is reliable and accurate for HPA genotyping, and can screen large numbers of donors.

SP206

Reactive Platelet Crossmatch Results in the Absence of HLA Antibodies: A Patient Case Series

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Background/Case Studies: Our Transfusion Service supports platelet refractory patients with crossmatch (XM) and/or HLAcompatible platelets. Generally, the platelet XM reactivity and Class I HLA calculated panel reactive antibodies (cPRA) results reflect a similar degree of alloimmunization. However, we have identified several patients in whom the XM showed significant reactivity when no or minimal HLA antibodies (Abs) were detected. **Study Design/Methods**: Records of all immune refractory patients (≥2 corrected count increments <7500) over a period of 15 months were reviewed. Those with a significant discrepancy between platelet XM (positive) and cPRA (negative or very low) were studied. Testing methodologies included: Platelet XM by Capture-P® (Immucor), HLA Abs by LABScreen single antigen assay (Luminex® technology, One Lambda), and HPA Abs by ELISA (PakPlus®, Immucor), flow cytometry, and/or monoclonal Ab immobilization of glycoproteins. For the Luminex® assay, a mean fluorescent intensity >1000 was considered positive. **Results/Findings**: Eleven of 51 (22%) immune refractory patients met our study criteria. Nine patients had additional non-immune causes of refractoriness (fever, bleeding, splenomegaly, infection, amphotericin B). At least one XM was performed for each patient (total of 19), with an average of 30 donors per test. XMs showed a mean of 72% donor incompatibility (range 32-100%), only 25% of which were 'weakly' reactive (range 0-83%). Eight patients had no Class I HLA Abs, and three patients had very low cPRAs (<1%, 4%, and 17%). The four patients who were tested for HPA Abs were negative. Three patients received intravenous immunoglobulin and/or antithymocyte globulin in the three weeks prior to XM or HLA testing, but none had HLA Abs and two were negative for HPA Abs. Therefore, it is unlikely that the positive XM results were due to passive Abs. All XMs were performed by experienced technologists (79% by one person). Technical errors resulting in false-positive XMs as noted in the package insert were not present. **Conclusion**: During a 15 month period, 22% of platelet refractory patients showed high XM incompatibility discordant with their HLA Ab tests. HPA testing performed in four of these eleven patients was negative. It is possible that a small number (but certainly not all) of the other seven patients may have been sensitized to HPA; this could explain the discordance. However, HPA Ab formation in the absence of HLA sensitization is generally uncommon. Undetected HLA Abs in the eleven patients is unlikely given the known sensitivity of the Luminex® assay. Overall, the data suggest the XMs were falsely positive. Careful assessment of the XM assay performance and correlation with other tests and clinical response is warranted.

TABLE.

Year	Platelet Antibody Screens Performed	% Positive Antibody Screens
2006	215	27
2007	221	38
2008	214	31
2009	234	22
2010	213	27
2011	211	35
2012	235	30
2014	148	67
2015	170	74
2016	43	74

No testing performed in 2013.

SP207

Increased Reactivity of Immucor Capture-P® Indicator Red Cells and Platelet Antibody Screens

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Background/Case Studies: Immucor Capture-P® Indicator Red Cells are used with Capture-P Ready Screen for detection of platelet antibodies. A recall of the Capture-P® Indicator Red Cells was issued in March 2013. Reduced reaction strength for the positive control and poor performance as the indicator cells approached expiration were reported. An issue with the raw material used and manufacturing process was identified and corrected. New Capture-P® Indicator Red Cells were released in 2014. **Study Design/Methods**: Platelet Antibody Screen data from ten years was analyzed to see what effect the new Capture-P® Indicator Red Cells had on results obtained. **Results/Findings**: Reactions indicating the presence of antibodies averaged at 29% from 2006 to 2012. Stronger reactions were observed when testing resumed in 2014, with a positive rate over 67%. (Table) Capture-P Ready Screen plates were treated with Chloroquine to remove HLA antigens from the cells. This method is used to determine if positive reactions are due to platelet-specific antibodies, HLA antibodies, or a combination of both. Both HLA and platelet-specific antibodies were reported in 55% of the positive cases from 2006 to 2011. There was a dramatic shift in results in 2012, preceding the recall. Expression of only HLA antibodies was observed in 69% of samples. Detection of both antibodies was reported in 28% of cases. Rate of detection of both antibody types in samples tested from 2014 to 2016 increased to 58%, 66% and 75%, respectively, using the new Capture-P® Indicator Red Cells. The number of positive samples expressing only platelet-specific antibodies has remained relatively unchanged at 5% in the ten year period. **Conclusion**: Capture-P® Indicator Red Cells were less sensitive prior to 2014. Reactions were weaker and antibodies were only detected in 29% of cases. Stronger reactions and 70% positive screens were observed since 2014. Poor performance of the indicator cells prior to the recall may have led to misclassification of samples as expressing only HLA antibodies, missing platelet-specific antibodies that may have been present. Modifications made to the Capture-P® Indicator Red Cells after the recall have yielded a better product that is more likely to detect the presence of platelet-specific antibodies.

SP208

Improvement in Corrected Count Increments with HLA platelets Using Lower Mean Fluorescent Intensity Thresholds

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Background/Case Studies: Poor response to platelet (plt) transfusion (tx) is common in hematology-oncology patients (pts), with immune and non-immune factors playing a role. HLA antibodies (abs) are most commonly implicated in immune mediated plt destruction. Providing HLA-compatible units has been shown to improve the corrected count increment (CCI) in immune refractory (IR) patients. Single bead assays are commonly used to identify the specificity and strength of HLA abs; however, there is little evidence to guide labs in determining which abs are clinically relevant. Ab strength is measured in mean fluorescent intensity (MFI). This preliminary study seeks to define the appropriate MFI cutoff for HLA abs in IR pts. **Study Design/Methods**: 16 IR pts were observed in this cohort study. A pt was considered to have possible immune-mediated plt refractoriness if (1) they had CCI's <5,000 with random donor units and (2) did not have any signs of non-immune refractoriness. Eligible patients had a platelet crossmatch (XM) and an HLA class I antibody identification performed. Plt units were selected for an HLA A and B locus and ABO match when possible, with ab avoidance used with the majority of mismatches. HLA abs were considered positive with MFI >450. **Results/Findings**: The tx success rate (CCI>5000 at 1-4 hours) was analyzed for 15 patients (226 plt tx). The 1-4 hr CCI was significantly higher with HLA-compatible units when compared to XM and random units (table). Multiple variables (peak MFI, patient gender, HLA-mismatch, MFI of ab transfused against, ABO compatibility) were analyzed for significance. The degree of HLA match gave the strongest odds ratio (1.97; 0.93-4.17 95% CI, p=0.076) for a positive tx outcome. As the peak MFI increased, the probability of a successful tx decreased (OR 0.91; 0.72 - 1.15 95% CI); however, no variable showed a statistically significant difference. All transfusions with an HLA ab (N=36, MFI range 100 −17,952) were included in a receiver operating curve (ROC) analysis. An MFI of 336 gave the maximum combination of sensitivity (74%) and specificity (67%). **Conclusion**: Evidence is needed to determine the MFI threshold to increase the probability of selecting a compatible unit. We found that an HLA match yielded a greater probability for a successful plt tx, and that greater MFIs decreased the probability of a successful tx. An MFI of 336 was the best cut-off value to use for a clinically relevant antibody. However, this value seems low, and is likely due to the small data set available. A larger study is needed to better define this important threshold.

TABLE. Comparison of post-tx CCI

Plt Type	N	Median CCI	Min/Max CCI	p-value
Random	107	2113	−7183/18460	<0.001
XM units	11	710	−2575/29820	
HLA-matched plt	108	6010	−3803/5070	

SP209

Evaluation of Platelet Mitochondrial Function after Polytrauma and Hemorrhage in Rats

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Background/Case Studies: Acute Traumatic Coagulopathy (ATC) can occur after polytrauma and hemorrhage in both the civilian and military patients and is associated with an increased mortality rate. We previously developed a rat polytrauma model that demonstrates a progression of coagulopathy. ATC is a complex injury that involves multiple pathologies including mitochondrial damage. The release of mediators after ATC activates multiple systems including fibrinolysis, complement, and coagulation. These in turn have wide-ranging effects on multiple cell types such as neutrophils and platelets. The objective of this study was to determine if polytrauma and hemorrhage are associated with altered platelet mitochondrial function. **Study Design/Methods**: Polytrauma was induced in anesthetized Sprague-Dawley rats (n=10) by damage to the small intestines, right and medial lobes of the liver, the right leg skeletal muscle, and by fracturing the right femur. The rats were then bled to an arterial pressure of 40mmHg until 40% of the blood volume was removed. No fluid resuscitation was given. Platelets were collected from blood taken at times 0 (BL), 30 min (immediately following trauma and hemorrhage), and 120 min (post trauma and hemorrhage). Mitochondrial respiration, maximal oxygen utilization, and individual mitochondrial complex-dependent respiration were assessed with high-resolution respirometry. **Results/Findings**: Basal mitochondrial respiration was lower at 120 min compared to BL (3.6 ± 0.6 vs. 7.9 ± 1.2; $P<0.05$), demonstrating loss of mitochondrial respiration. Additionally, maximal mitochondrial oxygen utilization was diminished at 120 min compared to BL (15.1 ± 2.1 vs. 9.4 ± 0.5; $P<0.05$), demonstrating loss of mitochondrial function in response to stimulation. No significant differences were seen between BL and 30 min samples. **Conclusion**: Polytrauma and hemorrhage lead to

complex changes in platelet function. This study evaluated the effects of polytrauma and hemorrhage on platelet mitochondrial function. A significant decrease in mitochondrial function was demonstrated at 120 min after polytrauma and hemorrhage when compared to BL. However, no difference was seen at 30 min compared to BL, suggesting that platelet mitochondrial damage requires key cellular processes to occur before mitochondrial damage can be seen. These findings are consistent with our previous work demonstrating loss of platelet aggregation at 120 min as a result of trauma in this same model. The correlation between platelet mitochondrial function and trauma-related injuries offer a unique perspective to the underlying mechanisms of such a complex injury and potentially allow for improved treatments.

SP210

Extended Platelet Storage: Is Vitamin C the Answer?

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Background/Case Studies: Whole blood derived platelet concentrates (PC) are primarily collected for therapeutic or prophylactic transfusions. PC are stored at 20 - 24°C on agitators with no additives. The shelf life of platelets (PLTs) prepared by different methods is limited to 5 days primarily due to bacterial contamination, the most frequent cause of post-transfusion infection. During storage, PLTs also undergo significant progressive functional deterioration, termed platelet storage lesion. Oxidative injury during storage leads to abnormal PLT morphology, increased release of granular content and cytosolic proteins, increased pro-coagulant activity, altered surface glycoprotein expression and a significant decrease in agonist-induced platelet aggregation. These limitations have deleterious economic and healthcare consequences, and often result in a critical shortage of PLTs for routine/emergency use. Vitamin C (VitC) is a water soluble anti-oxidant which has demonstrated bactericidal activity. We hypothesized that addition of VitC to PCs would reduce oxidative stress, and limit bacterial growth during storage without compromising PLT viability and function. **Study Design/Methods**: PC were treated according to three treatment arms: 1) normal saline; 2) 0.3mM VitC or 3) 3mM VitC as final concentrations. The added VitC was preservative-free buffered ascorbic acid in water (Ascor L500, McGuff Pharmaceuticals, Santa Ana, CA), with pH range 5.5 to 7.0. Prior to supplementation, a baseline sample was collected at the blood supplier facility. PC that passed standard screening tests were sampled again on days 2, 5, and 8 and tested by thromboelastography (TEG), aggregometry, flow cytometry, and mass spectrometry (Lipidomics) for functionality. The pH, and intracellular VitC and glutathione levels were also measured. Bacterial colony forming units on day 8 were assessed by bacterial enumeration studies on blood agar plates. **Results/Findings**: VitC supplementation at both doses increased PLT intracellular VitC levels (3 - 15 fold; $p<0.05$), suppressed bacterial colony forming units (>90%; $p<0.05$), induced the release of several free fatty acids with bacteriostatic/bactericidal functions (2 −3 fold; $p<0.05$), and reduced the pH of the PC (pH 6.2 - 6.5; $p<0.05$) without significantly altering platelet function. **Conclusion**: Addition of VitC had significant bacteriostatic/bactericidal effects in PC's without significant alteration of PLT function. Increasing the shelf life of PC by using an economical and safe supplement has the potential to prevent PLT wastage and save millions.

SP211

Ultrastructural Morphological Changes in Peripheral Blood Leukocytes in α-synuclein Knockout Mice

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Background/Case Studies: The role of α-synuclein in Parkinson's disease and dementia with Lewy bodies' pathogenesis has been described. Nevertheless, the effect of α-synuclein deficiency on other systems including the hematopoietic system has not been investigated. Recently, it was shown that α-synuclein is essential in the maturation and function of B and T lymphocytes suggesting that α-synuclein has an important role in adaptive immunity. However, the pathophysiology in different cellular blood components is unknown. This study is aimed to evaluate the ultrastructural changes of leukocytes in an α-synuclein knockout (KO) mouse model. **Study Design/Methods**: KO mice and age and sex-matched (8-10 weeks old) wild type (WT) mice were used for these experiments. Peripheral blood samples of WT and KO mice were scanned, examined using light microscopy (LM) and transmission electron microscopy (EM). The following ultrastructural characteristics were recorded in all cell types: numbers of mitochondria, primary granules, specific granules (SG), Golgi apparatus, inclusions, rough endoplasmic reticulum (RER), smooth endoplasmic reticulum (SER), and cellular projections (CP). Separately, peripheral blood smears and automated complete blood counts (CBCs) were obtained. Statistical significance was established using Student *t* test with significance set at $p<0.05$. **Results/Findings**: EM findings showed increased number of SG, inclusions, and SER in KO group (5.3 ± 4.5 in WT vs. 14.1 ± 10.3 in KO, $p=0.02$; 0.4 ± 0.9 in WT vs. 3.2 ± 2.8 in KO, $p=0.007$, and 7.7 ± 6.7 in WT vs. 17.7 ± 12.2 in KO, $p=0.03$, respectively). Although the number of CP was not significantly different between the two groups (13.4 ± 5.3 in WT vs. 16.3 ± 7.5 in KO, $p=0.32$), the sizes and shapes of CPs were markedly altered in KO mice. The mean WBC counts between the two groups were not statically different (4.7 ± 1.2 in WT vs. 4 ± 1.5 in KO, $p=0.32$). Manual 100-cell differential count by LM showed relative lymphopenia (88.4 ± 7.9 in WT vs. 69.2 ± 13.5 in KO, $p=0.03$) and neutrophilia (5 ± 4.1 in WT vs. 21.2 ± 8.8 in KO, $p=0.006$) in KO mice and these correlated with CBCs. The mean eosinophil count was higher in KO mice but did not reach statistical significance (0.6 ± 1.3 in WT vs. 0.8 ± 0.84 in KO, $p=0.8$). **Conclusion**: Absence of α-synuclein is associated with changes in the secretory system of leukocytes characterized by size alteration in the shape of secretory particles and increase in SER, SG, and inclusions. In addition to previous observations of lymphopenia due to α-synuclein deficiency, we report that deficiency also leads to significant neutrophilic leukocytosis. Further functional studies are needed to elucidate the physiological mechanisms mediated by α-synuclein.

SP212

Integrated Transcriptome and Proteome Analysis Reveals Cell Death and Inflammatory Response as the Most Significant Biological Disorders in Platelet Components Involved in Transfusion Reactions

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Background/Case Studies: Blood platelets destined for transfusion release inflammatory molecules during preparation and storage that are occasionally associated with transfusion adverse events (AEs). The rationale of this study is to decipher the transcriptome and the proteome of Platelet Components (PCs) involved in severe and immediate AEs (SAEs). **Study Design/Methods**: We analyzed 5 leukodepleted PCs implicated in SAEs versus 5 matched PC controls. The platelet RNA transcriptomes were acquired by RNA-Seq using the IonProton platform and data were mapped using CLC Bio software. Transcripts were counted using HTSeq-count software and differentially expressed genes were identified using DESeq2 package (Bioconductor). For quantitative proteomic analysis of the platelet pellets and the supernatants respectively, we performed a Label-Free LC-MS/MS method: LC system (Dionex, Amsterdam, The Netherlands) coupled to an Electrospray Q-Exactive quadrupole Orbitrap benchtop mass spectrometer. Subsequently, data were searched by SEQUEST through Proteome Discoverer 1.4 against the Homo sapiens Reference Proteome Set (Uniprot version 2015-07; 68482 entries). Raw LC-MS/MS data were imported in Progenesis QI 2.0 for peptide quantification and statistical comparison (ANOVA test). Differentially expressed genes/proteins ($p<0.05$; absolute Fold Change >2) were analyzed by the Ingenuity Pathway Analysis (IPA) bioinformatics software. **Results/Findings**: For the transcriptome study, out of 19.143 genes, 39 genes were differentially expressed. From the platelet pellet and the supernatant proteome study, 1000 and 187 proteins, respectively, were identified from which 430 and 83, respectively, were differentially expressed within the two studied groups. Cell death and inflammatory response were globally the most significant biological functions associated with ATR after platelet transfusion. Moreover, inflammatory disorders were among the most relevant disease mechanism associated with ATR after platelet transfusion. **Conclusion**: The integrating transcriptome and proteome data of PC supernatants reveal a significant association with apoptosis and inflammatory mechanisms which may be involved in platelet transfusion reactions. This better understanding of SAEs process may help prevention means.

SP213

Evaluation of 2 New Reverse Sequence-Specific Oligonucleotide Assays for Human Leukocyte Antigen Typing

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TABLE. Concordance between assays in 48 patient samples

	Assays used		
HLA Locus	Current	New	Concordance (%)
HLA-A	LABType SSO	LABType CWD	100%
HLA-B	SeCore SBT	LABType XR	97.9%
HLA-DRB1	SeCore SBT	LABType XR	97.9%

Background/Case Studies: High resolution human leukocyte antigen (HLA) typing with clinical applications is preferred in transfusion and transplantation medicine. Our current assays are reverse sequence specific oligonucleotide typing (rSSO; LABType SSO) and nucleotide sequence-based typing (SBT; SeCore). The goal of this study was to determine the concordance of results obtained by 2 new rSSO assays (LABType CWD and LABType XR) with that of our current assays. **Study Design/Methods**: Patient samples were randomly selected if they had been previously tested by our current rSSO and SBT assays. The 2 new assays and a new multiplex flow analyzer (LABScan3D) were applied to detect HLA-A common and well-defined alleles (LABType CWD) and HLA-B and DRB1 alleles at high resolution (LABType XR). All assays and instrumentation came from One Lambda, Canoga Park, CA. DNA was amplified with group specific primers targeting exons 2, 3, 4, and 5 for HLA-A and HLA-B, and exon 2 for HLA-DRB1. Genomic DNA was biotinylated during amplification, and the amplicons were hybridized to SSO probes on fluorescently-labeled microspheres. R-phycoerythrin-conjugated streptavidin (SAPE) was then added to detect amplified DNA bound to microspheres and automatically analyzed (HLA Fusion 4.0 analysis software). **Results/Findings**: We determined the concordances of the 2 new assays with our current assays (Table 1). The LABType CWD was able to identify 6 out of 96 HLA-A alleles (6.25%) at the allele level (4-digit resolution) and was also able to resolve 1 ambiguous allele combination, such exceeding the resolution obtained by our current LABType SSO. The LABType XR assay provided results with shorter allele strings in 59 out of 96 HLA-B alleles (61.5%) and 22 out of 96 HLA-DRB1 alleles (22.9%), respectively, such exceeding the resolution obtained by our current SeCore SBT without reflex testing. **Conclusion**: The 2 new assays allowed determining multiple HLA loci in multiple samples simultaneously, making them suitable platforms for high throughput testing. The LABType CWD assay was fully concordant with our current rSSO assay for HLA-A at low resolution and resolved a fraction of the HLA alleles (6.25%) at high resolution. The LABType XR assay was sometimes able to provide shorter allele strings compared to SBT, such providing better results for HLA-B and HLA-DRB1. However, even with LABType XR, additional testing may still be necessary to resolve any remaining discrepancies and ambiguities.

SP214

Denaturing High-Performance Liquid Chromatography/Sequencing Method for Mutational Analysis of the *ITGA2B* and *ITGB3* Genes in Tunisian Patients with Glanzmann Thrombasthenia

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Background/Case Studies: Glanzmann Thrombasthenia (GT) is a rare inherited severe bleeding disease caused by a quantitative or qualitative defect of the αIIbβ3 integrin platelet membrane receptor. Mutations associated with GT are highly heterogeneous, mostly sporadic and occur across the *ITGA2B* or *ITGB3* genes, coding for the αIIb and β3 subunits, respectively. This study aimed at identifying GT associated mutations in Tunisian patients using an easily accessible method such as Denaturing High-Performance Liquid Chromatography (DHPLC) associated with direct sequencing. **Study Design/Methods**: Three patients with GT issued from consanguineous marriage. The 3 patients are unrelated and originate from different Tunisian regions. GT diagnosis was based on patients and family bleeding histories, lack of platelet aggregation induced by ADP, collagen and TRAP and presence of normal or cyclical ristocetin-induced agglutination. 10 ml of EDTA-anticoagulated whole blood was used for DNA extraction. A hot-start/touch-down PCR program was performed followed by a heteroduplexing reaction with a known sequenced control DNA. DHPLC analysis was performed on a wave DNA fragment analysis system. To identify the type and position of the genetic variants, amplicons with abnormal elution profiles were re-amplified, and then subjected to both forward and reverse direct sequencing. **Results/Findings**: Using the same PCR program, we successfully amplified the 21 amplicons of *ITGA2B* gene and the 14 amplicons of *ITGB3* gene. Interestingly and for the three patients, DHPLC analysis of the 21 obtained amplicons of *ITGA2B* gene showed an abnormal elution profiles for two amplicons named A1 (covering exon 25-intron 25- exon 26) and A2 (covering: Ex14- In14-Ex15-In15-Ex16). Nucleotides sequence analysis of A1 identified the same homozygote point mutation in exon 26 at position **c.2702C>A**, inducing a nonsense mutation **S901X**. Sequencing of A2 revealed a new intronic homozygote SNP at position **g.8945G>A**. DHPLC analysis of the 14 amplicons of *ITGB3* gene revealed abnormal elution profiles for only one amplicon that includes exon 3. This anomaly was observed in only one patient. Sequence analyses identified a heterozygote mutation at position **c.176T>C,** resulting in a **Leu33Pro** substitution. This mutation corresponds to the HPA1a/HPA1b polymorphism of the Human Platelet Antigen 1. **Conclusion**: Since the S910X mutation was previously reported in a Tunisian GT patient and not in other populations, this mutation can be frequent and characteristic of Tunisian GT patients. Further validation studies including GT patients are needed to confirm these results.

SP215

Platelet Additive Solution (Intersol Platelet AdditiveSolution 3) as a Platelet Source for Capture-P® Solid Phase System for the Detection of IgG Antibodies to Platelets

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Background/Case Studies: Platelet crossmatching using Capture-P® (Immucor, Norcross, GA) solid phase system for detection of IgG antibodies to platelets is used to perform the platelet crossmatching. The Capture-P® instructions for Use (IFU) lists the source of platelet used for crossmatching as platelet rich plasma (PRP) derived from whole blood collected in EDTA, ACD, CPD or CPDA-1 or samples obtained directly from the platelet bag. Platelet suspended in InterSol Platelet Additive Solution 3 (PAS3) (Fenwal, Inc. Lake Zurich, IL) is not listed as a platelet source for Capture-P® testing. **Study Design/Methods**: Parallel Capture-P® testing for detection of antibodies to platelets with known refractory patient specimens using EDTA derived PRP and PAS3 aliquots as a platelet source was performed to determine if PAS3 is an acceptable source of platelets to detect IgG antibodies to platelets using Capture-P® testing methodology. The PAS3 test results were compared to the EDTA derived PRP results. **Results/Findings**: Platelet crossmatching using Capture-P® solid phase system for detection of IgG antibodies to platelets was performed on 59 platelet donors. Both the donor's PRP derived from whole blood collected in EDTA and PAS3 samples were tested in parallel with 29 known reactive patient specimens to give 266 parallel test occasions. Results consistent with the EDTA derived PRP results were considered the true positive and true negative results. PAS3 positive or negative interpretation result different than the EDTA derived PRP result were considered a false positive and false negative. The accuracy of the crossmatch when using PAS3 samples to correctly identify incompatible and compatible platelets was 98.9%. The sensitivity of the crossmatch when using PAS3 samples to correctly identify incompatible platelets was 99.5%. The specificity of the crossmatch when using PAS3 samples to correctly identify compatible platelets was 97.4%. **Conclusion**: Patients who receive multiple platelet transfusions are at risk of developing antibodies to the HLA and/or HPA platelet antigens. Platelet crossmatching using Capture-P® solid phase system for detection of IgG antibodies is an effective method for detecting antibodies to both the HLA and HPA platelet antigens. Our study demonstrated that a platelet aliquot obtained from AMICUS-leukoreduced apheresis platelets using PAS3 storage solution was an acceptable platelet source in Capture-P solid phase system for detection of IgG antibodies. As the transfusion medicine field is continually developing new platelet products for the reduction of transfusion associate reactions/diseases such as pathogen inactivated platelets, the acceptability of the newly developed platelet products for use in platelet crossmatching will be required.

SP216

Propofol Interferes with Microparticle Enumeration in Blood Samples

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Background/Case Studies: Propofol is a sedative agent used in the induction and maintenance of anesthesia. Propofol is not soluble in water and is formulated as a white, oil-in-water emulsion containing soybean oil, glycerol, and egg lecithin. Although it has a short pharmacokinetic half-life in plasma, a blood sample collected during infusion or soon afterward may be extremely lipemic and interfere with the interpretation of clinical tests such as plasma microparticle (MP) enumeration. Objective: To determine if propofol interferes with current MP enumeration method and to design strategies for alternate methods. **Study Design/Methods**: Blood samples were collected (pre and post propofol administration) from female Yorkshire cross pigs and platelet poor plasma was prepared by centrifugation at 3000 x g for 10 minutes at room temperature followed by a second centrifugation step at the same speed. Five microliters of each plasma sample was incubated with fluorescently labeled lactadherin that binds to phosphatidylserine (PS) for 30 minutes at 4°C and analyzed by a BD FACS Canto II flow cytometer. MP concentration was enumerated by flow cytometry using BD TruCount absolute counting beads. Particle content of 1% propofol solution in Hank's Balanced Salt Solution (HBSS) was also measured. Pre-propofol plasma was spiked with 1% propofol and MP concentration was measured. **Results/Findings**: MP concentratation in plasma samples of blood increased 4.7-208.3 folds after propofol admistration. Propofol has similar light scattering properties and falls in the same forward scatter (FSC) and side scatter (SSC) gate as plasma MP. Therefore, it interferes with accurate MP enumeration by flow cytometry. However, in order to characterize different subsets of MP, a fluorescence trigger can be used. **Conclusion**: Propofol interferes with MP enumeration in plasma.

SP217

Sphingosine-1-phosphate (S1P) and Lysophosphatidic Acid (LPA) Play a Role in Transfusion Refractoriness

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Background/Case Studies: Refractoriness to platelet transfusion is a complex process and poses a great challenge in the treatment of thrombocytopenic patients. While the vast majority (approximately 70%) of clinical platelet refractoriness has been attributed to non-immune factors such as splenomegaly, fever/sepsis, antibiotics or disseminated intravascular coagulation.Platelets undergo several modifications during storage that reduce their posttransfusion survival and functionality. One important feature of these changes, which are known as platelet storage lesion, is affected by levels of S1P and LPA. **Study Design/Methods**: In order to provide new ideas and methods for prevention and treatment of clinical platelet transfusion refractoriness. We detected and analyzed a series of morphological and function changes and the release rule of sphingosine-1-phosphate (S1P) and lysophosphatidic acid (LPA) of aphaeresis platelet during storage in vitro, to investigate the relation between S1P and LPA and platelet storage lesion. **Results/Findings**: Levels of platelet plasma S1P and LPA gradually increased during storage, but after increasing extracellular S1P concentrations, platelet preservation quality was better than the control group.Shows that platelet apoptosis rate, the aggregation rate, Hypotonic shock response (HSR) and Extent of shape change (ESC) are better than controls. The increasing of activation apoptosis was significantly inhibited ($P<0.05$). Sphingosine kinase activity was effectively inhibited after we added N,N-methylsphingosine directly (DMS) in the plasma,the generation of S1P was reduced . The platelet storage lesion significantly increased including apoptosis, activation significantly increased and aggregation rate, HSR, ESC decreased. The content of added S1P recovery of S1P in plasma after fifth days, platelet storage lesion platelet apoptosis was significantly inhibited. **Conclusion**: The above results show that S1P can effectively inhibit the occurrency of platelet storage lesion, N,N-Dimethylsphingosine (DMS) effectively inhibited sphingosine kinase activity, reduced the generation of S1P, and the platelet preserving quality was lower, compared with the control group. The above results showed that platelet S1P content increased gradually, this was probably because of the release of active molecules leading to more platelet during storage in vitro, resulted in the raise of S1P content in plasma. After the addition of S1P in vitro, the apoptosis pathway of platelet was inhibited (such as inhibit the activity of Caspase-3),reduced the release of active molecules, effectively inhibited the occurrence of platelet storage lesion, the mechanism needed further study.

SP218

The Study on PCR-SSP Technique for CD36 Exon-6 −1G>C Mutation Genotyping and the Distribution of CD36 Exon-6 −1G>C Polymorphism in Chinese Population

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Background/Case Studies: CD36 is an 88-kDa membrane glycoprotein (GP) expressed on platelets, monocytes, macrophages, nucleated erythrocytes and other tissues. Two types of CD36 deficiency have been described. Individuals with Type I deficiency lack CD36 on platelets and monocytes, while individuals with Type II deficiency lack CD36 only on platelets. CD36 gene mutation is the main reason that leads to CD36 deficiency. CD36 Exon-6 −1G>C (Change in splicing site) mutation is one of the novel CD36 mutations in Chinese population reported by us (GenBank: HM217023.1). It induces skipping exon-6 that results in the deletion of 144-203 amino on CD36 protein and CD36 deficiency. The aim of this study was to develop a PCR-SSP technique for the CD36 Exon-6 −1G>C mutation genotyping, and investigate the distribution of CD36 Exon-6 −1G>C polymorphism in Chinese population. **Study Design/Methods**: A PCR-SSP technique was developed to genotype the CD36 SNP Exon-6 −1G>C polymorphism. Designed sequence-specific forward primers for the CD36 SNP Exon-6 −1G and −1C alleles, as well as their common reverse primer. The effectiveness of the CD36 SNP Exon-6 −1G>C genotyping technique was evaluated by using eight CD36 exon-6 1-G>C mutations DNA samples (including one homozygote and seven heterozygote of the CD36 mutations) and 100 CD36 exon-6 −1G/G wild type DNA samples. All DNA samples were confirmed by sequencing for the CD36 gene. Total of 300 random samples from unrelated and healthy adults of Chinese population in Guangxi region were studied for the polymorphism of the CD36 Exon-6 −1G>C gene mutation by the developed technique. **Results/Findings**: We established a PCR-SSP technique for the genotyping of CD36 Exon-6 −1G>C mutation. 100% concordance of genotyping results of 108 DNA samples that included 8 CD36 Exon-6 −1G>C samples and 100 CD36 exon-6 −1G/G samples were showed by the comparison of the results of using the sequencing technique and our PCR-SSP technique. The distribution of CD36 SNP Exon-6 −1G>C polymorphism in Chinese population (n=300) by our developed technique were showed the frequency of CD36 Exon-6 −1G was 0.9933 and Exon-6 −1C was 0.0067, respectively. 4 individuals were CD36 exon-6-1-G/C heterozygote among 300 samples and none of homozygous individuals of this mutation was found in this study. **Conclusion**: In this study, we described the novel CD36 Exon-6 −1G>C mutations in Chinese population and successfully established a PCR-SSP technique for CD36 Exon-6-1G>C mutation genotyping. The gene frequency of CD36 exon-6 −1G was 0.9933 and exon-6 −1C was 0.0067 in Chinese population.

SP219

Leukocyte Cytokines Dominate over Cytokines Overtime in Non-leukoreduced Platelet Components

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Background/Case Studies: Leukoreduction of blood components—of which platelet components—is strongly encouraged but not yet universal, especially in countries presenting with medium level income such as Tunisia. As both leukocytes and platelets secrete copious amounts of pro-inflammatory cytokines/chemokines under various conditions and during storage, we aimed at investigating the potential of their respective secretory programs in platelet components obtained from Tunisian donors. **Study Design/Methods**: A total of 158 non-leukoreduced Standard Platelet Concentrate (SPC) prepared from whole Blood donation using the PRP method were analysed. For each SPC two samples were taken aseptically (one at the day of preparation: D0 and one at the day of delivery) and tested for characteristic biological response modifiers (BRMs) of leukocytes (IL-1β, IL-8), platelets (sCD62P, sCD40L) and both cell types (TNF-a, RANTES) in the presence or absence of thrombin stimulation and at different shelf life times (Day 0 to 5). BRMs were assayed using ELISA and Luminex technologies. **Results/Findings**: Leukocyte- and platelet-associated BRMs appeared in clearly distinct profiles both at the onset (Day 0) and termination (Day 5) of the observation period but shifted during the intermediate preservation periods to invert their respective importance; in fact, the profiles were likely merged and indistinguishable on days 2-3. The leukocyte-derived BRMs largely dominate over platelet-derived ones and further alter the BRM platelet secretion program. **Conclusion**: Herein we have showed that in non-leukoreduced PC, the leukocyte-derived BRMs largely dominate over

platelet-derived ones and further alter the BRM platelet secretion program. Thus, to prevent BRMs related transfusion adverse events, we recommend to do not transfuse non-leukoreduced PC aged more than three days particularly for critical ill patients.

SP220

miRNAs Expression in Platelet and Their Potential Role on Platelet Lesion during Storage

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Background/Case Studies: To investigate the expression of MicroRNAs (miRNAs) profiles, and platelet aggregation related proteins(P2Y12, VASP, GPIIb/IIIa)in platelets during storage, and probe into the relationship of miRNAs expression with proteins, as well as platelet aggregation function. **Study Design/Methods**: Platelet samples were collected from 15 male healthy donors with O blood group. MiRNAs profiles of platelets were tested by Agilent Human miRNA Array at 2, 5, and 8 day during storage. MiRNAs which may related to platelet aggregation (miR-223, miR-21-5p, miR-21-3p, miR-155, let-7b-3p, miR-3162)were selected and validated by RT-PCR. Flow cytometry was used to test P2Y12, VASP, GPIIb/IIIa, and apoptosis in platelets in banked conditions. **Results/Findings**: Results: Total 167 miRNAs were found changed expression on the 5th day of storage, 47 of them expressed increasing, and 120 of them expressed decreasing during storage. On the 8 day storage, total 230 miRNAs expression changed, 28 of them demonstrated an increasing trend, 202 of them showed a decreasing profile. Main changed miRNAs profiles were found to be related to platelet activation, degranulation, platelet-derived growth factor receptor signaling pathway and stem cell differentiation. Aggregation related miRNA were selected and validated, RT-PCR results showed that miR-21-5p, miR-21-3p, miR-155 decreased expression on the 5th day storage, while miR-223, miR-3162, let-7b increased. Proteins related to aggregation were also assay, P2Y12 expression increased, VASP phosphorylation level reduced, platelet membrane glycoprotein GPIIb/IIIa kept stable during storage. Apoptosis rate showed increaseing under banked conditions. **Conclusion**: miRNA expressions were found in banked platelet and these expressions changed with the time extension. Variational miRNAs expressions are related to proteins about platelet aggregation, such as P2Y12, VASP, GPIIb/IIIa, as well as platelet apoptosis. This result suggests miRNAs show potential as biomarkers of platelet storage lesion.

SP221

Vancomycin-induced Immunologic Thrombocytopenia Masquerading as Post-transfusion Purpura: A Diagnostic Pitfall

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Background/Case Studies: A 74 year old female with severe mitral valve insufficiency and dual vessel coronary artery disease underwent percutaneous mitral valve repair with right heart catheterization. She was transfused two units of packed red blood cells (PRBCs) the day prior to surgery with an appropriate rise in her hemoglobin concentration. Five days after the red blood cell transfusion her platelet count dropped precipitously from 243,000/mm3 to 6,000/mm3 over 22 hours. She had received IV vancomycin as routine prophylactic antibiotic therapy for three days post-operatively. **Study Design/Methods**: Post-transfusion purpura (PTP) was suspected and platelets lacking the HPA-1a antigen were requested from the regional donor center. She developed bleeding from her lungs and GI tract and was urgently transfused four random apheresis platelet (AP) units and two PRBC units during the search for an HPA-1a negative platelet donor. Additional reserved PRBC units were to be washed to avoid exposure to soluble HPA antigens. An urgent platelet crossmatch revealed 100% compatibility with random APs, inconsistent with PTP. Intravenous immunoglobulin (IVIG) at 1g/kg was administered. Her platelet count completely recovered within 2 days of IVIG administration and she had no further bleeding. She did not require transfusion of the acquired HPA-1a negative APs or washed PRBCs. **Results/Findings**: Reference laboratory testing was performed to determine the etiology of her acute thrombocytopenia. Initial testing revealed no evidence of anti-platelet antibodies. A monoclonal antibody immobilization of platelet antigens assay was negative for both HPA 15a/15a and HPA 15b/15b. A flow cytometry platelet antibody screen was negative on two targets for both IgG and IgM. A platelet antibody bead array was negative for specificity to glycoprotein (GP) IIb/IIIa-HPA1, GP IIb/IIIa-HPA3, GP Ib/IX-HPA2, GP Ia/IIa-HPA5, CD36-GPIV, and HLA class I antigens. Genotyping revealed the patient's platelet antigen type as: HPA 1a/1a, HPA 2a/2a, HPA 3a/3b, HPA 4a/4a, HPA 5a/5a, HPA 6a/6a, HPA 9a/9a, HPA 15a/15a. A followup drug dependent flow cytometry platelet antibody assay revealed vancomycin dependent anti-platelet IgG antibodies. Both scanning and transmission electron microscopy studies will be performed on the patient's platelets to investigate for the presence of immune complex deposition. **Conclusion**: This case highlights the overlapping clinical features of drug-induced immune thrombocytopenia and post-transfusion purpura and the test result differences between the two diagnoses. Both diagnostic entities should be considered in acute thrombocytopenia to optimize patient therapy. This rare case of vancomycin-induced immunologic thrombocytopenia was successfully treated with IVIG. It was advised to avoid the drug in the future.

SP222

Mutations in the Exon 10 of CD61 Gene (HPA-6bw) and Their Distributions in Han and Uyghur Blood Donors in China

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Background/Case Studies: While using Bloodchip to screen blood group gene type in Han population, we found that the type of HPA-6bw could not be determined in some individuals. Because the binding sites of the probe for HPA-6bw genotyping located in near the mutation site of HPA-6bw, there may be unknown mutations affecting the combination of primer and template, which resulted in no detection of signal. In order to realize the polymorphism of platelet membrane glycoprotein CD61 coding gene of HPA-6bw blood group system, to explore its reasonable gene primers and probes, we compare the mutations and their distributions between Han and Uyghur blood donors in China. **Study Design/Methods**: Blood samples were collected randomly from 149 Han healthy volunteer donors at Shanghai Blood Center and 96 Uyghur blood donors at Xinjiang Hetian Uighur hospital. The exon 10 of CD61 gene was amplified and confirmation with DNA sequencing analysis. **Results/Findings**: There were two mutations found at positions 1533 and 1545 at a quite high frequency in exon 10 of CD61 gene in both Han and Uyghur, and a new mutation C1529T was only found in the Han population. All of them were synonymous mutations. The mutations at positions 1533 and 1545 were located on the same chromosome. In the Han population, the phenotypic frequency of 1533A1545G was 48. 32% (72/149), 1533G1545A was 12. 75% (19/149), 1533A + G/1545G + A was 38. 93% (58/149). C1529T accounted for only about 0. 67% (1/149) . In the Uyghur population, the phenotypic frequency of 1533A1545G was 53. 12% (51/96) , 1533G1545A was 5. 32% (5/96), 1533A + G/1545G + A was 38. 93% (40/96). There was no C1529T found in Uyghur. **Conclusion**: There were 3 SNPs in the exon 10 of CD61 gene in both Han and Uyghur. The difference between Han and Uyghur was not statistically significant. This indicated the intimate lineage between the two ethnic populations.

SP223

Determine the Optimal Anti-Coagulant for Measurement of Platelet Counts

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Background/Case Studies: The reliability of platelet count is dependent upon stable anticoagulation. It is notable that platelet count varies in different anticoagulants. In this study, we determined what the optimal anticoagulant would be for counting platelets in human whole blood. **Study Design/Methods**: Blood samples were obtained from healthy adults (n=9). Whole blood was collected using one of the five commercially manufactured anticoagulants: three calcium chelators (Ethylenediamine tetracetic acid dipotassium (EDTA), Acid-Citrate-Dextrose Solution A (ACD-A), and Sodium Citrate), and two non-calcium chelators (Hirudin, and Lithium Heparin). Platelet count was measured by ADVIA120 and flow cytometry at 30min and 4hrs after collection. Platelet count and platelet distribution width (PDW) were obtained from the ADVIA. Platelet activation was measured by Flow Cytometry by CD62P staining. **Results/Findings**: The platelet count of the samples containing calcium chelators (EDTA, ACD, sodium citrate: 209 ± 15, $173 \pm 15{,}150 \pm 18$ $\times 10^3/\mu l$ respectively) were significantly higher than the samples with non-calcium chelator anticoagulants (heparin, hirudin: 96 ± 13, 95 ± 10 $\times 10^3/\mu l$ respectively) as measured by ADVIA. The platelet count of EDTA and ACD treated blood was equivalent by ADVIA and flow cytometry. However, the counts from sodium citrate, hirudin and heparin treated blood was significantly lower as measured by ADVIA compared to flow cytometry. Platelets from EDTA treated blood had significantly higher CD62P% ($12.3 \pm 0.9\%$) but lower PDW ($52.1 \pm 1.6\%$) in comparison to platelets from hirudin and heparin blood (CD62P%: 2.9 ± 0.2, $4.9 \pm 0.2\%$; PDW: 64.4 ± 1.3, $69.6 \pm 2.2\%$). At 4hrs from collection, CD62P% was almost three times higher ($31.7 \pm 1.7\%$) in platelets treated with EDTA, but

platelet count did not significantly change compared to the baseline. By contrast, the platelet count significantly dropped in other groups at 4hrs, especially in the hirudin and heparin treated blood, which were 30% reduced as measured by flow cytometry. **Conclusion**: This study suggests that EDTA is the most optimal and stable anticoagulant for platelet count. Although EDTA activates platelets and increases CD62% over time, EDTA has the least impact on platelet aggregation or morphologic change, which leads to stable and higher platelet count in comparison to other anticoagulants. Platelet counts of non-calcium chelator treated whole blood (hirudin and heparin) are unstable, and are dramatically reduced at 4hrs after collection. This study demonstrates the importance of using consistent anticoagulants for platelet counts in research, clinical diagnosis and treatment. This project was funded by US Army Medical Research and Materiel Command.

SP224

EDTA-dependent PTCP is Caused by a Factor that Retains EDTAAanticoagulation Activity in the Plasma

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Background/Case Studies: EDTA-dependent pseudothrombocytopenia (PTCP) is the phenomenon of a false low platelet count reported by an automated haematology analyzer due to in vitro aggregation of platelets. However, the precise cause of EDTA-dependent PTCP is still unknown. We found that EDTA-dependent PTCP is caused by a factor that retains EDTA anticoagulation activity in the plasma from a mother and her 8-day-old son. Both of them were diagnosed with PTCP. It may help to reveal the mechanism of EDTA-dependent PTCP. **Study Design/Methods**: Platelets in the mother and her neonate with pseudothrombocytopenia were measured by FCM and phase contrast microscopy, using K2EDTA and Na-citrate anticoagulants to collect blood samples. The results were compared with the counts obtained by adding the plasma from mother or neonate to normal blood samples. **Results/Findings**: Platelet count of mother was 12×10^9/L with K2EDTA, while 250×10^9/L with Na-citrate. Platelet count of neonate was 54×10^9/L with K2EDTA, while 207×10^9/L with Na-citrate. EDTA samples observed by microscopy showed some of platelet aggregation, while samples without EDTA were normal. Normal donor's platelet count was 35×10^9/L (reacted in vitro with mother's plasma with K2EDTA), while 361×10^9/L (reacted in vitro with mother's plasma with Na-citrate) . Platelet antibodies were detected both in mother and neonate with EDTA by FCM, while undetected without EDTA. **Conclusion**: We described a case of EDTA-dependent PTCP that retained EDTA anticoagulation activity in the plasma from a mother and her 8-day-old son. The neonatal PTCP may result from transplacental transport of maternal factor of EDTA anticoagulation activity. The factor may be the IgG antibodies against the EDTA-dependent platelet epitopes, but it still need the further confirmation. Since the recognition of pseudothrombocytopenia is important for clinical diagnostics and treatment of patients, our study may help to reveal the mechanism of EDTA-dependent PTCP.

RBC Immunohematology

SP225

Prevalence of Rh(D) Alloimmunization of RhD Negative Patients after Transfusion of RhD Positive RBC

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Background/Case Studies: The shortage of Rh negative RBCs units during certain periods of the year forces the transfusion practicionals some times to transfuse Rh(D) positive blood to elderly patients. The D antigen considered as highly immunogenic because only a small quantity of transfused Red Blood Cells (RBCs) are needed to obtain anti Rh vaccine as was shown by small volume Rh positive cells injections to male volunteers. Several studies however, have shown that percentage of Rh alloimmunization in patients receiving Rh positive RBCs and platelets is relatively low: 18-22%. These reports were based on small groups of patients (20-50). We decided to elucidate the prevalence of Rh (D) alloimmunization in our Medical Center patients. **Study Design/Methods**: Transfusion service computer records were examined to identify all Rh negative patients received at least one Rh positive RBCs unit during years 2010-2015. For some of the patients even earlier data (up to 11 year) was available. Alloimmunization to the D antigen recipients who had a follow-up antibody screen performed at least 10 days after initial D+ RBC transfusion(s) was investigated. The age and sex of the recipients, date and number of D+ unit's transfusion(s), all subsequent serological investigations and the department where the units were issued were recorded. **Results/Findings**: There were 926 (500males/424 women, mean age =72.6), Rh negative recipients identified who received a total of 2021 D+ RBC units. The mean follow-up length was 886 days. 412 recipients had at least 10 days follow-up antibody screen performed. 84 of 412 recipients (20%), 46 males/38 females, mean age= 71, developed anti D antibodies within 14 days up to 150 days (mean = 60 days) after 1 up to28 (mean=3.3) RBCs units. 26 (31%) of them developed anti D due to a single RBC unit transfusion. Out of these that did not develope anti D alloantibodies, 6 developed 2 anti E, 2 anti K, anti Jk^a and 2 anti Lu^a antibodies. Among anti D producers, 24 (28.5%) developed multiple alloantibodies: 18 anti C, 11 anti E, 5 anti K, 2 anti Jk^a, 2 anti Lu^a, 2 anti Le^a and one each of anti Jk^b and anti Kp^a. Out of 21 patients that were reexposed to D+ RBCs after initial bleeding episode at least 2 years later, anti D alloimunization was found in 6 (28.6%) patients. The percentage of hemato-oncology patients among Anti D producers and non producers was the same: 17%. **Conclusion**: To our best knowledge, this study included the biggest cohort ever described of Rh Neg. patients receiving Rh Pos. RBCs. We found 20% rate of anti-D alloimmunization in these patients that was in concordance with rates previously reported for small groups of D Neg. oncology patients transfused with D positive RBCs and platelets.

SP226

Reducing Commercial Reagent Expenses Utilizing Unlicensed Monoclonal Antibodies to Human Red Cell Antigens

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Background/Case Studies: FDA licensed reagents, required for confirming RBC antigens, are expensive and available from a limited number of vendors. Monoclonal antibodies (Mabs) to RBC antigens have been produced, and extensively studied in monoclonal workshops. Some hybridomas are available from ATCC or other commercial sources. Moreover the antibody supernatant can be purchased from companies or the antibody developer. Adapting these unlicensed reagents to certain tasks in the blood bank can reduce commercial antisera expenses. **Study Design/Methods**: Mabs were obtained with the following specificities: D, K, Kp^b, Js^b, Fy^a, Fy^b, Jk^a, M, S, s and A_1. They were validated for specificity and shown to meet the potency requirements as described in 21 CFR Sec. 660.25 (2015). Hemagglutination (HA) tests were performed by standard tube agglutination and by IgG gel card (ID-Micro Typing SystemTM, Ortho Clinical Diagnostics). Murine IgG Mabs were tested by tube and gel techniques using anti-mouse IgG (AMG) (Sigma-Aldrich, Inc) that was diluted in 6% albumin and titrated to optimal reactivity. Humanized IgM Mabs were tested by direct agglutination with the addition of Lo-Ion (Immucor, Inc,). **Results/Findings**: Methods and strength of reactions obtained is illustrated in Table 1. Anti-D, -Jk^a and -Fy^b are human IgM Mabs that reacted 3-4+ at RoomTemperature (RT). Humanized anti-Js^b and -Fy^a reacted 2-3+ at RT when tested with Lo-Ion., and anti-A_1 is murine IgG which reacts 3-4+ RT. To test the remaining Mabs, the AMG was titrated in 6% BSA to determine the optimal dilution for HA which was found to be 1:50. **Conclusion**: Mabs can be used in a number of applications in the IRL or transfusion service where licensed reagents are not required. This includes screening donor units, to confirm antigen profiles of

TABLE. Optimal Methods of Testing and Reaction Strength of Unlicensed Antisera

Human Anti-D	5 min. RT	3+
Murine Anti-K	AMG (tube and gel)	3+ tube 4+ gel
Murine Anti-Kpb	AMG (tube and gel)	3+ tube 4+ gel
Humanized Anti-Jsb	5 min. RT with Lo-Ion	3+
Humanized Anti-Fya	5 min. RT with Lo-Ion	3+
Human Anti-Fyb	5 min. RT	4+
Human Anti-Jka	5 min. RT	4+
Murine Anti-M	5 min. RT	4+
Murine Anti-S	AMG (tube or gel)	3+ tube 3+ gel
Murine Anti-s	AMG (tube or gel)	4+ tube 4+ gel
Murine Anti-A1	5 min. RT	4+

our in-house adsorbing cells, and investigating discrepant typing results on donor units and patient samples. Over time we estimate that we will decrease our cost for reagents by 15%, which in our institution, will save an estimated $20,000 this fiscal year.

SP227

Alloimmunization in Sickle Cell Disease Patients Using Phenotype-matched Red Blood Cells in the Transfusion Service of the Puerto Rico Medical Center

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Background/Case Studies: Sickle Cell Disease (SCD) refers to a group of hematologic disorders distinguished by an abnormal production of Hemoglobin S. It has a high prevalence in individuals with African ancestry. Red blood cells (RBC) transfusions are an essential part of the treatment for SCD. This leads to an increase risk of developing alloantibodies to RBC antigens. Phenotypically identical blood for some blood group antigens could be used in order to minimize the development of these alloantibodies.
Objective: To describe the SCD population in the Transfusion Service of the Puerto Rico Medical Center, and to determine the prevalence and significance of alloimmunization between identical-phenotype, partially-identical, and non-phenotyped matched RBC transfusions. **Study Design/Methods**: We identified 138 SCD patients in our database who had received blood transfusions from July 2005 to December 2014. A total of sixty-two patients were included in the study. The population's age, sex, RBC phenotype, number of transfusions, and alloantibody production were evaluated. A descriptive analysis of alloimmunization between identical-phenotype, partially-identical, and non-phenotyped transfusions was performed. **Results/Findings**: The overall transfusion event alloimmunization was 3% corresponding to 14.5% of all patients. Transfusions with identical-phenotype matching resulted in less alloimmunization (20%); extended identical-phenotype did not produce alloantibodies. Partially-identical and non-phenotyped transfusions induced the formation of alloantibodies in 80% of patients. **Conclusion**: Identical-phenotype matched transfusions seem to decrease the formation of alloantibodies; partially-identical and non-phenotyped transfusions increase alloimmunization. Preventing alloimmunization facilitates obtaining compatible blood for future transfusions.

SP228

Correlation of Capture-R Solid Phase Phenomenon to Patient Diagnoses

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Background/Case Studies: In June 2006, we began using solid phase technology to detect red blood cell (RBC) alloantibodies. Some patients' samples demonstrated non-specific pan-reactivity on both antibody screens and panels; our procedure requires switching to manual test tube methods. This pattern of non-specific reactivity is termed solid phase phenomenon (SPP), when patients' samples are reactive in the solid phase test system, but do not react in the manual test tube method. The goal is to determine if diagnosis is a predictor of SPP. **Study Design/Methods**: All SPP work-ups from June 2006 to December 2013 were retrieved and evaluated, retrospectively. Patients were categorized by admitting diagnosis upon identification of SPP. Correlations between SPP and autoimmune diagnoses were also evaluated. **Results/Findings**: There were 230 patient specimens exhibiting SPP. There were 20 admitting primary diagnostic categories. The most common admitting diagnoses with SPP were pregnancy (19.56%) followed by traumatic injury (11.74%) and cardiovascular diseases (11.3%). Autoimmune disorders, either as an admitting diagnosis (3.04%) or historical diagnosis (17.83%), accounted for a total of 20.87% of patients with SPP. **Conclusion**: The data shows an increased incidence of SPP among pregnant patients or those with inflammatory conditions. We attribute SPP to an increased serum concentration of non-specific, inflammatory proteins. Guven, et al.[1] showed that increased concentrations of IgG due to inflammation correlated to non-specific binding in solid phase immunoassays. Also, Anstee[2] describe a transient increase in Lewis b antibodies (anti-Le^b) in pregnant women which is due to a four-fold increase in circulating lipoproteins allowing for Le^b antigen to preferential bind to circulating lipoproteins rather than RBC membranes. These sources have demonstrated that inflammatory conditions and pregnancy increase protein production; this may lead to SPP. The direct relationship will need to be tested. If this theory is confirmed through further study, this could lead the way for the manufacturer to modify their test system. If these inflammatory proteins are similar to Human Anti-mouse Antibodies (HAMA), the system can include a step to absorb the antibodies and testing can be repeated to look for a reduction in reactivity in the testing system.[3]

References

1. Guven E, et al. *J Immunol Methods* 2014. 403:26-36.
2. Anstee D, et al. "The Lewis System" *Applied Blood Group Serology.* Peter Issitt. 4th ed. 1998: 261.
3. Madry N, et al. *Anticancer Res* 1997.17:2883-6.

SP229

A Case of Ssevere Bronchospasm Following Oral Administration of Amoxicillin Associated with Positive Antiglobulin Tests and Amoxicillin Antibodies

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Background/Case Studies: Amoxicillin is a broad spectrum β-lactam antibiotic, widely used in the treatment of bacterial infections. The most common adverse reactions include nausea, diarrhea, rash. Immune hemolytic anemia induced by amoxicillin is rarely reported.
We report a case of a sixty two-year-old-untransfused woman with a history of asthma, recurrent bronchitis, allergy to nonsteroidal anti-inflammatory drugs, who developed a sensation near-death experience associated with a severe acute bronchospasm with hypoxemia (pO2 61 mmHg) and hypotension (95/72), right after the first oral administration of amoxicillin for odynophagia and a flu-like syndrome. Although there were no evidence of clinical or laboratory hemolysis, investigation was performed to determine the presence of amoxicillin- dependent antibodies. **Study Design/Methods**: Serological studies including direct and indirect antiglobulin tests (DAT and IATs) were performed in a blood sample collected from the patient right after the adverse reaction of the drug and a second one 48 hours later. In this latter sample, the investigation for amoxicillin antibodies by testing patient's serum and eluate obtained from the patient's red blood cells (RBCs) in the presence of the drug against normal donor RBCs that had not been previously treated with the drug (i.e., by the so-called "immune complex" method) was also realized. **Results/Findings**: In the first blood sample, the DAT was moderately IgG positive and C3d negative and there was evidence of an apparent warm autoantibody by the IAT. The autoantibody was no longer detected in the second sample whereas the DAT remained positive with anti-IgG.
An antibody directed against enzyme-treated normal donor RBCs in the presence of amoxicillin was demonstrated both in patient's serum (titer 8) and eluate (titer 1). **Conclusion**: The patient with positive antiglobulin tests, described in this report, was demonstrated to have amoxicillin-dependent antibodies. She was also found to have positive skin testing to this drug, following allergy consultation, one month after her discharge. Amoxicillin and amoxicillin related drugs are thus contraindicated in this patient. As amoxicillin is commonly used in the treatment of oropharyngeal and bronchial infections, anti-amoxicillin should be considered whenever patients with these infections develop severe hypersensitivity reactions and or positive DATs even if there was no evidence of drug-induced immune hemolysis.

SP230

Storage Survival Period of DTT Treated Red Cells

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Background/Case Studies: CD38 monoclonal antibodies are a therapeutic agent used in treating patients with multiple myeloma without achieving remission. It is known that CD38 antibodies will interfere with serological tests by causing positive IATs. Since the drug will be pan-reactive with IAT screening and panel cells, clinically significant alloantibodies may be masked. Dithiothreitol (DTT) is a reducing reagent that breaks disulfide bonds and will effectively destroy antigenic sites for CD38 on red cells. DTT treated cells are used for assessing alloantibody production in patients

undergoing anti-CD38 treatment. We performed a validation to determine the storage life of DTT treated reagent cells when stored in red cell support solution. **Study Design/Methods**: The study was conducted over a period of 12 days. Three examples from 4 different manufacturers consisting of Rh phenotypes: C+c-E-, C-c+E+, and C-c+E- were treated with 0.2M DTT. A starting volume of 10.5mL treated cells and 0.6mL untreated cells diluted to 3-5% in red cell support solution.
Daily evaluation:

1. Visual grading of hemolysis (mg/dl) for treated and untreated samples using a standard hemolysis chart.
2. Antigen testing of DTT treated cells to evaluate k(KEL2) antigen and Rh antigens C, E, and c.
3. IATs with DTT treated cells and a positive (0.9% commercial confidence antibody) and negative (6% Albumin) reagent using 3 methods (column agglutination testing, tube testing with polyethylene glycol (PEG) additive, and tube testing with no additive).
4. Day 9, 1mL of supernatant was removed to correct concentration of cells back to 3-5%.

Results/Findings: Hemolysis did not affect expected performance of reagent cells. However, this may have contributed to the decreased amount of available reagent which prompted the study to end at day 12. Although cells tested 0 to 1+ for k(KEL2) antigen after DTT treatment, cells were acceptable for use as CD38 negative cells. Antigen testing for k(KEL2) remained 1+ or less throughout the study. Satisfactory Rh antigen reactivity remained on samples with 3+ to 4+ throughout the study. Column agglutination and tube tests with PEG and no additive were greater than 1+ with dilute confidence antibody (positive control) throughout the evaluation. There were no false positive reactions with 6% albumin (negative control). **Conclusion**: Our study has shown DTT treated cells stored in red cell support solution to maintain potency for up to 12 days. Satisfactory results were demonstrated with positive and negative controls for all test methods (Column agglutination and tube tests with PEG and no additive). Rh antigen integrity was maintained. Hemolysis did not interfere with antigen/antibody testing. Having these cells available provides a useful reagent for investigating anti-CD38, as well as, antibodies to Lutheran, Kell, Cartwright, Scianna, Dombrock, LW, Cromer, Knops, Indian, and JMH.

SP231

Management of a High Risk Pregnancy with Anti-Jr^a

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Background/Case Studies: Anti-Jr^a is a rare antibody (Ab) against a high prevalence RBC antigen (Ag). It has been associated with mild and moderate hemolytic transfusion reactions. Although hemolytic disease of the fetus and newborn (HDFN) is not typical, one fatal case has been reported. We present the management and outcome of a pregnant patient with anti-Jr^a and increased hemorrhage risk due to abnormal placentation. **Study Design/Methods**: Ab identification was performed using PEG and LISS enhancement. Jr^a Ag typing was performed with unlicensed anti-sera. **Results/Findings**: A 37 year old O-positive G6P2123 Caucasian woman with a history of anti-Jr^a had evidence of placenta accreta at 28 weeks' gestation. Our laboratory received a sample at 30 weeks and confirmed the patient's Jr(a-) phenotype and anti-Jr^a Ab (titer 4). Other significant alloantibodies were ruled out. A C-section with hysterectomy was planned at 34 weeks, and a nationwide search for Jr(a-) RBC units was initiated. The patient's sibling was unavailable for Jr^a testing, and the search identified only 6 frozen units collected from one donor at our center. This donor was actively recruited and donated 2 more units in the 2 weeks before surgery. The 2nd unit was collected 10 days after the 1st; donor evaluation and approval by the center physician was required. Ultimately, 8 Jr(a-) units (6 frozen, 2 liquid) were procured. During surgery, the patient received 4 Jr(a-) units, and then, per the agreed upon transfusion plan, was switched to Jr(a+) units; one Jr(a+) unit was transfused. In surgery, placenta percreta was found (placenta on bladder and vagina), which carries an increased bleeding risk. Major bleeding did occur post-operatively, and a laparotomy was performed with transfusion of 10 more Jr(a+) units. During recovery, 1 Jr(a-) unit was transfused and the patient was discharged on hospital day 8. In total, the patient received 11 Jr(a+) incompatible RBC units without evidence of acute hemolysis. There was no HDFN; the baby's hemoglobin was 15.2 g/dL and the DAT and Ab screen were negative. Four weeks later, the patient was admitted for a pelvic hematoma but required no transfusions or surgery. Her DAT was positive and eluate showed anti-Jr^a, but delayed hemolysis was not reported. At subsequent follow up, mother and baby were doing well. The unused Jr(a-) units are frozen for future use. **Conclusion**: Management of this patient with placenta percreta and an anti-Jr^a required close coordination between the blood center, transfusion service, and clinical services to achieve a good outcome. Only 1 donor in the country was found to support this patient, and when the supply of Ag negative blood is limited, creating a transfusion plan is necessary if major bleeding is expected. Fortunately, in this case, the anti-Jr^a did not appear to be clinically significant for the mother, and the baby showed no evidence of HDFN.

SP232

Low-frequency Antibody, Anti-Ytb, Identified in a Prenatal Sample: A Case Study

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Background/Case Studies: A 34 years old female G2P1 was admitted to the Family Birthing Unit to deliver her second child. A type and screen sample was ordered and sent to the blood bank. The patient was typed as A positive with a positive antibody screen using a three cell panel- lot VSS 789, with only Cell I R1R1 (Donor 317135) being 2+ positive. An antibody investigation using Panel A (Ortho Diagnostics) VRA 244 was performed, however all clinically significant antibodies were ruled out, with only cell 5, r'r (donor 317268) being 2+ positive. Due to lack of specificity of the antibody, an additional panel B, lot VRB 216 was tested. Two cells, 13 rr (donor 309306) and 14 rr (donor 310235) yielding a 2+ positive result. A low frequency antibody was suspected and further investigation was performed. **Study Design/Methods**: A Twelve cell panel was assembled using 3 different lots of Immucor cells that had extended antigen typing for Cobalt, Diego, Cartwright, Bga and Mia. The cells were converted to 0.8% and incubated with patient plasma using gel methodology. The cells were incubated at 37°C for 15 min. The gel cards were centrifuged for 10 min and the wells examined for reactions. The infant was delivered shortly after the maternal type and screen was received, therefore, the infant cord blood was also tested for ABO/Rh type and antibody screen, as well as DAT to determine the risk of HDFN. For research purpose, an eluate was also performed with the infant's cord blood cells. **Results/Findings**: Three cells, 7 (Immucor lot 01506) and cell 17 and 18 (Immucor lot 04537) were 2+ positive. All three cells were positive for Ytb, confirming the rule of three for antibody identification and identifying the antibody as anti-Ytb. All other cells tested for other low frequency antigen as Dia, Cob, Bga and Mia were negative. The infant cord blood was typed as A negative, antibody screen positive with Ytb positive cells and DAT negative with IgG. The eluate performed was non-reactive with all Ytb positive cells tested with the antibody screen. **Conclusion**: A healthy baby boy infant was delivered. The infant's total bilirubin was within normal range and no signs of HDFN were noted. Mother and infant were discharged without complications. It is known that the Cartwright blood group, YT 011, is composed of 2 antigens. Yta high frequency antigen present in 99.7% of the population, and Ytb is a low frequency antigen, present in 8% of the general population and 23.7% of Israeli Jews. Antibodies to these antigens are IgG and cross the placenta as shown on the present case study. Ytb antigen is known to be poor immunogenic and weakly expressed at birth. At this moment there are no reported cases of HDFN due to anti-Ytb, with this antibody being quite uncommon when identified in a sample without additional allo-antibodies.

SP233

Variable Serologic Reactivity Associated with Daratumumab (Anti-CD38) Interference

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Background/Case Studies: Daratumumab (DARA) is the first anti-CD38 monoclonal antibody approved for treatment of refractory multiple myeloma by the Food and Drug Administration (FDA). Drug-related interference with serologic testing occurs in patients following initiation of therapy due to binding of anti-CD38 IgG antibodies in patient plasma to CD38 antigen expressed on reagent and donor Red Blood Cells (RBCs). Previously published studies described panreactivity in the majority of patients and complete mitigation of reactivity following treatment of reagent cells with dithiothreitol (DTT), a sulfhydryl agent which denatures CD38. **Study Design/Methods**: We performed routine indirect antiglobulin testing utilizing automated solid phase methodology for all multiple myeloma patients initiating DARA therapy. Of the thirteen patients encountered to date, four were tested subsequent to their first DARA

TABLE. Summary of Serologic Findings in DARA Patients

Patient	Treatment Day	Antibody Screen (Solid Phase)	Antibody Panel (Manual PEG)	DTT-Treated Antibody Panel	DAT	AHG Crossmatch
1	Day 34 (sample #1) Day 35 (sample #2)	Sample #1: 3+/3+/3+ Sample #2: 1+/2+/2+	Panreactive (2-3+)	7 of 11 cells reactive (very weak to 1+)	Negative	2 of 2 incompatible (weak and 1+)
2	Day 35	4+/4+/3+	7 of 15 reactive (weak to 1+)	7 of 7 non-reactive	Negative	Compatible
3	Day 36	Negative	N/A	N/A	N/A	1 of 3 incompatible (weak+)
4	Days 28, 35, 41, 48	Negative	N/A	N/A	N/A	N/A

dose and are described in the table below. For those patients with suspected DARA reactivity, we performed reflex manual antibody panels with polyethylene glycol (PEG) enhancement using both untreated and DTT-treated reagent RBCs. Although several DARA patients did have pre-existing alloantibodies, none of the four patients above had positive antibody screens prior to initiation of therapy. **Results/Findings**: Delayed recognition of DARA interference in the first patient resulted in the pursuit of various differential diagnoses including misdiagnosis as a high titer low avidity (HTLA) antibody (due to a titer of 512) before correct identification of the underlying cause. Even in our small patient cohort, we observed a wide variety of serologic reactivity patterns ranging from panreactivity of variable reaction strengths to repeatedly negative solid phase antibody screens with incompatible antihuman globulin (AHG) crossmatches. Unlike previously published studies, DTT treatment of reagent RBCs resulted in weak but persistent reactivity in 7 of 11 reagent cells tested in one patient. Transfusion of PEG AHG crossmatch-incompatible antigen-matched (Rh and K) RBCs did not result in adverse transfusion reactions. **Conclusion**: Based on our findings above, we have observed greater variability in DARA-related serologic reactivity than has been previously described in the literature, including HTLA antibody-like titers and persistent positive testing with DTT-treated cells, and will likely continue to see a broad range of patterns. Since platelets are also known to express CD38, we also plan to investigate the effect of anti-CD38 on platelet serology in future studies.

SP234

Inconclusive Antibody Reactivity with Commercial Reagent Red Cells

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Background/Case Studies: In an Immunohematology Reference Lab (IRL), it was discovered that some patients displayed inconclusive, yet apparently specific, red cell antibody reactivity which could not be characterized when testing commercial reagent red cells. This apparent specificity was often elusive and time consuming to evaluate. Red cells that had not been exposed to a commercial preparation process were eventually tested and the previously observed inconclusive reactivity was absent. **Study Design/Methods**: Antibody identification studies during a period of 27 months were reviewed. Ten examples of the phenomenon were identified. Test methods included solid phase and test tube using LISS and PEG enhancements with serum and/or plasma. The inconclusive reactivity was observed using all test methods and negative results were viewed microscopically. Commercial reagent red cells were from one manufacturer. Non-commercial cells included freshly prepared donor suspensions from EDTA tubes, CPDA-1 segments, and/or stored cells prepared for the LN2 frozen library from in-house samples, donors, and rare donor exchange. Eluates were prepared with a commercial acid elution kit. Adsorptions were performed using a 20 minute PEG-enhanced incubation; autoadsorptions used ZZAP treated autologous cells, allogeneic adsorptions used untreated donor units. Patients included prenatal and transfusion candidates; medical histories were unavailable. **Results/Findings**: Variable reactivity ranging from negative to 4+ was observed often indicating the apparent presence of multiple or uncommon red cell antibodies. The classic presentation of the phenomenon most often displayed 40-85% of expected negative reactions to be macroscopically positive and all unexpected common alloantibodies were ruled out. Other presentations revealed 100% reactivity with commercial cells. The use of red cells treated with ficin or 0.2M DTT had variable effects on the unexplained reactivity. Upon further investigation, the variable reactivity was absent when testing cells that had not been prepared by a commercial manufacturing process. After evaluation it was noted that 8 of the 10 cases had a positive DAT due to IgG; 6 of the 8 positive DATs had a pan-reactive eluate and the other 2 PEG-enhanced eluates revealed no reactivity; 5 samples had warm autoantibodies and the variable reactivity described was observed in both auto and selected adsorptions ***only*** when using commercially prepared red cells. All samples had either an alloantibody, autoantibody or both identified using non-commercial red cells. **Conclusion**: Inconclusive and/or elusive antibody reactivity patterns with apparent specificity have been observed in some patients when using commercial red cells. When such reactivity is seen, testing of a non-commercial red cell panel may be beneficial before investigating rare or uncommon antibody combinations.

SP235

Severe Immune Hemolytic Anemia, Associated with Anti-piperacillin, Detected by the "Immune Complex" Method

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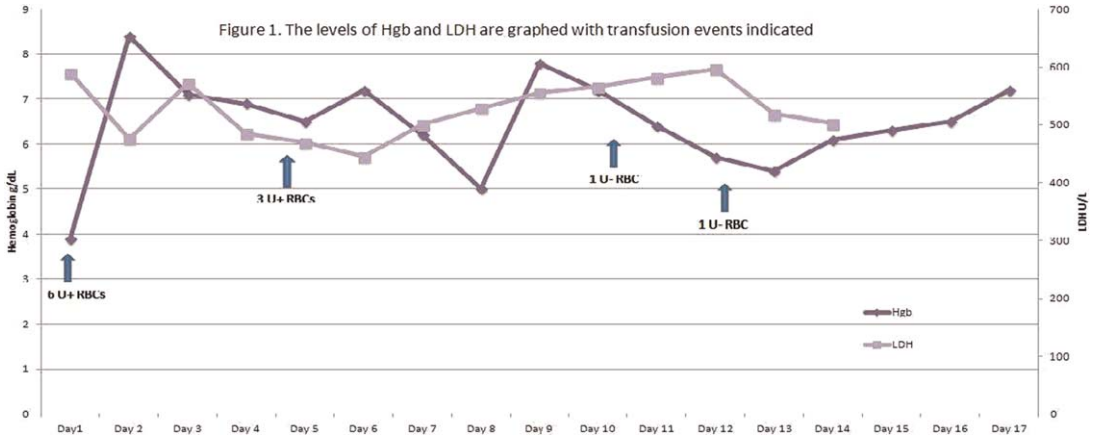
Background/Case Studies: Piperacillin-tazobactam belongs to the β-lactam group of antibiotics. It consists of piperacillin, a broad spectrum semi-synthetic penicillin and tazobactam which is a potent inhibitor of many β lactamases. This latter molecule is known to cause non-immunologic protein adsorption (NIPA) onto red blood cells (RBCs). The combined antibiotic is active against many Gram-positive and Gram-negative bacteria. Several cases of piperacillin or piperacillin-tazobactam-induced immune hemolytic anemia (IHA) have been reported. We present a case of severe IHA with a decreased hemoglobin level to 3,9 g/dl, occuring on day 14, in a seventy two-year-old untransfused woman with a history of chronic respiratory failure. She was treated with piperacillin-tazobactam for a secondary bronchial infection due to *Pseudomonas aeruginosa*. Laboratory studies were performed to determine the presence of piperacillin-dependent antibodies. **Study Design/Methods**: Direct, indirect antiglobulin tests (DAT, IATs) and investigation for piperacillin antibodies were performed in a sample collected on day 16, two days after the discontinuation of the drug. The patient's serum was adsorbed with enzyme-treated allogenic RBCs to remove RBC autoantibodies before testing for drug antibodies. Drug investigation was realized by incubating patient's adsorbed serum and eluate obtained from the patient's RBCs in the presence of the drug against normal donor RBCs that had not been previously treated with the drug (i.e., by the so-called "immune complex" method) . A pool of fresh normal sera was tested as a control for the presence of NIPA. Drugs tested included piperacillin and piperacillin-tazobactam. **Results/Findings**: Serological studies showed a strongly IgG and moderately C3d positive DAT and evidence of a warm autoantibody in the patient's serum by the IAT. An antibody showing a relative anti-RH5(e) specificity, directed against enzyme-treated normal donor RBCs in the presence of piperacillin-tazobactam was demonstrated both in patient's adsorbed serum (titer 128) and eluate (titer 16). The same antibody



titer was also obtained when patient's adsorbed serum was tested in the presence of piperacillin alone. The pool of normal sera did not react in the presence of piperacillin or piperacillin-tazobactam. **Conclusion**: The patient with IHA in this report, was demonstrated to have high titer piperacillin - dependent antibodies. Piperacillin and piperacillin related drugs are thus contraindicated in this patient. There was no evidence of NIPA when piperacillin-tazobactam was tested using the "immune complex" method. As tests using tazobactam singly were not performed in this study, the contribution of NIPA to the patient's hemolytic anemia could not be excluded.

SP236

Autoimmune Hemolytic Anemia due to Anti-U in a Caucasian Female

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Background/Case Studies: A 66-year-old Caucasian female presented to the emergency room with dizziness and vision changes. She was diagnosed with multiple recent occipital infarcts and evidence of remote cerebellar infarcts. She was stabilized and discharged on aspirin. Two days later she returned with fatigue, jaundice, and worsening headache. Lab results were consistent with hemolysis: Hgb 3.9 g/dL, undetectable haptoglobin, elevated bilirubin, and elevated LDH. She had no history of transfusion or pregnancy. Antibody ID panel and direct antiglobulin test (DAT) were both reactive (4+). A sample was referred to the immunohematology reference laboratory. **Study Design/Methods**: Antibody ID and DAT were performed by standard tube methods. Rapid acid eluates were made with Gamma ELU-KIT II(Immucor) and tested by tube. Adsorptions were done using ZZAP-treated autologous RBCs and non-enzyme antigen typed allogeneic RBCs. A sample was sent to an outside lab for DNA molecular genotyping. **Results/Findings**: Initial serologic testing showed strongly reactive panel, eluate, and DAT. Autologous and allogeneic adsorptions were incomplete. A select panel of high frequency antigens showed no reactivity with one Rh null cell. Least incompatible RBCs were recommended and a sample was sent for DNA molecular genotyping. A common panel indicated the patient was C+E-c+e+K-k+Fy(a+b+)Jk(a+b+)M+N+S-s+U+. With additional testing the patient's plasma failed to react with one U- reagent cell. A panel of U- cells was non-reactive, ruling out other antibody specificities. The course of her hospital stay is illustrated in Figure 1. Upon admission she received 6 RBCs resulting in transient elevation of Hgb, which decreased over the next 3 days. On day five, 3 U+ RBCs were transfused. A peritoneal hematoma discovered on day 12 contributed to a drop in Hgb after transfusion of 1 U- unit, with post transfusion Hgb 6.1 g/dL. The bleeding stopped by day 13 and she responded to a second unit of U- RBCs. She was discharged with a Hgb 7.2 g/dL. At follow-up, lab results were: Hgb 9.2 g/dL, LDH 403 U/L, haptoglobin 33 mg/dL. **Conclusion**: This is a case of AIHA due to an autoantibody with anti-U specificity. AIHA due to anti-U has been known to cause severe hemolytic events in 6-13% of cases. Emergency transfusion of incompatible blood may be required until matched blood becomes available. In this case, incompatible transfusions stabilized the patient until U- blood could be given.

SP237

Sample Suitability for Solid-phase Antibody Identification

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Background/Case Studies: Highly sensitive solid-phase antibody detection systems can lead to non-specific reactions and the detection of weak red cell (RBC) autoantibodies. The goal of this study was to determine if sample suitability, as determined by automated hemolysis (HI) and lipemia (LI) indices, affected results of antibody screening (ABS) and identification (AID) performed on these systems. **Study Design/Methods**: One-hundred (100) sequential samples collected in EDTA, submitted for blood group typing and ABS were tested for HI, LI, and plasma sodium (Na) on an automated chemistry platform (Abbott, Abbott Park, IL, USA). ABS was performed using a solid-phase system (Neo, Immucor Inc, Norcross, GA, USA). The same tests were performed on 4 additional groups: (1) Negative ABS (n=20), (2) Positive ABS due to RBC alloantibodies (n=20), (3) Positive ABS due to weak non-specific reactions not attributed to a RBC alloantibody or autoantibody (n=20), and (4) Panagglutinin consistent with RBC autoantibodies (n=19). Na, HI, and LI measurements were compared between these groups. **Results/Findings**: The table shows arithmetic means and 95% confidence intervals for Na, HI, and LI measurements performed on the sequential control specimens and 4 test groups. The number of samples with non-zero HI scores (graded 0 to 4) is also noted. No significant differences were seen between the control and any of the 4 test groups for the

TABLE.

Group	n	HI	HI score >0 (%)	LI	Na
Sequential controls	100	27.0 [20.3-33.7]	29 (29)	4.4 [3.3-5.5]	136.1 [135.5-136.8]
Negative ABS	20	23.8 [13.2-34.4]	6 (30)	3.6 [1.0-4.6]	136.0 [134.4-137.6]
Positive ABS					
RBC Alloantibodies	20	43.3 [14.3-72.3]	7 (35)	4.6 [2.7-6.5]	136.4 [135.0-137.8]
Non-specific Reactions	20	21.9 [12.7-31.1]	6 (30)	5.2 [2.2-8.2]	137.2 [135.9-138.5]
RBC Autoantibodies	19	32.1 [0.0-64.4]	3 (16)	4.3 [0.9-7.7]	137.5 [136.0-152.5]

measurements of sample suitability. In addition, there were no significant correlations observed between HI and plasma Na across the entire study set (n=179, r=-0.1836, p=.07) or within any of the individual test groups. **Conclusion**: There is generally a low degree of clinically significant hemolysis or lipemia in samples submitted for typing and screening as estimated by automated indices. Neither hemolysis nor lipemia appear to influence the rate of weak positive reactions and panagglutinins seen in solid-phase testing. Assessing sample suitability of blood bank samples is operationally feasible using automated chemistry systems.

SP238

A Blood Center's Experience Negating the Serological Interference of Daratumumab

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Background/Case Studies: Daratumumab is an anti-CD38 monoclonal antibody approved by the FDA in November 2015 to treat relapsed or refractory multiple myeloma. CD38 is a type II transmembrane glycoprotein whose primary functions include receptor-mediated adhesion and ectoenzymatic activity in the catabolism of extracellular nucleotides. CD38 is overexpressed on multiple myeloma cells and has a large extracellular domain, making it an ideal target for daratumumab. CD38 is also expressed on other cells including red blood cells. Patients undergoing treatment with daratumumab will exhibit panreactivity on antibody screen and crossmatch compatibility testing. This interference creates a complication in providing safe and timely blood products for patients requiring transfusion support while receiving daratumumab treatment. Our reference laboratory saw its first patient receiving daratumumab therapy in December 2015. **Study Design/Methods**: If testing was requested prior to the patient starting daratumumab we performed an ABO/Rh type, baseline antibody screen, and offered to perform a red blood cell phenotype or genotype at the preference of the referring facility. If testing was requested after treatment was started, we performed an ABO/Rh type, antibody screen with dithiothreitol (DTT) treated reagent red blood cells (rbcs). If the antibody screen was negative with the DTT treated rbcs, we issued ABO compatible, KEL1 negative red cell units. If a genotype had been performed, phenotypically matched red cell units would be issued and testing with DTT treated rbcs would not be performed. In March 2016, we also started testing two samples of cord blood (confirmed positive for the KEL2 and KEL4 antigens) with the patient's plasma in parallel with the DTT treated rbcs to exclude high frequency antibodies from the Kell system if the genotype had not been performed. All red cell units were negative for the KEL1 antigen and issued as crossmatch incompatible due to interference caused by daratumumab. **Results/Findings**: To date we have performed a total of 54 workups on 21 patients referred for pretransfusion testing. On each workup every patient had panreactive antibody screens with all cells tested but negative antibody screens after DTT treating the rbcs; and no reactivity seen when testing the patient's plasma with cord cells. No adverse reactions were reported for any of the transfusions. **Conclusion**: By testing the plasma of patients receiving daratumumab with DTT treated rbcs and cord blood cells, it is possible to exclude clinically significant antibodies with the exception of KEL1. However, the DTT treatment of the reagent red cells takes approximately one hour to complete. If the patient requires urgent transfusion, phenotypically matched red blood cells would be a better option.

SP239

Paroxysmal Cold Hemoglobinuria in an Adult Patient Secondary to Respiratory Syncytial Virus (RSV): A Case Report

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Background/Case Studies: Paroxysmal cold hemoglobinuria (PCH) is a rare form of cold autoimmune hemolytic anemia resulting from a biphasic IgG hemolysin (aka, Donath-Landsteiner antibody). The great majority of cases occur in children, often after a viral or bacterial infection. Cases in adults, historically associated with chronic syphilis infection, are now extremely rare. **Study Design/Methods**: The blood bank was contacted to investigate a case of sudden-onset hemolytic anemia in a 45-year old man following a tandem autologous stem cell transplant for multiple myeloma. During this time, the patient's hemoglobin fell from 122 to 56 g/L over an 11-day period, accompanied by a reticulocyte count of 147 x 10^9/L, an indirect bilirubin of 30 μmol/L, an LDH of 949 U/L, and a haptoglobin $<$ 0.07 g/L. Blood film revealed polychromasia with occasional spherocytes. Urine dipstick reported 3+ hemoglobinuria with detectable protein and urobilinogen. The patient had a history of an anaphylactic transfusion reaction to platelets several months earlier (anti-IgA antibody negative) but had not been transfused any blood product in the month preceding the onset of hemolysis. An RBC transfusion was given and the patient started empirically on high-dose steroids. **Results/Findings**: Patient blood group was O-pos with a negative antibody panel. Direct antiglobulin test was negative with polyspecifc Coombs reagent and no cold agglutinins were detectable at 20C. Using papain-treated cells, the anti-IgG autocontrol was found to be 2+ by immediate spin and after incubation for one hour at room temperature, and weakly positive by indirect antiglobulin test. Additional testing with monospecific reagents detected C3d deposition. Indirect Donath-Landsteiner (DL) antibody testing was positive for biphasic hemolysis. P-negative cells were not available to confirm specificity. Syphilis screen was negative. However, approximately two weeks prior to the onset of hemolysis, the patient had developed an RSV infection confirmed by nasopharyngeal swab. Steroids were discontinued and the patient's hemolysis gradually resolved over the following two weeks. **Conclusion**: The case represents a rare instance of PCH in an adult, and the first case ever reported secondary to RSV infection (two previous case reports in children have been published). PCH should be considered in cases of otherwise unexplained hemolytic anemia in adult patients, even in the absence of syphilis.

SP240

Testing the Limits and Efficiency of Anti-A Titer Testing for Renal Transplant Patients

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Background/Case Studies: Anti-A titer testing is used to monitor patients for potential ABO incompatible kidney transplant. Initial testing at our regional Immunohematology Reference Lab (IRL) followed a standard method provided by a regional HLA Laboratory. The titer studies were completed in parallel as untreated-two-fold serial dilutions and DTT-treated two fold serial dilutions tested with Gp. A1 and Gp. A2 cells. After initial testing was started, the IRL studied if the DTT-treated serum could be stored after treatment then tested the next day, and how many samples could be in a batch of anti-A testing with a single control. The aim of this study is to improve the efficiency of the Anti-A testing. **Study Design/Methods**: EDTA samples from 12 random O+ and B+ donors were chosen from the same draw date. Testing was set into 4 groups. All testing was completed with a standard DTT-treated serum and titration methods. Group A was tested per current protocol. Group B had 3 samples with one control, Group C had 6 samples with one control while Group D had three samples with one control DTT-treated and stored in 1-6C then tested the next day ($>$25 hours). **Results/Findings**: Table 1 summarizes the results of the study groups. The testing worked as expected in all scenarios. Gp A testing and Gp D testing were equivicol, demonstrating no impact on the anti-A titer with the use of stored ($>$25 hours) DTT-treated serum. **Conclusion**: The study demonstrated it was acceptable to DTT-treat multiple samples at the same time using one control. If needed, it is acceptable to store the DTT-treated samples and control in the refrigerator overnight, in case testing can't be completed . There is no time to gain by DTT-treating 6 samples (Group C) compared to 3 samples (Group B). It was preferable to test 3 samples with one control since it is a reasonable amount of tubes to label and test. These updates were implemented in the IRL and have improved the overall efficiency, and timing of the anti-A testing process in our regional IRL.

TABLE. Anti-A Efficency Study

	Method	Avg Timing/Batch
Gp A	1 Sample 1 Cntrl	109 min
Gp B	3 samples 1 cntl	130 min
Gp C	6 samples 1 cntl	260 min
Gp D	DTT-treated stored overnight	Testing Matched Gp A - No difference

SP241

False-negative Compatible Antiglobulin Crossmatches in Patients with an Alloantibody to a Cognate Antigen on Donor Red Cells is Related to Antibody Titer and Red Cell Donor Zygosity

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Background/Case Studies: We have previously reported that patients with a positive indirect antiglobulin test and a clearly identified alloantibody may exhibit a compatible antiglobulin phase cross match with ABO compatible donor red cells phenotypically positive for the cognate antigen . In order to explore this observation further, we characterized alloantibodies by titration and crossmatched against heterozygous and where possible homozygous red cells. **Study Design/Methods**: Patient samples with positive antibody screens and adequate sample volume were chosen for study. The plasma samples were titered using a tube method and heterozygotic red cells. For crossmatching, ABO compatible donor cells were phenotyped to identify the presence of the cognate antigen and determine zygosity. Both heterozygous and homozygous cells were chosen for crossmatching, where possible. Crossmatches were performed using an automated column agglutination method . Crossmatches were dichotomously classified by the device as incompatible or compatible in order to mimic routine practice. **Results/Findings**: Thirteen phenotypically characterized alloantibodies were chosen for evaluation; Four anti-Fya; three anti-E; two anti-D, and anti-K and one each anti-c, anti-M . The antibody titers varied from 0 to 256. Overall 24/75 (31%) of the crossmatches were compatible. Of these 4/17 (23%) were compatible with homozygous cells and 20/58(34%) with heterozygous cells. If the antibody titer was 2 or greater, all homozygous crossmatches were incompatible and if the antibody titer was 8 or greater, all heterozygous crossmatches were incompatible. **Conclusion**: The observation of unexpected compatible crossmatches in patients with a well defined alloantibody is related to antibody titer and donor cell zygosity. Low titer antibodies will frequently yield compatible crossmatches even with homozygous red cells. Since phenotypically negative red cells are always selected for transfusion, this raises the question as to what additional safety is achieved using the AHG crossmatch in patients with well characterized alloantibodies, especially in the context of an urgent need for transfusion

SP242

A Case of cisA_2B_3 Discovered by Family Study

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Background/Case Studies: CisA_2B_3 blood type exists in the part of Japanese and Korean. This blood type was reported that *A* and *B* gene were located on the same chromosome (cis-position: Genotype A_2B_3/O)and both genes were inherited together. We'd report that the case of cisA_2B_3 which was discovered by the family study. Case: A 43-year-old woman who has never been transfused and has never gotten pregnant was periodically following up chocolate cyst. But she was hospitalized with acute pelvic peritonitis, and got an operation few days after. **Study Design/Methods**: Serological test result: We performed a blood typing and an antibody screening test the day before an operation. The typing result by using the column agglutination test (ORTHO BioVue System) was Anti-A(4+), Anti-B(3+), Anti-D(4+), control(0), A1 cells(0) and B cells(w+). For that reason, ABO blood type couldn't be identified. An antibody screening test was negative. We performed some additional tests by using tube method. The test result was Anti-A(4+), Anti-B(3+), Anti-D(4+), control(0), A1 cells(0), B cells(1+), Anti-A1 lectin(0) and Anti-H lectin(4+). For that reason, we suspected AB subtype. An indirect antiglobulin test with B cells was negative with plasma sample and 1+ with serum sample. Family study was performed. And the results were as follows. Mother(AB), Father(B), Compatriot(O). As a result we suggested that cisA_2B_3. **Course**: She needed to have the blood transfusion though a blood type was not identified. She was transfused 10 units (1 unit is made from 200mL whole blood) type O RhD positive RBC and 4 units of type AB RhD positive flesh frozen plasma. We didn't see the side effects by the blood transfusion. Additional test: We conducted additional test another day. The agglutination titer was 128 (control: A1B 512) with monoclonal anti-A(Wako, Japan) and 128 (control: A1B 256) with anti-B (Wako, Japan).We didn't detect anti-A using the patient plasma/serum at the immediate spin (IS) phase and the indirect antiglobulin (IAT) phase. The titer of anti-B in the patient plasma was 2 at IS phase and <2 at IAT phase. But the titer of anti-B in the patient serum was 2 at IAT phase. **Results/Findings**: A and B glycosyltransferase could not be detected in her serum. We identified that the patient was a cisA_2B_3. **Conclusion**: We could discover a cisAB phenotype by carrying out the family study and the serological test. It's important to collect the patient information to identify the blood subgroups.

SP243

Novel Mutation in GTB Flexible Loop Affects B Antigen expression

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Background/Case Studies: Glycosyltransferases (GT) A and B are responsible for the synthesis of A and B antigen in ABO blood group. High resolution structures of GTA and GTB revealed the internal flexible loop (amino acids 179-194) is involved in the multistage process of substrate binding. However, the mechanism of ABO subgroup with mutations in the loop has not been extensively explored.By in vitro eukaryotic system, we evaluated the B antigen expression associated with a novel B subgroup mutation located in the loop. **Study Design/Methods**: Serologic investigations including serum B transferases activity assay were performed in a Chinese individual and his family members with standard methods. Saliva of ABx members was determined for water-soluble ABH antigens by agglutination inhibition tests. DNA sequences of all 7 exons and exon-intron boundaries of ABO gene were analyzed using genomic DNA by polymerase chain reaction (PCR) and sequencing. Flow cytometric analysis of B antigen expression on RBCs and HeLa cells transfected with mutant plasmid were also performed, as well as B transferases activity assay in cell supernatant. Cell agglutination intensity was compared by direct microscopy after adding anti-B antibody to the Hela-Bx cells. **Results/Findings**: ABx phenotypes were detected in the proband and his father by serologic typing. The ABx samples displayed Bw-like patterns by flow cytometric analysis using anti-B antibody, consistence with the serologic typing. Plasma from both ABx samples in this study showed almost no B-transferase activities (titer:<1) and the soluble B antigen level in saliva of the proband and his father was obviously lower (both of the titers:64) than that of B secretor (tite:2). A novel allele *Bx11* (538C>T; R180C) was identified by DNA sequencing and sequencing after cloning in the father and son. The B antigen remarkably declined on cell surface upon ectopic expression of *Bx11* cDNAs in the Hela cells, and B transferases activity significantly reduced (titer: 32) in cell supernatants compared with the wild tpye B control (titer: 1024). Decreased cell agglutination was also observed by direct microscopy, which mimicking the weak agglutination of RBCs detected in ABx father and son. **Conclusion**: We report for the first time that 538C>T mutation represents a new molecular basis for the B_x blood subgroup. Amino acid residue Arg180, which is located on the edge of internal disordered loop, may play a critical role for the shift of GTB's three conformations when the enzyme catalyses the synthesis of B antigen.

SP244

Clinical Significance of Panreactivity with Solid Phase Automated Antibody Screening

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Background/Case Studies: The use of automated solid phase antibody testing is associated with specimens that show panreactivity which disappears when tested using tube methodology. These patients may or may not have underlying alloantibodies. The clinical significance of the solid phase panreactivity phenomenon is poorly understood. This study was undertaken to determine the incidence of solid phase panreactivity at our institution. We also examined the transfusion reaction reporting rate in these patients following blood component transfusion and the incidence of new clinically significant alloantibodies in patients who had follow-up type and screen testing performed following red blood cell transfusion. **Study Design/Methods**: Data was collected on all patients undergoing type and screen testing from 1/1/2009 to 12/31/2015. The study population consisted of all patients with solid phase panreactivity with or without concurrent clinically significant alloantibodies. Patients who also had panreactivity using tube methodology or any evidence of autoantibody reactivity were excluded. Study patients who were transfused following the identification of solid phase panreactivity were evaluated to identify any reported transfusion reactions following the transfusion of any blood component. In addition, patients who received a red blood cell transfusion and had antibody screening 8 or more days following the transfusion were also evaluated to determine the incidence of the formation of new alloantibodies. **Results/Findings**: A total of 76,051 patients underwent type and screen testing within the study period. Of these, 0.7% (524/76,051) demonstrated solid phase panreactivity. Of these 524 patients, 92% (480/524) had isolated solid phase panreactivity and 8% (44/524) had

solid phase panreactivity and a concurrent clinically significant alloantibody. Amongst all 524 patients with solid phase panreactivity, 145 subsequently received transfusion of 1551 blood components. The transfusion reaction reporting rate was 2% (28/1551). This rate was significantly higher than the transfusion reaction reporting rate of 1% for the entire hospital within the same time period ($p=0.008$). A subset of 98 of the transfused patients with solid phase panreactivity received at least one red blood cell transfusion followed by repeat type and screen testing at least 8 days following transfusion. Of these, 9% (9/98) subsequently developed new alloantibodies. **Conclusion**: Our data suggest that patients with solid phase panreactivity have higher rates of reported transfusion reactions and may be at an increased risk for developing subsequent alloantibodies.

SP245

Prevalence of Antibodies to Human Leukocyte Antigens Detected During Red Cell Antibody Investigation

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Background/Case Studies: The Bennett-Goodpeed (Bg) antibodies anti-Bg^a, -Bg^b, and -Bg^c are directed toward HLA-B7, HLA-B17, and HLA-A28/A2, respectively. The detection of these usually benign antibodies can contribute to delays in transfusion by lengthening the antibody identification process. This study was undertaken to determine how frequently Bg antibodies are detected during red cell antibody investigation within various patient populations served by our transfusion service. **Study Design/Methods**: A retrospective analysis of 3,620 patient alloantibody reports was performed, and the following data were collected: presence of Bg antibodies, additional allo- or auto-antibody(ies) identified, patient gender, date of birth, and date the antibody workup was resulted. A subset of antibody reports completed over a period of two years was analyzed, and the following additional information was collected: patient admission location, testing media used for antibody screening, test kit lot numbers, and units of packed RBCs transfused with emergency-released status while awaiting the finalized antibody identification results. **Results/Findings**: Of 3,620 patients with antibodies identified within a period of seven years, anti-Bg antibodies were found in 369 patients (prevalence=10.2%). Anti-Bg antibodies reported as a patient's single alloantibody specificity occurred in 196 patients (53.1%), and in combination with other antibodies in 173 patients (46.9%). Anti-Bg antibodies were reported in 318 females (86.2%) and in 51 males (13.8%). Additional HLA antibodies identified as part of investigation of platelet refractoriness occurred in 20 patients with anti-Bg antibodies (5.4%). In the subset of antibody workups performed within the most recent two-year window, anti-Bg antibodies were detected in 91 patients. Of these, 65 were detected with a solid phase method (71.4%), and 26 were detected with the traditional tube technique using polyethylene glycol enhancement media (28.6%). Within the two-year subset, seven patients were transfused with emergency-released packed RBCs prior to the conclusion of antibody identification (7.7%). **Conclusion**: The presence of anti-Bg antibodies contributes to the difficulty and length of the antibody identification process from several hours to days, particularly when autoantibodies and/or additional alloantibodies are present. Cases referred to a reference laboratory carry the potential for causing delays in transfusion and the need to issue emergency-released blood pending the conclusion of the workup. Knowledge of the prevalence of Bg antibodies detected in the various patient populations tested at our facility assists the antibody identification process and facilitates the triage of specimens for referral testing.

SP246

Titers of Blood Group B Patients Using Non-A1 Reagent/Donor Cells for ABO Incompatible Kidney Transplantation

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Background/Case Studies: Blood group B patients are eligible to receive offers from non-A1 or non-A1B kidney donors. Current practice in many institutions involves using A1 reagent cells to perform ABO titers for prequalification of patients. Since non-A1 cells express weaker antigenicity than A1 cells, "Why would surrogate ABO titer testing include target cells with higher antigenicity than the donor organ?" **Study Design/Methods**: A comparison was done to determine the significance of A1 vs non-A1 titers in potential "non-A1/non-A1B donor to B patient transplants". Parallel ABO titer testing was performed on 63 patients using A1 and non-A1 reagent cells. Pre-transplant titers were performed using donor cells, non-A1 reagent cells, and A1 reagent cells on 17 sample sets. Post-transplant outcomes were analyzed on 16 patients who received non-A1 kidneys with a low titer using non-A1 reagent cells (≤ 4), a higher titer using A1 reagent cells (>4), and a low titer using non-A1 donor cells (≤ 4).
Results/Findings:

a. A1 Pre-titer IgM was 3.0X higher than non-A1 Pre-titer IgM
b. IgM score of A1 was 1.6X higher than IgM score of non-A1
c. A1 Pre-titer IgG was 4.3X higher than non-A1 Pre-titer IgG
d. IgG score of A1 was 2.1X higher than IgG score of non-A1

Titers using non-A1 donor cells were comparable to the titers using non-A1 reagent cells. Post-transplant data revealed 15 patients are doing well and 1 expired 1 month post-transplant with unknown cause of death. **Conclusion**: Blood group B patient titers against non-A1 reagent cells or non-A1 donor cells were generally low and, as expected, A1 titers were generally higher. If the A1 titer results were used by transplant centers for prequalification for inclusion in the "non-A1/non-A1B donor to B patient" transplant program, patients would have been excluded. We conclude that the results of using

TABLE. Titers

Pt	IgM Titer			IgG Titer		
#	Non-A1 Donor Cells	Non-A1 Reagent Cells	A1 Reagent Cells	Non-A1 Donor Cells	Non-A1 Reagent Cells	A1 Reagent Cells
1	2	1	16	0	0	2
2	2	4	32	4	2	16
3	0	4	16	0	2	16
4	2	2	16	1	1	16
5	4	2	8	8	4	16
6	4	4	8	2	2	2
7	0	2	16	0	4	8
8	4	2	16	2	1	8
9	4	2	8	2	1	4
10	4	4	32	2	2	16
11	0	2	16	0	1	4
12	2	4	16	4	2	16
13	1	1	8	0	0	4
14	1	2	8	1	1	4
15	2	4	32	1	1	16
16	4	4	16	2	2	8
17	2	2	32	1	2	8

A1 titers for B patients receiving non-A1 kidneys do not appear to be clinically significant.

SP247
Use of a Low Volume Dual Phase Tube/Gel Method
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Background/Case Studies: High incidence antigen screening is necessary to provide compatible blood for transfusion. Laboratories often prioritize high incidence antigen screening according to need and available antisera. Our lab had three anti-Lan cases. This provided a supply of anti-Lan and a future potential need for Lan- units. Hybrid PEG/gel method has been used to enhance antisera reactivity and allow limited supply of antisera to be extended, that method used 100 ul of antisera and 100 ul of PeG. Monoclonal anti-K is routinely used to confirm units K- status for transfusion of patients that have made anti-K. With this in mind our lab developed a low volume dual phase hybrid tube/gel method using salvaged monoclonal anti-K and human anti-Lan plasma to test for both antigens simultaneously. **Study Design/Methods**: Upon completion of routine K type confirmation, negative test tubes were collected, pooled, and spun to salvage monoclonal anti-K. Human source anti-Lan was diluted (1:500 in our case) using salvaged monoclonal anti-K. The resulting dual phase anti-K,-Lan contained direct reactive monoclonal anti-K and indirect antiglobulin reactive human source anti-Lan. The K antigen was tested first at room temperature where anti-Lan was non-reactive. For those that were K negative, this was followed by the indirect antiglobulin test for Lan. Approximately 25 ul of washed 2-5% cell suspension was added to 50 ul (one drop) of anti-K,-Lan. This was incubated for 2-5 minutes, spun and read. The K+ units were tested for k. These units were reported as (K+k+) or (K+k-) and evaluation was completed. 50 ul of MTS diluent 2 (Micro Typing Systems, Pompano Beach, FL) was added to K- samples and incubated at 37C for 15 minutes. The entire contents of the tubes were transferred to positions on labeled MTS anti-IgG Gel cards, spun and read. These units were reported as (K-, Lan+) or (K-, Lan-) and evaluation was completed. **Results/Findings**: The 6820 units evaluated had the following phenotypes: 6205 (90.98%) K- Lan+, 602 (8.83%) K+k+, 12 (0.18%) K+ k-, 1 (0.01%) K- Lan-. This method reduced the number of tests by 50% (13640 vs 6820) by eliminating need to test two antigens separately. It also reduced amount of antisera needed by 50% (50ul antisera by current method vs. 100ul previous hybrid method). Additionally one Lan- was found (confirmed by manufacturer) that ironically was a panel cell selected as a positive control. **Conclusion**: The development of a low volume dual phase hybrid tube/gel method using salvaged monoclonal anti-K and human anti-Lan plasma decreased use of reagents, total number of tests conducted, technologists' time performing tests, increased number of Lan system antigen types performed by our laboratory, and demonstrated effectiveness of the dual phase method to type for a low and high incidence antigen in the same tube/test system.

SP248
Standardized Blood Group A Kodecytes Allow for Determination of Anti-A,B Titres without the Need for Sample Dilution
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Background/Case Studies: There is a need for accuracy in determination of ABO antibody levels, particularly for A_2 to O kidney transplantation, as antibody levels determine eligibility for transplant. Additionally exclusion of hemolytic antibodies from blood components for transfusion and intravenous immunoglobulin preparation is necessary. Quantification of ABO antibodies by titration produces variable results between testing centres (inter laboratory) and assays (intra laboratory), probably due in part to a lack of a standardised cell. Current methods use natural cells for indicators, but the level of ABO antigen on these cells is unknown and uncontrollable. However kodecytes (RBCs modified with function-spacer-lipid constructs) have been established to have known and standardized levels of ABO antigen expression. **Study Design/Methods**: Two plasma samples with high levels of anti-A,B were used neat, and diluted to represent medium and low titres, for evalution of kodecyte panels. An 11 cell kodecyte panel ranging from 80 - 0.5 μmol/L of A type 2 antigen was prepared. Kodecytes were tested against these plasma samples to select those that would give a distinct pattern for the different levels of antibody. A further 20 group O plasma samples were assayed by conventional tube technique (Tube) and column agglutination technology (CAT), by direct (saline) and Indirect Antiglobulin Technique (IAT), and assessed for significance with the *t* test. Indicator cells used were both natural A_1 cells (tested against plasma dilutions) and the selected three cell A kodecyte panel (tested against undiluted plasma). **Results/Findings**: The kodecyte panel profiling found the three concentrations of FSL-A that would give reactions of + + + with high level antibodies, + + 0 with medium level antibodies and + 0 0 with low level antibodies were 80, 10 and 2 μmol/L of A type 2 antigen. Analysis of the 20 samples showed methodological inconsistencies in determining (IAT) titres with natural A_1 cells, which showed up to three dilutions variance between Tube and CAT ($p=0.07$). In contrast kodecytes showed good correlation between CAT and Tube by IAT ($p=0.46$). There was no statistically significant difference in assignment of IAT antibody levels between kodecytes and A_1 cells by CAT ($p=0.18$) or Tube ($p=0.19$). However, only 70% of samples were assigned exactly the same level of high, medium or low when kodecytes or A_1 cells were used. Extended validation assays are in progress. **Conclusion**: In three reaction tubes kodecytes could determine if undiluted plasma contained high, medium or low level of anti-A,B and as kodecytes can be standardized it is expected this result would be reproducible both inter and intra laboratory.

SP249
Importance of the Du Test in Blood Transfusion
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Background/Case Studies: The Rhesus D (RhD) antigen is expressed on the surface of red blood cells (RBCs). The Rh antigens are highly immunogenic and the individuals who do not express the D antigen on RBCs generate antibodies (anti-D) upon blood transfusion with D antigen on transfused RBCs causing a hemolytic transfusion reaction. For this reason, current practice requires RBCs of first time blood donors to be tested for D antigen using two potent agglutinating anti-D reagents and a sensitive automated method. Subsequent donations need to be confined with only a single potent anti-D. The term Du is now redundant and has been replaced by the term weak D, which defines any D phenotype where the expression of D antigen is quantitatively weaker than normal. As red cells expressing qualitatively different D antigens may also give weak reactions with some anti-D antigens. This whole area of blood grouping has been a source of great confusion over many years. **Study Design/Methods**: A retrospective study was conducted from January 2015 to March 2016. In total 11,294 blood grouping samples including 5,182 donors and 6112 patients were tested for Du in the Galileo device using potent antibodies D1 and D2 for RhD typing. Any blood donor sample that was typed RhD negative by the slide or rapid tube method was tested further by an indirect antiglobulin technique. If both tests were negative the donor sample was considered Rh negative. If the donor sample tests came positive in any phase of RhD testing the sample was considered Rh positive. **Results/Findings**: Out of 5,182 blood donor samples 4,944 were positive and 238 were negative. Du test was performed on all the 238 negative samples using antiglobulin technique. Out of 238 samples 236(99.2%) were Du negative and 2(0.8%) were Du positive. Out of 6112 patient samples 5628 were positive and 484 were negative. Du test was performed on all the 484 negative patient blood samples using antiglobulin technique. Out of 484 samples 471(97.3%) were Du negative and 13(2.7%) were Du positive. **Conclusion**: Study showed if Du test was not performed on donor samples 0.84% of negative samples could have been missed and wrongly marked as RhD negative. Policies regarding D typing procedures and selection of blood components for transfusion should be based on the patient population, risk of immunization and limited supply of D negative blood components. Anti-D is clinically significant antibody and preventing immunization in females of child bearing potential is important to avoid the complication of hemolytic disease of newborn. The complications of anti-D in other patients are less serious and therefore decisions to transfuse Rh positive or Rh negative blood should be considered individually.

SP250
A Lean Approach: Lot Qualification of the Antibody Screen Prior to Distribution for Testing
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Background/Case Studies: Our facility uses solid phase testing on the Immucor Echo as the primary method of antibody screen testing in 4 transfusion service laboratories. We observed significant variability in equivocal results between lot numbers of the Ready Screen 3(RS3). This resulted in significant re-work, in terms of samples requiring evaluation by different methods. It also resulted in slower turn- around of blood products to patients. We decided to pursue lot qualification of the RS3 reagent strips prior to release for testing. **Study Design/Methods**: New lots of RS3 strips are

placed into quarantine during lot qualification. The reagents are then tested on one of 2 designated instruments. After performing QC, a sensitivity check is done using 5 previously-frozen samples with known antibodies. If the screening pattern matches that of the antibodies, the RS3 strips advance to a specificity check. If, however, the sensitivity check results in 10 or more equivocal results, the lot is set aside and the company is contacted for technical support/troubleshooting. The specificity check is performed by testing 200 samples per lot. Any positive or equivocal result is further tested using gel and tube-PEG methods. Two positive tests (out of the 3 methods used) is considered true positive. Positive testing found with only solid phase is considered a false positive. A negative test on solid phase is considered to be a "true" negative. The percent specificity is then calculated. A lot that has a specificity check less than 90.7% is not used. A lot with specificity between 90.7% and 95% is closely monitored for performance. **Results/Findings**: We have been performing this testing since March 2015, and have tested 18 lots of RS3 reagent strips. Of these, all passed the sensitivity check. One of 18 lots was rejected due to a specificity check less than 90.7%. Six of 18 lots had specificity between 90.7% and 95%; all 6 were kept when it was determined that the problem was outside of the strip quality (unstable indicator cells, dirty wash manifold or probe). **Conclusion**: Value to the customer means that an activity must be done correctly the first time. By performing lot qualification of the RS3 screening strips, we believe we have improved the value of our testing by identifying performance issues prior to placing a lot into use. Abnormally high numbers of equivocal results are addressed quickly and before impacting transfusion support to a patient. Furthermore, a standard approach to lot qualification has allowed us to discern other factors that can lead to an unexpected number of equivocal results. These include unstable indicator cells and mechanical issues such as a dirty wash manifold and probe. We hope that the dialogue that this effort has generated with Immucor will ultimately benefit all who use this technology for patient testing.

SP251

Typing Red Blood Cells for JK, FY and Ss Blood Group Antigens was not Impaired by a Positive Direct Antiglobulin Test when Using the Lateral Flow Technique

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Background/Case Studies: Serological typing of blood group antigens is commonly done with the hemagglutination test. Red blood cells (RBC) are incubated with antiserum and the specific antibodies bind to the blood group antigens. IgM antibodies can directly agglutinate, thereby showing the presence of the blood group antigen on the RBC tested. IgG antibodies, in contrast, may bind to the blood group antigens but cannot span the distance between the RBC. To cause agglutination, the antiglobulin technique is required for blood group typing with IgG antisera. For this reason, RBC already coated in vivo with IgG autoantibodies are difficult to type with IgG antisera. Even after cell sparing elution steps, phenotyping of such cells most often is not reliable. Recently, the lateral flow technique was refined to type RBC for Fy^a, Fy^b, Jk^a, Jk^b, S, and s. RBC are pipeted onto the center of a membrane and get flushed with rinsing solution to the periphery. The antisera are deposited at six from the center equidistant locations. Antigen-positive RBC reaching the antiserum are captured in a visible line, whereas antigen-negative RBC are rinsed through. IgM and IgG antisera, but not the antiglobulin technique, are part of the test system. Thus we investigated whether a positive direct antiglobulin test (DAT) interferes with phenotyping with the lateral flow technique. **Study Design/Methods**: Samples from 10 patients with a reactive DAT (2+ to 4+) were typed for Fy^a, Fy^b, Jk^a, Jk^b, S, and s with the MDmulticard Basic Extended Phenotype from Grifols: 100 µl of diluted blood were dropped onto the card and rinsed with 300 µl of rinsing solution. After 5 minutes the cards were rinsed again with 300 µl. After 10 minutes the reactions were evaluated. For comparison, all samples were typed with the gel card and the tube method using commercially available antisera. For control all samples were genotyped by SSP. **Results/Findings**: The reactive DAT did not interfere with the lateral flow technique. All samples were typed correctly for Fy^a, Fy^b, Jk^a, Jk^b, S, and s, as confirmed by SSP-PCR. In contrast, when the samples were tested with IgG antisera, the tube or gel card method gave false positive results. **Conclusion**: In this small preliminary study the lateral flow technique was not prone to false positive results when red cells with a reactive DAT were phenotyped. However, further studies and the use in routine testing are needed to confirm this finding.

SP252

Controlling Antigen-Antibody Mediated Hemolysis by Manipulating the Amount of Antigen on the RBC Surface on Heterophile Kodecytes

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Background/Case Studies: Hemolysis is a well known serological reaction that is not commonly observed in modern transfusion laboratories, yet it underpins one of the most important serological processes. Today observation of complement activity is usually only from diagnostic signatures of complement activation secondarily detectable on RBCs. Progression to lysis of the RBCs is no longer observed with anticoagulated samples due to the inhibition of the complement cascade by chelators. Although this important reaction has been side-lined, the ability to recognise hemolysis, and to prepare controls with varying levels of complement signatutures (e.g C3d) remain useful to transfusion medicine. Current in vitro antibody-antigen hemolysis methods such as the CH_{50}, which utilise sheep RBCs and rabbit heterophile antibodies, are difficult to standardise. **Study Design/Methods**: Heterophile kodecytes were created with human group O RBCs modified with FSL-Galili function-spacer-lipids at concentrations ranging from 340 to 7 µmol/L. These kodecytes were incubated for 1 hour at 37°C with undiluted pooled human serum containing active complement and naturally present complement-activating anti-Galili. After incubation the supernatant was sampled for measurement of hemolysis (Drabkin's method) and compared against an artifically made calibration curve to calculate percentage lysis. This heterophile kodecyte method was compared with the standard CH_{50} method, which uses sheep RBCs sensitised with rabbit anti-sheep RBC, and was tested against human serum dilutions to determine complement activity. **Results/Findings**: Heterophile (Galili) kodecytes were reproducibly created from human RBCs. These kodecytes produced a full range of quantifiable reactions ranging from 10-100% hemolysis, with inter- and intra-assay variation of less than 10%. This method, when contrasted against the CH_{50} assay, showed virtually identical sensitivity. However unlike the CH_{50} method which uses antibody presensitised RBCs, the kodecyte method utilizes the instrinsic heterophile antibodies present in the sample. As a consequence the kodecyte method is dependent on both heterophile antibody levels and complement in a sample, and thus is not suitable to measure complement activity in individuals. This method together with a standardized stored serum sample was used to re-evaluate the storage stability of complement. **Conclusion**: Kodecytes can be created that will controllably hemolyse in the presence of undiluted human serum. This method is potentially useful to create examples of antibody mediated hemolysis for teaching purposes, or hemolysis standards, or for investigative purposes such as measurement of complement activity in stored samples.

SP253

Antibodies of Undetermined Significance in Solid-phase Technology, Exploring Incidence, Associated Patient Factors and Laboratory Impact

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Background/Case Studies: Detection of antibodies of undetermined significance/specificity (AUS) increases testing time, complexity and resources and can result in delayed transfusion. AUS are often detected following implementation of solid-phase technology and may be due to increased sensitivity of this testing platform. There is a paucity of evidence surrounding AUS incidence, natural history and associated patient factors. This study aims to determine frequency of AUS and other antibodies detected using solid phase technology; to report on the number and type of reflective tests performed by the laboratory; to reach a conclusion of AUS; and, to identify associations between patient factors and positive AUS results. **Study Design/Methods**: We conducted a retrospective review of Transfusion Medicine Laboratory antibody records at a large academic institute. All patients undergoing an antibody screen from January 1 2014 until December 31 2014 were included. Data were extracted from a network of databases and included variables on patient demographics and laboratory test results. AUS was defined as a positive antibody screen result using solid phase that was not an antibody whose specificity could be identified, passive antibody,

warm autoantibody, or cold agglutinins. We analyzed AUS results by patient age and sex. **Results/Findings**: Our study includes a total of 37,382 patients: 23,711(63.4%) female and 13,671(36.3%) male. Mean age was 50.4 years(SD23.5), female 46.9(SD22.5) and male 56.6(23.9). AUS were detected in 1,956(3.5%) of 54,373 samples. In patients without AUS, an average of 1.07 tests related to antibody-investigation were conducted compared to 1.55 tests in patient with an AUS. Of 720 patients with AUS, 513(71.3%) female and 207(28.7%) male. The frequency of AUS was significantly higher in female patients (2.2%) compared to males (1.5%); absolute difference 0.7%, 95% CI(0.4%-0.9%);($p<0.0001$). Age did not show variation in frequency between sexes. Frequency of other alloantibodies was calculated and the combination of AUS and Anti E was most common. Patients with an alloantibody were ~7 times more likely to have coexisting AUS compared to patients without. **Conclusion**: AUS lead to increased testing and use of resources. They are seen more frequently in females. Additional investigations are required to better understand related patient factors and elucidate natural history.

SP254

Evaluation of Red Blood Cell Antigen Genotyping Platforms (ID CORE XT) using Red Blood Cell Phenotype Matching for Transfusion Medicine Practice

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Background/Case Studies: Genotyping platforms enable simultaneous analysis of multiple polymorphisms for blood group typing. ID CORE XT is a genotyping platform based on Luminex® xMAP technology for simultaneous determination of 37 red blood cell (RBC) antigens. **Study Design/Methods**: In this study, the performance of ID CORE XT was evaluated using the ID-Antigen Profile (Bio-Rad Laboratories, USA) as the reference for comparison of 17 antigens (C,c,E,e,Lu^a,Lu^b,k,Kp^a,Kp^b,Jk^a,Jk^b,M,N,S,s,Fy^a,Fy^b). DNA was extracted from whole blood in EDTA with Qiagen methodologies. 96 previously phenotyped samples were processed per assay: 87 testing samples plus 5 positive controls and 4 negative controls. **Results/Findings**: Results were available for 208 samples. Agreement between the tests and reference methods was 99.5% for ID CORE XT (3442/3459 antigens determined). There were 17 discrepancies in antigen results in 8 RBC samples, most of which could not be investigated due to lack of sufficient sample to perform additional tests. The total hands-on time was 40 minutes for a batch of 16 samples. Compared with the reference methods, ID CORE XT was simpler to use and had shorter processing times. **Conclusion**: ID CORE XT genotyping platforms for RBC systems were accurate and user friendly in transfusion laboratory settings.

SP255

Managing Routine Antenatal Anti-D Prophylaxis (RAADP) in Red Cell Antibody Screening Samples at 36 Weeks of Pregnancy

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Background/Case Studies: Most antenatal screening protocols do not include antibody screening after 28 weeks as it is assumed that antibodies that become detectable after that do not cause severe HDN. In our country, a 36 week screening sample has traditionally been included in the national protocol. When RAADP was introduced in 2014 (1,250-1,500 IU at 28-30 weeks to women carrying an RhD positive fetus), information on the late onset antibodies was still considered important for remote delivery hospitals because of transfusions or postnatal care. As it is impossible to differentiate between prophylactic and immune anti-D, an additional screening test at 36 weeks was required for RhD negative women receiving RAADP. This study was performed to assess the ability of the new screening test to detect late developing transfusion related antibodies without increasing the number of identifications required or missing high-titer anti-D immunizations requiring intervention. **Study Design/Methods**: All 36-week screening samples were tested using two RhD positive screening cells (O1 and O2) (by LISS/Coombs gel cards; Bio-Rad, Switzerland). If the reaction strength was a weak positive ($\leq$1+), an additional RhD negative screening (O4, O5, O6) was performed. Samples where the reaction strength was 2+ by gel technique were subsequently screened with the same cells by the tube technique. If reaction strength in the tube test was weak positive, the sample was screened with O4, O5, O6 cells, and antibody identification was only carried out when reaction strength in the tube test with O1, O2 was $\geq$1+. Antibody identification was performed with gel cards and titers were determined with the tube method. **Results/Findings**: In the first two years, the 36-week screening test was positive in 6,362 of 11,589 (55%) RhD negative mothers. In 5,525 (87%) cases, the additional RhD negative screening test was performed, with clinically significant antibody identified only in two cases (anti-Jka, -S). In 837 (13%) cases, antibody identification was performed. Immune anti-D was detected in 12 samples: in six mothers not receiving RAADP (titers 1 to 16), in four mothers receiving RAADP (titers 4 to 32), and in two cases with no information on RAADP (titers 1 and 16). In all cases with an anti-D titer of $\geq$8, the reaction strength of the O1 or O2 cells was $\geq$3+. No other clinically significant antibodies were observed. **Conclusion**: Use of an additional 36-week screening test is feasible in detection of late developing transfusion related antibodies without increasing the number of identifications. However, formation of new antibodies other than anti-D in the third trimester seems to be extremely rare. With a cut-off level $\geq$3+, no high titer anti-D immunizations requiring interventions will be missed.

SP256

Algorithm for Management of Patients with Warm Autoantibodies in Taiwan

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Background/Case Studies: Pre-transfusion testing for patients with warm autoantibodies represents a challenge and requires special procedures, including multiple absorptions and complete phenotyping. We advocate a local modified protocol that takes account of blood group antigen distributions of Taiwanese to streamline the pre-transfusion testing cost-effectively without compromising transfusion safety. **Study Design/Methods**: Given the blood group distribution frequency of local population, we perform phenotype study of Rh and Kidd antigens and provide Rh- and Kidd phenotype matched units for patients with warm autoantibodies. Thirty adult patients with warm autoantibodies (August 2014 to July 2015) were tested and received transfusions according to this modified policy. **Results/Findings**: Thirteen of 30 patients demonstrated preexisting alloantibodies (43.3%). Twenty-four patients were typed for Rh and Kidd antigens and received prophylactic antigen-matched units. Six patients whose Kidd blood phenotypes could not be determined due to frequent transfusions received Rh antigen-matched units. These 30 patients totally received 702 units of donor red cells (range 2-116 units/patient, mean 23.4 units/patient) during the study period (In Taiwan, one unit of red cells is derived from 250 mL whole blood, equal half western standard unit). All patients had expected post-transfusion increments in hemoglobin and hematocrit levels. **Conclusion**: We instituted a protocol for local patients with warm autoantibodies with limited phenotype-matched transfusion. Our algorithm simplified the pretransfusion work-up while maintain adequate transfusion safety for local patients.

SP257

Alloanti-Fy^b in a Fy(a-b-) Patient Homozygous for GATA Mutation

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Background/Case Studies: Duffy system antibodies can cause transfusion reactions and hemolytic disease of the fetus and newborn. The Fy(a-b-) phenotype in people of African descent is associated with a mutation in the GATA erythroid promoter motif c.−67t>c which silences expression of Fy^b in RBCs but not in nonerythroid tissues. Individuals who are homozygous for the GATA mutation are not predicted to make anti-Fy^b. We report the case of an African American woman homozygous for the GATA mutation whose plasma and eluate contained alloanti-Fy^b and additional alloantibodies after transfusion of Fy(a-b+) units. **Study Design/Methods**: All tests were performed by tube methods. Indirect antiglobulin tests (IATs) were performed using untreated and 0.2M dithiothreitol-treated RBCs with PEG and ficin-treated RBCs. Antigen typing was performed by standard methods. Acid eluates were prepared with the Gamma Elu-Kit II (Immucor). Genomic DNA was isolated from WBCs. HEA PreciseType was performed according to manufacturer's instructions. Amplification and sequencing of *FY* coding exons 1-2 and a portion of the promoter region was performed. **Results/Findings**: On initial investigation, the patient was 9 days post transfusion having received two D-negative units;1 historically E-, K-, Fy(a-), Jk(b-) and 1 extended phenotype unknown. The patient's RBCs were DAT negative and her plasma contained anti-E, -K, -Fy^a, -Jk^b, -S, -M and HLA antibody by the IAT. The patient's microhematocrit separated reticulocytes typed E-, c+,

C+, e+; K-: Fy(a-b-); Jk(a+b-); M-, S-, s+. HEA Beadchip analysis confirmed the serologic antigen typings and indicated the patient had the GATA mutation. Two E-, K-, Fy(a-b+), Jk(b-), M-, S- units were transfused. Five days post transfusion, her RBCs were DAT+ (IgG and C3) and an eluate contained anti-M, anti-Fy^b and 2 unexplained reactions. The plasma contained anti-Fy^b, anti-Do^a and the previous HLA antibody. The previous anti-Fy^a was not detected and no testing was performed to detect the other alloantibodies. Subsequently, it was discovered the patient had a history from an out of state facility of anti-E, -K, -Js^a, -Fy^a, -Fy^b, -M, -S, -Do^a and HLA antibodies. *FY* sequencing confirmed the HEA PreciseType results, *FY*02/*02* and −67c/c (*Fy*02N.01/*02N.01*) and no additional changes were found. **Conclusion**: Investigation of a reported delayed transfusion reaction demonstrated the patient's eluate and plasma contained alloanti-Fy^b in combination with additional antibodies following transfusion of E-, K-, Fy(a-b+), Jk(b-), M-, S- units compatible with the patient's plasma. *FY* sequencing confirmed the patient was homozygous for the GATA mutation with no additional changes detected. The production of anti-Fy^b remains unexplained. There are anecdotal reports of similar cases, however a biological explanation has not been reported.

SP258

Persistence of Red Blood Cell Alloantibodies after Non-myeloablative Stem Cell Transplant for Sickle Cell Disease

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Background/Case Studies: Allogeneic stem cell transplantation is the only available curative option for sickle cell disease (SCD). Many SCD patients have red blood cell (RBC) alloantibodies. We sought to determine whether RBC alloantibodies persisted post-transplant in our cohort. **Study Design/Methods**: An alemtuzumab/total body irradiation (300 cGy) regimen with sirolimus as post-transplantation immunosuppression was used for 16 patients receiving HLA-matched sibling donor transplants. Recipient alloimmunization history was reviewed; recipients and donors had molecular RBC phenotyping prior to transplant. Prospective donors who expressed a RBC antigen to which a recipient had a circulating alloantibody were avoided. ABO/Rh typing, antibody screening and identification were performed by standard methods. Two recipient/donor pairs were ABO mismatched (A+ recipient/B+ donor and O+ recipient/A+ donor). A RBC exchange was performed on Day −10 with goal of hemoglobin S <30% and end hematocrit of 30% using phenotype matched RBC for Rh, Kell, Kidd, Duffy and MNS antigens. RBC transfusion was administered to keep hemoglobin 9-10 g/dL during immediate post-transplant period. **Results/Findings**: Seven patients (44%) had a history of RBC alloimmunization pre-transplant (patient 1: C,E,Jk^b; patient 2: C^w; patient 3: C,K,Kp^a,Fy^a,S Lu^a,Bg; patient 4: Le^a; patient 5: C, E; patient 6: E, V, K, Fy^a, M, S; patient 7: C, E, V, K, Jk^b, Le^a, Le^b, Bg). The pre-transplant antibody screen was performed a median of 2 days prior to transplant (range 0-3 days) and was positive for 4 patients (patients 3, 5, 6, 7). The first post-transplant antibody screen was performed a median of 2 days post-transplant (range 1-5 days). The last antibody screen post-transplant was at a median of 121 days (range 11-1550 days). Patients 5 and 6 antibody screens converted to negative at 3 days post-transplant, and remained negative at 11 and 613 days, respectively. Patients 3 and 7 antibody screens remained positive post-transplant to 261 and 1550 days respectively. At day 261 patient 3 (O+ recipient/A+ donor) had HbS 66%, chimerism 100% recipient; anti-Bg and anti-S in plasma. At day 918 in patient 7, chimerism was 80% donor;at day 1550 anti-V and anti-E found in plasma; at day 1592 HbS was undetectable. No new alloantibodies were detected in any recipients. **Conclusion**: 28.5%(2/7) of previously alloimmunized patients continued to have positive antibody screens after receipt of a stem cell transplant; however patient 3 lost the graft. Both patients with persistent positive antibody screens had poor compliance with sirolimus. While this regimen is well tolerated and eradicates chronic RBC transfusions, prior RBC alloimmunization may continue to be an issue during pregnancy or surgical procedures if immunosuppression cannot be maintained post-transplant.

SP259

Autoimmune Hemolytic Anemia Following Allogeneic Hematopoietic Stem Cell Transplantation

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Background/Case Studies: Autoimmune hemolytic anemia (AIHA) after stem cell transplantation (HSCT) is a recognized complication, with an estimated incidence of 3.1% to 6%, affecting both adults and children. AIHA after HSCT has been associated with unrelated donor transplant and chronic graft-versus-host disease (GVHD). Possible reasons for this complication include: receptor antibodies against donor cells, the donor antibodies transferred to the receiver during the infusion of marrow, grafted donor lymphocytes that produce active erythrocyte antibodies and AIHA by the donor antibodies. We report a case of a child with AIHA concomitant with thrombocytopenia after HSCT. **Study Design/Methods**: A 2 year-old male, Caucasian patient receiving C, E and K negative blood, with chronic granulomatous disease undergoing allogeneic HSCT unrelated full-match 10/10 with major ABO incompatibility. Red cell and HPA genotyping performed by BeadChip (Immucor) in both patient and donor DNA samples. DAT and antibody screening were performed by gel test. Antibodies against platelets were detected by MAIPA. **Results/Findings**: A mismatch between donor and patient was observed for E antigen. Patient was E- while the donor was E+. HPA genotyping showed that both patient and donors were HPA 1aa. In D+104 HSCT, patients red blood cells (RBCs) showed a DAT positive with IgG and C3d and it was identified an anti-E in his serum. At this time he had a chronic GVHD skin grade 3 and started the use of cyclosporine and mycophenolate. After onset of hemolytic anemia with transfusion requirements, it was chosen to initiate systemic corticosteroid prednisolone with subsequent need of immunoglobulin and rituximab. Patient improved hemolytic anemia on D+ 191 without RBC transfusion, but with persistent thrombocytopenia. Anti-HPA 1b was identified in his serum as an alloantibody. In the presence of hemolysis frame, the patient also had neutropenia associated with good response to granulocyte-colony stimulating factor, being removed the causes of infectious origin for pancytopenia. During follow-up, patient progresses requiring hemodialysis, due to nephrotic syndrome in D+334, diagnosed with focal segmental glomerulosclerosis in renal biopsy with antinuclear antibody markers and positive anti-DNA. The findings were attributed to chronic GVHD, and immunosuppression was changed. Patient developed recurrence of hemolytic anemia and thrombocytopenia and transfusion was required. The patient was discharged in D+365, with improved hemolysis without RBC transfusion and improvement of renal function, without the need for hemodialysis. **Conclusion**: AIHA is a complication after HSCT with significant morbidity and mortality and difficult treatment. Hemolysis may be accompanied by other autoimmune complications such as thrombocytopenia and this picture can persist for months or even years.

SP260

Whole Exome Sequencing in Sickle Cell Disease Patients with Hyperhemolysis Syndrome

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Background/Case Studies: A small subset of sickle cell disease (SCD) patients receiving recurrent RBC transfusions goes on to exhibit hyperhemolysis syndrome (HHS), where breakdown of autologous and antigen-matched donor RBCs results in lower post-transfusion Hb levels vis-à-vis pre-transfusion, in contrast to the traditional definition of delayed hemolytic transfusion reaction, in which only the donor blood is hemolyzed. This phenomenon, whose pathophysiology is poorly understood, is difficult to diagnose or treat and results in substantial morbidity. **Study Design/Methods**: Whole Exome Sequencing of genomic DNA, from 12 HHS patients from Louisiana and SE Texas, was undertaken to investigate the role of recipient genetic factors on HHS development. Variants were called, annotated (Mercury pipeline), and filtered (Variant Tools), to get a final list of high quality, likely damaging, rare variants (MAF< 5% in individuals of African ancestry (AFR), using 3 public databases) and observed in 3 or more patients. **Results/Findings**: Of the resulting 682 variants, 3 were heterozygous, stop-gain, single nucleotide variants occurring in strong biological candidate genes. These were then genotyped in a larger non-HHS control cohort of ∼300 SCD transfusion recipients from the same region (see Table). Four of the HHS patients (25%) had more than 1 of the 3 variants, but not the controls; these variants all occurred in the final exon, resulting in predicted Premature Termination Codons and truncated proteins through escape of nonsense-mediated mRNA decay, suggesting a dominant negative, gain-of-function, or novel phenotype. **Conclusion**: Our preliminary results suggest that innate immunity defects may play a role in HHS. We are in the process

TABLE. Summary of candidate variants

Protein change (Gene)	Cases	Controls	MAF (AFR)	OR (95% CI)	p-value	Function
E210X (MBL2)	25% (3/12)	1.5% (3/199)	0.01	21.8 [3.9,123.4]	0.0005	Plays a central role in innate immunity via lectin-binding to initiate complement by recognizing carbohydrate moieties. Plays a role in Hemolytic uremic syndrome and autoimmunity
K244X (KLRC3)	42% (5/12)	6.8% (10/147)	0.06	9.8 [2.6,36.5]	0.0007	Receptor for MHC class I HLA-E molecules by Natural killer (NK) cells and some cytotoxic T-cells. NK cells have been implicated in some hemolytic transfusion reactions, and altered KLRC3 expression associated with autoimmunity
W666X (PCSK5)	33% cases (4/12)	currently evaluating	N/A	N/A	N/A	Assists in processing immature proteins, e.g. integrin subunits, to biologically active forms. Integrins play a role in destruction of SCD reticulocytes and donor RBCs by activated macrophages. Involved in processing some inflammatory cytokines and clotting factors.

of assembling a larger, diversified cohort of genomic DNA from individuals with SCD and HHS in order to validate these findings. We will also perform functional assays of variant effect, and relate the collective burden of candidate variants to HHS clinical phenotype. If confirmed, these results may help prospectively identifying individuals with susceptibility to HHS and lead to new therapeutic options for this challenging disorder.

SP261

DTT's DARA Dilemma

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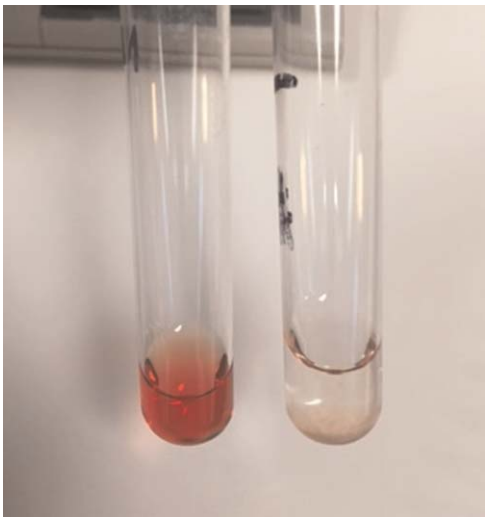
Background/Case Studies: The influx of Daratumumab (DARA) use for the treatment of multiple myeloma is interfering with pretransfusion testing. DARA patient samples exhibit panreactivity when tested with reagent red blood cells (RBCs) used in antibody screen/identification tests. Dithiothreitol (DTT) treatment of reagent RBCs negates this reactivity. This study investigated the stability of the antigens on DTT-treated Panocell®-10 (Immucor, Inc.Norcross, GA) to determine if large quantities of the reagent RBCs could be treated at one time, stored, and used for testing at a later time. **Study Design/Methods**: Panel cells were treated with DTT (Sigma Aldrich Saint Louis, MO) then stored as three sets. Set 1, DTT-treated cells were tested with antisera by manual tube method. The DTT-treated panel cells were stored in Alsever's Solution (Sigma Aldrich Saint Louis, MO) at 2-8°C. The DTT-treated panel cells were manually washed each day with saline, then re-suspended in pH 7.3 PBS (Sigma Aldrich Saint Louis, MO) prior to antigen testing. Set 2, DTT-treated panel cells were stored in pH 7.3 PBS. Set 3, DTT-treated panel cells were stored in Alsever's Solution. Sets 2 and 3 were visually compared daily for observation of any indication of hemolysis. **Results/Findings**: In Set 1, all antigen reactivity remained at a 2+ strength or greater with both homozygous and heterozygous panel cells. The Rh system displayed higher reaction strengths for longer periods of time compared to Duffy, Kidd, M and S. On day 3, Set 2 displayed slight hemolysis. By Day 8, complete hemolysis was displayed in Set 2 (Figure 1). Set 3 never displayed any hemolysis throughout the fourteen day investigation. **Conclusion**: A large volume of red cells can be treated with DTT and stored in Alsever's solution for later use without deterioration of the red cell antigen sites on the cells saving institutions tech time, resources and money.



SP262

Serological Investigation in a Multiple Myeloma Patient receiving Daratumumab (Anti-CD38)

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Background/Case Studies: Our reference laboratory received a sample on a 73 year old man with multiple myeloma. He had received a total of 90 grams of intravenous immunoglobulin (IVIg) over the last three months and was transfused 2 years ago with no evidence of transfusion reaction. The hospital reported the patient's antibody screen as negative prior to receiving IVIg, but the recent investigation showed 1+ to 3+ reactions with all panel cells and a negative autocontrol tested by solid-phase assay. The plasma remained positive after inhibition testing, but was non-reactive with enzyme treated panel cells. A sample was sent for investigation of possible high frequency antigen or weak autoantibody. **Study Design/Methods**: ABO/Rh and DAT were performed in tube by standard serological methods. Antibody investigation was performed using gel IAT, ficin treated red cells in gel, DTT

treated red cells and saline IAT. In-house rare cells negative for high incidence cells were thawed and tested by gel IAT. **Results/Findings**: No anomalous results were found in the ABO and D grouping. DAT was weakly reactive with anti-IgG and negative with anti-C3bC3d. The patient's plasma showed pan-reactivity, with reaction strength of 1+ to 3+ when tested by gel IAT, autocontrol was 1+. Saline IAT showed weak to 2+ reactions and negative autocontrol. In-house rare cells negative for high incidence cells all reacted 1+ to 3+ when tested by gel IAT. The plasma was non-reactive when tested against ficin treated red cells. At this point, the patient's medical history was reviewed and we discovered that the patient had been receiving Daratumumab (DARA) weekly, starting twenty days prior to sample collection. We then tested the patient's plasma against DTT treated red cells and all were negative by gel IAT. We concluded that the reactions were related to DARA binding to the reagent red cells. Clinically significant antibodies were ruled out except anti-K, as DTT denatures K antigens. We recommended the use of K negative red cells and requested a sample for genotyping. **Conclusion**: CD38 is a glycoprotein highly expressed on the surface of multiple myeloma cells. DARA is a monoclonal antibody that binds to the CD38 molecule and is believed to induce rapid death of myeloma cells. CD38 is weakly expressed on normal human red blood cells and can consequently bind to human reagent red blood cells, interfering with alloantibody investigation studies. The serological findings in this case are consistent with previous reports of antibody investigation in patients on DARA treatment. This case illustrates the importance of reviewing patient's diagnosis and medication history when the serological findings are inconclusive to ensure timely response to serological investigation and transfusion requirements.

SP263

Identifying a High Prevalence Antibody: Two Cases of Anti-Jk3

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Background/Case Studies: The Kidd blood group system consists of two major antigens, Jka and Jkb. The null phenotype Jk(a-b-) was first reported in a Filipino woman with a pan-reacting alloantibody, later named anti-Jk3. We report 2 cases of anti-Jk3 identified in our laboratory. Patient 1 is a 45 year old female with a connective tissue disorder and a history of three pregnancies. She has been treated with prednisone and intravenous immunoglobulin but has never received red cell transfusion. A Type and Screen in preparation for orthopedic surgery found a pan-agglutinating antibody. Patient 2 is a 35 year old female, two days post-partum, with no history of previous transfusions. Her newborn had a positive DAT, pan-reactive eluate, but no evidence of hemolysis. Both plasmas reacted 2+ with all panel cells by Gel IAT, weak to 1+ by saline IAT. Autocontrols and DATs were negative. **Study Design/Methods**: Samples from both patients were tested in our reference laboratory. ABO/Rh, DAT and antigen typing were performed by tube method. Antibody investigation was performed by gel IAT and saline IAT using commercial and in-house panel cells, commercially prepared ficin treated red cells and in-house prepared DTT treated red cells. **Results/Findings**: Both patients were DAT negative and their plasmas demonstrated pan-reactivity with all panel cells by gel IAT and saline IAT. The plasmas reacted 4+/3+ with all ficin treated panel cells in gel IAT and 1+/2+ with all DTT treated red cells. The list of high prevalence antibodies that are resistant to both ficin and DTT is extensive. To narrow down the possibilities, the referring hospitals were contacted for further information on the patients' ethnicity. We learned that both patients were originally from the Philippines. In-house Jk(a-b-) frozen red cells were then thawed and found to be negative when tested against both patient's plasmas by gel IAT. Other major blood group antigens were excluded using Jk(a-b-) red cells. To confirm the antibody was indeed anti-Jk3, samples were sent to the national reference laboratory for genotyping. Testing by the Progenika ID CORE XT™ found both patients to be JK*B_null (IVS5-1a). **Conclusion**: The serological antibody investigations identified an extremely rare, but clinically significant antibody. Anti-Jk3 reacts with Jk^a and Jk^b antigens present on all red cell samples, except red cells with a Jk(a-b-) phenotype. Anti-Jk3 is an immunogenic antibody which may cause an immediate or delayed hemolytic transfusion reaction, or mild HDFN. Jk(a-b-) red cells must be used for transfusion. These two patients have Jk null phenotype, very rare in most populations, but not uncommon among Asians and Polynesians. These 2 cases illustrated the contribution of ethnic information in investigation of unusual antibodies.

SP264

Extended Use of DTT-Treated Reagent Cells in the Era of Anti-CD38 Therapy

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Background/Case Studies: Daratumumab (DARA) is an anti-CD38 monoclonal antibody used in the treatment of multiple myeloma. CD38 is a membrane protein overexpressed on myeloma cells and weakly expressed on red blood cells (RBCs). This poses a new challenge in serologic testing as plasma from patients receiving DARA causes panreactivity in RBC panels. Dithiothreitol (DTT) is a sulfhydryl reagent that destroys disulfide bonds and can be used to treat RBCs to eliminate drug interference during antibody screening and identification. The duration of stability of DTT-treated reagent cells is not established and the aim of this study is to characterize the effects of DTT on reagent RBCs over time. **Study Design/Methods**: Three Ortho reagent screening cells were treated with DTT and tested daily with commercial antisera to detect clinically significant antigens by standard tube methods. Once prepared, DTT-treated reagent RBCs were stored at 2-8°C. Agglutination reactions were graded on a scale of 0-4+ and any hemolysis was noted. **Results/Findings**: Clinically significant antigens present on the screening cells were detectable 9 days following DTT treatment, with the exception of K, which is known to be destroyed by DTT. D, E, c, Jka, M, Fya, and Fyb showed no change in reaction strength. The reactivity of C, Jkb, S, s, and N decreased 1 grade by 9 days. The reactivity of e decreased 2 grades by 9 days. Since Kell antigens are destroyed by DTT treatment, loss of K reactivity confirmed DTT treatment was adequate. Hemolysis was first noted on day 4, however, testing continued until marked hemolysis was noted on day 9. **Conclusion**: DTT can be used to eliminate anti-CD38 drug interference during standard pretransfusion testing. This study demonstrates that all clinically significant antigens, except K, are detectable up to 9 days following DTT treatment of reagent RBCs. Our findings suggest that DTT-treated cells may be used for an extended period leading to more efficient use of resources.

SP265

Variation In Anti-A/-B Titers over Time – An Observational Study in Healthy Volunteers and in Patients with End Stage Renal Disease

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TABLE. Reaction Grading by Day

Day	DTT-Treated Cells	C	E	c	e	K	D	Jka	Jkb	S	s	M	N	Fya	Fyb	Hemolysis
1	1	4+	0	0	3+	0	4+	3+	0	4+	0	4+	0	2+	1+	None
	2	0	4+	4+	0	0	4+	0	3+	4+	4+	4+	4+	2+	0	
	3	0	0	4+	3+	0	0	0	3+	0	4+	0	4+	0	2+	
4	1	4+	0	0	4+	0	4+	3+	0	4+	0	4+	0	2+	2+	Slight-moderate
	2	0	4+	4+	0	0	4+	0	3+	4+	4+	4+	4+	2+	0	
	3	0	0	4+	3+	0	0	0	3+	0	4+	0	4+	0	1+	
9	1	3+	0	0	2+	0	4+	3+	0	4+	0	4+	0	2+	1+	Marked
	2	0	4+	4+	0	0	4+	0	3+	3+	3+	4+	3+	2+	0	
	3	0	0	4+	1+	0	0	0	2+	0	4+	0	4+	0	1+	

TABLE. Mean anti-A/-B titers (mean SD)

Group	ABO group	N	Anti-A, IgG	Anti-A, IgM	Anti-B, IgG	Anti-B, IgM
Volunteers	O	18	4.9 (0.28)	4.7 (0.33)	3.7 (0.18)	4.5 (0.40)
	A	27	-	-	0.7 (0.09)	3.5 (0.30)
	B	10	0.83 (0.33)	4.0 (0.26)	-	-
Patients	O	23	6.2 (0.48)	4.9 (0.49)	4.9 (0.43)	3.4 (0.29)
	A	23	-	-	0.6 (0.20)	3.1 (0.27)
	B	9	1.3 (0.27)	3.3 (0.26)	-	-

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Background/Case Studies: Measurement of anti-A and anti-B (anti-A/-B) is clinically relevant for ABO-incompatible kidney transplant and for using group A plasma in emergency situations in recipients of unknown blood group. The aim of this study was to investigate the intra-personal changes in anti-A/-B titers over time in a group of healthy volunteers and in a group of patients with end stage renal disease. **Study Design/Methods**: Fifty-seven volunteers (36 M, 21 F; median age 57 [range 24-67]), of which 44 were blood donors and 13 were laboratory personnel, and 66 patients with renal failure disease (42 M, 24 F; median age 69 [range 25-90]) entered the study after informed consent. The study involved measuring the titers of IgG and IgM anti-A/-B every 3 months for a year (4 samples drawn per patient in total). Anti-A/anti-B IgM and IgG titers were assayed automatically and in batches using the Immucor NEO solid phase analyzer. Results were converted to log (2) titer steps (e.g., titer 32 = 5 titer steps). The mean anti-A/-B titer step and the standard deviation (SD) for all 4 titer measurements were calculated for each participant. **Results/Findings**: In total 55 volunteers and 54 patients completed the study. In each group the average of each participant's 4 titers was calculated and then that average was averaged with all other participants in their group. The same procedure was performed to obtain the group's mean SD. This data is presented in the table. As expected, the group O volunteers and patients had significantly higher levels of IgG anti-A and anti-B ($p=0.023$ and 0.026, respectively), compared to group A and group B. Only minor variations in anti-A/-B titers were seen over time; the mean of the participants' SDs in both groups for any of the 4 titers measured were below 0.5 titer step. Furthermore, in 52/55 (95%) volunteers and in 42/54 (78%) patients, the range of titer measurements over the 4 samples drawn for the study was within 1 titer step, regardless of the isotype and specificity of the antibody (data not shown). **Conclusion**: The IgG and IgM anti-A and anti-B titers demonstrated minimal variation within a person over time. Although the range of titers appeared to vary slightly more in patients than in volunteers, the variations over time were still minor. The clinical ramification of these data is that it appears to be sufficient to measure anti-A/anti-B titers only once in any individual.

SP266

Relevance of Serological Red Cell Typing in a Patient with Complex Alloimmunization

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Background/Case Studies: Anti-Gy^a is the antibody characteristically produced by immunized individuals with the Dombrock-null phenotype, which results from various inactivating mutations. Anti-Gy^a could cause transfusion reactions but has not been implicated in hemolytic disease of the fetus/newborn (HDFN). A specimen collected from a 33-year old female, untransfused primigravida woman at 25th week gestation, was sent to our Reference Laboratory for antibody identification from Varese Hospital. The referring hospital reported a positive reactivity with all tested cells and a negative direct antiglobulin test (DAT). Her group was A, Rh(D)+, ccEe, Kell negative. **Study Design/Methods**: The antibody screening, performed by indirect antiglobulin test (IAT) in microcolumn method (CAT) with BioVue System (Ortho-Clinical Diagnostics, Raritan, USA), was positive with all cells. The antibody identification, performed by IAT in CAT, by tube method with polyetylene glycol (PeG), with low-ionic-strength saline solution (LISS) and in saline method (S20) was positive with all cells in IAT and negative in S20. The autocontrol, performed by different IAT methods, was non reactive. An alloantibody to a high-frequency antigen (HFA) was suspected. We performed an extended phenotype on the patient's red cells by molecular typing (Immucor-BioArray Solution, Warren NJ, USA; Inno-Train, Diagnostick GMBH, Germany) and by serology with selected HFA antisera. **Results/Findings**: We identified antibodies against DO system (anti-Gy^a) but the red cell typing in molecular typing was positive. Therefore we performed patient's type for DO system by serology too, which resulted discrepant with molecular typing . The sample was sent for sequencing to an outside laboratory. Sequencing showed that the sample was Doa homozygous for a missense mutation at 608G>T (R203I) with no known clinical impact and for two silent mutations at 624C>t (L208I) and 378t>c (Y126Y). The patient delivered at the 40th week of gestation and the newborn presented no clinical symptoms of HDFN. Although no tranfusion support was required by either mother or child, we noted that only 4 possibile matches were detected at International Rare Donor Panel. **Conclusion**: There are many genetic events that cause discrepant results between serology and DNA test results; the genotype is not the phenotype. For this reason the confirmation of predicted phenotype is recommended using also serology when possibile.

SP267

How Performance of Proper and Reliable Pre-transfusion Tests Could Have the Impact on Red Blood Cell Alloimmunization of Recipients Undergoing Elective Surgery

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Background/Case Studies: Red blood cell alloimmunization is a major complication of transfusion therapy and may cause hemolytic transfusion reactions. Non-ABO antibodies have been one of the main leading cause of transfusion-associated death. Clinically significant alloantibodies also cause morbidity in a form of anemia, hemolytic disease of newborn and decrease in the survival of transfused RBCs. The other problem is autoantibodies formation against RBC antigen after alloimmunization, these alloantibodies make the hemolytic condition more severe, so it is important to study transfusion history of patients who form alloantibody after transfusion and carrying out pre-transfusion tests (ABO group and Rh D type, antibody screening test and identification of unexpected antibodies) for all the patients who were to receive transfusion. The aim of this study was to investigate the prevalence and specificity of red blood cell alloantibodies among transfused patients due to surgery. **Study Design/Methods**: A total of 6 029 patients (3982 female and 2067 male) who undergo elective surgery were retrieved for analysis from September 2015 to January 2016. The data collected from a regional general teaching hospital in Asia that has an active blood bank with the high cross-match ratio (more than 10 000 in a year). Clinical data included sex, age, medical history, transfusion history, pregnancy and abortion history were collected. Ab screening was performed by tube method using the 11 cell identification panel. **Results/Findings**: Data from 6 029 were analyzed and a total of 50 alloantibody found in 31 patients. The incidence of RBC alloimmunization in the patients for whom cross-match has been done was 0.5%. This lower alloimunization rate in comparison to similar studies sheds the light on the necessity of improvement in pre-transfusion screening tests. The most frequent antibodies were anti-D (38%) (19 patients), anti-E (20%) (10 patients) and anti-K (12%) (6 patients). **Conclusion**: the most common clinically significant alloantibody in male was anti-K and in female was anti-D. The women shown a higher rate of alloimmunization than men, this is possibly because of more exposure to immunizing events through pregnancy. In this study, pregnancy for women and non-extended matched transfusions for men appeared to be risk factors for alloimmunization. Identification of alloantibodies with pre-transfusion tests have a significant role in reducing the risk of a hemolytic reactions and increase the survival of transfused RBCs and must be done for all the patients who might be candidate to receive blood transfusion.

SP268

Possible False Positive Results in Stored Fetal Maternal Hemorrhage (FMH) Samples using a Flow Cytometric Method (FCM)

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Background/Case Studies: FMH is commonly assessed by the quantification of fetal red blood cells (RBC) in the maternal circulation to determine the

TABLE.

Maternal Sample	KBT	FCM Day Tested	FCM (mL)	Microscopic Agglutination	Maternal Sample	KBT	FCM Day Tested	FCM (mL)	Microscopic Agglutination
A	No fetal cells detected	8	1.32	Negative	B	Fetal cells detected at a ratio 15/2007 = 0.0074 (FMH ~15-30mL)	5	17.16	Negative
		15	2.86	Negative			12	46.86	Negative
		22	13.20	Negative			19	246.18	Negative
		29	25.96	Negative			26	749.32	Negative
		43	31.46	Negative			40	1331.88	Negative

therapeutic dose of Rh-immune globulin (RhIG). The Kleihauer-Betke test (KBT) is regularly used, but its poor reproducibility and low sensitivity has led to the increased use of FMH FCM (Cytometry 2002;50:285-290). Delayed FCM testing has been reported to increase RBC agglutination and may affect the quantification (Transfusion Medicine 2013;23:175-186). Our laboratory performed an IRB approved unlinked comparability study between KBT and FCM to investigate sample stability and identify FCM storage parameters. The KBT was performed using a fetal hemoglobin stain kit (Sure-Tech™ Diagnostic Associates, St. Louis, MO) that allows storage of refrigerated EDTA blood up to 2 weeks, but recommends testing promptly as possible (Sure-Tech™ manufacturer insert). FCM was performed based on a reported anti-hemoglobin F (HbF) monoclonal antibody method (Transfusion 2014;54:1305-1316). **Study Design/Methods**: The KBT used maternal EDTA anticoagulated blood, by the Sure-Tech™ fetal hemoglobin stain kit following the manufacture insert. Cord blood was used as a control. FCM used 20uL of a 5% washed RBC to 100uL of 0.05% Glutaraldehyde (Sigma-Aldrich, St Louis, MO), incubate 10 minutes (min), washed; 100uL of 0.1% Triton X-100 (Sigma-Aldrich) added, incubated for 3-5 min, washed; 10uL of FITC labeled Anti-HbF (EMD Millipore, Billerica, MA) was added, incubated for 15 min, washed; resuspended in buffer, racked and tested (50,000 events) on the Becton Dickinson FACScanTM (San Jose, CA). Gated side vs. forward scatter plots and fluorescence histogram were marked to identify fetal RBCs. FCM samples were observed microscopically for agglutination. FetalTROL (R&D Systems Inc., Minneapolis, MN) was used as a control. FMH was calculated by multiplying the % fetal cells by 22 (Transfusion 2014;54:1305-1316). **Results/Findings**: Patients (A and B) suspected of FMH were evaluated by KBT stat on the draw date. The FCM samples were stored at 2-8°C and tested over a 35 day period, giving accurate results on days 5 and 8. RBC loss observed in the fixation of the RBCs stage in later storage dates could have contributed to the change in results. **Conclusion**: FMH calculated by FCM matched KBT, but doubled by the second testing and increased with storage. This could yield a false positive result thus affecting the dose RhIG administered. RBC agglutination was ruled out by microscopic evaluation. The use of older, stored samples is unreliable and should not be used when determining RhIG dose by FCM.

SP269

Reagent Stability Determination for Flow Cytometric (FC) Anti-IgA Assay

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Background/Case Studies: A FC based anti-IgA detection assay was developed using IgA coated RBCs (RBC/IgA) under IRB approval. Over 21 months, 45 assays were performed which assessed the stability of reagents. 20 pools of RBCS were tannic acid (TA) treated, coated with IgA, stored and evaluated for levels of IgA with fluorescein isothiocyanate (FITC)-labeled anti-IgA and for cross-reactivity with FITC-labeled anti-IgG. **Study Design/Methods**: RBC/IgA pools were prepared with residual RBCs from 10 group O donors. The pool was washed 4x in Dulbecco's PBS (DPBS) and TA (Sigma-Aldrich, St Louis, MO) treated (25ug/mL) in a dry air incubator 37°C±1-C for 15 ±1minute (min). The tanned RBCs were washed 4x in DPBS, mixed with a 0.5mg IgA/mL solution of human IgA (MP Biomedicals, Santa Ana, CA) and incubated at 37°C±1°C for 1 hour ±5 min. The RBC/IgA was stored in RBC storage solution (Immucor Inc, Norcross, GA) up to 30 days after collection. The RBC/IgA were washed 4x in DPBS and 1x in DPBS containing 0.6% bovine serum albumin (BSA). Test plasma diluted in 0.6% BSA was incubated with RBC/IgA for 30 ±5 min., washed 4x in 0.6% BSA and incubated with fluorescein isothiocyanate (FITC)-labeled anti-human IgG (Jackson ImmunoResearch Lab, West Grove, PA) at lot specific optimal dilutions for 45 ±15 min. As a control, an aliquot of the RBC/IgA was incubated with FITC-labeled anti-human IgA (Jackson ImmunoResearch Lab) at lot specific optimal dilutions for 45 ±15 min. The RBCs were washed and 50k RBCs were acquired from each sample by the Becton Dickinson FACScanTM (San Jose, CA) FC for analysis. **Results/Findings**: The RBC/IgA was coated on average 10.1 days post collection and studies showed stability over 30 days of use allowing the RBC/IgA to be used in multiple test runs. The FC reports the %RBCs above the normal range (indicated by %M2 set by operator) indicating presence or absence of anti-IgA. The mean result of the RBC/IgA pool was 99.46% coating level, had a standard deviation (SD) of 0.68 between each assay run and SD of 0.43 between each separate RBC/IgA pool. Over the 1 to 20 days of storage of each RBC/IgA pool, there was no evidence of coating degradation or antibody cross-reactivity. Comparisons were made of both the high positive control with anti-IgA detected at 77.23% (SD 11.27); and the low positive control at 51.25% (SD 12.89) in 19 assay runs. **Conclusion**: Contrary to the expectation that IgA coating on RBCs would diminish over time, the RBC/IgA results showed low variance, likely due to the IgA being bound using a TA method. This study data established the parameters of storage for the prepared RBC/IgA in this assay and the stability of the assay as determined by high and low positive controls. The use of a stored RBC/IgA is reliable and cost effective, saves 3 hours per test run and reagent stability is important for reproducibility.

SP270

Standard Lab Techniques Can Be Used to Overcome Daratumumab Interference with Pre-transfusion Testing

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Background/Case Studies: Daratumumab is a IgG1k monoclonal antibody which binds CD38 and is currently used in the treatment of refractory multiple myeloma. In addition to being a marker of plasma cells, CD38 is weakly expressed on red blood cells (RBCs). Because of this weak expression on red blood cells, reports have demonstrated that patients being treated with daratumumab show pan-reactivity during the AHG phase of RBC antigen/antibody screening. This observation has been seen in a variety of medium, including low ionic strength saline (LISS) and polyethylene glycol (PEG), as well as in all indirect antibody testing (IAT) methods. In concordance with these observations, it is recommended that a baseline phenotype or genotype be established prior to starting treatment with daratumumab. Should RBCs require screening after the start of daratumumab treatment, dithiothreitol (DTT) treatment of cells should be conducted for antibody screening; however, DTT testing is not widely available, necessitating send-out testing, which may be costly and time consuming. **Study Design/Methods**: To evaluate if standard lab techniques could be used to eliminate this interference, the medical charts of 4 patients being treated with daratumumab (dose: 16 mg/kg) were reviewed. The individual number of doses ranged from 1-14; patient age ranged from 55-78; there were two males and two females patients included in the review. Type and screen data was collected over 33 encounters for each individual ranging from 1 to 13. All samples were initially tested with automated solid phase testing. Any reactivity with solid phase lead to tube testing with either LISS, PEG or both. With continued interference, a 60 minute incubation with no enhancement was done. If this failed to eliminate the reactivity, the sample was sent out for DTT treatment and phenotyping. Results were also compared to number of half lives from their last dose of daratumumab (half life: 21 days). **Results/Findings**: Of the 33 instances of testing, 23 (69.7%) had reactivity in solid phase testing. In 8 of the 10 tests that did not react in the solid phase, testing was conducted more than 4 half-lives after the last dose of Daratumumab. The two other

tests were uninterpretable by solid phase technology. Of the 23 that had solid phase reactivity, 16 (69.6%) demonstrated loss of agglutination using standard laboratory techniques. For the 7 instances where the reactivity was not initially eliminated, phenotypically matched blood from prior testing was provided in 6 of the cases. Only 1 sample was sent for DTT treatment. **Conclusion**: These results suggest that daratumumab interference with pre-transfusion testing can be addressed using standard lab techniques. This finding could save time and money for labs that do not have DTT available.

SP271

Therapeutic Anti-CD38 Monoclonal Antibody as a Cause of Panreactive Antibody Screening in Immunohematology

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Background/Case Studies: Multiple myeloma (MM) is an incurable disease with malignant plasma cells that secrete high levels of monoclonal immunoglobulins. Daratumumab (DARA) is a novel IgG1-mAb against CD38 on myeloma cells. The use of DARA in our country is restricted to clinical research or direct importation. **Study Design/Methods**: Recently we came across 2 patients with MM that received DARA (16 mg/Kg), although this information was not provided to blood bank at time of transfusion. Before DARA, both patients had been transfused repeatedly in our service and showed negative antibody screenings in tube (polyethylene glycol (PEG)), gel column (Liss/Coombs) and Neutral-NaCl with papainized RBC (NaCl-PAP). Patient S.L.A. received 2 DARA doses (12/31/15; 01/07/16), serologic tests were performed on 01/05/16 between DARA doses, patient was deceased on 01/15/16. Second patient, P.A.P.G., received 3 DARA doses (03/16/16; 03/24/16; 04/01/16), and tests were performed on 03/23/16 and 03/31/16. Patient was discharged on 05/01/16. We started serologic tests for ABO/RhD typing, antibody screening in tube (PEG), direct antiglobulin test (DAT) and antihuman globulin crossmatch. **Results/Findings**: Neither patient had hemolysis. Reactions were weakly positive for both patients in gel (LISS/Coombs) 1+ and weak in tube (PEG). P.A.P.G. also had weak reactions (1+) in DAT gel. We didn't find C3d/C3c or other immunoglobulin besides IgG attached to RBC and in this case the result for acid elution was negative. Results from gel NaCl-PAP were variable from 0 to 1+ but when we used the same treated RBC in gel (LISS/Coombs), the results were 1+ for all cells. Due to panreactive results we suspected of drug interference. Patients' serum was tested against RBC treated with DTT (200Mm Sigma®) and phenotyped cord blood RBC. Antibody screening was negative and we were able to attend all transfusion requests. Patient S.L.A. received 10 apheresis platelets (AP) and 01 RBC. Patient P.A.P.G received 5 AP and 2 RBC. DARA infusion was confirmed on patients' medical records only after transfusions. **Conclusion**: Although we couldn't perform any specific test for DARA, combined results of tests and patient's medical records allow us to conclude that DARA was the cause of positive antibody screening. Since DARA is not officially approved in our country, there is no bulletin about its interference in serologic tests. Our service has established a protocol to investigate DARA interference as it may become a frequent treatment. Physicians were oriented to request a pre-transfusion sample and notify blood bank before first infusion of DARA to prevent antibody misidentification and transfusion delays.

SP272

Clinical Significance of Positive Direct Antiglobulin Test in Pregnant Patients and Potential Impact to the Newborn

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Background/Case Studies: Little is known regarding the significance of warm autoantibodies (WAA) in pregnancy. Two recent studies, one from Canada and another from Germany, both concluded such WAA are generally benign. In this study we evaluated a cohort of prenatal patients and their newborns for clinical impact of WAA in pregnancy. **Study Design/Methods**: In this retrospective chart review a database of 3104 pregnancies with identified antibodies from Jan 2006 to Dec 2013 at a centralized laboratory in the upper Midwest U.S.A. was analyzed. Patients with positive antibody detection test, positive DAT and WAA detected in plasma and/or eluate were selected. Women with repeat pregnancies were counted more than once. Column agglutination testing was the primary method used for antibody detection. Test tube DATs were performed using polyspecific AHG. All positive DATs were tested with anti-IgG and anti-C3b,-C3d. Rapid acid eluates were tested using PEG tube. Maternal and their newborn records were reviewed for clinical history, laboratory evidence of hemolysis (total bilirubin, haptoglobin, reticulocyte count, hemoglobin) and need for obstetric or neonatal management, including any transfusions. **Results/Findings**: Thirty patients with detectable WAA and available records were identified. This included 34 total pregnancies (1.1%) and 36 live births [32 singleton, 2 multiple (each twins)]. Prenatal patient DATs were ≤2+ in 91% (31 of 34) with 62% due to IgG and 38% IgG and C3. Ten women had preexisting autoimmune disease (5 with Systemic lupus erythematosus, 2 with Raynaud's, 1 with Celiac disease and 2 had Lupus anticoagulant). DATs and antibody screens of 4 women taking methyldopa became negative after changing medication. Maternal records were either lacking data or there was no laboratory or clinical evidence of hemolytic anemia in any women. Only 10% (3/30) of the women were referred for follow-up evaluation. Cord blood studies were performed on only 31% (11/36) of newborns. Of the 11 cord blood samples tested only 2 were DAT positive with broadly reactive eluates. No baby was anemic at birth or required phototherapy during their hospital stay. **Conclusion**: Based upon the clinical and serologic information available, no women in this study appear to have developed warm autoimmune hemolytic anemia. The lack of follow-up testing for hemolysis in both the women and their newborns indicates clinicians were not overly concerned with underlying hemolytic anemia. Our findings corroborate those of others that WAA detected in pregnancy is essentially benign. This is also consistent with the weaker positive (≤2+) DAT seen in our cohort of prenatal patients.

SP273

Evaluation of the Blood Typing Device MDmulticard® ABO-D-Rh-K using a Simplified Protocol and Performed on Blood Samples in Native, Diluted, or Concentrated Form

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Background/Case Studies: MDmulticard® is a card-format device that uses lateral flow technology for determination of blood type in 5 min. MDmulticard® allows simple and simultaneous multi-parameter testing in a single assay with only one drop of blood, providing end-point results without centrifugation. According to the manufacturer's recommendations, MDmulticard® implementation requires a preliminary dilution. The aim of the study was twofold: (i) to assess the performance of MDmulticard® through a simplified protocol carried out on native blood samples; (ii) to verify the reliability of this method on blood samples diluted with physiological saline solution or on concentrated blood samples. **Study Design/Methods**: In a first step, the simplified protocol consists in dispensing 2 drops (100 µl) of Diluent F then 1 drop (50 µl) of whole blood in the application zone; in a second step, waiting for 30 seconds and dispensing 6 drops (300 µl) of Diluent F; the results are read after 5 min. According to the manufacturer's recommendations, in rare cases, unspecific shadows or very faint bands may appear also in negative results; in such cases, it should be rinsed again with 6 drops (300 µl) of Diluent F to enable reading. MDmulticard® simplified protocol test was performed on 52 EDTA anticoagulated blood samples from donors collected for less than 4 days. Forty-two out of 52 samples in native form were tested for hemoglobin (Hb) then with a 1:2 dilution and 1:4 dilution. Ten out of 52 samples, were also tested first in native form and then after removal of 500 µl of plasma. The reference blood type (ABO-D-RH-KEL1) was performed on a Beckman Coulter PK7300® automated microplate system using Diagast reagents. Discrepancies were tested with MDmulticard® standard method and ID-Card Diaclon® gel agglutination system (Bio-Rad). **Results/Findings**: Mean Hb concentration in the 42 samples group was 16.3 g/dL in native form, 7.8 g/dL in 1:2 dilution and 3.9 g/dL in 1:4 dilution. Mean Hb concentration in the 10 samples group was 16.2 g/dL in native form and 18.2g/dL in concentrated form. Blood type distribution was as follows: A (22), O (20), B (7), AB (3), 17% are RH-1. All the results with the simplified protocol were consistent with those of the reference method. Three tests required 300 µl additional Diluent F. **Conclusion**: The simplified protocol for MDmulticard® use was reliable and easy to implement. The use of the MDmulticard® by a non-laboratory user could be considered in remote and austere locations such as war and road traffic accidents. The simplified protocol could be performed on hemorrhagic casualties, patients severely hemodiluted due to crystalloid infusion and dehydrated soldiers after several hours of fighting

SP274

Anti-Sc2 of the Scianna Blood Group System Can Cause Hemolytic Transfusion Reactions: Serendipity Confirms Clinical Significance

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Background/Case Studies: A sample was referred to the reference laboratory from an adult hospital for investigation of an acute hemolytic transfusion reaction. A thalassemic patient, after 75mL of plasma reduced red cells, had a fever of 39.4°C, with elevated unconjugated bilirubin and LDH. The unit was issued by electronic crossmatch but was found to be 3+ incompatible on re-crossmatch by Gel-IAT. The post-reaction DAT was negative. **Study Design/Methods**: This patient had been previously investigated by the reference laboratory. In 2007, while receiving transfusion in a pediatric hospital, she developed severe back pain, vomiting, dark urine, fever of 39°C, and elevated unconjugated bilirubin. Units were crossmatched by immediate spin as she was antibody screen negative and had no history of red cell antibody. Re-crossmatch found the unit 1+ incompatible by Gel-IAT with both pre and post-transfusion samples. DAT was negative pre-transfusion and 1+ positive with IgG post-transfusion. Post-transfusion urine was positive for hemoglobin. At the reference laboratory, the patient's plasma was non-reactive by Gel-IAT with panel cells positive for a number of low prevalence antigens including C^w, Wr^a, Co^b, Js^a, Go^a, Yt^b, V, VS, Di^a, Bg/HLA, Lu^a, Kp^a, Vw. The donor of the unit was not known to express any unusual phenotype. As the antibody was not identified, the pediatric hospital switched to Gel-IAT crossmatch for further transfusions. In 2009, one of 4 units crossmatched was found to be 3+ incompatible by Gel-IAT and was not transfused. The reference laboratory found that the patient's plasma tested negative against all panel cells except for two in-house Sc2 positive cells (2+ by Gel-IAT). Red cells from the segment of the incompatible unit typed Sc2 positive with two in-house antisera. This was not the same donor as the 2007 donor, who later returned to donate in 2012 and was phenotyped as Sc:1,2. **Results/Findings**: In 2010, the patient was transferred to the adult hospital, who was aware of the previously detected anti-Sc2 but did not consider the antibody to be clinically significant. The unit transfused was selected from the hospital's general inventory. Review of donor records by the reference laboratory discovered that this unit was donated by the same donor as the 2007 unit. **Conclusion**: Anti-Sc2 is not known to cause hemolytic transfusion reaction. When the first reaction occurred in 2007, anti-Sc2 was not included in the investigation. After the patient was discovered to have anti-Sc2, it could not be determined in retrospect if this was the basis for the hemolytic transfusion reaction. However, given the similarity in the clinicolaboratory outcome when re-exposed to the same donor, we conclude that anti-Sc2 likely accounted for the acute hemolytic transfusion reaction in both instances.

SP275

A New Antibody in the Gerbich Blood System against a Novel High Prevalence Antigen Named GEAR

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Background/Case Studies: The Gerbich blood system consists of 11 antigens, six of high-prevalence and five of low-prevalence. The antigens are located on single pass type 1 membrane sialoglycoproteins glycophorin C and/or glycophorin D encoded by *GYPC*. Ge antibodies may be clinically significant. We investigated a sample from a 38 year-old Caucasian woman with a possible delayed transfusion reaction whose plasma contained an antibody to a high-prevalence antigen. **Study Design/Methods**: Standard hemagglutination methods in tube were used for antibody identification and antigen typing. Acid eluates were prepared using Gamma ELU-KIT II (Immucor). Genomic DNA was isolated from WBCs. *GYPC* exons were amplified and sequenced. **Results/Findings**: The patient's plasma demonstrated anti-M in saline at room temperature and anti-Jk^a by papain IAT. Additionally, the plasma reacted 1+ by albumin IAT and 3+ by LISS or PEG IAT with phenotypically similar, M-, Jk(a-) RBCs; the autologous control was negative. Phenotypically similar RBCs treated with 0.2 M DTT or α-chymotrypsin were reactive, but the plasma was non-reactive with papain or trypsin treated RBCs suggesting possible Gerbich specificity. An eluate containing the high-prevalence antibody was made by adsorption/elution from M- Jk(a-) RBCs. The eluate reacted with GE:-2,3 RBCs but not with GE:-2,-3,4 or GE:-2,-3,-4 RBCs suggesting anti-Ge3 specificity. However, the patient's RBCs typed Ge2+ and Ge3+ using single donor source antibodies and Ge4+ with monoclonal anti-Ge4; interestingly, the RBCs failed to react with one monoclonal anti-Ge3, but the pattern of plasma reactivity with enzymes and DTT was not consistent with anti-Ge3. *GYPC* exon sequencing identified a novel homozygous change in exon 3, c.118G>A (p.Gly40Arg). This change is present in the rs database (rS772372126) with a rare minor allele frequency (MFA) of 0.0000247. The non-encoding change c.333A>C in exon 4 (rS1050967) was also found. **Conclusion**: The plasma and eluate reactivity pattern and the target antigen characteristics, combined with *GYPC* sequencing, confirmed the alloantibody in the patient's plasma recognizes a novel high prevalence antigen in the Gerbich system. We named the antigen GEAR, and lack of the antigen is predicted to be associated with c.118G>A change in *GYPC* exon 3 encoding amino acid change p.Gly40Arg in glycophorin C (or Gly19Arg in GPD). Similar to Ge2 and Ge4, this novel high-prevalence antigen is sensitive to treatment with papain or trypsin. The role of anti-GEAR as causative in the patient's delayed transfusion reaction is unknown as there was no information on the M and Jk^a phenotypes of the three transfused RBC units associated with the delayed transfusion reaction.

SP276

Improvement in Efficiency of Cord Blood Testing Using Solid Phase Technology

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Background/Case Studies: Our blood bank is a high volume laboratory that processes approximately 5,500 cord blood specimens each year. In August of 2015, we validated the Echo® (Immucor) for cord blood testing. This solid phase technology has allowed us to have cord ABORh and direct antiglobulin test (DAT) results with a significantly shorter turnaround time (TAT) and has improved efficiency. However, during our validation of the Echo®, we did find a higher rate of false positives (FP) which was defined as positive in solid phase testing and negative when repeated using tube method. To ensure any problems with this new process were detected early, a process control monitor was implemented and we tracked when our false positive DAT rate was trending up and exceeded acceptable upper limits. **Study Design/Methods**: Automated cord blood testing began in August of 2015. The amount of technologist time (TT) saved per test and the number of tests performed on the instrument was calculated. All positive DATs on the Echo® were repeated in tube and the number of FP DAT results was recorded and tracked monthly. If trends were identified or established limits were exceeded, an investigation would ensue and corrective action would be taken if necessary. **Results/Findings**: The Echo® had a TAT of 14 minutes for cord ABORh and DAT results and saved 16 minutes of TT per test. Our mean TT saved (Table 1) per month was 64.60 hours which equates to approximately 2 hours per day. The FP DAT rate using this technology was 2.7%. **Conclusion**: The implementation of cord blood testing on the Echo® has added value to our blood bank. Although FP DATs are seen with the Echo®, our method of verifying the positive results using tube testing has allowed us to efficiently manage this issue. Our new process has improved our productivity and decreased TAT. An ongoing evaluation of our results will add data points to support our process.

TABLE. Tech Time Savings since the implementation of Cord Blood Testing on the Echo®

	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15	Jan-16	Feb-16	Mar-16	Mean
Cord Specimens Run on Echo	278	215	259	254	205	219	243	265	242.25
Tech Time Saved (Hours)	74.13	57.33	69.07	67.73	54.67	58.40	64.80	70.67	64.60

SP277

Alloimmunization Caused by Platelet Transfusion

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Background/Case Studies: Platelet transfusion is a known cause of alloimmunization against HLA and platelet specific antigens. However, it is rarely the cause of alloimmunization against red cell antigens presumably due to the low red blood cell content of apheresis platelets. In this case, we examine the possibility of the formation of anti-c caused by platelet transfusion in a patient with myelodysplastic syndrome. **Study Design/Methods**: Bonfils Immunohematology Reference Lab (IRL) first received the patient sample and identified anti-E on 5/20/14. At that time it was determined that the patient was c-, but the patient had not yet formed anti-c. From 5/20/14 to 10/26/15, Bonfils IRL served as the transfusion services for facility the patient frequented and received requests for transfusion for this patient on average every 2 weeks to treat myelodysplastic syndrome. During this time period Bonfils sent the transfusing facility 78 red blood cell units antigen negative for the E and c antigens per Bonfils IRL procedure and 23 apheresis platelets for patient transfusion. It was also determined that 2 local hospital facilities did transfuse the patient. One facility transfused the patient with a platelet on 3/2014 a c- red cell unit on 5/2/2014. The other facility transfused at least 2 platetets and c- red cells in January of 2016. **Results/Findings**: On 11/9/2015, Bonfils IRL identified a new anti-c. The lookback indicates that the red blood cell units the patient received were c negative in the time period studied. Therefore, the formation of alloanti-c in this patient is likely due to platelet transfusion as 80% of D positive individuals are c+ and the patient primarily received D positive platelets. Assuming the maximum volume in an apheresis platelet is 400mL and approximately 0.31mL of RBCs in every apheresis platelet, the patient would have been exposed to up to 8.06mL little c positive red cells in the platelets over the course of therapy. **Conclusion**: It is possible that trace residual red blood cells contributed to the anti-c alloimmunization. Our finding raises the following question: For patients needing regular platelet transfusion, should the extended donor Rh phenotype be considered when selecting platelets?

SP278

A Lookback of Acid Eluate Results from Patient Samples with a Positive IgG Direct Antiglobulin Test (DAT)

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Background/Case Studies: There is debate in the medical community as it relates to the efficacy and use of the acid eluate test. Although some labs contend that the acid eluate test adds little value clinically or serologically, other facilities perform eluate testing on every patient sample with a positive DAT. We hypothesize that the acid eluate test reveals important clinical and serologic information. The purpose of this study is to show four months of eluate testing results and to highlight the validity of acid eluate testing for patients with a positive IgG DAT. **Study Design/Methods**: A total of 73 DATs from 73 patients were evaluated from 1/1-4/20/2016. Bonfils Immunohematology Reference Laboratory (IRL) is AABB accredited and has policies with regard to the frequency of acid eluate testing. If the IgG DAT result is positive (complement result positive or negative), an acid elution is required if one or more of the following apply: transfusion reaction is suspected; clinical signs of hemolysis are present; increased avidity of the IgG DAT result by one grade since last tested; mixed field IgG DAT result is present; unexpected serum results with no definable specificity are noted; IgG positive DAT is seen on a patient with no history of a prior IgG positive DAT; or the requesting facility asks for an elution. Outside of the parameters stated, if the patient is chronically transfused, the elution is repeated every 6 months unless specifically requested. **Results/Findings**: Of the 73 eluates evaluated, 53 (72.6%) demonstrated panagglutination which may be indicative of autoimmune disease, 14 (~19%) demonstrated alloantibody specificity, which helps manage transfusion and transfusion reaction treatment, and 6 (~8%) were negative. Upon analysis of the negative results, 2 were associated with antibiotic therapy, 1 was associated with anti-CD38 administration and 3 were cause unknown. **Conclusion**: In this look back study, eluate testing results provided the clinician valuable information in 96% of cases. When used appropriately, the acid eluate test provides valuable clinical information and also helps laboratory staff explain panel reactivity which enables staff to provide the patient with the safest blood product.

SP279

Cryopreserved Buffy Coat-Derived Monocytes for Assessment of Erythrophagocytic Response

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Background/Case Studies: The mononuclear phagocytic system is an important mediator of the innate immune system. Monocytes phagocytose senescent or sensitized red blood cells (RBCs). The monocyte monolayer assay (MMA) is an *in vitro* test used to evaluate the *in vivo* immune response by the mononuclear phagocytic cells. This assay can be used to evaluate clinical significance of alloantibodies that may be associated with hemolytic transfusion reactions or to evaluate RBC immunomodulatory activity. However, current MMA practices require tedious and time-consuming processing of fresh peripheral blood monocytes obtained by venipuncture. **Study Design/Methods**: Mononuclear cells (MCs) isolated from both pooled buffy coats and fresh peripheral blood were isolated by Ficoll-Paque density gradient. For cryopreservation, buffy coat MC concentration was adjusted with cryopreservation media (RPMI-1640: fetal bovine serum (FBS): dimethyl sulfoxide (DMSO), 2:2:1 mol%). Aliquots were frozen to −80°C before transfer to liquid nitrogen storage. Once thawed and washed, the trypan blue exclusion method was used to adjust the viable cell concentration. Briefly, cell suspensions (1mL of 2.0 x 10^6 cells/mL in supplemented culture media) were incubated at 37°C and 5% carbon dioxide on a coverslip treated with poly-L-lysine solution and then washed to remove non-adherent cells. The resulting cell monolayers were incubated with 5% anti-D-sensitized RBCs in culture media for 2 hours before washing and staining. The phagocytic index (number of phagocytosed RBCs per 100 monocytes) of cryopreserved MCs was determined and compared to that of fresh peripheral MCs. **Results/Findings**: Ficoll-Paque PLUS isolation consistently yielded >60% PBMC isolation with low contamination (RBCs ≤5%, platelets <20%). Supplemented culture media supported monocyte viability after 1-hour incubation (95 ±1%). Cryopreservation with DMSO preserved cell function as assessed by cell yield (83 ± 4%), trypan blue stain for viability (93 ±1%), adhesion to a glass coverslip (36% ±3 monocytes before adhesion, 95 ±1% post-adhesion), and phagocytic index using sensitized RBCs (82.7 ± 5.0). This is comparable to the phagocytic index of the fresh peripheral monocytes (96.7 ±19.6). **Conclusion**: Cryopreserved buffy coat-derived monocytes were found to have an adequate phagocytosis response in comparison with fresh peripheral blood monocytes. The use of cryopreserved buffy coat-derived monocytes allows for consistent analysis of immune response without extensive preparation and creates utility for unused buffy coat units.

SP280

Fetal Inheritance of *GP.Mur* Causing Hydrops due to Miltenberger Antibodies

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Background/Case Studies: A preterm infant was born with hydrops. Initial hematocrit was 9% and she was given several 5 mL/kg packed red blood cell transfusions during the first twelve hours of life. Erythroblastosis fetalis was evident from a peripheral blood smear and together with positive DAT and hyperbilirubinemia, hemolytic disease of fetus and newborn was suspected. She received a double volume exchange transfusion and was transferred to a higher level of care where she developed acute renal failure and expired on day 5. **Study Design/Methods**: Serologic antibody investigations were performed using solid phase, LISS tube and Gel column agglutination methods. Blood group and phenotyping for Miltenberger antigens was performed using unlicensed reagents and standard tube tests. Genomic DNA was extracted from paternal whole blood for glycophorin A and B exon 3 and 4 PCR-amplification and sequencing using a cycle (Sanger) sequence kit. **Results/Findings**: The initial maternal antibody screen was negative. Her serum was tested for the presence of an antibody to a low-prevalence antigen. Maternal plasma reacted with 4 examples of Mi(a+) RBCs; one

example of Mi(a+)Vw+ and three examples of Mi(a+)Mur+. All other low prevalence antibodies were ruled out. Maternal antibodies were detected in the baby's plasma and paternal RBCs were incompatible with the cord plasma. Further Miltenberger specificity could not be determined due to lack of appropriate reagent RBCs. Specimens from both parents were referred for antibody confirmation, Miltenberger phenotyping and gene sequencing. The reference lab showed that the maternal serum reacted weakly with one example of Mi(a+)Vw+ reagent RBCs. Strong hemagglutination (3 to 4+) was observed with one example of Mur+ DANE+, three examples of Mi(a+)Mur+MUT+, and 2 examples of Mi(a+),MUT+, Hut+ RBCs. Paternal RBCs were Hil+ MINY+ Vw-when tested with unlicensed anti-Hil, anti-MINY, and anti-Vw antibodies consistent with GP.Mur. A hybrid *GYPA/B* exon 3 was successfully PCR-amplified and sequence analysis determined it was identical to *GP.Mur*. The *GP.Mur* allele is linked *in cis* to the s antigen. *GYPB* exon 4 sequencing showed that paternal DNA was homozygous MNS*04 (S-s+). Paternal DNA contained one wildtype *GYPB* allele based on detection of a *GYPB* pseudoexon 3 (*GYPB**e3Y). **Conclusion**: *GP.Mur* is inherited in a classic Mendelian fashion. Maternal alloimmunization has been reported and is associated with severe HDFN. Given the obstetrical history, future children of this couple have a 50% chance of inheriting the *GP.Mur* allele and risk for HDFN.

SP281

Serologic Findings in Patients Treated with Daratumumab – Experience of a Transfusion Service

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Background/Case Studies: Daratumumab (DARA) is an IgG anti-CD38 monoclonal antibody (Ab) recently approved by the FDA for treatment of refractory multiple myeloma. Due to expression of CD38 on RBCs, DARA present in plasma samples interferes with blood bank tests. **Study Design/Methods**: Medical records and 4 months of laboratory data from patients who had received DARA were reviewed. Antibody screens (ABS) were done by gel (ProVue, Ortho Diagnostics) or PEG indirect antiglobulin (IAT), and in a few patients, also by solid phase assay (SPA, Capture-R, ECHO, Immucor). All Ab identifications (ABID) were performed by PEG-IAT. Dithiothreitol (DTT)-treated cells were used to resolve DARA interference. **Results/Findings**: Twenty-nine patients were studied. None had pre-existing RBC Abs. After starting DARA, 21 patients had follow-up ABSs; all were positive. A total of 59 ABIDs were performed: 47 were pan-reactive, while 12 had 1-4 negative panel cells. Two of the 17 donors testing negative with various patients were repeatedly non-reactive in panels: 1 was non-reactive with 3 patients, and another with 2 others. Reaction strength ranged from 0-2+ in gel ABS (n=83), and 0-3+ in PEG-IAT (n=73, majority weak or 1+). DTT-treated cells showed no reactivity, indicating DARA interference in all samples. ABS by SPA method (8 patients) showed variable reactivity (0-4+). When compared with PEG-IAT or gel, 6 samples showed stronger reactions and 1 each showed similar or weaker reaction strength. Auto-controls were positive in only 8 of 64 (13%) tested samples. Direct antiglobulin test was positive for IgG (weak-2+), but negative for complement (n=7). Of the 5 elutions done, 3 were negative, one reacted 1+ with 1 of 6 panel cells (DTT not performed, so unclear if this was DARA-related), and one showed weak reactivity with screening cells that resolved after DTT treatment, suggesting it was DARA-related. Eighteen patients received 127 RBC transfusions; 94 were phenotypically matched for both Rh and K, while 33 were only matched for K. No new RBC Abs were identified during the study. During this 4-month period, DARA was stopped in 8 patients, 4 of which had follow up testing available: while 1 continued to show DARA interference at 13.5 weeks after stopping DARA, this was no longer demonstrable in the other 3 patients sometime between 4-6, 15-18.5, and 7-14 weeks, respectively. **Conclusion**: Our findings are consistent with prior reports. We noted a trend toward stronger reactions with SPA compared to gel and PEG-IAT. Of the samples showing DARA interference, only 80% showed a panagglutinin. Interestingly, panel cells from 2 donors were repeatedly non-reactive with different patients, suggesting low CD38 expression. Screening cells formulated from adult donors with low expression of CD38 could potentially expedite laboratory work up of patients on DARA.

SP282

Anti-LW: Distinguishing Autoimmune from Alloimmune Antibodies

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Background/Case Studies: Anti-LW^a is often considered clinically insignificant and autoimmune. Antigen suppression is common and limits the ability to determine whether the antibody is auto or alloimmune. We report a case of anti-LW^a where red cell genotyping aided in differentiating the nature of the antibody. **Case**: An 83 year-old, Caucasian female with history of lower GI bleed, cardiac disease, diabetes, and warfarin use for pulmonary embolism presented for left total knee replacement. Preop testing confirmed blood type as O Positive and a historical anti-LW which could not be classified as auto or alloimmune in nature that was weakly reactive (w-1+) with only D+ reagent cells (RC) by LISS and PEG IAT, and a negative autocontrol. Automated SPRCA showed stronger reactions (3-4+) with D+ RC, variable reactivity (neg-3+) with D- RC. One crossmatch compatible, D- RBC was transfused on postop day 2 (Hb 8.4 g/dL) without complications. Next day she was discharged with Hb of 9 g/dL. Three weeks later patient returned with surgical wound infection and request for RBC crossmatch. She was managed medically without transfusion. Due to incompatible crossmatches (IS and LISS IAT) with all D+ and D- RBC units, samples were sent to local IRL for antibody identification in anticipation of future transfusion needs. **Study Design/Methods**: IRL testing included routine saline IAT, PEG IAT, use of AET-treated cells, and allogeneic adsorptions by tube methods. Molecular testing with DNA isolated from WBCs utilized Immucor PreciseType™ HEA Test. **Results/Findings**: Patient's serum reacted at IS (4+), 37C (w+) and saline IAT (4+) with all LW(a+) RC. Autocontrol was negative and DAT (w+) with Poly, IgG, and C3. In addition, AET-treated RC reacted 3-4+. Sample was negative with Rh null RC and weak with LW(a-) RC. Multiple alloadsorptions failed to remove the antibody and reactivity remained 4+. Due to the strong and atypical reactions, sample was sent for RBC genotyping. Prior to availability of these results patient re-presented with lower GI bleed and symptomatic anemia (Hb 6.9 g/dL). Two incompatible, phenotyped matched D-, E-, K-, Fy(a-), Jk(a-) RBC units were transfused. No evidence of an acute reaction was noted. Post transfusion, Hb rose to 8.3 g/dL. Bleeding was controlled and she received no further transfusions. Her Hb post-discharge was stable. Molecular results confirmed patient's LW genotype as $LW^{a}LW^{b}$, indicating antibody as alloimmune. **Conclusion**: Our case supports the importance of red cell genotyping to differentiate allo- versus autoantibodies. Although this patient's anti-LW^a presently is of questionable clinical significance, it is important to distinguish between autoimmune and alloimmune antibodies. The immune nature of the antibody provides important information to monitor the outcome of future transfusions.

SP283

The Evaluation and Comparative Analysis of ABO Isoagglutinin Titration using Saline Tube, DTT, and Solid Phase Technique

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Background/Case Studies: ABO incompatible organ transplants often require multiple isoagglutinin titrations prior to surgery. Patients found with high ABO isoagglutinin titers require apheresis to lower the titer and allow for organ engraftment. Differentiating IgG and IgM isoagglutinins with dithiothreitol (DTT) prevents a high-titer IgM from interfering and avoids unnecessary apheresis procedures. Solid phase technology was compared to DTT and tube in determining IgG and IgM ABO isoagglutinin levels. **Study Design/Methods**: For the purpose of this study, selected 10 group A, 10 group B and 9 group O patients with at least a 3+ ABO isoagglutinin level had titrations performed by solid phase technique on the Immucor NEO® instrument, DTT treatment with a saline control and a conventional tube technique following a validated ABO titration protocol. The group O patients had A and B isoagglutinin levels evaluated. None of the patients tested had been transfused an out-of-group plasma-containing product. All methods included an incubation and reading at room temperature (RT) followed by 37°C incubation and reading at IgG. The NEO® assays used for the determination of IgM and IgG titers were the RT antigen screening assay (IgM) and the IgG crossmatching assay (IgG). The diluent for the titrations was isotonic saline and the NEO® IgG assay required a 6% albumin diluent and the addition of LISS in the test system. **Results/Findings**: When comparing the ABO titrations performed on the instrument and in the tube (n=38), 45% (n=17) of IgM titers were identical, 47% (n=18) were within 1 dilution and 8% (n=3) were within 2 dilutions. Of the IgM titers that were not identical (n=21), 71% (n=15) had a lower titer on the instrument than in tube. When comparing the titrations performed on the instrument and with DTT treated plasma (n=38), 37% (n=14) of the IgG titers were identical, 29% (n=11) were within 1 dilution, 8% (n=3) were within 2 dilutions and 26% (n=10) were within 3 dilutions. Of the IgG titers that were not identical (n=24), 83% (n=20) had a higher titer on the instrument than in DTT. **Conclusion**: The

results demonstrated that the NEO® IgG crossmatching assay currently is not an alternative to DTT treated plasma for determining IgG ABO isoagglutinin levels. The instrument's IgG titers trended higher than tube, which could lead to unnecessary apheresis and delay the transplant procedure. A possible explanation could be the addition of LISS and albumin in the test system. The IgM ABO isoagglutinin titers from the NEO® RT antigen screening assay and tube were comparable but would have a limited role in transfusion medicine.

SP284

Red Cell Alloimmunization followed by Refractory Autoimmune Hemolytic Anemia Post-Bone Marrow Transplant in an Infant with SCID

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Background/Case Studies: Red cell alloantibody formation and autoimmune hemolytic anemia (AIHA) have been described as a complication of bone marrow transplant (BMT) for Severe Combined Immune Deficiency (SCID). We describe a 4 month old male with Adenine Deaminase Deficiency type SCID who was transplanted with a matched unrelated bone marrow. His ABO/Rh phenotype was B+ and his donor ABO/Rh type was B-. On day +273 post-transplant, he had an acute drop in hemoglobin followed by emergence of red cell alloantibodies to Jk(a) and E antigens. It was noted that there was no exposure to E antigen positive RBC transfusion and his white blood cell chimerism was 100% donor by short tandem repeats. On day +305, he developed warm autoimmune hemolytic anemia (AIHA) with associated acute drop in hemoglobin, panreactive panel cells, and IgG 4+ direct antiglobulin test. He subsequently had a partial clinical and laboratory response to AIHA with multiple courses of Rituximab and Bortezomib. **Study Design/Methods**: A retrospective review of patient records and a review of current published data on red cell antibody formation following bone marrow transplant was performed. Data was captured and analyzed in Microsoft Excel 2010, and Graphpad Prism version 6.0 for Windows. Red cell molecular phenotyping was performed with Biorarray HEA BeadChip, Bioarray Solutions. **Results/Findings**: Between 3 and 9 months post-transplant, 32% (n=28) of Rh forward types by serological agglutination in test tube indicated weak positive agglutination. 100% WBC chimerism was confirmed in bone marrow and peripheral blood, suggesting mixed erythropoietic chimerism in the setting of 100% donor WBC chimerism. Red cell molecular phenotype by buccal swab, showed patient's pre-transplant RBC expressed E and Jk(a) antigen. Red cell molecular phenotype of peripheral blood WBC, confirmed donor RBC did not express E and Jk(a) antigen. RBC transfusion data confirmed that no E antigen positive RBC were transfused during patient's lifespan. Historic RBC typing for Jk(a) antigen for transfused RBC was not available. For AIHA that developed post RBC alloimmunization, patient received 4 doses of Rituximab (CD19 target of $<0.2\%$), and Bortezomib (4 repeat cycles, 16 doses). Following treatment course patient has remained transfusion independent with hemoglobin >9g/dl for 1 year, although he has detectable DAT IgG 1+, and Anti-E antibody present in his blood. **Conclusion**: This case suggests RBC alloimmunization to pre-transplant RBC can occur as a result of mixed erythropoietic chimerism in the setting of 100% donor WBC chimerism post bone marrow transplant. It also demonstrates a pediatric AIHA case where administration of multiple cycles of Bortezomib was tolerated without toxicity, and may have contributed to transfusion independence.

SP285

Anti-Jk3 during Pregnancy and Risk for Hemolytic Disease of the Fetus and Newborn

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Background/Case Studies: The Kidd-null phenotype occurs in individuals who do not express this multi-pass transmembrane glycoprotein, and arises either through inheritance of a dominant inhibitor gene or from a silent allele. Kidd-null individuals possess the ability to make an antibody against the Jk3 antigen - a high incidence antigen present in >99.9% of most populations. While such individuals are rarely encountered by transfusion services, they present a number of challenges to the blood bank including determination of the presence of the phenotype, accurate identification of the antibody, masking of other antibodies, and management of transfusion support given the rarity of Jk3-negative blood products. Antibodies against the Kidd blood group, including anti-Jk3, are clinically significant, can cause both acute and delayed hemolytic reactions, and have been implicated in hemolytic disease of the fetus and newborn (HDFN). Ethnic groups with an increased prevalence of the Kidd-null phenotype include Polynesians and Pacific Islanders, Finnish, and certain Southeast Asians. This case series reviews the clinical and laboratory aspects of anti-Jk3 antibodies with a focus on hemolytic disease of the fetus and newborn (HDFN). We present four cases of anti-Jk3 alloantibodies encountered during pregnancy demonstrating a range in clinical presentations of Kidd-related HDFN. **Study Design/Methods**: The clinical and blood bank records for four patients and their newborns encountered at four different institutions in Tennessee, Missouri, Hawaii, and Guam with an anti-Jk3 antibody identified during pregnancy were retrospectively reviewed. **Results/Findings**: See table. **Conclusion**: Clinical manifestations of anti-Jk3 related HDFN are clinically variable. Our case series showed no significant evidence for HDFN in two of the cases while the remaining two cases were mild-moderate in intensity requiring only phototherapy for hyperbilirubinemia. No intrauterine or neonatal transfusions were necessary. Anti-Jk3 antibody titers were not found to correlate with HDFN risk or severity, however elevated middle cerebral artery flow velocities monitored by Doppler ultrasound were predictive of HDFN when performed. Difficulties in the transfusion support of patients with an alloantibody directed against a high incidence antigen such as reference lab antibody identification, timing of procurement and transfusion of rare donor blood, and communication across specialties in a complex clinical situation were also encountered.

SP286

Prevalence of Unexpected Red Cell Antibodies in Blood Donors, Pregnant Women, and Patients: A Retrospective Study from Chinese Zhejiang Area

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TABLE. Clinical Features of Patients with an Anti-Jk3 Antibody Identified During Pregnancy

	Age	Obstetric History	Anti-Jk3 Titer	Additional Erythrocyte Antibodies	Fetal Age at Delivery in Weeks	Clinical Diagnosis of HDFN	Cord Blood DAT	Newborn Bilirubin Peak (mg/dL)	Ethnicity
Case 1	28	G2P1001	1:32	Jka, Jkb, c, E, K, Fyb, S	33 4/7 (induced)	Yes	Positive	7.0 (at 48 hours)	Polynesian
Case 2	32	G10P5146	1:16	E	33 6/7 (induced)	Yes	Positive	9.6 (on day 4)	Mennonite
Case 3	34	G7P5025	1:2	None	39 6/7 (spontaneous)	No	Negative	7.2 (at 36 hours)	Polynesian
Case 4	32	G9P9009	1:32	Jkb	39 (spontaneous)	No	N/A	N/A	Chamorro

Background/Case Studies: Chinese populations have multiethnic groups and wide variety of genetic background. The immune responses to erythrocyte alloantigens in Chinese may differ from that in Caucasian, but there is only limited data on unexpected antibodies in China. In this study we tried to analyze the distribution of unexpected antibody for erythrocyte in blood donors, pregnant women and patients of Chinese Zhejiang area. **Study Design/Methods**: The retrospective study was performed in ten institutions including a hospital and nine blood services spread all over the Zhejiang Province. The total numbers of independent samples included 2939 clinic patients, 114906 pregnant women and approximate 1446200 blood donors, in which the donors and pregnant women were random samples, but the patients were pre-screened by hospitals and then referred to their blood services due to suspicious antibody. The work was supported by Science Research Foundation of MOH, China (WKJ-ZJ-1510) and Zhejiang High-Level Innovative Health Talents. **Results/Findings**: Total of 2238 antibodies including 450 auto-antibodies (or cold agglutinins) and 1788 allo-antibodies were detected in 2081 cases. In all samples with allo-antibodies, the specificity of 1412 antibodies was determined, but the specificity of remaining 376 antibodies could not be determined. The distribution of unexpected antibody in these 1412 antibodies was as follows: anti-M, 33.5%; anti-E, 26.0%; anti-D, 12.1%; anti-cE, 5.9%; anti-P_1, 3.8%; anti-Le^a, 3.1%; anti-Le^b, 2.3%; anti-Ce, 1.6%; anti-C, 1.6%, and other antibodies with frequency lower than 1% (including anti-e, -S, -Jk^a, -H, -Jk^b, -Fy^b, -Di^a, -N, -s, -Mur, -Fy^a, -Hr_0). The allo-antibody frequency was 0.034% in blood donors, in which anti-M (64.3%), anti-P1 (8.5%) and anti-D (6.8%) were significantly frequently detected. The allo-antibody frequency was 0.165% in pregnant women, in which anti-D (37.9%), anti-E/cE (23.2%) and anti-M (15.3%) were most frequently detected. Although overall antibody frequency in patients could not be estimated, it can also be found that anti-E (42.0%), anti-M (16.6%), anti-c/cE (8.6%) and anti-D (8.3%) were most frequently detected in patients. **Conclusion**: In Chinese population, approximate 20% agglutination reactions were due to the auto-antibodies or cold agglutinin. In allo-antibodies, the major immune antibodies were anti-E, anti-D and anti-cE. Meanwhile, the major natural antibodies were anti-M, anti-P_1 and anti-Le^a/Le^b. It is worth noting that the anti-E is the most frequent antibody in patients now, so the E antigen-identical (not only compatible) transfusion should be also considered in China.

SP287

Consistency Achieved: Automated ABO Antibody Titrations on the Galileo Neo® Platform

E Preuss[1], S Oldekamp[1], J Muehl[1], A Gellerer[1], S Blincko[1]. [1]*R&D, Immucor, Roedermark, Germany*

Background/Case Studies: ABO antibody titration is clinically relevant for many different applications such as organ and stem cell transplantations, ABO incompatible pregnancies and blood group O donor characterization in transfusions. However, the consistency of methods employed has not been satisfactory and studies can show as much as 7 doubling dilutions differences in results. Automated titrations on the Galileo NEO® platform, employing quality reagents, have been developed and evaluated for their consistency. **Study Design/Methods**: The Galileo NEO® offers fully automated IgG assays with dilutions from neat up to 1/4096 and IgM assays from neat to 1/128. The Galileo NEO® also offers titer screen assays for the detection of high titer specimens. The results are obtained without manual intervention and do not require dithiothreitol (DTT) treatment to specifically measure human IgG (detection employs a specific monoclonal to human IgG). IgG gel methods without DTT by contrast measure a mixture of IgG and IgM according to the pack inserts. Donor and patient (pregnancy and transplant) specimens were employed in the studies. Repeatability and reproducibility: two specimens were tested on each assay in triplicate, morning and afternoon, on three Galileo NEO®s, on 5 non-consecutive days within a 21 day period. Lot to Lot consistency: $\geq$2 specimens were tested on each assay with three discrete sets of reagents on one Galileo NEO®. Comparison of precision vs tube: $\geq$2 specimens were tested on each assay in triplicate on the Galileo NEO® and manually using the tube method. Refrigerated specimens: $\geq$2 specimens were tested on each assay over 15 days while being stored at 1-10°C. Frozen/thawed specimens (3 x freeze/thaw): $\geq$2 specimens were tested on each assay before and after 1x, 2x and 3x freezing ($-$15 to $-$25°C) and thawing. Tube types: Serum, EDTA and CPDA plasma tube types: $\geq$2 matched sets of specimens were tested on each assay. Range vs screen assay comparison: $\geq$10 specimens were tested on both screen and corresponding range assays in triplicate. **Results/Findings**: All studies showed results $\leq$+/-1 doubling dilution from the median result. Comparision of precision vs manual tube showed that the Galileo NEO® gave better precision (all results within 1 doubling dilution) than the manual tube method (all results within 2 doubling dilutions). **Conclusion**: The automated Galileo NEO® ABO titration assays demonstrate excellent consistency across lots, instruments, time, and with sample types and storage. These assays offer a consistent and complete picture of IgG and IgM titers and fully automate the currently labor intensive and less precise manual alternatives. The results will need to be confirmed in clinical settings.

SP288

Case Study of a Previously Typed Jk Null Donor to be Jk^a weak Positive

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Background/Case Studies: Antibodies to Kidd antigens are associated with delayed hemolytic transfusion reactions and hemolytic disease of the newborn (HDN). The major antigens of Kidd are Jk^a and Jk^b, the frequency of Jk(a+b+) is 49%, and Jk(a+b-) and Jk(a-b+) are 23%, 27% respectively in Asian population, Jk(a-b-) is considered as Jk null, and is rare. Donations with Jk null are often made into frozen RBC to provide special request from hospitals. A previously typed Jk null RBC was ordered for a patient with Anti-JK3. However, the cross match was incompatible, blood was returned for further investigation. **Study Design/Methods**: Our aim is to investigate the incompatibility and the Kidd antigen expression by the donor. Sample segments from frozen RBCs were obtained, also fresh sample was collected. Phenotype of Jk^a/Jk^b antigens were performed using tube (Sanquin, Bio-Rad, Immucor) and CAT (ID-card profile II, Bio-Rad) methods according to manufacture manual. All testing was validated with known controls. Sample was sent to Sanquin Reference Lab for erythrocyte analysis and genotyping. **Results/Findings**: The donor has 4 previous donations all tested JK null from 2012 to 2015. Phenotype of latest donated blood segments and fresh samples suggest Jk($a+^w$,b-). Jk^b were found negative in all tests. However, Jk^a was found negative in 3 antiserums used (Sanquin lot:8000217090, 8000211839, and Bio-Rad lot:176203610), and weak expression (1+) in just one (Sanquin lot:8000197772). Weak expression (2+) with mix-field was observed with Jk^a in CAT method. Erythrocyte analysis from Sanquin Reference Lab gives Jk^a weak positive (1+) and Jk^b negative, and the genotyping shows *JK*01W.01* and *JK*02N.02* alleles. These results suggest weak expression of Jk^a. **Conclusion**: (1)This donor was determined as weak expression of Jk^a. (2) CAT method is more sensitive than tube method detecting weak Jk^a expression. (3) For Jk^a negative result, we suggest further confirmation with CAT method using antisera from several manufacturers and/or several manufacturing lots, for weak Jk^a expression.

SP289

Specificity Achieved: Automated ABO Antibody Titrations on the Galileo Neo® Platform

E Preuss[1], S Oldekamp[1], J Muehl[1], A Gellerer[1], S Blincko[1]. [1]*R&D, Immucor, Roedermark, Germany*

Background/Case Studies: ABO antibody titration is clinically relevant for many different applications such as organ and stem cell transplantations, ABO incompatible pregnancies and blood group O donor characterization in transfusions. Tube and gel based methods have been developed but are reported to have poor consistency. Additionally the methods are not able to measure IgG specifically (as stated in pack insert) as IgM reacts additionally. Dithiothreitol (DTT) may be added to specimens to remove IgM but it is not optimal. The Immucor Capture-R® Select technology, by design (employing a monoclonal antihuman IgG), enables the specific measurement of IgG and excludes IgM without requiring the addition of DTT. These studies describe results from the fully automated ABO titration assays on the Immucor Galileo NEO® platform, which allow the specific titration of either IgM or IgG antibodies from donor and patient, serum and plasma to A1, A2 and B cells in comparison to gel (with and without DTT). We additionally describe the relationship of IgM concentration and its effects on IgG concentrations as measured by Galileo NEO® and gel. **Study Design/Methods**: The Galileo NEO® offers fully automated IgG assays with dilutions from neat up to 1/4096 and IgM assays from neat to 1/128. Results are obtained by the instrument without manual intervention. 25 group O, 25 group A and 25 group B specimens (serum and plasma from donors, pregnancy and transplant patients) were tested by the full set of range assays and by Bio-Rad® gel with and without DTT following the AABB manual method for DTT treatment. **Results/Findings**: Good correlations were obtained ($R^2 = 0.78$, 0.81 and 0.71 on A1, A2 and B cells respectively) between the Galileo NEO® IgG and the corresponding AABB gel method with DTT. Good correlations were

obtained ($R^2 = 0.79$, 0.84 and 0.71 on A1, A2 and B cells respectively) between the Galileo NEO® IgM and the corresponding gel IgM method. Difference plots of gel IgG (without DTT) minus Galileo NEO® IgG versus IgM (Galileo NEO®) show that the difference increases for many specimens (notably those from group A and B plasma but not O) as IgM concentration increases. **Conclusion**: The Galileo NEO® ABO titration assays demonstrate good specificity for IgG and do not require the addition of DTT. The data supports the contention that to obtain a more specific IgG titer with gel then DTT should be added. IgM concentration appears to drive the differences seen between gel results without DTT treatment and Galileo NEO® with group A and B specimens but not significantly with O. The Galileo NEO® assays offer a specific, consistent and complete picture of IgG and IgM titers and automate the currently labor intensive and less precise manual alternatives. These results will need to be confirmed in clinical settings.

SP290

Multi-site Evaluation for Performance of a Platform-based Fully Automated Immunohematology (IH) Instrument

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Background/Case Studies: Evaluation of a new immunohematology testing system is necessary to show that the performance of a new instrument demonstrates equivalence from a method-based perspective when compared to results of a predicate method or instrument. A next generation larger capacity instrument is being designed to fully automate IH testing using the ID-MTS™ Gel Card (GEL) test. A multi-site study was conducted to evaluate the performance of the instrument under development compared to the predicate, the ORTHO VISION® Analyzer. Consistency in reaction grade evaluation across the instrument platform is critical to confidence in the results produced. **Study Design/Methods**: Testing occurred across five laboratory study sites. Method comparison testing was conducted on greater than 8000 samples acquired from the sites' routine workload to meet required sample criteria. Results were assessed at the microtube and interpretation level for direct agglutination tests and AHG tests. Discordant samples between the test and predicate methods were repeated using the site's manual GEL method. Direct agglutination tests included: ABO (Forward and Reverse), Rh, Rh phenotype and immediate spin (IS) crossmatch (XM). AHG based tests included Abscr, AbID, AHGXM and the direct antiglobulin test (DAT). Data from direct agglutination, DAT and IAT testing was assessed by comparison of interpreted tests to determine % concordance (CC) between the two instruments at the one sided lower 95% confidence bound (LCB95). The acceptance criteria for concordance were $\geq$99.4% for direct agglutination tests and $\geq$98.0% for AHG tests. **Results/Findings**: High CC between the two systems was observed for both direct agglutination and AHG (DAT/IAT) for each site and across all sites combined. Direct agglutination testing was performed on $>$36,000 microtubes with 15,100 interpreted results. 15,081 interpreted results were concordant and 19 interpreted results were discordant. The system comparison demonstrated a CC of 99.8% at a LCB95 interval for direct agglutination. DAT or IAT testing was performed on $>$17,000 microtubes resulting in 7,361 interpreted results. 7,344 interpreted results were concordant and 17 interpreted results were discordant. The system CC was 98.7% at the LCB95 interval for AHG tests. **Conclusion**: The multi-site evaluation demonstrated that the instrument under development, ORTHO VISION® Max Analyzer, showed equivalent performance versus the predicate system exceeding the LCB95 concordance acceptance criteria of $\geq$99.4% for direct agglutination tests and $\geq$98% for AHG tests in the intended use environment

SP291

Implementation of Automated Phenotyping Testing on the NEO

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Background/Case Studies: Donor phenotype testing was centralized to two Blood Center Testing Laboratories in 2011, the Rh (C,c,E,e) and Kell antigen typing were automated on the Immucor Galileo instruments. Phenotyping of additional extended antigens (Fy^a, Fy^b, Jk^a,J k^b, S and s) continued to be performed manually because no licensed reagent for automated testing was available for donors. In Europe, Immucor had CE marked reagents to perform testing on the NEO for extended antigens. Immucor was required to apply for a medical device license of the CE marked reagents and assays with the national regulatory body for testing donor samples. In collaboration with Immucor, the Blood Center supported the vendor submission to license the reagents and assays for use on the NEO. **Study Design/Methods**: In 2011, six Galileo instruments were upgraded to the SP11 software and qualifed for Rh (C,c,E,e) and Kell phenotyping, in addition to other assays with an automated interface of test results to LIS. To support Immucor's submission to license the extended antigen testing on the NEO, the Blood Center participated in a clinical performanace evaluation. Three hundred random donor samples with no previous antigen results were tested on the NEO for Fy^a, Fy^b, Jk^a, Jk^b,S and s assays. These samples were then tested once by manual tube method using a different source of antiserea. Samples testing as equivocal or No Type Determined on the NEO were repeated in duplicate on the NEO. Samples with discrepant results between NEO and manual testing were repeated manually in duplicate. Six discrepant results were found with the anti-Fy(b) and one with anti-S reagents between NEO and manual testing. These discrepant results could not be resolved and were sent to Immucor for further testing. Immucor required 200 additional samples to be tested for Fy^b and S to support the criteria in the package insert and submission for licensure. No discrepancies were noted for these 200 samples. **Results/Findings**: Immucor received licensure from the regulatory body in 2014 to perform extended antigen testing on the NEO for donor samples. In 2014, the Blood Center executed an installation operational qualification protocol to support its submission for approval to use the NEO for donor testing. In November 2014 approval was received and in 2015, eight NEO instruments were installed at the two Blood Centers. With implementation of the NEO the 11 common antigens (C, c, E, e, K, Fy^a, Fy^b, Jk^a, Jk^b, S and s) are performed on the NEO platform with an interface of test results to LIS. **Conclusion**: The Blood Center supported Immucor with the data required for the vendor to receive regulatory approval. Automation and elimination of manual test result entry has allowed an increase in the volume of testing by 30% with no increase in budget and improved quality with decreased opportunity for transcription or manual entry.

SP292

The Rare Specificity Anti-Nob (Anti-MNS27) Associated with a Transfusion Reaction following an Electronic Crossmatch

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Background/Case Studies: Antibodies to low-prevalence antigens are not routinely detected by antibody screening but rather are often revealed as the cause of a transfusion reaction or hemolytic disease of the fetus and newborn. The MNS system has over 30 low-prevalence antigens; many are expressed on hybrid glycophorin (GP) molecules composed of portions of GPA and GPB. The rare Nob antigen is expressed on either a GP(A-B-A) or a GP(B-A-B) hybrid. Anti-Nob is a very rare specificity with one report of a mild transfusion reaction. We investigated a sample from an 83 year-old man with symptoms of a febrile, non-hemolytic transfusion reaction following an electronic crossmatch. His plasma reacted only with RBCs from the implicated donor unit suggesting an antibody to a low-prevalence antigen. **Study Design/Methods**: Standard hemagglutination methods were used for antibody identification and antigen typing. Gamma ELU-KIT II (Immucor) was used to prepare an acid eluate. RBCs expressing low-prevalence antigens were from our in-house collection. **Results/Findings**: The patient's plasma reacted ($1+^S$) by PEG IAT and 1+ by CAT only with RBCs from the implicated donor unit but not with other panel cells, consistent with an antibody to a low-prevalence antigen. The plasma continued to react with RBCs treated with 0.2 M DTT or α-chymotrypsin but not with with papain or trypsin treated RBCs suggesting possible MNS specificity. RBCs expressing MNS antigens M^g, Mit and Vr, and RBCs expressing the following hybrid GP molecules: GP.Hut (Mia+, Hut+, MUT+), GP.Mur (Mia+, Mur+, Hil+, MINY+, MUT+), GP.Hop (Mia+, Mur+, Hop+, TSEN+, MINY+, MUT+), GP.Nob (Nob+) were tested by PEG IAT. Only the Nob+ RBCs reacted. The presence of anti-Nob was confirmed by testing a second example of GP.Nob RBCs. The patient's RBCs reacted very weakly (microscopic) in the DAT (IgG). An acid eluate prepared from his RBCs reacted very weakly by PEG IAT with only RBCs from the donor unit and with two examples of Nob+ RBCs. Suitable anti-Nob was not available to test the donor RBCs and DNA testing could not be performed as the donor unit was leukoreduced. **Conclusion**: Anti-Nob is an exceedingly rare specificity with little information regarding clinical significance. We report an example of anti-Nob that was the likely cause of a febrile transfusion reaction to an RBC unit transfused following an electronic crossmatch. Treatment of donor RBCs with enzymes and DTT guided the testing toward an MNS antigen. Interestingly, Nob antigen on the donor's RBCs was sensitive to trypsin treatment which is unexpected as previously it was thought to be resistant.

SP293

Microbiota Specifically Regulate the Development of Anti-Blood Group Antibodies

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Background/Case Studies: Despite Landsteiner's discovery of ABO blood group antigens over a century ago, many questions remain regarding the factors that regulate anti-ABO antibody formation. Early studies demonstrated that anti-ABO antibodies develop within the first few months of life despite the lack of a known antigenic exposure. However, subsequent studies suggested that environmental triggers, such as microbial exposure, might impact the development of anti-ABO antibodies. As distinct microbes can stimulate specific anti-carbohydrate antibodies, we hypothesized that individual strains of microbes with blood group reactivity may be required for the development of naturally occurring antibody formation. **Study Design/Methods**: To examine the impact of microbiota on naturally occurring antibody formation, we generated a model of ABO(H) blood group antigens. As lower mammals do not express ABO(H) antigens, we knocked out (KO) the glycosyltransferase responsible for the synthesis of the carbohydrate B^{dis} antigen, an antigen very similar to blood group B. Microbial flora was assessed in WT (Blood group B-like) or B^{dis} KO (Blood group O-like) by sequencing ribosomal DNA isolated from stool samples. Serum was assessed for B^{dis} reactivity at baseline and following B^{dis+} microbial exposure using a glycan microarray. WT or B^{dis} KO recipients were transfused with B^{dis+} RBCs followed by the evaluation of RBC clearance, antibody engagement and complement fixation by flow cytometry. **Results/Findings**: Similar to blood group O individuals, B^{dis} KO recipients spontaneously develop variable levels of anti-B^{dis} antibodies. Naturally occurring anti-B^{dis} antibodies engage B^{dis+} RBCs and induce an acute hemolytic transfusion reaction following B^{dis+} RBC transfusion. To determine whether environmental exposures may influence anti-B^{dis} antibody formation, we separately housed B^{dis} KO recipients with low titer anti-B^{dis} antibodies. This resulted in an entire B^{dis} KO colony that never developed anti-B^{dis} antibodies, despite the presence of diverse microbial flora. Intentional exposure of B^{dis} KO recipients that lacked detectable anti-B^{dis} antibodies to specific microbes that express the B^{dis} antigen induced robust anti-B^{dis} antibodies capable of causing a hemolytic transfusion reaction following B^{dis+} RBC transfusion. **Conclusion**: These results demonstrate that B^{dis} KO recipients provide an attractive model to study naturally occurring antibody formation and suggest that anti-ABO antibodies are not an inevitable outcome of not expressing ABO blood group antigens. As an individual's microbiota may dictate the development of anti-ABO antibody formation, intentional manipulation of an individual's microbial flora may provide a unique and previously unrecognized approach to prevent anti-ABO antibody formation in patients requiring transplantation or chronic transfusion.

SP294

Immunohematological Alterations in Liver Transplantations: Prospective Analysis

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Background/Case Studies: Solid organ transplants are associated with many hematological abnormalities, including graft versus host disease and post-transplant lymphoproliferative neoplasms. Immune hemolytic anemia is a possible complication of orthotopic liver transplantation (OLT), but its frequency was never studied prospectively. **Study Design/Methods**: All patients submitted to OLT at a university hospital in northeast Brazil, from September 2014 to April 2016, that consented to participate, were included in the study. Each patient, before transplant, and the available samples of cadaveric donors were evaluated for ABO/RhD, antibody screening (AS), direct antiglobulin test (DAT) and eluate, if DAT+. Also, the patients were evaluated with AS and DAT for at least 7 consecutive days and once a week until day 30. **Results/Findings**: A total of 175 patients undergoing 178 OLT were analyzed. 60% were male with mean age of 51 years-old. The most prevalent causes of cirrhosis were HCV (51 patients, 29%) alcohol (34, 19.4%) and cryptogenic (27, 15.4%). The mean MELD score was 20. Seventy-eight patients (44.7%) were O+, 4 (2.3%) O-, 60 (34.3%) A+, 3 (1.7%) A-, 23 (13.1%) B+, 2 (1.1%) B-, 2 (1.1%) AB+ and 3 (1.7%) AB-. Sixteen OLT were ABO nonidentical (1 AB received A; 1 AB received B; 5 A and 9 B received O). AS was positive in 13 patients before OLT, 1 patient had anti-C,-e, 2 anti-E and 1 Anti-V. The other patients presented nonspecific RBC antibodies, reacting in tube or enzyme treated cells. Seventeen patients presented AS+ after OLT and transfusion (4-29 days), with 4 anti-E, 1 anti-D, 1 anti-Di^a, 1 anti-Le^a, 1 anti-I and 9 nonspecific RBC antibodies. DAT was positive in 53/175 (30.3%) patients before transplant, with 3.8% IgG+C3d and 96.2% IgG. Nine of the previous 13 negative DAT patients (69.3%) submitted to minor ABO incompatibility OLT presented DAT+ post transplant, comparing to 46/109 (42%, p=0.07) of identical ABO OLT. Five of the 16 (31.2%) patients submitted to nonidentical ABO OLT exhibited ABO antibodies in eluate/plasma, being diagnosed with passenger lymphocyte syndrome (PLS). Four patients (25%) presented clinical significant hemolysis. All the patients with PLS received organs from O donors. Only one patient submitted to ABO identical OLT presented positive eluate, anti-E, but both the patient and the donor were E+, with no variants detected on *RHCE* BeadChip (possible auto-anti-E). All the other eluates were nonreactive, probably drug-induced. Two donors presented DAT+ and 2, AS+ (anti-c and anti-Le^a). The recipient from the donor with anti-c was c+, but did not present DAT or AS+ after transplantation. **Conclusion**: Immune hemolytic anemia in OLT is common and includes PLS, transfusion hemolytic reactions, autoimmune and drug induced hemolytic anemia. These should always be evaluated as possible diagnoses for recipients with anemia.

SP295

Anti-C Alloimmunization following Rh-positive Apheresis Platelet Transfusion in an Rh-negative Recipient: A Case Report

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Background/Case Studies: Although apheresis platelets contain small volumes of red blood cells (RBC), they have been associated with RBC alloimmunization. We report a case of anti-C antibodies identified in an Rh-negative recipient following transfusion of Rh-positive apheresis platelets. **Study Design/Methods**: Patient's chart and literature were reviewed. Routine blood bank testing, including ABO/Rh type, indirect antiglobulin test (IAT) screen, and direct antiglobulin test (DAT), were performed in gel (Provue; Ortho Clinical Diagnostics; Raritan, NJ). Red blood cell phenotyping was performed in tube using monoclonal blood grouping antisera (Immucor Inc., Norcross, GA). Adsorption/elution studies using R0r and r'r cells were performed in tube to evaluate for anti-G antibodies. **Results/Findings**: A 71-year-old Caucasian woman with acute-on-chronic combined systolic and diastolic heart failure was admitted for further evaluation after worsening of her symptoms. She had a past medical history of placement of a biventricular implantable cardioverter defibrillator 5 years prior and a known history of asthma, chronic obstructive pulmonary disease on oxygen, obstructive sleep apnea, and pulmonary embolism. The patient was not a candidate for heart transplant, and therefore surgical placement of a left ventricular assist device (LVAD) was planned. Blood products were requested for the operation. Pre-operatively, the patient's blood type was group B, Rh-negative and her IAT screen demonstrated a previously identified anti-D. During and after the surgery, the patient was transfused with 4 units of B, Rh-negative packed RBCs, 2 units of fresh frozen plasma, and 1 unit of B, Rh-positive apheresis platelets. Her post-operative course was not significant. Eight days following transfusion, a repeat IAT screen was positive with anti-D and anti-C specificities (4+ on gel). Transfusion reaction work up was negative, including DAT and laboratory indicators of hemolysis. She was therefore diagnosed with a delayed serologic transfusion reaction. The patient's phenotype was C(-). She had no prior transfusions or pregnancy in the prior 3 months. All 4 RBC

TABLE. Frequency (%) of RBC Alloantibodies Identified (173 antibodies in 150 patients)

Antibody	anti-E	anti-c	anti-Jk^a	anti-D	anti-K	anti-C	anti-S	anti-e	anti-Fy^a	anti-Jk^b	anti-G	anti-Fy^b	anti-f	anti-Kp^a	anti-C^w	anti-Wr^a
Frequency (%)	32	14	12	10	10	7	4	3	2	2	1	1	0.5	0.5	0.5	0.5

units were found to be C(-). The donor of the transfused platelet unit was not available for phenotyping. Anti-C was confirmed after ruling out anti-G. It was concluded that the anti-C was due to primary or secondary alloimmunization against RBCs in the platelet product. At a 3-month follow-up visit, the patient continued to demonstrate anti-D and anti-C antibodies. **Conclusion**: Although anti-D alloimmunization is a rare but well-known complication of apheresis platelet transfusion, alloimmunization to non-D antigens may also occur.

SP296

Prevalence of Clinically Significant Prenatal Red Blood Cell Alloantibodies

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Background/Case Studies: Clinically significant prenatal antibodies could lead to Hemolytic Disease of the Fetus and Newborn (HDFN). Despite a decrease in the incidence of HDFN due to anti-D, attributed to the widespread use of Rh Immune Globulin (RhIG) during pregnancy since the 1960's, HDFN due to other clinically significant antibodies continues to be of great concern to fetal and neonatal outcomes. **Study Design/Methods**: A retrospective review of all pregnant patients tested from January 1, 2006 to April 1, 2016 in a single tertiary centre was performed. Data were collected on gestational age, clinical significance of the antibody identified, as well as antibody titre. Patients who delivered at this centre were also followed for postnatal outcomes. **Results/Findings**: Over 10 years, approximately one quarter of all specimens tested for ABO/Rh and antibody screen were on pregnant patients. Three hundred pregnant patients had a positive antibody screen by column-agglutination technology; 150 patients were determined to have 173 clinically significant red blood cell (RBC) alloantibodies (some patients had multiple antibodies). The prevalence of a positive antibody screen among pregnant women was approximately 1.4%, as compared to 3.6% for all patients tested. The clinically significant alloantibodies identified are listed in Table 1. There were 47 pregnant patients with clinically significant alloantibodies who delivered at this centre. These antibodies were titred during the pregnancy. In total, there were 53 deliveries from these 47 patients: 5 patients had multiple pregnancies and one patient had twins. Of these 53 deliveries, 31 neonates (by cord testing) were positive for the corresponding antigen and therefore at risk for HDN. The most common alloantibodies in these pregnancies were Rh antibodies and accounted for over 80%. The data on neonatal anemia, treatment and outcomes are being collected. **Conclusion**: RBC alloimunization in prenatal population is low (1.4%) compared to all other patients tested at this centre (3.6%). Despite stringent prenatal policies for RhIG, anti-D along with other Rh antibodies, continues to be one of the most prevalent clinically significant RBC alloantibodies detected in prenatal specimens. The data on neonatal anemia, treatment and outcomes are still being collected. Of interest, two of the pregnant patients had anti-G, which mimics anti-D and anti-C reactivity and may lead to inappropriate omission of prenatal RhIG administration.

SP297

Direct Blood Group Typing of Kpa and Kpb using Polyclonal Antibodies in MDmulticard Lateral Flow Technique

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Background/Case Studies: A lateral flow assay for simultaneous typing of ABO, RhD, Rhesus phenotype and K with stable end-point and without a centrifugation step is in routine use since several years (MDmulticard). In previous studies, the successful use of monoclonal antibodies of the IgM and IgG class for this direct typing assay has been demonstrated. The objective of this study was to evaluate the performance characteristics of polyclonal antibody based direct typing of the two model antigens Kpa and Kpb with this technique. **Study Design/Methods**: Fresh blood was obtained from individuals previously determined serologically for Kpa and Kpb with established CE certified techniques (Anti-Kpa and Anti-Kpb, Medion Grifols Diagnostics, Duedingen, Switzerland). Considering the distribution of Kell system antigens in a normal Caucasian population, Kpa positive and Kpb negative samples were statistically overrepresented (Kpa+b- n=2, Kpa+b+ n=6, Kpa-b+ n=40). The credit-card sized lateral flow test device consists of a membrane, which is embedded in a cassette housing. Two detection areas containing antibody reagents against up to ten different blood group specificities and internal controls are left and right of a central application zone. In this study, affinity purified human polyclonal antibodies against Kpa and Kpb antigens were applied on the membrane. For blood group typing, 100 µl of diluted whole blood or erythrocyte sediment are pipetted to the central application zone, followed by 300 µl of a rinsing solution. Results may be interpreted after 5 minutes. Positive results clearly impose as distinct red bands, whereas negative results lack the respective bands. See Table. **Results/Findings**: All results of the blood samples tested were in full accordance with those of the CE certified comparative methods. **Conclusion**: MDmulticard lateral flow technique was presented earlier with unique features, e.g. simultaneous multiparameter blood grouping without the need of centrifugation and results within 5 minutes. The detection of antigens in this technique was, however, limited to the use of monoclonal antibodies as source. In this study, first performance results for the direct detection of Kpa and Kpb antigens, two blood group antigens for which no monoclonal antibodies are available, are shown. The possibility to employ not only monoclonal antibodies, but also polyclonal antibodies may allow to detect any combination of blood group antigens with lateral flow technique in a direct 5 minute assay.

TABLE. Performance characteristics of anti-Kpa/Kpb in lateral flow technique

Phenotype	n=	Sensitivity	Phenotype	n=	Specificity
Kpa pos.	8	100%	Kpa neg.	40	100%
Kpb pos.	46	100%	Kpb neg.	2	100%

SP298

Evaluation of Recombinant Blood Group Proteins for Antibody Neutralization using Tube Testing

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Background/Case Studies: The molecular identification of most blood group antigens has resulted in the ability to produce recombinant blood group proteins (rBGP). rBGP can be useful in the identification of antibodies to high-prevalence antigens or detection of underlying alloantibodies. Thus, we evaluated eight different rBGP for their ability to specifically neutralize corresponding antibodies. **Study Design/Methods**: A total of 78 specimens with previously identified antibodies were obtained from a frozen collection of antisera and were checked for reactivity prior to being used for this study. Reagent rBGP expressing CR1 (KN), CROM, DO, FY, KEL, JMH, LU, and YT antigens (Imusyn GmbH & Co., Hannover, Germany) were tested in accordance with the manufacturer's instructions with minor modifications. The volumes in the directions were optimal for testing in gel cards. Therefore, the amounts were scaled up to have sufficient volume for tube testing. **Results/Findings**: The appropriate rBGP inhibited all of the following: anti-Kn^a (19), anti-Sl^a (2), anti-KCAM (1), anti-Yk^a (2), anti-Cr^a (9), anti-Tc^a (2), anti-Dr^a(1), anti-IFC (1), anti-Jo^a (2), anti-Do^b (2), anti-Hy (1), anti-Fy^a (3), anti-k (3), anti-Kp^b (6), anti-JMH (4), anti-Lu^b (4), anti-Lu8 (1) and anti-Yt^a (8). Two anti-k reacting 4+ and an anti-K11 required additional amounts of rBGP for complete neutralization. Four samples including: two anti-Yk^a, one anti-Do^a and one anti-K22, were not inhibited by the rBGP even with additional rBGP. Fifteen samples with KN, LU or YT antibodies also contained underlying antibodies including: anti-K1, -C^w, -Kp^a, -E or -Le^a. None of the concomitant antibodies were inhibited by the rBGP. **Conclusion**: The rBGP performed satisfactorily using tube testing; however, some samples required additional rBGP to completely inhibit the alloantibody. This may be due to the protein concentration of the rBGP reagents. Because the CR1-rBGP used was limited to the long homologous region D containing the known KN antigens, we postulate that the lack of inhibition with two anti-Yk^a samples may be due to other single nucleotide polymorphisms in CR1 near Yk^a that may affect antibody binding. Further investigation would be required to determine why the samples with anti-Do^a or anti-K22 were not neutralized. However, given the rarity of K22 negative individuals, it may not be relevant for routine testing.

SP299

A Pre-transfusion Testing Algorithm and Notification System for Patients on Daratumumab Can Reduce Turn-around Time

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Background/Case Studies: Daratumumab (DARA) is a new drug for treatment of patients with relapsed, refractory multiple myeloma. DARA is a human IgG1κ monoclonal antibody (ab) that binds to CD38 on myeloma tumor cells. Endogenous CD38 is also expressed on red cells and thus can interfere with pre-transfusion testing (PT). Previous investigations found that DARA interference with serological workups can be successfully negated by denaturing CD38 from red cell surfaces using dithiothreitol (DTT). We report experience with a cohort of 60 DARA patients with emphasis on the management of allo/autoimunized patients. **Study Design/Methods**: We evaluated PT and transfusion requirements for DARA patients in a single academic institution from 6/2015-4/2016. We reviewed patients' antibody screens, antibody identifications (ABID) and crossmatches (XM), including turnaround time (TAT). Statistical analysis was performed using STATA 14.1. **Results/Findings**: Sixty patients received DARA; mean age was 64.7 years (range 45 to 89). 75% received stem cell transplant (68% autologous, 7% allogeneic). The initial DARA patients encountered by our blood bank had a significant delay in TAT for pre-transfusion testing, predominantly due to lack of clinical history and the time required for send-out to a reference laboratory. To avoid delays in transfusion, we established a notification system before a patient starts DARA and validated in-house DTT treatment for the antibody screen. We created an algorithm for management of serologic testing using DTT-treated panels for patients with allo- and auto-immunization. All DARA patients receive K-RBCs, unless known to be K+. Only immunized patients receive phenotype-matched units. Overall immunization rate for DARA patients was 23% (14/60); 8% alloimmunization, 15% autoimmunization and 5% nonspecific reactivity. Two patients made an allo ab after DARA (anti-c,-S, -Co^b). The Co^b patient required XM with DTT treated RBCs. After testing algorithm and notification system implementation, the TAT for all ABID testing for DARA patients decreased significantly from mean 24.6 ± 59.9 (h) to 5.56 ± 14.2(h). (t-test, $p=0.002$). Patients had an average drop in hemoglobin of 1.7 ± 1.3 g/dL (pre DARA 10.0 ± 1.6 g/dL to nadir of 8.4 ± 1.9 g/dL post DARA) (paired t-test $p<0.0001$). 30% of patients required RBC transfusion support (1-22 RBC units/patient). **Conclusion**: Daratumumab has a significant impact on the need for transfusion and the ability to perform pre-transfusion testing. In order to provide safe and expedient transfusions, we established a DARA testing algorithm and notification system. After implementation, we noted a significant decrease in TAT for pre-transfusion testing.

SP300

Genome-wide Screen for Loci Associated with Alloimmunization in Sickle Cell Disease

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Background/Case Studies: Sickle Cell Disease (SCD) is a genetic disorder characterized by abnormal hemoglobin. Blood transfusions are used to manage the disease; however, complications do occur due to red blood cell alloimmunization, which affects up to 30% of transfused patients. Immunologically distinct phenotypes in transfused patients have been described. 'Responders', form multiple antibodies after most RBC transfusions, which is much less robust in 'Non-responders'. Genetic elements have been tentatively associated with susceptibility to alloimmunization, however none of these have been replicated in other cohorts. This study aimed to identify possible genetic markers associated with alloimmunization which might be useful understanding its pathophysiology and identifying potential responders. **Study Design/Methods**: African-American SCD patients (N=288) were genotyped on Bead Chips with 2.5 million markers, then data quality control and association analysis performed using PLINK. Regions with SNPs approaching genome-wide significance (5×10^{-8}) were imputed using IMPUTE2, followed by association testing of imputed SNPs. African-Americans are genetically admixed, hence local genetic ancestry using ELAI was evaluated and ancestry-informed genome-wide allele dosage analyzed. Haplotype analyses using a novel method that integrates Bayesian association with inferred local ancestry implemented in hapQTL software package. **Results/Findings**: Samples were excluded (N=21) due to low call rate, familial relatedness, and ancestry, resulting in 145 cases and 122 controls. Association tests ($\lambda = 1.01$) revealed a cluster of SNPs in strong LD on chromosomes 2 and 5 (maximum P observed; 2.0×10^{-8} and 8.4×10^{-8}, respectively). Chromosome 2 SNP cluster is close to a gene recently implicated in regulation of inflammatory response genes and fever-dependent acute recurrent liver failure in pediatric patients. Chromosome 5 SNP cluster is located in a regulatory shown to regulate expression of genes involved in immune and inflammatory responses. Significant differences in local ancestry between cases and controls at these regions (C.I 95%) were not observed. However, African-specific allele dosages showed significant association at the chromosome 5 region (Bayes Factor: 10^4.954). This ancestry-related association was not detected by local ancestry analysis and allelic tests, indicating that association is driven by interaction between an allele and its African ancestry background. **Conclusion**: Two loci associated with alloimmunization in SCD transfusion patients have been identified, with implications for both diagnosing at-risk SCD transfusion recipients and further understanding the underlying pathophysiology; efforts to replicate these findings using larger and more diverse datasets are underway.

SP301

Red Blood Cells with a Rare Ge:-2,-3 Type are Confirmed to Show a Kell Antigen Depression with a Monoclonal Anti-k Reagent but not Obviously Detectable by a Routine Typing Procedure

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Background/Case Studies: Depression of Kell antigens in the Ge:-2,-3 rare type (Gerbich) was first reported in a K+ woman and her brother, with approximately half the number of K antigen sites compared to K+k+, Ge:2,3 control red blood cells (RBCs) (Muller A & al, *Rev Franc Transfus* 1973). Daniels GL described in 1982 various degrees of weakening of high-frequency Kell antigens, especially K11, in 9 out of 11 Ge:-2,-3 subjects. Another group observed that K+k+, Ge:-2,-3 RBCs showed a K antigen density three times lower than K+k-, Ge:2,3 RBCs (Jaber A & al *Blood 1989*). **Study Design/Methods**: We aimed to confirm the weakening of the Kell antigens in Ge:-2,-3 RBCs using a marketed monoclonal anti-k reagent (LK1, Bio-Rad). We studied 15 K-k+, Ge:-2,-3 unrelated subjects, 8 of Western European and 7 of Eastern European or Northern African ancestry. We also tested 15 K-k+, Ge:-2,3 (Yus) unrelated individuals, 6 originating from Western Europe and 9 from Northern Africa. Semi-quantitative Cellano typing (titer/score) was performed by gel-test (Bio-Rad) with an indirect antiglobulin test. **Results/Findings**: A weakening of the Cellano antigen expression could not obviously be noticed when phenotyping with undiluted anti-k reagent (3+ for K-k+, Ge:-2,-3 *vs* 4+ for K-k+, Ge:2,3 RBCs). However, when using a semi-quantitative typing procedure (titer/score), a moderate depression of the k antigen could be seen. Indeed, as the positive control (pool of 6 K-k+, Ge:2,3 RBCs) showed a titer/score of 32/54, the K-k+, Ge:-2,-3 RBCs displayed a min/max titer of 8/32 with a mean score of 40. As a result, the k antigen expression appeared to demonstrate a decrease around 25% in Ge:-2,-3 RBCs compared to the Ge:2,3 control. Moreover, the K-k+, Ge:-2,3 RBCs exhibited a min/max titer of 32/64 (14/15 had a titer of 64) with a mean score of 60. This surprising score value, about 10% higher than the Ge:2,3 controls, could be consistent with a slight overexpression of the Kell antigens in people with a Yus type. **Conclusion**: Our results show a weakened expression of the k antigen in Ge:-2,-3 people, this being consistent with previously published works, though still not fully explained. However, this antigen depression appears to be moderate (about -25%) and cannot be easily detected with a standard typing procedure. We unexpectedly found a seemingly higher expression of the k antigen in Ge:-2,3 RBCs, never reported before; this needs to be confirmed with an expression study of other high-frequency Kell antigens (Kp^b, Js^b, etc.). In conclusion, our results suggest a Gerbich phenotyping to be exclusively performed in individuals with a slightly weak Kell antigen. In case of a strong global Kell antigen depression, this does not seem relevant and a McLeod type has to be searched for.

SP302

Red Blood Cell Alloimmunization Among Patients with Transfusion-Dependent β Thalassemia Major; A 15-year Experience at a Tertiary Care University Hospital in Oman

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Background/Case Studies: Thalassemia is a common hemoglobin disorder in Oman. Red blood cell (RBC) transfusion is a cornerstone for the management of β thalassemia major. Transfusion, however, can create significant medical challenges in the management of these patients including iron overload and alloimmunization. The alloimmunization rate is variable among reports. There is no data on the frequency and risk factors of alloimmunization in patients with β thalassemia major in Oman. Herein, we examine the prevalence of alloimmunization and the associated risk factors among transfusion dependent β thalassemia patients in our center. **Study Design/Methods**: A retrospective review of all adult and pediatric β thalassemia major attending our center over the last 15 years was performed. Clinical and serologic records were retrieved and examined. Chi-square test was used to assess the association between the categorical variables. Non-parametric Mann-Whitney test was used to assess the association between RBC transfusion and the risk of alloimmunization. Statistical analysis was performed using IBM SPSS software, version 22.0. **Results/Findings**: A total of 268 patients were identified (167 adults and 101 pediatrics), of which 226 are alive (84.3%). Male patients accounted for 53.6% of the cohort. The cohort had a median age of 16 years (range: 2-40 years). The most common blood group is O+ (39.2%), followed by A+ (25.9%), B+ (21.3%), AB+ (5.3%), O- (4.6%), A- (2.7%), B- (0.8%) and AB- (0.2%). The rate of alloimmunization was 11%. The most common antibodies identified in the cohort were anti-E (25%) and anti-K (25%), followed by anti-D (12.5%), anti-c (12.5%), anti-C (8.3%), anti-KPa (8.3%) and anti-e (4.2%). One patient had an auto anti-e. There was a statistical significant association between age and RBC alloimmunization with 80% of alloimmmunized patients were in the age group of 18-30 years ($P< 0.0001$). In addition, there was a statistical significant association between RBC alloimmunization and both female gender and number of units transfused ($P< 0.005$ for each). There is no association between RBC alloimmunization and past history of pregnancy or splenectomy. **Conclusion**: Our study shows that the most common RBC antibodies associated with alloimmunization in β thalassemia major are directed against the E, and Kell antigens. There was an association between risk of alloimmunization and age, female gender and number of units transfused. Transfusion support of this group of patients necessitates the availability of needed expertise and blood bank facilities.

SP303

The Prevalence of Rh and K Phenotypes in African Blood Donors in a Hospital Based Blood Donor Unit in Nairobi

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Background/Case Studies: There is no published data available on the prevalence of the blood group phenotypes other than ABO and Rh D in the Kenyan population. There is paucity of published data on the prevalence of delayed serologic and delayed hemolytic transfusion reactions in Sub Saharan Africa, as well as commonly implicated antibodies. Published data reveals that after ABO and Rh D; antibodies to K, Rh E, Rh e, Rh C and Rh c are most implicated in causing clinically significant hemolytic reactions and hemolytic disease of the fetus and newborn. Differences in the prevalence of these red cell phenotypes amongst different populations and races have been described. **Study Design/Methods**: The study objective was to determine the prevalence of Rh D, C, c, E,e; and K phenotypes in African blood donors. A cross sectional study was carried out at a hospital based blood bank in Nairobi. Study participants were recruited at the hospital blood donor unit, and from blood donor recruitment drives in Nairobi conducted by the hospital's blood donor unit. Convenient sampling was conducted from July to December 2014. Blood group phenotypes were determined using the Ortho AutoVue® column agglutination system. **Results/Findings**: A total of 340 African blood donors were recruited. The overall prevalence of the various phenotypes presented as % with 95% CI was as follows: Rh D 90.3% (87.15-93.45), Rh C 10% (6.81-13.19), Rh c 99.4% (98.58-100.2), Rh E 10% (6.81-13.19), Rh e 99.4%(98.58-100.2), and K 0.3% (−0.28-0.88) Calculation of the 95% CI surpassed the 100% for Rh C and Rh c, suggesting a larger sample size would be required. The confidence intervals were however quite narrow at 98.58-100.2, and it is unlikely that even with a larger sample size that the prevalence reported would change significantly. The 95% CI of K phenotype in the African population was −0.28-0.88%, indicating that a larger study population would be required to determine the prevalence. A bigger sample size was not recruited due to financial limitations, but additional funding is being sought. **Conclusion**: Compared to published results of the prevalence of Rh and K phenotypes in other African populations, the results of the Kenyan study were similar a study done in Malawi, and differed from the results of studies conducted in Mauritius and Morocco. This is likely due to the fact that the Malawian population is largely Bantu, and 80% of our study participants were of Bantu origin. This supports the need for local based prevalence studies, as results of other populations may not be generalizable across the continent.

SP304

Red Cell Antibodies in Egyptian Thalassemic Patients

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Background/Case Studies: Thalassemia is a common disease in Egypt that requires long life blood transfusion which may lead to allo-immunization to red cell Ags that can significantly complicate transfusion therapy. Stem cell transplantation still remains the only cure currently available for patients with thalassemia. Known blood group Ags are 344 in number till now, not all of them are highly immunogenic. Significant Abs can lead to red cell destruction and hemolytic transfusion reactions. **Study Design/Methods**: The aim of the study is to find out the frequency and factors influencing red cell alloimmunization in Egyptian thalassemic patients. The study conducted on 320 thalassemic patients; presented to Egyptian NBTC for blood transfusion. Age of the patients was ranging from 1 to 25 years.
Patients subjected to:

- Screening for red cell Abs (panel of 3 blood group O- cells) using appropriate IAT by CAT
- Antibody identification for positive screening results (panel of 11 blood group O- cells) using appropriate IAT by CAT
- Red cell phenotyping using monoclonal anti-sera

Results/Findings: A total of 320 patients screened for the presence of red cell allo-antibodies. 84 (26.25%) found to have allo-antibodies. Of these patients, 33 (39.30%) developed one allo-antibody, 28 (33.30%) developed two allo-antibodies and 23 (27.40%) patients developed more than two allo-antibodies. The most frequent allo-antibodies found was: anti-K antibody (32/84) representing 38.1%, anti-E (21/84) representing 25%, anti-C (13/84) representing 15.5%, anti-D (12/84) representing 14.3%, anti-Fya (11/84) representing 13.1%, followed by anti-Jka (10/84) representing 11.9% of alloantibodies found. The majority of patients were previously transfused for years with non- phenotyped blood, and the majority of red blood cell allo-antibodies formation was against the Kell and Rh blood group systems **Conclusion**: Allo-immunization to red cell antigens is a frequent finding among Egyptian thalassemic patients, which requires screening. It is important to have protocols for dealing with transfusion dependent patients. We recommend routinely performing RBCs phenotyping for all transfusion-dependent thalassemic patients before starting RBCs transfusion. Evaluation of Abs status should be done before each transfusion, to give the patients Ags free blood transfusion for the relevant Abs

SP305

Special Pre-transfusion Serological Testing for Patients with Warm-type AIHA

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Background/Case Studies: Warm auto-antibodies are directed against patients' own red blood cell antigens and can interfere with and complicate investigations for the detection and identification of RBC allo-antibodies. Most patients with AIHA have already been transfused and the patients' phenotype can be difficult to determine. In warm type AIHA; the auto- antibodies in the patient's serum react with all normal red blood cells and make it impossible to find compatible blood. Special appropriate compatibility test procedures in a reference laboratory allow the detection and identification of clinically significant allo- Abs that may be masked by the auto- Abs. **Study Design/Methods**: The study done on 322 patients with warm type AIHA, presented to the Red Cell Reference Lab at Egyptian NBTS. Routine lab investigations in the form of screening for red cell Abs and auto-control were done for all these patients and revealed positive auto-control with pan-positive reactivity with different phenotyped RBCs, using Column Agglutination Technique. Patients subjected to allo-adsorption; in this procedure adsorption of auto-antibodies from the patient's serum is carried out using three to four samples of allogeneic red cells of varying phenotypes; these samples should be complementary lacking the clinical significant red cell Ags, and are used to adsorb auto-antibodies from the patient's serum at 37C on several phases to ensure complete successful adsorption of auto-antibodies. The adsorbed serum then tested for allo-antibodies. Although auto-adsorption technique is much easier than

allogenic adsorption in interpretation, it was not achieved due to deficient enough patients' samples and also most of the patients were recently transfused making auto- adsorption inappropriate **Results/Findings**: Of the 322 patients; 132(41%) revealed co-existing allo-antibodies, of which 45.8% of the antibodies were against the (Rh) blood group antigens, 16.7% against (Kell) blood group antigens, 14.6% against (MNSs) antigens, 7.8% against (Kidd) antigens, 3.1% against (Duffy) antigens and 12% against other blood group antigens. Of the 322 patients, 190(59%) revealed only auto-Antibodies without no co-existing allo-antibodies. Clear identification of the masked coexisting allo-Abs directed us to transfuse the patients with Ag/s free blood units for the relevant identified Ab/s, and hence we avoided the risk of hemolytic transfusion adverse effect of these allo-Abs This changed the previous wrong concept of transfusion of the least incompatible blood units to patients with AIHA **Conclusion**: Proper management of patients with AIHA requires the implementation of techniques that can differentiate between auto- & allo-antibodies and allow the identification of co-existing allo-antibodies which are present in a high percentage of patients with AIHA and can cause red cell destruction

RBC Molecular Testing and Genetics: Assay Development and Evaluation

SP306

The Use of Next-Generation Sequencing for Determination of Alleles of Rare Blood Group Antigens

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Background/Case Studies: Commercially available blood group genotyping kits detect single nucleotide polymorphisms (SNPs) that specify common blood group antigens. However, rare SNPs or SNPs in blood group systems not typically covered by commercial kits can be missed leading either to incorrect phenotype interpretation or confounding the process of antibody identification. A next generation sequencing (NGS) assay allowing for analysis of the genes of 15 blood group systems excluding ABO and Rh is presented. **Study Design/Methods**: A customized Ampliseq panel for use with Ion Torrent PGM was designed. The panel includes the coding regions of the genes of Gerbich, Yt, Dombrock, Colton, Kell, Kidd, P1PK, Globoside, Duffy, Lutheran, Landsteiner-Weiner, Diego, Vel, Knops (exon 26, 29) and Chido/Rodgers (exon 25-28). DNA amplification and sequencing were performed according to the manufacturer's instructions. Data analysis was carried out using CLC Biomedical Workbench 3.0 software. Data extracted from the software were transferred to an in house spreadsheet for the identification and interpretation of SNPs associated with blood group antigens. **Results/Findings**: Samples from 8 individuals previously genotyped using commercially available kits were used for verification of the panel. The results for 6/8 samples were fully consistent with previous results. For 2/8 samples previously determined as Jk(a+b+), the allele, JK*01W.01 encoding Jka^{weak} was identified. This was subsequently confirmed by Sanger sequencing. Additional samples from Hispanic (9), Middle Eastern (6) and Black (1) blood donors were analyzed. In these 16 samples, the NGS assay detected common SNPs but also revealed SNPs that would have been missed using commercially available kits: All samples were found to be heterozygous or homozygous for different SNPs in Knops, including KCAM- and Yk(a-). In addition, rare alleles were detected in the genes encoding Diego, Kidd, Dombrock, Lutheran and P1PK antigens. Several donors were heterozygous (2 Hispanics and 2 Middle Eastern) and one homozygous (Middle Eastern) for LU*02.19 encoding Au^{b}. One Hispanic donor was JK*01W.03/JK*01W.04, encoding Jk(a+^{w}, b-) and two Hispanics were heterozygous for K56E in the SLC4A1 gene encoding a Diego variant. Finally, the NGS assay detected several heterozygous rare missense mutations that are not currently associated with known blood group antigens: a G251D change for Yt (Hispanic), a K451Q for Lutheran (Hispanic) and E906Q for Diego (Middle Eastern). **Conclusion**: This NGS assay enables comprehensive genotype analysis of blood group systems and it is capable of detecting common and rare alleles including some not currently detected by commercial assays.

SP307

Next-Gen Sequencing for Rare Blood Group Genotyping: Highly Parallel and Multiplexed Strategy

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Background/Case Studies: Thirty-five blood group systems are listed by the International Society of Blood Transfusion. They contain more than three hundred antigens and most of these antigens result from a single nucleotide polymorphism (SNP). Blood group typing is conventionally carried out by serology. However, this technique has some limitations and cannot respond to the growing demand of blood products typed for a large number of rare antigens. Once molecular basis of these red blood cell systems are known, molecular biology methods can be implemented in immunohematology laboratories. **Study Design/Methods**: Here we describe a blood group genotyping assay directly from whole blood samples using Next-Generation-Sequencing (NGS). The developed method allows the simultaneous identification of 15 SNPs associated with blood group systems of 95 patients at once, leading to the determination of extended genotypes. After an automated DNA extraction, targets are amplified by multiplex polymerase chain reaction (PCRm). Two panels have been developed. Panel 1 includes *KEL*01*, *KEL*02*, *KEL*03*, *KEL*04*; *JK*01*, *JK*02*; *GYPA*01*, *GYPA*02*, *GYPB*03*, *GYPB*04*; *FY*01*, *FY*02*; *FY*02N.01* (*FY*Fy*) and *FY*X*. Panel 2 contains *YT*01*, *YT*02*; *CO*01*, *CO*02*; *LU*01*, *LU*02*; *DI*01*, *DI*02; DO*01*, *DO*02*, *DO*02.−04* (Hy-), *DO*01.−05* (Jo(a-)). For each sample, both panels are pooled and library is generated from amplicons and then sequenced using MiSeq (Illumina). **Results/Findings**: In a single experiment, 95 blood donor samples have been sequenced on the genes of interest. Amongst the 1,425 targeted SNPs, 1,420 were identified by sequencing, reflecting a coverage of 99.65%. The obtained data show a very good correlation (99% for all SNPs) with other blood group typing methods (genotyping or serology) (see Figure). Depending on the couple of alleles analyzed, correlations vary between 97.12 and 100%. **Conclusion**: The use of NGS for blood group genotyping supplements serological and molecular techniques and, in the near future, could replace it with complete and fast results acquisition. The power of NGS technology is here advantageously employed to read a large amount of SNPs at the same time on many patients, in a single read. Potentially, 1,000 patient samples could be analyzed in a single read, each for 15 SNPs, allowing the identification of 15,000 SNPs. The resulting contraction of cost enables here to be used as an accessible IVD test service for blood banks.

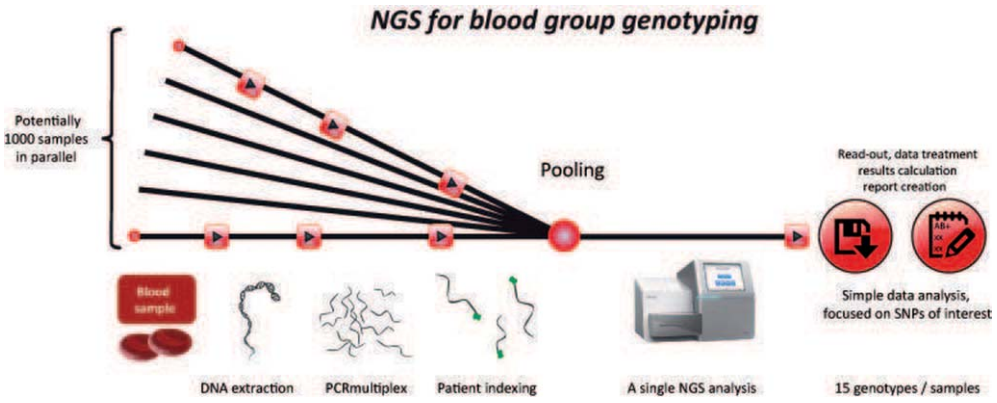

TABLE. Zygosity, aCGH MLR (average from N=3), and gene copy range (±3SD) for RHD and GYPB

Zygosity	MLR	1 SD	Range (± 3SD)	p value
				vs RHD*01N/RHD*01N
RHD*01/RHD*01	0.435	0.019	0.378–0.492	p<0.001
RHD*01/RHD*01N	0.036	0.062	−0.150–−0.222	p<0.001
RHD*01N/RHD*01N	−0.502	0.061	−0.685–−0.319	N/A
				vs GYPB*01N/GYPB*01N
GYPB*01/GYPB*01	−0.029	0.016	−0.077–0.019	p<0.001
GYPB*03N.03(IVS5 + 5g/t)	−0.077	0.072	−0.293–0.139	p<0.001
GYPB*03N.03(IVS5 + 5t/t)	−0.489	0.021	−0.552–−0.426	p<0.001
GYPB*01N/GYPB*01N	−1.166	0.017	−1.217–−1.115	N/A
GYPB*c.234T (s-variant)	−0.441*			
GYPB*c.230-IVS5 + 5t (S-variant)	−0.482*			

N/A = not applicable;
*MLR for single samples, p value not calculated

SP308

Comparative Genomic Hybridization Array Analysis of Blood Group Gene Chromosomal Alterations

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Background/Case Studies: Comparative Genomic Hybridization Array (aCGH) analysis is an accurate method to detect loss or gain of genetic material. Some blood group phenotypes are due to large deletions or duplications. We examined aCGH analysis to detect gene deletions for MNS and RH genes. **Study Design/Methods**: *RHD* and *GYPB* gene copy numbers were evaluated by aCGH. *RHD* was covered by 75 probes; *GYPB* by 39 probes. DNA samples were compared to a control of pooled human genomic DNA. The mean log ratio (MLR) for sample signal intensity *vs* control was calculated and analyzed statistically. *RHD* aCGH analysis was compared to an established quantitative PCR *RHD* zygosity (N=3 for each genotype). U+ and U- samples from self-declared Caucasian and African American blood donors (N=3) were used to establish *GYPB* homozygous (2 gene copy number) or null (0 gene copy number) genotype, respectively. Homozygous and heterozygous *GYPB*03N.03* variants (N=3 each) and 2 novel *GYPB* SNP variants were examined for *GYPB* copy number. **Results/Findings**: *RHD* copy number based on aCGH MLRs was statistically different from the *RHD*01N*/*RHD*01N*, had non-overlapping MLR ±3SD ranges, and correlated with *RHD* zygosity (Table 1). *GYPB* aCGH analysis identified statistically different MLRs for the U+ and U- phenotypes in the region of *GYPB* exons 2 - 6. Three apparent homozygous *GYPB*03N.03* samples had intermediate MLR compared to U- suggesting *GYPB* hemizygosity. The 3 heterozygous IVS5 + 5g/t samples had MLR consistent with 2 gene copies. The 2 *GYPB* variants, a c.234T s-variant and an *in cis* S-silencing *GYPB*03N.01-GYPB*03N.03*, had intermediate MLRs consistent with *GYPB* hemizygosity (Table 1). **Conclusion**: *RHD* aCGH analysis had gene copy numbers identical to qPCR *RHD* zygosity. *GYPB* aCGH analysis showed that the apparent homozygous *GYPB*03N.03* samples had statistically different MLRs between the wildtype and U- indicating that they were hemizygous for the U- deletional allele. This work shows that aCGH analysis detects large genetic deletions and can fill the gap in the characterization of blood group gene chromosomal alterations.

SP309

Development and Evaluation of a Transfusion Medicine Genome-wide SNP Array

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Background/Case Studies: The Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) RBC-Omics study has characterized fresh and 42-day stored blood samples from 13,197 enrolled multi-racial blood donors for whom data including donation history are available. This cohort was enrolled to study the epidemiology and genetics of storage hemolysis, pica, restless legs (RLS), hemoglobin, and ferritin recovery after donations. High yield DNA was obtained from WBC eluted from leukocyte reduction (LR) filters. Due to the multi-racial make-up of the RBC-Omics population and our interest in studying rare genetic variation in transfusion medicine relevant genes, we developed an Affymetrix Axiom genome wide SNP array which we call the TM-Array. **Study Design/Methods**: To develop the array content, we recruited a panel of subject matter experts in the areas of RBC, platelets, blood groups, transfusion, sickle cell disease, pica, RLS, iron and other disorders to identify relevant genes and genetic variation for inclusion. We also conducted extensive bioinformatics mining of resources such as Pubmed, the GWA SNP catalog, and the Affymetrix catalog of variation. **Results/Findings**: The TM-Array includes 549,000 SNPs to provide coverage down to a minor allele frequency (MAF) of 5% in European, African, and East Asian descended populations. The panel includes SNPs with a MAF of >1% in genes relevant to iron metabolism (n=141), platelets (3856), red blood cells (1285), cytokines (238), transforming growth factors (155), and sickle cell disease (48). In addition specific SNPS in transplant relevant genes (n=145), RLS (13), blood and iron disorders (3885), blood groups (729), previously significant GWA studies (34,000), HLA/KIR (14,000), ADME (2000), non-synonymous SNPs (80,000) and in coagulation and cytokine genes (125). We also tiled the alpha globin, beta globin, RHD, and RHCE loci with ~1000 CNPs to allow the detection of copy number changes. In total, the TM-Array includes 875,188 SNPs and 1000 CNPs polymorphisms. We successfully extracted sufficient DNA for GWA studies from the WBCs collected by LR filters in 13,153 of 13,197 (99.7%) samples. Evaluating the performance of the array on the first 12,214 RBC-Omics samples revealed a less than 0.5% failure rate and an average genotype call rate above 99.1%. **Conclusion**: Extracting DNA from WBC collected via LR filters is a highly efficient technique for genetic studies. Initial findings indicate that the TM-Array provides high quality data. The TM-Array is a powerful tool for studying blood and transfusion related disorders. We are making the design of the TM-Array available to other investigators who may wish to use this tool.

SP310

Validation of Automated DNA Extraction from Buccal Swab Samples

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Background/Case Studies: Extraction of DNA is most commonly performed on white blood cells found in whole blood, EDTA samples. However, there are occasions when whole blood is not a viable option to obtain sufficient DNA for testing, including patients with extremely low white cell counts or those who are post stem cell transplant. DNA extraction from buccal swabs can become an alternative sample source; however buccal swabs often yield very low DNA concentrations and poor purity ratios. If customary sample acceptance criteria of concentrations ≥10ng/μl and purity absorbance A260/A280 ratios of 1.6 - 2.2 are applied to these samples, many would be deemed unfit for DNA testing. **Study Design/Methods**: DNA extraction from buccal swabs was performed on 25 samples. Swabs were processed using the extraction protocol supplied by Qiagen for the QIAcube (QIAamp DNA Blood Mini - Buccal swab). Extracted DNA was analyzed for purity and concentration using spectrophotometric technology (NanoDrop,

TABLE. Statistical Analysis

n=25	ng/μl (≥10 preferred)	A260/A280 ratio (1.6-2.2 preferred)
min	0.6	0.55
max	35.8	2.22
mean	7.4	1.51
median	5.4	1.56
mode	4.9	1.46

Wilmington, DE). All samples were amplified according to the test method selected. Twenty-two of gDNA samples were amplified using primers specific for *HGH* and visualized on an electrophoresis gel. The remaining 3 gDNA samples were tested on a microarray assay. **Results/Findings**: Of the 25 samples tested, 12 yielded A260/A280 ratios ranging from 0.55 - 1.5 (1.6 - 2.2 preferred) with 19 of 25 samples yielding a concentration <10ng/μl (≥10ng/μl preferred). Regardless of purity and concentration values, all 25 samples yielded acceptable results from their respective PCR tests. **Conclusion**: Using the QIAcube protocol for buccal swab extraction yields DNA of sufficient quality for PCR processing despite obtaining low purity and quantity readings. This validation demonstrates that conventional sample acceptance criteria may be too strict for buccal swab extraction as all of these samples produced acceptable results upon PCR amplification.

SP311

Renewable DNA Reference Panels for Blood Group Genotyping

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Background/Case Studies: Extended typing of RBCs is an effective strategy to reduce hemolytic transfusion reactions due to alloimmunization in patients who receive multiple transfusions. Screening of large numbers of donors is impractical using traditional serological methods, and matching for rare antigens is therefore often limited, constraining comprehensive characterization of blood donations and stifling the efforts to establish rare donor blood repositories. Molecular blood group genotyping is a reliable method that allows high-throughput typing of blood groups for which serological reagents are not available; however, lack of well-validated DNA reference panels is a barrier to development, manufacturing and quality control of molecular blood genotyping assays. Manufacturers of genotyping kits and genotyping laboratories use non-renewable clinical materials for reference, some of which are poorly characterized, increasing the probability of mistypings. In this study we aimed to develop renewable DNA reference panels to be used by manufacturers for development and validation of assay kits and by genotyping laboratories for test calibration and monitoring of performance. **Study Design/Methods**: A preliminary characterization of more than 30,000 donors was performed by a collaborating blood establishment, and 53 donors were selected based on the results of this screening. PBMCs were isolated and transformed with EBV to establish immortalized cell lines for use as renewable source of genomic DNA. Custom TaqMan assays and Sanger sequencing, covering multiple polymorphisms, were employed to confirm the genotypes associated with RBC antigens of interest. For the formulation of panel, cell lines were expanded, DNA isolated and lyophilized. **Results/Findings**: To do that, we developed 39 unique TaqMan assays, 25 PCR-SSP assays and a PCR-RFLP, and comprehensive characterization of each sample for each polymorphism is ongoing. To date, we tested all SNPs by allelic discrimination assays and 30 SNPs by Sanger sequencing in all 53 blood donors, covering polymorphisms associated with 41 target alleles in 18 blood group systems. We have selected 17 donor samples covering all collected alleles for panel formulation. We are currently in the final stages of lyophilization of the panel members and are planning quality control studies. Stability and accelerated degradation studies are ongoing. We have also identified potential collaborators who will be asked to participate in characterization of the panel to establish its suitability as reference material. **Conclusion**: We have produced cell lines for use as renewable reference panels for RBC genotyping, and have developed a prototype DNA panel. This panel will support availability of accurate RBC genotyping to wider audiences, and help ensure the safety of blood transfusions.

SP312

A High-resolution Genetic Atlas of Blood Cell Variation and Function in Humans

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Background/Case Studies: Hematopoiesis generates mature blood cells from hematopoietic stem cells (HSC) in distinct lineages to release of trillions of mature cells each day into the peripheral blood stream to perform essential functions such as oxygen transport, hemostasis and host defence. The formation and turnover of blood cells are tightly controlled and so the properties of blood cells, including their volume and count, have large heritabilities and are easily influenced by genetic variation. **Study Design/Methods**: Here we describe the most statistically powerful genome wide association study (GWAS) of blood cell indices to date. We tested associations of 29.5 million polymorphic DNA sequence variants derived using the Affymetrix axiom array with interpolation of more than 20 million variants using the UK10K+1000G panel genome data with 36 different hematological indices of red cells, white cells and platelets, some of which, such as the reticulocyte count, have been explored for the first time. **Results/Findings**: We discovered significant associations at 1,652 associated genetic variants, of which only 148 were previously reported, resulting in 1,504 novel associations. Notably, 32% of the 1,652 associated genetic variants are for low frequency genetic variants and identify associations with larger effects on indices than those reported for common variants by previous discovery studies. We have described detailed follow-up studies of the novel associations. Using cell type-specific epigenome and gene expression data generated by the BLUEPRINT project and results from chromatin conformation capture in major blood cell types, we can identify putative causal variants and their functional impact at a large number of the novel loci. Finally, we have compared these genetic variants with variants known to affect common and complex diseases and have discovered that there is indeed a notable overlap for some disease groups suggesting some common biological mechanisms. **Conclusion**: We have interrogated phenotypes across the whole hematopoietic tree and increased the number of traits associated with blood cell phenotypes by an order of magnitude. Overall, our results demonstrate widespread and powerful genetic influences on the formation and regulation of the major human blood cell types, identifying many novel genes involved and show the value of genome-wide functional annotation from relevant primary cell populations for interpreting genetic association results.

RBC Molecular Testing and Genetics: Clinical Implementation

SP313

RBC Blood Group DNA-Based Phenotyping Shortens Subsequent Antibody Workups

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Background/Case Studies: In patients with alloantibodies, RBC phenotyping is usually limited to the antigens to which antibodies have formed. RBC blood group DNA-based phenotyping is not prevented by recent transfusions or positive direct antiglobulin tests (DATs) and could guide future workups by identifying other antigens for which the patient is negative or positive. **Study Design/Methods**: Antibodies were detected with solid-phase red cell adherence (Immucor, Norcross, GA), supplemented by polyethylene-glycol and low-ionic-strength-saline testing. In initial workups, 3 homozygous RBCs were used to rule out antibodies to major non-ABO antigens. DNA-based phenotyping in all RBC antibody patients without prior full phenotyping was performed by multiplex PCR with oligonucleotide extension (HEA BeadChip™, Immucor BioArray, Warren, NJ), batched at 10-day intervals. After phenotyping, antibodies were ruled out with 1 homozygous reagent RBC (Kk for anti-K) for each major antigen for which the patient was negative,

TABLE. RBC Blood Group DNA-Based Phenotyping Shortens Subsequent Antibody Workups

	Pre-Phenotype Workups			Post-Phenotype Workups			
		Reagent RBCs			Reagent RBCs		
Antibodies	Workups	median	mean	Workups	median	mean	p, means
1	27	16	18.1	62	6	10.2	<0.001
2	8	14	16.4	36	9	12.0	0.30
≥ 3	9	16	17.6	19	7	8.4	<0.04
All	44	**16**	**17.7**	117	**7**	**10.5**	**<0.0001**

unless more antibodies were found. Antibody files were retrospectively reviewed 21-24 months after the initial workups to enumerate the screening and panel RBCs needed in each subsequent workup. Initial records were examined for RBC transfusions in the past 3 months and for IgG+ tube DATs. The number of antibodies in each patient included past antibodies, warm and cold autoantibodies and nonspecific reactivity. Means were compared statistically by two-tailed t-test seeking $p<0.05$. **Results/Findings**: In 138 consecutive transfusion-service patients with antibody problems, 33 (24%) had recently received RBCs (26, 19%) and/or had IgG+ DATs (15, 11%); 8 (6%) had both factors. In the following 21-24 months, 68 patients (49%) had subsequent antibody workups. Table 1 compares the average reagent RBCs used in followup workups done before and after phenotyping. Phenotyping shortened subsequent antibody workups by an average of 41% (mean reagent RBCs 17.7 vs 10.5 ($p<0.0001$), median 16 vs 7). **Conclusion**: In a cohort of transfusion-service patients with RBC antibodies and DNA-based phenotyping, subsequent phenotype-guided antibody workups over the next 21-24 months needed substantially fewer reagent RBCs compared to workups in early pre-phenotype follow-up. In nearly one-fourth of all patients, recent RBC transfusions or IgG+ DATs would have complicated serological phenotyping. DNA phenotyping in patients with RBC antibody problems can significantly streamline later antibody workups.

SP314

Red Cell Antigen Genotyping Compared to Serological Phenotyping in Sickle Cell Disease Patients in Canada: Potential for Reducing Alloimmunization

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Background/Case Studies: Red blood cell (RBC) transfusions are part of clinical management for many patients with sickle cell disease (SCD). However, RBC transfusion can be complicated by alloimmunization and hemolytic transfusion reactions (HTRs) in this population despite providing extended phenotype-matched RBC transfusions, due to unique variant RBC antigen mutations. We evaluated the level of discrepancy between RBC antigen genotyping and traditional phenotyping methods and their impact on the development of outcomes at our centre. **Study Design/Methods**: Commencing in January 2015, RBC antigen genotyping has been standard of care for patients with SCD treated at our academic teaching hospital in Canada. RBC antigen phenotyping was performed locally using both tube and automated solid phase assays. Patients are transfused blood that is phenotype-matched for Rh and Kell, until an alloantibody is formed where additional matching for Kidd, Duffy, Ss, and the antigen for which the alloantibody has specificity occurs. Patient blood samples are sent to a reference laboratory to perform genotyping of Rh (excluding RhD), Kell, Kidd, Duffy, and MNSs antigen expression. Clinical data, demographic, and transfusion-related data were obtained from a local transfusion registry database and thorough clinical chart reviews. Local research ethics board approval was obtained. **Results/Findings**: To date, RBC antigen genotyping has been performed on 69/90 SCD patients treated at our centre. The mean age of these patients was 25 ± 20 years, 57% were females, 65% were HbSS, and 29% were HbSC. Overall, 56/69 (81%) of patients had variant mutations or a discrepancy between phenotyping and genotyping. The GATA mutation was detected in 33 patients (48%). Rh variant mutations were observed in 20 (29%) patients, all having the GATA mutation except one. The largest discrepancy was seen in the Rh system, with the e antigen having a kappa of 0.19 and the c antigen having a kappa of 0.49. Alloantibodies were found in 5/20 (25%) patients with variant mutations; and 10/49 (20%) patients with a GATA mutation or no variant mutations. If a genotype-matched (or extended-phenotype matched) strategy was utilized at our centre, 40% of patients with alloimmunization could have been potentially prevented. HTRs occurred in 4 (27%) alloimmunized patients. **Conclusion**: Our results showed a high frequency of variant mutations and significant discrepancies between genotyping and phenotyping methods, most notably in the Rh antigen system. Genotyping SCD patients before transfusion may prevent alloimmunization and HTRs and knowledge of the GATA mutation will allow blood banks to increase the feasibility of finding compatible blood.

SP315

Integrating Red Blood Cell Molecular Genotyping into the Reference Lab: How to Manage Patients with warm Autoantibodies

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Background/Case Studies: Warm autoantibodies (WAA) present complex challenges for hospital transfusion services and reference laboratories (IRL). Molecular DNA genotype analysis can be used to reduce delays in patient care associated with time-consuming serological workups by enabling provision of phenotypically matched red blood cells (RBC). **Study Design/Methods**: Patient samples with WAA present in neat plasma were sent for molecular genotyping. A red cell common panel (C, E, c, e, K, k, Kp^a, Kp^b, Js^a, Js^b, Fy^a, Fy^b, Jk^a, Jk^b, M, N, S, s, U, Lu^a, Lu^b, Do^a, Do^b) was performed. With subsequent RBC orders, hospital transfusion services were advised to compare the current type and screen and crossmatch reactivity to the most recent serologic reactivity. If findings were similar (e.g. previous and current samples reacted 3+), RBC negative for selected antigens (C, E, c, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, S, s) were provided without further testing. If RBC matching the patient's phenotype were not available, the IRL provided Rh and Kell negative blood and matched the remaining phenotype as closely as possible. Additional adsorptions were not performed unless requested by the hospital transfusion service or if serological changes were noted. **Results/Findings**: Since January 2014 molecular DNA genotyping decreased the number of adsorptions performed by 58%. From January 2015 to March 2016, nine patients received a total of 72 phenotypically matched units based on molecular genotype results. In 2 of the 9 cases, patients received RBC that did not completely match their common phenotype due to available inventory. One of the 9 patients developed a new antibody (anti-Kp^a) which was identified after the hospital transfusion service noticed a change in reaction strength. Time between adsorption studies ranged from 1 to 12 months. Additionally, in 3 of the 9 cases, the predicted phenotype indicated that some suspected antibody specificities were autoantibody, thus not requiring matched blood. Following this practice omitted approximately 24 patient workups and decreased turnaround time for RBC. **Conclusion**: There is no standard procedure established to determine if/when the IRL should repeat adsorption studies. RBC molecular genotyping improves customer service by reducing the number of costly workups, including adsorptions, and allows faster turnaround time for transfusion. Based upon these results, if RBC phenotypically matched for common red cell antigens are provided, additional adsorptions are not necessary unless a change in neat plasma reactivity is observed.

TABLE. Blood donor automated and manual antigen discrepancies and molecular findings.

Alleles	ABO	D	C	E	c	e	K
Total	5	56	11	12	18	33	2
Variant (%)	2 (40)	39 (70)	2 (18)	5 (42)	15 (83)	27 (82)	0 (0)
Novel (%)	-	8 (14)	4 (36)	4 (33)	1 (6)	4 (12)	-
Wild-type (%)	3 (60)	9 (16)	5 (46)	3 (25)	2 (11)	2 (6)	2 (100)

SP316

Molecular Analysis of Automated Phenotype Discrepancies among US Blood Donors

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Background/Case Studies: Automated blood group phenotyping is used extensively to ABO/Rh type blood and to identify units with antigen-negative attributes. Discrepancies between automated and manual techniques become evident when antigen confirmation testing is performed by a receiving blood bank. We sought to determine the root cause of donor automated *vs* manual phenotype discrepancies using red cell genotyping and genomic DNA sequencing. **Study Design/Methods**: Serologic discrepancies were confirmed by repeat PK7300 automated and manual tube tests. DNA was extracted from whole blood for red cell genotyping (antigen-associated single nucleotide polymorphisms; SNPs), *ABO* exon 6 and 7, and *RHD/RHCE* complete exon Sanger sequencing. **Results/Findings**: A total of 137 samples were analyzed: ABO (n=5), D (n=56), C (n=11), E (n=12), c (n=18), e (n=33) and K (n=2) (Table 1). A wildtype allele or no evidence of a variant allele was present in 26 samples. Two of 5 ABO discrepancies were: a subgroup of A (with a wildtype B allele) and a subgroup of B (with a deletional O allele). Among the 109 non-ABO variant alleles observed, 21 novel alleles were characterized: D antigen discrepancies included 4 weak D type alleles and 4 *RHCE*ceCF*-like alleles (*RHCE*ce697G*) missing 48C and 733G SNPs; C antigen discrepancies included 3 *RHCE*Ce*733G* alleles and 1 *RHCE*Ce712G* allele; E antigen discrepancies included 3 *RHCE*cEFM*-like alleles (*RHCE*cE697C*) missing 712G SNP and 1 *RHCE*cE674G*; c antigen discrepancies included 1 *RHCE*ceJAL* (*RHCE*ce340T*) missing the 733G SNP; e antigen discrepancies included 3 *RHCE*ceMO*-like alleles (*RHCE*ce667T*) missing 48C SNP and 1 *RHCE*CeVA*-like allele (position 800 was a consensus nucleotide). Taken together with the variant alleles, a significant number of weak D type alleles were found among D discrepancies (n=28), either alone or *in trans* with dCe (*RHD*01W.01*, *W01.1*, *W.02*, *W.5*, *W.15*, *W.16*, *W.18, W.78*) along with *RHCE*ceCF* (n=4) and *RHCE*ceRT* (n=2) alleles. *RHCE*ceMO* was the most frequent allele (n=23) among e antigen discrepancies. **Conclusion**: Although automated serologic testing can rapidly type donors, occasionally the phenotype results can be inconsistent among various serologic reagents. Molecular analyses of these discrepancies determined the root cause in greater than 80% of samples. The cumulative data indicate that weak D types and *RHCE*ceMO* are most often implicated in serologic phenotype discrepancies.

RBC Molecular Testing and Genetics: Non-RH

SP317

Sequence Analysis of Alpha (1,2) Fucosyltransferase Gene for Eight Individuals with Para-Bombay Phenotype

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Background/Case Studies: The H blood group system is importance in the context of blood transfusion. Individuals with para-Bombay phenotype lack H antigens on red blood cells and maybe secrete ABH antigens in their saliva, as a result of deficiency in the enzyme alpha (1,2) fucosyltransferase. The purpose of this study was determined the molecular basis of eight individuals with para-Bombay phenotype in China. **Study Design/Methods**: A, B and H antigens on RBCs of the individuals with para-Bombay phenotype were detected with monoclonal anti-A, anti-B, anti-H, and antibodies in the serum were also detected with A, B and O cells using tube tests. The full coding region of alpha (1,2) fucosyltransferase gene (*FUT1*) was amplified by polymerase chain reaction (PCR). The PCR product was purified with enzyme digestion and directly sequenced analysis. The haplotypes were separated from the samples with different mutations by TOPO TA cloning technique. **Results/Findings**: Eight individuals with para-Bombay phenotype were collected from 2013 to 2015. The red blood cells of the para-Bombay phenotype were lack of the H antigen and with anti-H antibody in their serum. Three individuals were homozygotes with deletion AG at 547-552 position in coding region sequences of *FUT1*, which caused a reading frame shift and a premature stop codon. Three individuals were heterozygotes with 547-552delAG/658T, 547-552delAG/424T, 293T/880-882delTT. The other two individuals were 661T/T, 547-552delAG+814G/547-552delAG+814G homozygotes respectively. The percent of 547-552delAG haplotype of the individuals with para-Bombay phenotype was 40%. **Conclusion**: Molecular genetic analysis was performed for eight Chinese individuals with the para-Bombay phenotype. Molecular basis of the para-Bombay phenotype was diversify with the common haplotype 547-552delAG in China.

SP318

Research for the Molecular Basis of Gene Deletion on the B Glycosyltransferase Responsible for One Individual with Bel Variant

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Background/Case Studies: ABO genotyping of donors and patients is not routine practice. However, it is helpful for resolving the cases of ABO discrepancies. The characteristic of the ABO blood subgroup is crucial for elucidating the mechanisms of the variant phenotype. Here, the molecular basis of one individual with Bel variant was studied. **Study Design/Methods**: The ABO antigen and serum antibody of proband were detected by the serology method. The whole coding regions and flanking introns of *ABO* gene were amplified by polymerase chain reaction (PCR) and the PCR products were sequenced bidirectionally. The haplotypes of the proband were analyzed by cloning and sequencing. The three dimensional model of mutant protein was built and analysis. **Results/Findings**: The proband expressed very weak B antigen on red blood cells using absorption and elution test, which was identified as a Bel variant phenotype. The heterozygous sites in exon 6 (261del/G) and exon 7 (297 A/G,484del/G,526C/G,657C/T,703G/A,796C/A,803G/C,930G/A) of the coding region of the *ABO* gene were identified by directly sequencing analysis. Further haplotype analysis showed that the proband was carried with *O01* allele and a novle B allele. The sequence of the novel B allele was identical to *B101* except for delG at nucleotide position 484 and was nominated as *B120* by dbRBC of NCBI. 484 delG of B allele could lead to a read frame shift and create a premature terminal codon of glycosyltransferase (GT) enzyme. 3D structure was showed the GT enzyme was anincomplete protein only with N-terminal region. **Conclusion**: The 484delG of the glycosyltransferase B gene may decrease or abort the enzymatic activity and result in the Bel variant

SP319

A cis-AB Variant Allele Arising from a de novo Nucleotide Substitution A796C in the B Glycosyltransferase Gene

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Background/Case Studies: The cis-AB phenotype is very rare, and only nine genotypes that correspond to specific ABO allele changes have been reported. It may lead to ABO discrepancies and a delay in establishing the blood group. Until now, gene sequences of nine *cis-AB* alleles were characterised and none of these *cis-AB* alleles were reported as *de novo* polymorphisms. **Study Design/Methods**: We performed phenotype investigations by serology studies, analyzed the DNA sequence of the ABO gene by sequencing of exon 6 and exon 7 after cloning. **Results/Findings**: Serologically, the forward group test showed that the sample was AB, while the reverse group test showed that the sample had the anti-B and anti-H + + . The auto antibodies were negative. Genotyping showed the sample was B. Exon 6 and exon 7 sequencing from clones of the proband's alleles and her

family members were performed. The results showed that the proband has one O1 allele and the second allele is almost identical to B101 allele except for a single point mutation at nucleotide position 796, where a C replaces an A and leads to a change of methionine to leucine at amino acid 266. One of her sons has the same sequences. A cis-AB allele arising from nucleotide substitution 796A>C in the B glycosyltransferase gene were discovered. **Conclusion**: The Chinese family described carries a cis-AB allele that differs molecularly from all previously reported cis-AB alleles.

SP320

A New *KEL*02* Allele in a Blood Donor with a Serological k- Phenotype Identified through Rare Donor Confirmation by DNA-based Testing

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Background/Case Studies: The Kell blood group system currently consists of 35 antigens and more than 70 alleles. The K+k- phenotype is associated with *KEL*01.01* with c.578C>T encoding p.Thr193Met. Approximately 28 silenced *KEL*02* alleles have been reported and most encode premature stops, frame shifts, or alternative spliced products. Only three of the 28, *KEL*02* (**02N.05*, **02N.28* and **02N.29*), encode a k- phenotype resulting from a single amino acid change. A rare RBC donor, group O Rh- negative and who phenotyped K+k− on two different donations, was sent for HEA PreciseType testing to predict the extended phenotype and to confirm the molecular basis of the K+k- phenotype. **Study Design/Methods**: Standard hemagglutination methods were performed for antigen typing and adsorption/elution studies. Donor RBCs were typed with Ortho anti-K and Immucor anti-k; additional k typing was done using single donor source anti-k. Acid eluates were prepared using Gamma ELU-KIT II (Immucor). Genomic DNA was isolated from WBCs. HEA PreciseType testing was performed. *KEL* exons 1 to 19 were amplified and sequenced. **Results/Findings**: The donor's RBCs typed K+ (3+) and k- with polyclonal anti-k and with a single donor source anti-k reagent. Surprisingly, HEA predicted a K+k+ phenotype, as well as Kp(a−b+) and Js(a−b+). Amplification and sequencing of *KEL* revealed the donor was heterozygous for a novel nucleotide change, c.1130C>T encoding a p.Leu377Pro. No additional changes were found. To determine if this change is associated with very weak (mod, M allele) or silenced (null, N allele) k antigen expression, adsorption/elution studies of the RBCs were performed. Two sources of polyclonal anti-k (Immucor and single donor) were adsorbed with the donor's RBCs and with K+k+ and k- controls. Acid eluates were made from the sensitized RBCs. The eluate prepared from the donor's RBCs failed to react in the PEG IAT or IgG gel test with K-k+ RBCs; control eluates reacted as expected. **Conclusion**: A new change, c.1130C>T, in *KEL*02* exon 10 encoding p.Leu377Pro was identified in a Caucasian blood donor whose RBCs typed K+k-. Adsorption/elution studies failed to demonstrate detectable k antigen on the RBCs, indicating that this single amino acid change results in a serological k− phenotype. It is now becoming clear from recent reports in the literature that K+k- donors rather than genotyping as *KEL*01/01* are not infrequently *KEL*01/02*, and have silenced *KEL*02*. Confirming the molecular basis of the apparent null phenotypes of historical rare donors provides insight into the prevalence of altered alleles in the population and is beneficial for distinguishing true null phenotypes from potentially weak phenotypes.

SP321

A Novel *KEL* Silencing Allele in a Brazilian Patient with anti-Ku

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Background/Case Studies: The Kell system is highly immunogenic and Kell antibodies are considered clinically significant. Nucleotide changes that occur in the *KEL* gene may give raise to silent alleles (K_0 alleles) responsible for the lack of Kell antigens expression. Kell null phenotype is rare, with most individuals identified after they have made anti-Ku. We report a case of a previously transfused 49 year-old Brazilian woman with a history of cardiac surgery for mitral prosthetic valve placement admitted in the hospital with Hgb of 5.4g/dL due to hemorrhagic complications of warfarin, who presented with an antibody that reacted with all red blood cells (RBCs) except her own. **Study Design/Methods**: Antigen typing and antibody identification were performed by hemagglutination in gel cards (BioRad). The patient's serum was tested with RBCs treated and untreated with papain or 200mM DTT and RBCs lacking high-prevalence antigens. Genomic DNA was isolated from peripheral blood with the QiAmp Blood Mini Kit (Qiagen). *KEL* genotyping was performed by HEA BeadChip (Bioarray, Immucor). The 19 *KEL* exons and intron-exon boundaries were sequenced using the Sanger dideoxy method. **Results/Findings**: The patient RBCs typed K-k-, Kp(a-b-), Js(a-b-). Her serum reacted 2+ by IAT with all RBC samples and with papain-treated RBCs, but not with DTT-treated RBCs. The patient's serum was nonreactive with her own RBCs and with K_0 cells, confirming the presence of anti-Ku. Other underlying antibodies were ruled out by testing alloadsorbed serum or K_0 RBCs. HEA predicted the RBCs to be K-k+, Kp(a-b+), Js(a-b+). Sequencing of KEL exons showed homozygosity for a new change in exon 4 c.267C>G, on *KEL*02* encoding p.Tyr89Stop. No other changes were identified and no mutations were found on *XK* gene. **Conclusion**: We identified a new *KEL*02* allele, c.267C>G (p.Tyr89Stop), associated with a K_0 phenotype in a Brazilian patient female from the Northeast Brazil and with production of anti-Ku, an antibody associated to hemolytic disease of the newborn and hemolytic transfusion reactions.

SP322

Two Novel Non-coding Changes in *JK*A* Silence Antigen Expression

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Background/Case Studies: Unexpected Jk antibodies and antigen typing discrepancies have led to the identification of novel JK alleles and more than thirty alleles coding for altered or silenced expression of Jk have been reported. We analyzed *JK* in three individuals (2 patients and 1 blood donor) whose Jk(a-) phenotype differed from Jk(a+) prediction by DNA testing. **Study Design/Methods**: RBC typing was performed by standard tube methods with polyclonal and monoclonal anti-Jk^a and -Jk^b. Genomic DNA was isolated from WBCs. HEA PreciseType was performed and the *JK* coding exons were amplified and sequenced. NetGene2 was used to evaluate pre-mRNA splicing. **Results/Findings**: Sample 1 was from a 79 year old female patient; ethnicity not known. Her RBCs typed Jk(a-b+) but were predicted to be Jk(a+b+) by HEA PreciseType. Additional serologic testing confirmed the RBCs were non-reactive with four anti-Jk^a reagents: Ortho BioClone monoclonal, Immucor Gamma-clone, Immucor polyclonal and Bio-Rad Seraclone. Sample 2 was from a 32 year old male with sickle cell disease who had a history of anti-Jk^a and had been transfused three weeks prior with antigen-negative blood. However, by HEA his RBCs were predicted to type Jk(a+b+). The RBCs were non-reactive with Ortho BioClone monoclonal anti-Jk^a and Immucor monoclonal anti-Jk^a. *JK* sequencing of both samples confirmed the *JK*A/*B* genotype, but revealed a new change in exon 8, c.810G>A, that does not encode an amino acid change but is located near the conserved donor splice site. RBCs samples were unavailable for adsorption-elution studies. Sample 3 was from an 18 year old female donor; ethnicity not known. Her RBCs typed Jk(a-b+) but HEA PreciseType predicted Jk(a+b+). Additional testing showed the RBCs were negative with Ortho BioClone and Immucor Gamma-clone anti-Jk^a. The RBCs did not adsorb and elute anti-Jk^a. *JK* sequencing confirmed *JK*A/*B*, and identified a novel splice site change in intron 9 consisting of a +2t>c change. **Conclusion**: We report two new JK*A alleles with non-coding synonymous changes; c.810G>A in exon 8 in two patient samples, and an intron 9 +2t>c splice site change in a donor. The c.810G>A is located two nucleotides from the conserved gt-donor splice site in the 3' region of exon 8 and splicing software predicts alternative exon splicing of pre-mRNA, consistent with the serologic phenotype . The intron 9 change +2t>c (HGVS designation c.946 + 2c) is located in the 100% conserved splice site region predicted to abolish pre-mRNA transcript splicing, consistent with the serologic null phenotype. While gene sequencing is useful for resolving discrepancies between serology results and SNP-based assay predictions, only serology testing can determine the effect of novel polymorphisms on the encoded protein.

SP323

Two Novel Kidd Variants identified in a Donor with a Jk^b Typing Discrepancy

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Background/Case Studies: The Kidd blood group system has been notoriously associated with an ever-growing population of new polymorphisms identified in the SLC14A1 (*JK*) gene, many found during investigation of Jk antigen typing discrepancies or cases where anti-Jk^a, anti-Jk^b or even anti-

Jk3 are identified in antigen-positive samples. Here, we describe two novel alleles found in an African American donor who was predicted to type Jk(a+b+) by a HEA genotyping panel but who typed Jk(b-) on two previous donations with Immucor antisera. Jk^a status was not investigated. **Study Design/Methods**: Serologic testing was performed using standard tube agglutination methods. Genomic DNA was isolated from WBCs and genotyping was performed using PreciseType HEA Molecular BeadChip (Immucor), SSP-PCR and/or Sanger sequence analysis. RNA was isolated from reticulocytes and *JK*-cDNA PCR, plasmid cloning and Sanger sequence analysis were performed. **Results/Findings**: SSP-PCR showed the donor sample was c.130A (p.E44). Sequencing of *JK* exon 4 revealed the sample was heterozygous for c.28G/A and c.118G/A. *JK*-cDNA sequence analysis revealed the presence of both *JK*A* and *JK*B* alleles. The *JK*A* allele contained c.28A (p.10M), c.226A (p.76I), 303A (silent) and 588G (silent). The *JK*B* allele carried c.118A (p.40S); this variant has not been reported. **Conclusion**: Variable Jk antigen expression can frequently be explained by the genetic variation within the SLC14A1 gene. Here we describe a case in which the Kidd antigen expression is impacted by compound heterozygosity for two novel *JK* alleles. The *JK*B* allele contains the non-synonymous single nucleotide polymorphism (SNP) c.118A, predicted to change amino acid residue 40 from glycine to serine in the N-terminal tail of the protein. This amino acid change is likely responsible for the Jk^b typing discrepancy. This variant is in a protein domain that is likely to be critical to antigen expression as another variant (*JK*01N.09*) with a 7 amino acid deletion in this region is associated with a null phenotype. The *JK*A* allele carries c.28A (rs113578396, p.10Met) and c.226A (rs113029149, p.76Ile) SNPs *in cis*. These two variants were described separately [*JK*01W.03* and *JK*01W.04*, respectively, Deal *et al.*, *Transfusion* 2011:51(suppl):24-25A] and associated with weakened Jk^a. The novel *JK*A* allele described in this donor may not be rare, as we have three other Jk(a+b+) cases where c.28G>A and c.226G>A were identified by genomic sequencing but for which cDNA analysis is pending to determine the phase of the variants.

SP324

A Novel *JK*A* Allele in a Jk(a-b-) Patient with Anti-Jk3 and Anti-Jk^a

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Background/Case Studies: The Kidd (Jk) blood group system consists of three antigens: Jk^a, Jk^b, and Jk3. The Jk^a and Jk^b antigens result from a single nucleotide polypmorphism (SNP) at c.838A>G (Asp280Asn). The Jk3 antigen is distinct from Jk^a and Jk^b, and is absent in the rare Jk:-3 phenotype. Anti-Jk3 antibodies are clinically significant and may be associated with acute and delayed hemolytic transfusion reactions as well as hemolytic disease of the newborn. Here we describe the case of a 41-year-old Cape Verdean woman who developed acute anemia with evidence of hemolysis and a newly-positive direct antiglobulin test approximately 3 weeks after receiving red blood cells following a meningioma resection. We describe the subsequent serologic and molecular testing that identified anti-Jk3 and anti-Jk^a antibodies and a novel *JK*A* allele. **Study Design/Methods**: RBC phenotyping was performed by tube method with anti-Jk^a and -Jk^b (Immucor). Antibody identification was performed by standard methods. Genomic DNA was isolated from WBCs using standard methods. Genotyping was performed using PreciseType HEA Molecular BeadChip (HEA, Immucor), SSP-PCR for c.130G/A. RNA was isolated from reticulocytes and JK-cDNA was amplified and subjected to Sanger sequencing. **Results/Findings**: The patient's sample reacted with all reagent and autologous red blood cells tested at Ficin-IgG-AGT, PEG-IgG-AGT and ALB-IgG-AGT phases. Weaker reactivity was observed with Jk:-3 reagent red cells, consistent with anti-Jk3 antibody and a warm autoantibody. Allogeneic adsorptions identified anti-Jk^a reactivity at ALB-IgG-AGT. A sample taken approximately 2 months after the last red cell transfusion typed Jk(a-b-). HEA predicted the sample to type Jk(a+b-). SSP-PCR ruled out the presence of c.130A associated with weakened Jk^a. cDNA analysis demonstrated the sample was homozygous for c.838G associated with the *JK*A* allele. The sample was homozygous for four other SNPs including c.28G>A (rs113578396, Val10Met), C.226G>A (rs113029149, Val76Ile), and synonymous SNPs at c.303G>A and c.588A>G. **Conclusion**: The patient is homozygous for a novel *JK*A* allele carrying nonsynonymous SNPs c.28G>A and c.226G>A. This is distinct from the *JK*01W.03* and *JK*01W.04 alleles,* that each carry one of these SNPs. A patient with both alleles whose red cells typed Jk(a+b-), with anti-Jk^a has been previously described (Deal *et al. Transfusion,* 51, 24A-25A [2011]). While those findings support that either of these SNPs, when inherited separately, result in partial Jk^a, the case described here suggests that when present on the same *JK*A* allele, these SNPs interfere with *JK* antigen expression and, in a homozygous patient, lead to the potential to develop anti-Jk3 antibody.

SP325

Discovery of Novel *FY* Allele Similar to Known GATA Variant

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Background/Case Studies: The Duffy blood group antigens are encoded by a 336 amino acid multipass membrane glycoprotein called the Duffy Antigen Receptor for Chemokines (aka DARC, CD234, FY). A single nucleotide polymorphism (SNP) in *FY* exon 2 at c.125 determines whether the glycoprotein encodes Fy^a (c.125G) or Fy^b (c.125A). The Fy(a-b-) phenotype common in African descent individuals is most often associated with *FY*02N.01, an FY* allele encoding Fy^b where a promoter variant (c.1-67T>C) results in gene silencing in erythroid cells. A patient sample whose RBCs typed Fy(a-b-) yielded indeterminate Fy antigen phenotypes on the HEA BeadChip (Immucor). High resolution testing of the *FY* gene using genomic DNA sequencing was employed to resolve the indeterminate call. **Study Design/Methods**: Genomic DNA was isolated from mononuclear cells from peripheral blood using standard techniques followed by genotyping using the HEA BeadChip (Immucor). Additional genotyping was performed using lab-developed protocols for *FY* exon and promoter region sequencing. Cloning of the PCR-amplified promoter region was performed followed by Sanger sequencing of the resulting plasmids. **Results/Findings**: The HEA BeadChip was unable to predict Fy antigen phenotypes, instead resulting indeterminate calls (IC). Genotype results were *FY* c.1-67C, c.125G/A and c.265C (FYX variant absent). Sequencing of the promoter region and *FY* exon 1 revealed the sample was compound heterozygous at c.1-67T>C and c.1-69T>C. Cloning of the PCR product and sequencing of the resulting plasmids showed the variants to be on separate alleles. **Conclusion**: This case highlights the need for investigation of indeterminate calls found by low-resolution array-based genotyping methods. Discrepancies can result from the presence of variants located in or around the primer or probe binding regions that interfere with the testing assay. In this case, the HEA BeadChip failed to detect heterozygosity at *FY* c.1-67 likely due to interference by the novel *FY* c.1-69C variant. Though cloning demonstrated that the two promoter variants are located on separate alleles, this testing was unable to determine the phase of the promoter variants with the c.125 variants. Though c.1-67C has been reported on both *FY*01* and *FY*02* alleles, the *FY*02N.01* allele is much more common. We hypothesize that the c.1-69C silencing variant identified in this patient is carried on the *FY*01* allele. The c.1-69 variant falls within the canonical G-A-T-A binding site, likely disrupting binding of the erythroid GATA-1 transcription factor to the *FY*01* promoter resulting in loss of Fy^a expression on the RBCs. This would be consistent with the serologic typing of Fy(a-b-) in this patient.

SP326

New FY Alleles Identified After Discrepancy between Serology Results and DNA Prediction

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Background/Case Studies: Duffy is a relatively simple blood group system with 5 antigens. Sixteen altered alleles have been reported to date with 7 *FY*A* and 3 *FY*B* associated with silenced antigen expression and 2 *FY*A* and 4 *FY*B* with reduced or weak expression on the RBCs. We investigated 2 samples with discordant DNA and serology results; one predicted to be Fy(a+b+) but the RBCs typed as Fy(a+b−), and the other predicted to be Fy(a+b+) but typed as Fy(a−b+). Case 1 was a pregnant female with an antibody to high prevalence antigen; ethnicity was not known. Her RBCs were Es(a−) with anti-Es^a in the plasma. The sample was also tested by HEA PreciseType and a discrepancy noted between the Fy(b−) serology and Fy(b+) HEA prediction. Case 2 was a Canadian blood donor whose RBCs historically typed Fy(a−), but DNA testing with Progenika IDCoreXT predicted Fy(a+). **Study Design/Methods**: Serologic testing was performed by standard tube methods. Genomic DNA was isolated from WBCs. *FY* sequencing was performed. FY*A- and FY*B-specific PCR products

were amplified and sequenced to link the novel polymorphism to specific allele. **Results/Findings**: Sample 1 RBCs typed as Fy(b−) with Immucor, Ortho, Quotient, and a single donor source anti-Fy^b. *FY* exon 2 sequencing found c.125G/A (p.42Gly/Asp), consistent with the HEA PreciseType *FY*A/*B* results, but found a novel change, c.214G>C encoding amino acid change p.Gly72Arg. No other changes were found. Sample 2 RBCs typed Fy(a−) with Immucor and Bio-Rad anti-Fy^a. *FY* exon 2 sequencing found c.125G/A (42Gly/Asp), consistent with the HEA PreciseType *FY*A/*B* results, c.298G/A (100Ala/Thr), which is a commonly reported polymorphism, and a novel deletion at position c.854 deletion T that causes a frameshift and premature stop at p.286 [*FY*01(854_delT);* Leu285Argfs*2]. FY*A- and FY*B-specific PCR amplification and sequencing linked the common c.298A to *FY*B*, which is found in approximately 15% of FY*B alleles in Caucasians but not reported to affect the Fy^b protein, and c.854 deleted T to *FY*A*. The 854 deleted T is predicted to silence Fy^a antigen expression which is consistent with the Fy(a−) serology results. **Conclusion**: We identified two novel FY alleles, *FY*B* with c.214G>C (p.Gly72Arg) and *FY*A* with a c.854 deleted T. The c.214G>C change encoding p.Gly72Arg causes a serologic null Fy(b−) phenotype but the sample was insufficient for adsorption/elution studies to confirm complete absence of Fy^b expression. The c.854 deletion of T causes a frameshift and premature stop and a Fy^a null phenotype. Both novel polymorphisms are not in the dbSNP or ExAC databases. As SNP-based DNA assays are increasingly used to predict extended red cell phenotypes for patients and donors, it is important to investigate discrepancies between serology and DNA results as these give important insight into the diversity of blood group alleles.

SP327

Changes in Erythrocyte Antigen in the Republic of Korea: Becoming a Multicultural Society

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Background/Case Studies: It is important to check the blood group antigens of blood donors and recipients for ensure safe blood transfusion. Recently, the number of multicultural family have been increased in republic of korea, the survey for red blood cell antigen, antibody for foreigners and multicultural families in republic of korea is need to establish national blood policy of upcoming multicultural era. In addition, children from multicultural families have the possibility of changes in the erythrocyte antigen of their parents. We performed genotyping and phenotyping of the red blood cell antigens in republic of Korea youth and find of changes in erythrocyte antigen between this study and previous studies in Korean. **Study Design/Methods**: We recruited young people under the age of 25. The participants were divided 2 groups, single-cultural youth group and multicultural youth group. The subjects were performed genotyping and phenotyping of erythrocyte antigens. DNA was extracted from whole blood in EDTA with Qiagen methodologies. ID CORE ^{XT} (Progenika Biopharma, S.A, Spain), which based on Luminex® xMAP technology was used for genotyping of 37 red blood cell antigens. Phenotyping including the ABO, Rh, Kell, Kidd, Duffy, MNS, Diego blood type was performed using the test kit for phenotyping (Diagast, France). **Results/Findings**: Total 214 subjects (84 multicultural youth group, 130 single-cultural youth group) were recruited from September, 2015 to February, 2016. The frequencies of blood group antigens in single-cultural youth group were similar results with the previous studies in Korean. In genotyping assay, blood groups with significant difference between multicultural youth group and single-cultural youth group were Kidd (Jk^a), MNS (Mi^a) (*P* value<0.05). Mi^a and Yt^b, which were not expressed in single-cultural youth group, were identified 8.3% and 4.2% in multicultural youth group. In phenotyping assay, frequency of type B in the ABO blood group is higher in multicultural youth group, type A is higher in single-cultural youth group. The frequency of DCe expression in Rh blood group was higher in multicultural youth group respectively. Two cases of Fy(a-b+) and MNS(S+s-) were confirmed in multicultural youth group, which were rare blood type in Korean. **Conclusion**: The difference in frequency of blood group antigens between multicultural youth group in this study and previous studies in Korean and single-cultural youth group have been identified. These results suggest that national blood policy reflect increasing number of multicultural family and changing in the population and society in Republic of Korea should be prepared. Therefore, further research to predict of problem in blood transfusion safety is necessary. And we need to review of racial presentation of blood donor and blood drive of multicultural family.

RBC Molecular Testing and Genetics: RH

SP328

A Serological and Molecular Analysis to Determine RH Variants

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Background/Case Studies: Serologic testing is routinely used for DCE antigens typing, but some RH variants are not correctly detected. Genotyping is a powerful adjunct to serology for detecting the presence of D, C, c, E or e variants, especially in chronic transfusion patients to avoid alloimmunization. The aim of this study was to compare the performance of serological direct typing agglutination gel test with molecular tests to detect clinically relevant RH variants. **Study Design/Methods**: Twenty eight patient blood samples with rare RH variants were tested for phenotype and molecular analysis. Serological typing methods were performed using different DG Gel reagents by direct agglutination gel test (Diagnostic Grifols). The samples were tested manually by two reagents for each phenotype specificity: Anti-DVI- (clone P3x61 and clone MS-201), Anti-DVI+ (clones P3x290 +P3x35 +P3x61 +P3x21223B10 and clones RUM+ ESD1M), Anti-C (clone MS-24 and clone P3x25513G8), Anti-E (clone MS-260 and clone 906), Anti-c (clone H-48 and clone MS-33) and Anti-e (clones MS-21+MS-63+MS-16 and clones MS-63+MS-16). Molecular tests were performed after DNA extraction using BLOODchip v4.2, ID CORE XT, ID RHD XT and/or sequencing. **Results/Findings**: he phenotypes obtained by serology and the RH alleles obtained by molecular tests agreed with those previously reported by the hospital. Nineteen samples with RHD variants were identified using molecular tests: 8 weak type 4.0, 4 DAR, two DV, 2 weak D type 1, 1 weak D type 2, 1 weak D type 3 and 1 DWN. All these samples give positive results by serological methods using four different Anti-D antibodies. In 12/19 samples it was possible to suggest the presence of a variant due to a decrease in the agglutination intensity (<4+) depending on the Anti-D reagent, this fact is more evident in case of variants that express low levels of D antigen such as weak D type 1, weak D type 2 and DAR. Fourteen samples with RHCE variants were identified using molecular tests: 4 ceAR, 3 CeRN, 3 ceMO, 2 r's, 1 Ce602 and 1 ce48. Three samples gave discordant results in serology using two different Anti-C reagents (clone MS-24 and clone P3x25513G8) suggesting the presence of a partial C. Two samples were identified as RHD*r's-RHCE*ce[733G,1006T] allele carriers by genotyping predicting a partial expression of C antigen, despite these samples gave normal positive results in serologic typing. Five RHCE variants that affect to the expression of E and e antigens showed a normal pattern of reactivity with the Anti-E anti Anti-e typing reagents. **Conclusion**: Serological techniques can be complemented by molecular methods to identify variant RH alleles that affect antigens expression and to solve serological discrepancies. The use of both techniques, as complementary, can prevent alloimmunization in frequently transfused patients.

SP329

A Pilot Study to Evaluate a Genotyping Assay, ID RHD XT, for Donor Screening Application

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Background/Case Studies: Routine serological tests cannot detect some potentially immunogenic D variants, such as DEL, Partial D, and some Weak D types (Daniels G. Human Blood Groups. 3rd ed. Blackwell Science; 2013). D negative patients transfused with D positive blood from mistyped D negative donors may be at risk of anti-D alloimmunization. Molecular screening of blood donors can overcome this serology limitation. The aim of this proof of concept study was to demonstrate the feasibility of ID RHD XT, a genotyping assay, to be used as a tool for RHD screening in D negative sample pools. **Study Design/Methods**: Randomly, whole blood and plasma from blood donations and routine RhD serologic typing data were collected. Twenty blood samples were stored at a temperature between 2°C and 8°C while twenty plasma samples were stored at −20°C, until DNA extraction. DNA was extracted from blood and plasma, individually and pre-pooling one D positive in 19 D negative samples, using the QIAamp DNA mini kit (QIAGEN). The DNA of the pools was extracted in triplicates. Extracted DNA samples were processed with ID RHD XT for *RHD* gene detection and the results were automatically analyzed by the proprietary software. The ID RHD XT assay uses Luminex® xMAP technology for the simultaneous amplification of *RHD* exons 1, 6 and 9 and intron 3 for the identification of

*RHD*weak D types 1*, *2*, and *3*, *RHD deletion*, RHD*Pseudogene and RHD*DIIIa-CE(3-7)-D alleles. An internal Human Growth Hormone (*HGH*) amplification control is also included in the test. **Results/Findings**: DNA samples, individually and pooled (three extraction replicates) from blood and plasma (n=46), gave the correct *RHD* genotyping result (*RHD* gene positive or negative) in comparison to serology typing. The internal amplification control was also detected in all DNA samples. The signal of *RHD* exons 1, 6 and 9 obtained with ID RHD XT using DNA samples extracted from plasma and blood samples, in individual and pool extractions were equivalent. The pool extraction replicates yielded identical results. **Conclusion**: ID RHD XT can detect *RHD* gene in biological samples, plasma and whole blood, in pools of twenty D negative samples. A study with D variant samples is in progress to confirm that ID RHD XT is a sensitive tool and yields reproducible results for cost-effective *RHD* screening in serologically D- typed donors to prevent potential alloimmunization of receptors.

SP330

Performance Evaluation of a Genotyping Assay for the Detection of High-Prevalence RHD Negative And Weak D Types in a Cohort of *RHD* Variant Samples

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Background/Case Studies: It is well established that the higher-prevalence RHD weak D 1, 2 and 3 phenotypes are not at risk for forming allo-anti-D, whereas a few weak D and all partial D and negative phenotypes are. Most importantly, routine serologic D typing does not distinguish among weak D subtypes or partial D phenotypes, and consequently *RHD* genotyping is recommended, especially in patients. The objective of this study was to evaluate the performance of ID RHD XT genotyping assay (Progenika, Grifols) in the detection of high-prevalence D negative and weak D types by challenging it with an extensive number of *RHD* gene variants. **Study Design/Methods**: A cohort of 160 samples harboring 72 different *RHD* genotypes (59 allelic variants) associated with a Weak D, Partial D or D negative phenotype were selected for the evaluation. The ID RHD XT assay uses Luminex® xMAP technology for the simultaneous interrogation of *RHD*weak D types 1*, *2*, and *3*, *RHD deletion*, *RHD*Pseudogene* and *RHD*DIIIa-CE(3-7)-D* alleles. Genotypes and predicted phenotypes are reported from the combination of these allelic variants. Results obtained with ID RHD XT automated software were compared with results from three test sites that used molecular reference methods: in-house SSP-PCR, BAGene Weak D-TYPE kit (BAG Healthcare), RHD kit (GTI), RHD BeadChip kit (BioArray Solutions), BLOODchip Reference (Progenika, Grifols), and bi-directional Sanger sequencing. **Results/Findings**: All samples with Weak D types 1, 2 and 3 and all with D negative variants: (*RHD deletion*, *RHD*Pseudogene* and *RHD*DIIIa-CE(3-7)-D)* were correctly genotyped by ID RHD XT among the 72 different *RHD* variants tested. The rest of variants were detected by ID RHD XT as: "No weak D types 1, 2 or 3"; "No amplification variant", in *RHD-CE* rearrangements; D- in the cases of *RHD(1)-CE(2-10)* and *RHCE*ceHAR*. *RHCE*ceHAR* variant is an *ID RHD* XT limitation for donor typing, as the associated predicted phenotype is *Partial D*. In addition, 3 samples gave "No call" result: two due to RHD*1157A nucleotidic change, due to its proximity to RHD*1154C_(*Weak D type 2),* and *RHD*807A* due to its location at the same position as RHD*807G_(*RHD*Pseudogene).* All the *Weak D types 1, 2* and *3* phenotyped samples are correctly detected by ID RHD XT and can be considered as RhD positives for transfusion. The rest of the RHD variants tested encode Weak D, Partial D or D negative phenotypes, for which transfusion of D negative blood is recommended. **Conclusion**: ID RHD XT is an accurate test for the detection of high-prevalence weak D and D negative alleles. That makes it a useful tool for the implementation of the recent recommendations by the Work Group for RHD Genotyping on blood transfusion and anti-D prophylaxis.

SP331

Weak D Type 42 in Quebec: A Thorough Portrait

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Background/Case Studies: The most prevalent forms of weak D in Europe and North America are weak D type 1, 2 and 3. In Quebec (Canada), the number of weak D type 42 cases equal these three types combined (37% *vs* 36%). Weak D type 42 (c.1226A>T, p.Lys409Met) was first described in 2005 (Denomme *et al. Transfusion*, 45, 1554-1560). During the last decade, 162 weak D type 42 subjects have been identified by PCR-SSP among Quebec patients and blood donors. Very little is known related to this *RHD* variant. A few suspected alloimmunization cases were found. Molecular analyses were performed to learn more about the haplotype and zygosity of the subjects, and the weak D type 42 antigen relative density was measured by flow cytometry and compared to others. **Study Design/Methods**: PCR-SSP analyses were performed to identify the *RHCE*C/c* and *RHCE*E/e* profiles. *RHD* zygosity was done by PCR-RFLP. Red blood cells (RBCs) of different phenotypes were used for flow cytometry (R1R1, R2r, rr, weak D type 1, weak D type 3) to compare with weak D type 42 RBCs either tested fresh or after freezing in optimal conditions. Monoclonal anti-D coupled to R-PE was used (NATH109-1G2). A standard curve was established using beads (SPHERO Rainbow Calibration Particles) to estimate the molecules of equivalent soluble fluorochrome (MESF). **Results/Findings**: The haplotype linked to the weak D type 42 is R2r for 24 out of 26 random samples tested. A homozygous R2R2 haplotype was observed, and in another case, a R2r". The weak D 42 antigen density was the weakest found among the RBCs tested, except for the D-negative ones. The order goes as follows: R1R1 > R2r > weak D type 3 > weak D type 1 > weak D type 42 > rr. **Conclusion**: The high prevalence of the weak D type 42 in the Quebec population is probably due to a founder effect. A genealogy study is ongoing. Most *RHD* variants have been linked to the Ce haplotype. In this case, a cE haplotype has been observed, and mostly on a hemizygote background (Dd). The low D antigen density calculated seems similar to other weak Ds associated with alloimmunization (weak D type 5, type 11 and type 15). Further studies are needed to elucidate the alloimmunization potential of weak D type 42.

SP332

Novel Weak D Alleles Found in China and the Reporter Gene Assay Used for the Investigation of *RHD* Gene Regulation

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Background/Case Studies: Weak D phenotype is clinically important and mainly caused by amino acid substitutions locating in intracellular or transmembrane segments of the RhD protein. However, some new rare mechanisms which lead to weak D types have been reported recently. In addition, new weak D alleles have been constantly identified in the past few years. In this study, we aimed to analyze the molecular background of *RHD* gene of weak D blood donors obtained from routine screening in our blood center, and tried to explain the underlying mechanisms in weak D types caused by *RHD intron 4 +5A* and *RHD intron 4 +5T*. **Study Design/Methods**: Rh phenotypes were determined by routinely used serologic reagents and monoclonal anti-D panel. The *RHD* coding sequence, including adjacent intronic regions were specifically amplified and fully sequenced. Partial D types were excluded by *RHD* sequencing. The whole intron 4 of *RHD* gene was subcloned into the pGL3-promoter vector. Site-directed mutagenesis was used to construct the two mutant recombinant vectors. The plasmids of the empty vector control, the wild type recombinant vector, as well as two mutant vectors were co-transfected with renilla luciferase plasmids into K562 cells separately. Dual-luciferase reporter assays were performed by using a commercial kit. Statistical analysis of the t-test was performed using the results obtained from repeated experiments. **Results/Findings**: Six novel weak D alleles have been identified. They are *RHD 41T*, *RHD 357C*, *RHD 781G*, *RHD 947A*, *RHD 1022A*, and *RHD 577A,594T,602G* respectively. However, the results of the luciferase activity assay suggested that the transcriptional activity of the mutated intron 4 of *RHD* gene was higher than that of the wild type. **Conclusion**: The identification of six new weak D alleles expands our understanding of weak D types. Surprisingly, the unexpected results of the reporter gene assay suggest the complexity of the regulation of *RHD* gene expression.

SP333

***RHD* Genotyping and its Implication in the Prediction of Fetal D Status in Multi-ethnic Populations**

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Background/Case Studies: Fetal *RHD* genotyping from fetal DNA in maternal plasma has become a significant aid to the management of pregnancies at risk for hemolytic disease of the fetus and newborn (HDFN) due to maternal anti-D. Most protocols involve amplification of two or three exons to avoid obtaining false positive results with the more common variants of *RHD*. It is important that false positives do not result from the presence of the inactive

African genes *RHDΨ* and *RHD-CE-D^S*. Amplification of any *RHD* sequence within exons 4-7 will give a correct negative result with *RHD-CE-D^S*. We report a case of a DNA sample serologically typed as D-negative and genotyped as *RHDΨ/DIIIa-CE(4-7)-D* with positive results in exons 4, 5 and 7 of *RHD* during an evaluation of the accuracy of fetal *RHD* genotyping in a Brazilian female population. **Study Design/Methods**: We examined 7 female DNA samples serologically typed as D-negative to verify the specificity of *RHD* (exons 4, 5 and 7) for prediction of fetal D status. Real time multiplex PCR was used to amplify three regions of *RHD* in exons 4, 5 and 7, with exons 4 and 5 discriminating against detection of *RHD* and *RHDΨ*. **Results/Findings**: Of those seven samples, 5 samples were negative for exons 4, 5 and 7, one sample was positive for exons 4 and 7 and one sample was positive for exons 4, 5 and 7. *RHD* genotyping on female DNA samples performed by RHD BeadChip (Immucor, Warren, NJ), revealed that the five samples negative for exons 4, 5 and 7 had the *RHD* deletion and the sample positive for exons 4 and 7, was homozygous for *RHDΨ*. The sample with positive results for exons 4, 5 and 7 had one allele containing *RHDΨ* and one allele with *DIIIa-CE(4-7)-D* inactive genes. **Conclusion**: Although the *RHD* deletion was the most common genetic mechanism responsible for the RhD-negative typing in the Brazilian samples evaluated, we also found the *RHDΨ* and the *DIIIa-CE(4-7)-D* hybrid gene. The sample typed D-negative with the compound heterozygote *RHDΨ/DIIIa-CE(4-7)-D* genotype showed discrepant results for exon 4 (*RHDΨ+*) and exons 5 and 7 (*RHD+*) and could be classified as RhD+ if only exons 5 and 7of *RHD* had been analyzed. This result emphasizes the importance to include amplifications of more than one exon discriminating *RHD+*, *RHDΨ* and *RHD-* in the prediction of fetal D status in multi-ethnic populations, in order to avoid false-positive results. This knowledge helped us on the development of a feasible protocol for fetal *RHD* genotyping on DNA from maternal plasma.

SP334

Novel *RHCE*ce* Alleles Containing c.307T Cause C Typing Discrepancies

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Background/Case Studies: Red blood cell (RBC) genotyping of donors and patients is becoming the standard of care for certain patient groups, such as those with sickle cell disease, where it is common to match for C, c, E, e and K antigens to avoid alloimmunization. With an increase in RBC genotyping comes the identification of samples in which the genotype-predicted phenotype is found to be discordant with the serologic type. Here we report several cases of C typing discrepancies where RBC genotyping predicted an individual to type C negative, while the sample serologically typed C positive. Investigation using higher resolution *RHCE* genotyping identified 2 novel *RHCE*ce* alleles that share Ser103, an amino acid substitution involved in RhC antigen expression. **Study Design/Methods**: Specimens from 2 blood donors and 1 patient were analyzed for discrepancy resolution. Genomic DNA was isolated from peripheral blood mononuclear cells followed by genotyping using HEA BeadChip (Immucor). Once the genotype-phenotype discrepancy was identified, additional genotyping was performed using the RHCE BeadChip (Immucor). C typing was performed using Immucor and Bio-Rad anti-C antisera. **Results/Findings: Case 1**: 62 year old African American man with a warm autoantibody, auto-anti-D and -c. PreciseType HEA Molecular BeadChip predicted the patient to type C-c+ but the patient typed C+c+. RHCE BeadChip showed the sample to be heterozygous for RHCE c.307C/T and c.733C/G. **Case 2**: 36 year old African American female blood donor. PreciseType HEA Molecular BeadChip predicted the patient to type C-c+ but the patient typed C+ with two sources of anti-C: Immucor (Monoclonal) Gamma-clone (2-3+) and Bio-Rad Seraclone Human Monoclonal MS-24 (4+). RHCE BeadChip showed the sample to be heterozygous for *RHCE* c.307C/T and homozygous for c.733G. **Case 3**: 17 year old African American male blood donor. PreciseType HEA Molecular BeadChip predicted the patient to type C-c+ but the patient typed C+ (2+ Immucor; 3+ Bio-Rad). RHCE BeadChip showed the sample to be heterozygous for *RHCE* c.307 C/T yet predicted the donor to carry wild-type alleles and predicted them to type C- c+ E- e+. **Conclusion**: These cases highlight the need for investigation of discrepancies between a genotype-predicted phenotype and serologic type for the C antigen. The RhC antigen is encoded by a *RHCE* allele containing c.48G>C, 178C>A, 203A>G and 307C>T that encode Trp16Cys, Leu60Ile, Asn68Ser and Pro103Ser, respectively. Case #2 carries *RHCE*ce* with c.307T and c.733G and Case #3 carries *RHCE*ce* with 307T while Case#1 carries *RHCE*ce* with c.307C/T and c.733C/G such that cDNA analysis would be needed to resolve the phase of these variants. Taken together, these cases suggest that the serine at residue 103 is supporting the binding of the anti-C reagent. It is not clear if these represent partial C antigens.

SP335

Discovery of Novel *RHCE*ce* Allele in a Pregnant Patient with Sickle Cell Disease, Anti-E, and Anti-hr^B

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Background/Case Studies: A novel *RHCE* allele was identified in a 30-year-old G1P0 female with sickle cell disease who was 14 weeks pregnant when admitted to the hospital for management of a pain crisis. The patient had a history of autoimmune hemolytic anemia, pseudotumor cerebri, multiple PE/DVTs, prolonged QT, chronic opioid dependence, obesity, hemorrhoids and severe transfusion reaction. The patient was group O, Rh positive with a history of red blood cell alloantibodies, including anti-E, -Jk^b, -Fy^a, and warm autoantibody. On current admission, the antibody screen was positive with 1+ to 2+ reactivity to all panel cells. The autologous control was negative. **Study Design/Methods**: A monocyte monolayer assay (MMA) was performed with hr^B+ cells. Genomic DNA was isolated from mononuclear cells from peripheral blood using standard techniques followed by genotyping using the HEA and RHCE BeadChips (Immucor). Total RNA was isolated from reticulocytes and used for *RHCE* cDNA PCR, plasmid cloning and Sanger sequencing. **Results/Findings**: Alloanti-E and alloanti-hr^B were identified in the patient's serum. The previously-identified anti-Fy^a and anti-Jk^b were not demonstrable. The anti-E titer was 1:1,024; the anti-hr^B titer measured <1. IgG subclassing was not performed. HEA BeadChip predicted the patient was Fy(a-) and Jk(b-). RHCE BeadChip and cDNA analysis identified the patient was hemizygous or homozygous for RHCE c.667T. The MMA result was 2.7% indicating that the alloanti-hr^B was unlikely to cause acute hemolysis of transfused hr^B+ cells. Weekly middle cerebral artery Doppler studies were performed on the fetus beginning at 18 weeks gestation. These studies remained normal and the fetus did not require intrauterine transfusion. At 25 6/7 weeks gestation, the fetus was delivered by emergent caesarian section for prolonged fetal heart rate decelerations. The patient received two units of crossmatch-compatible RBC units that lacked the E, Jk^b, and Fy^a antigens and that were presumed positive for hr^B without clinical complication. **Conclusion**: This case highlights the need for transfusion medicine workup to assess the risk for hemolytic disease of the fetus and newborn in a patient with currently demonstrable alloanti-E and alloanti-hr^B, as well as to address the potential need for maternal transfusion during pregnancy. The patient was found to carry a novel *RHCE*ce* allele similar to *RHCE*ceMO*, with c.667T but without c.48C. *RHCE*ceMO* is known to encode an hr^B- and hr^S- phenotype. The alloanti-hr^B identified in this patient suggests this allele also encodes an hr^B- phenotype, though the hr^S status was not characterized. The MMA assay was useful in assessing the risk of transfusing hr^B+ cells and the results aided in blood product selection.

SP336

A Novel Polymorphism in the RHCE Gene Resulting in Silencing of c and E Expression

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Background/Case Studies: Blood group antigen genotyping is a useful technology for blood donor screening. However, several genetic events may cause discrepant results between hemagglutination and DNA typing. The Rh blood group system is the most polymorphic red blood cell system and a number of *RHCE* alleles associated with silencing of Rh antigen expression have been identified. The aim of this study was to investigate the cause of the discrepancy between the *RHCE* genotype and phenotype observed in a male Caucasian blood donor of Italian origin. **Study Design/Methods**: Phenotyping was done whit the microcolumn (BioVue System, Ortho Clinical

Diagnostics, USA) and tube agglutination methods using commercial monoclonal reagents (BioRad, Germany and Medion Grifols, Switzerland). Genomic DNA was extracted from whole blood using the QIAamp DNA Blood Kit (QIAGEN, Germany) and red cell genotyping was performed whit the HEA and RHCE BeadChip™ kits (Immucor-BioArray Solution, Warren NJ, USA) and the PCR-SSP kit (RH-TYPE BAGene, Germany). Since the phenotype and genotype results were discordant, the sample was further characterized by sequencing all ten *RHCE* exons using Sanger sequencing. **Results/Findings**: The donor in this study had a R_1R_1 (CCDee) phenotype and was referred for red blood cell genotyping. However, both the HEA and RH-TYPE kits predicted a R_1R_2 (CcDeE) phenotype while the RHCE BeadChip™ test did not identify any altered alleles. In addition, the donor's RBCs were non-reactive with multiple, commercial anti-c (including MS33 and MS42) and anti-E (including C2, MS258, MS906 and MS80) monoclonal reagents. Sequence analysis of the *RHCE* gene indicated that the individual was C+c+E+e+. However, the donor was also heterozygous for a polymorphism at *c.554G>A* in exon 4, resulting in a frameshift mutation and a premature stop codon at p.(Trp185Stop). The result was an aberrant *RHCE*cE* sequence raising the silencing of c and E expression. A similar polymorphism has been previously described in the same amino acid in RHD (*c.555G>A*, p.Trp185Stop), resulting in a predicted D silencing phenotype. **Conclusion**: The present study describes a novel polymorphism in exon 4 of the *RHCE* gene resulted in silencing of c and E expression in an Italian blood donor with R_1R_1 (CCDee) phenotype. Resolution of genotype/phenotype discrepancies can lead to identification of new alleles resulting in silencing phenotype.

SP337

Discovery of Novel *RHCE* Allele Associated with E Typing Discrepancies

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Background/Case Studies: The Rh blood group system includes two homologous genes responsible for 5 major antigens. *RHD* encodes the D antigen, and *RHCE* encodes the C, E, c and e antigens. Variation in these genes can cause altered proteins which result in typing discrepancies or variable reactivity for the respective antigens. Altered antigen status can result from presence of single nucleotide polymorphisms (SNPs) or hybrid genes where a portion of one gene is replaced with a portion of the homolog. Here we describe an E typing discrepancy in a Caucasian blood donor. Investigation using higher resolution *RHCE* genotyping identified a novel hybrid RH allele. **Study Design/Methods**: E phenotyping was performed with Biotest antisera using standard tube agglutination techniques, and Gel methodology. Genomic DNA was isolated from peripheral blood mononuclear cells using standard techniques. Genotyping was performed using the HEA and RHCE BeadChip (Immucor), exon-specific genomic Sanger sequencing, and PCR-restriction fragment length polymorphism (RFLP) assays. Total RNA was isolated from reticulocytes and *RHCE*-cDNA was amplified and analyzed using Sanger sequencing. **Results/Findings**: The donor historically phenotyped E negative. The current donation was E negative with standard tube agglutination methods using Biotest antisera. A hospital phenotyped the donor weakly E positive using Gel. HEA BeadChip testing predicted the donor to type E positive. Discrepancy investigation included *RHCE* BeadChip and PCR-RFLP assays, which both identified the donor to be heterozygous at c.676, the SNP responsible for determination of e and E antigens. Genomic sequencing of *RHCE* exons 1, 3, 4 and 6 identified no changes when compared to the reference sequence. Cloning of the *RHCE*-cDNA PCR product and sequencing of the resulting plasmids revealed a *RHCE*cE* allele with the following nucleotide changes in exon 3: c.361T, c.380T, c.384A and c.455A. **Conclusion**: This case highlights the need for investigation of discrepancies between genotype-predicted phenotype and serologic type. While the reference RhE antigen is encoded by a *RHCE* allele containing c.676G>C that encodes Ala226Pro, the novel allele identified in this case also contains nucleotides usually found in exon 3 of the *RHD* gene; thus demonstrating that in this donor *RHCE* exon 3 has been replaced by that of *RHD*. Allele dropout was observed, as amplification of *RHCE* exon 3 in genomic DNA failed to amplify the hybrid exon. *RHCE*-cEKK*, a hybrid *RHCE*D(1-3)-CE* allele, has been associated with a partial E phenotype. Based on the variable E reactivity demonstrated in this donor and the reactivity of the similar hybrid allele reported previously, it would be reasonable to predict this *RHCE*CE-D(3)-cE* allele encodes a partial E antigen.

TABLE.

Sample	Source	Ethnicity	*RHCE**
1	Donor	AA	*cEIV/ce733G*
2	Donor	Cauc	*cEIV/Ce*
3	Donor	AA	*cEIV/ce733G*
4	Donor	Cauc	*cEIV/Ce*
5	Patient	AA	*cEIV/ce48C*
6	Patient	AA	*cEIV/ce*
7	Patient	AA	*cEIV/ce48C*
8	Study	N/A	*cEIV/Ce*

SP338

Variant E Alleles (EIV) as a Cause of E Typing Discrepancies

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Background/Case Studies: RhE variants are uncommon and are often discovered only after a serologic discordance between a historical and current type or when a E+ person makes alloanti-E. Here we investigated eight samples; four donors whose RBCs historically tested E+ but typed E- on the current donation when tested on an automated instrument, one trial study sample reported to have variable E typing, and three samples from patients with sickle cell disease (SCD) referred for routine RH genotyping. **Study Design/Methods**: Serologic testing was performed by standard tube agglutination. Genomic DNA was isolated from WBCs and used for *RHCE* BeadChip prototype assay (BioArray/Immucor) and manual PCR tests. **Results/Findings**: RBCs from the four donors were non-reactive with anti-E formulated from clone 906 used on an automated instrument in routine use in blood centers. In tube testing, the RBCs demonstrated variable reactivity with four commercial anti-E reagents: +w to 2+ with Immucor Gammaclone, 2+ with Ortho BioClone and Bio-Rad Seraclone, and 4+ with Quotient ALBAclone. DNA testing identified an exon 4 c.602G>C change, reported as *RHCE*cEIV,* encoding amino acid change Arg201Thr. *RHCE*cE type IV* is associated with weak E antigen expression. The study sample reported to give variable reactivity also carried this allele, as did the three samples from patients with SCD. Ethnicity was available for seven of the eight samples: two were Caucasians and five were African American (AA). **Conclusion**: We report eight samples with the EIV variant antigen, four in blood donors, three in sickle cell patients, and one study sample. The RHCE*EIV allele was originally reported in Caucasians; here, we found the allele in five individuals of African descent. This study shows anti-E reagents formulated from different clones show variable reactivity with EIV RBCs, and E expression is not detected with the anti-E (formulated from clone 906) on the automated platform commonly used to type donors.

Recipient Non-Infectious Adverse Events

SP339

Hemovigilance and the Developing World – A Chicken and Egg Problem

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Background/Case Studies: Hemovigilance is being advocated worldwide. However, there is distinct difference between advocating the principles as part of quality culture, and stimulating the set-up and implementation as a seemingly stand alone measure; *First the pudding, then the tasting*. Performance of the blood supply and consumption in general follows the key elements of Quality Management -

1. Organization/(infra-)Structure;
2. Standards/References;
3. Documentation (quality pyramid);
4. Education (teaching and training);
5. Assessment - monitoring and evaluation (M&E).

Hemovigilance as a surveillance tool is part of the assessment, based on M&E of what has been done, and whether that matches standards of

TABLE. Countries involved

WHO Region	Countries involved
Europe	Estonia, Kazakhstan, Kyrgyzstan, Montenegro, Slovenia,Tajikistan, Uzbekistan
Africa	Cameroun, Rwanda, Tanzania, Uganda
Eastern Mediterranean	Jordan, Pakistan, Sudan
Southeast Asia	Bangladesh, Cambodia, India
Western Pacific	Mongolia

performance. Hence, hemovigilance is an integral part of the blood transfusion chain, a gate keeping tool to sustain overall quality. **Study Design/ Methods**: Hemovigilance systems and management were evaluated for 18 developing countries (2001-2014) in 5 WHO Regions (table) as part of projects focused on strengthening existing blood transfusion structures. Projects were based on a step-by-step introduction of concept and principles of quality. Beneficiaries were solicited to indicate development priorities. **Results/ Findings**: WHO Regions involved (table):

Europe (Newly Independent States/Central Asia) - 7;
Africa (Sub-Sahara)- 4;
Eastern Mediterranean - 3;
South-East Asia - 3;
Western Pacific - 1.

Countries belong to low and medium Human Development Index (L- and M-HDI) groups and range from a highly fragmented to regionalized national blood transfusion organization. None of them had a quality system and management in place, no current national standards and a grossly underdeveloped non-structured documentation system. Staff competence showed major knowledge gaps, particularly among clinicians. Hemovigilance is virtually non-developed, albeit listed high priority.Countres listed hemovigilance a top priotity - 12/18, and 2nd or 3rd - 3/18. Only 3 more advanced countries understood the importance to first have the managerial and operational framework developed. **Conclusion**: Hemovigilance is virtually non-developed, albeit listed a high priority in the majority of L- and M-HDI countries: a chicken and egg problem. Fundamental to hemovigilance as a surveillance and overall assessment tool, is a well-developed quality-based vein-to-vein blood transfusion organization and related quality culture with proper understanding of M&E values.

SP340

Febrile Non-hemolytic Transfusion Reaction among Inpatient U.S. Elderly Medicare Beneficiaries, as Recorded during 2011-2014

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Background/Case Studies: Febrile Non-Hemolytic Transfusion Reaction (FNHTR) is an acute transfusion complication resulting in fever, chills, rigors, headache, nausea, and vomiting. FNHTR can result in prolonged hospitalization and may lead to increased morbidity and mortality. The study objective was to assess FNHTR occurrence and potential risk factors among elderly Medicare beneficiaries, ages 65 and older, transfused in the inpatient setting during 2011-2014. **Study Design/Methods**: This retrospective claims-based study utilized large Medicare databases for the calendar years 2011-2014 in coordination with the Centers for Medicare & Medicaid Services. Transfusions of blood and blood components were identified by recorded ICD-9-CM procedure and revenue center codes, and FNHTR was ascertained via the diagnosis code. Our study evaluated FNHTR rates (per 100,000 inpatient transfusion stays) among the elderly, overall and by calendar year, age, sex, race, blood components and number of units transfused. Fisher's exact tests were performed to compare FNHTR rates, and Cochran-Armitage tests were used to detect trends by calendar year, age, and transfusion volume. **Results/Findings**: Among 8,310,566 inpatient transfusion stays for elderly beneficiaries during 2011-2014, 4,768 had a FNHTR diagnosis code recorded, for an overall rate of 57.4 per 100,000 stays. FNHTR rates (per 100,000) varied by blood components and number of units transfused as well as by age and sex. FNHTR rates by blood component groups were as follows: 24.8 for plasma only, 63.1 for platelets only, 68.0 for RBCs only, 33.3 for platelets and plasma, 65.9 for RBCs and plasma, 215.3 for RBCs and platelets, and 75.8 for RBCs, plasma and platelets. FNHTR rates for age categories 65-69, 70-74, 75-79, 80-84, 85 and over were: 62.3, 62.0, 59.6, 56.4, and 48.2, respectively ($p<0.001$). Females and males had FNHTR rates of 59.7 and 54.5, respectively ($p=0.002$). FNHTR rates by number of units transfused were: 40.5 for 1 unit, 53.9 for 2-4 units, 78.8 for 5-9 units, and 87.0 for >9 units ($p<0.001$). **Conclusion**: Our population-based study among the elderly identified a significant increase in FNHTR occurrence with greater number of units transfused and suggests decline in FNHTR occurrence with older age. The study also showed substantially elevated FNHTR rates for stays with RBCs transfused in combination with platelets as compared to plasma only recipients, and suggests higher FNHTR risk in females, which need further investigations. The study was based on claims data and thus limitations include potential under- or mis-recording of FNHTR diagnosis code, transfusion procedures, and units transfused as well as lack of clinical details to validate the recorded FNHTR diagnosis.

SP341

Post-transfusion Purpura (PTP) among U.S. Elderly Medicare Beneficiaries, as Recorded during 2011-2014

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Background/Case Studies: Post-Transfusion Purpura (PTP) is a rare and serious immune-mediated transfusion complication resulting in thrombocytopenia with mucous membrane hemorrhage, epistaxis, as well as gastrointestinal and urinary tract bleeding. PTP may cause substantial morbidity, prolongation of hospitalization, and result in death. The study objective was to assess PTP occurrence and potential risk factors among inpatient elderly Medicare beneficiaries, ages 65 and older, during 2011-2014. **Study Design/Methods**: This retrospective claims-based study utilized large Medicare databases for the calendar years 2011 through 2014 in coordination with Centers for Medicare & Medicaid Services. Transfusions of blood and blood components were identified by recorded ICD-9-CM procedure and revenue center codes, and PTP was ascertained via the diagnosis code. Our study evaluated PTP rates (per 100,000 inpatient transfusion stays) among elderly Medicare beneficiaries, overall and by calendar year, age, sex, race, number of units and blood components transfused. Fisher's exact tests were performed to compare PTP rates, and Cochran-Armitage tests were used to ascertain PTP occurrence trends by calendar year, age and number of units transfused. **Results/Findings**: Among 8,310,566 inpatient transfusion stays for elderly beneficiaries during 2011-2014, 131 had a PTP diagnosis code recorded, for an overall rate of 1.6 per 100,000 stays. PTP rates (per 100,000) varied by calendar year, age, blood components and number of units transfused. Annual PTP rates were 1.9 in 2011, 1.6 in 2012, 1.4 in 2013 and 1.3 in 2014 ($p=0.075$). PTP rates by blood component groups were: 1.1 for RBCs only, 1.4 for plasma only, 11.6 for platelets only, 9.5 for platelets and plasma, 1.9 for RBCs and plasma, 12.2 for RBCs and platelets, and 8.4 for RBCs, plasma and platelets. PTP rates for age categories 65-69, 70-74, 75-79, 80-84, 85 and over were 2.0, 1.9, 1.3, 1.3, and 1.5, respectively ($p=0.103$). PTP rates by number of units transfused were: 1.0 for 1 unit, 0.9 for 2-4 units, 3.0 for 5-9 units, and 5.3 for >9 units ($p<0.001$). **Conclusion**: Our population-based study is the largest to-date and shows significantly increased PTP risk with greater number of units transfused and substantially higher PTP rates for platelet transfusions, either by themselves or in combination with RBCs and/or plasma. The study also suggests decline in PTP rates over time as well as a potential reduction in PTP risk with advancing age, which need further investigation. The study was based on claims data and thus limitations include potential under- or mis-recording of PTP diagnosis code, transfusion procedures, and units transfused, as well as lack of clinical details to validate the recorded PTP diagnosis.

SP342

Transfusion-related Anaphylaxis among Inpatient U.S. Elderly Medicare Beneficiaries during 2012-2014

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Background/Case Studies: Transfusion-related anaphylaxis (TRA) is a serious transfusion complication, occurring generally within the first couple of hours following transfusion and resulting in sudden pruritus, urticaria, dyspnea, hypotension, shock, and, possibly, death. The study objective was to

assess TRA occurrence and potential risk factors among the inpatient US elderly, ages 65 and older, during 2012-2014 study period. **Study Design/Methods**: This retrospective claims-based study utilized large Medicare databases for calendar years 2012-2014 in coordination with the Centers for Medicare & Medicaid Services. Transfusions were identified by recorded ICD-9-CM procedure and revenue center codes, and TRA was ascertained via the diagnosis code. Our study evaluated TRA rates (per 100,000 inpatient transfusion stays) among the elderly, overall and by calendar year, age, gender, race, number of units and blood components transfused. Fisher's exact tests were performed to compare TRA rates, and Cochran-Armitage tests were used to ascertain TRA occurrence trends by calendar year, age, and transfusion volume. **Results/Findings**: Among 6,050,040 inpatient transfusion stays for elderly beneficiaries during 2012-2014, 469 had a TRA diagnosis code recorded, an overall rate of 7.8 per 100,000 stays. TRA rates (per 100,000) varied by calendar year, blood components and number of units transfused, as well as by age, sex, and race. Annual TRA rates were 8.1 in 2012, 8.2 in 2013, and 6.8 in 2014 ($p=0.130$). TRA rates by blood component groups were: 2.8 for RBCs only, 34.1 for plasma only, 37.2 for platelets only, 50.3 for platelets and plasma, 19.3 for RBCs and plasma, 30.4 for RBCs and platelets, and 33.2 for RBCs, plasma and platelets. TRA rates for ages 65-69, 70-74, 75-79, 80-84, 85 and over were 10.1, 9.3, 8.2, 6.9, and 4.7, respectively ($p<0.001$). Females and males had TRA rates of 6.1 and 9.9 (<0.001), respectively; whites and non-whites had TRA rates of 8.4 and 4.6 (<0.001), respectively. TRA rates by number of units transfused were: 7.0 for 1 unit, 5.4 for 2-4 units, 12.1 for 5-9 units, and 21.7 for >9 units ($p<0.001$). **Conclusion**: Our population-based study is the largest to date on TRA occurrence and shows substantially higher TRA rates with plasma and/or platelet transfusions as compared to RBCs only. The study also identified significantly increased TRA rates with greater number of units transfused and suggests a reduced TRA risk with advancing age. The study also suggests increased TRA risk in males and whites, which needs further investigation. Study was based on claims data, and thus limitations include potential under- or mis-recording of transfusion procedures, units, and diagnosis codes, as well as lack of clinical details to validate recorded TRA.

SP343

Transfusion-related Acute Lung Injury among Inpatient U.S. Elderly Medicare Beneficiaries during 2007-2014

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Background/Case Studies: Transfusion-Related Acute Lung Injury (TRALI) is a serious complication resulting in pulmonary edema and respiratory distress. TRALI accounts for significant transfusion-related morbidity and mortality in the U.S. The objective of our study was to assess TRALI occurrence and potential risk factors in the U.S. elderly transfused in the inpatient setting during 2007-2014. **Study Design/Methods**: Our retrospective claims-based study utilized large Medicare databases for calendar years 2007-2014. Transfusions were identified by recorded ICD-9-CM procedure and revenue center codes, and TRALI was ascertained via the diagnosis code. Our study evaluated TRALI rates (per 100,000 inpatient transfusion stays) among the elderly, overall and by calendar year, age, sex, race, blood components and number of units transfused. Fisher's exact tests were performed to compare TRALI rates, and Cochran-Armitage tests were used to detect trends by calendar year, age, and transfusion volume. **Results/Findings**: Among 17,549,057 inpatient transfusion stays for elderly beneficiaries during 2007-2014, 5,103 had a TRALI diagnosis code recorded, an overall rate of 29.1 per 100,000 stays. TRALI rates (per 100,000) varied by calendar year, blood components and number of units transfused, as well as by age, sex, and race. The annual TRALI rates in 2007, 2008, 2009, 2010, 2011, 2012, 2013, and 2014 were 14.4, 17.9, 20.7, 25.3, 35.5, 39.7, 39.7, and 44.5, respectively ($p<0.001$). TRALI rates by blood component groups were: 21.6 for RBCs only, 35.9 for plasma only, 48.1 for platelets only, 95.1 for platelets and plasma, 75.3 for RBCs and plasma, 116.8 for RBCs and platelets, and 230.4 for RBCs, plasma and platelets. TRALI rates for age categories 65-69, 70-74, 75-79, 80-84, 85 and over were 35.8, 33.0, 30.9, 25.7, and 21.7, respectively ($p<0.001$). Females and males had TRALI rates of 28.1 and 30.3, respectively ($p=0.007$); whites and non-whites had TRALI rates of 30.4 and 22.6, respectively ($p<0.001$). TRALI rates by number of units transfused were: 14.7 for 1 unit, 19.1 for 2-4 units, 39.9 for 5-9 units, and 109.8 for >9 units ($p<0.001$). **Conclusion**: Our eight-year population-based study on TRALI occurrence is the largest to date. It shows significantly increasing TRALI occurrence trends over time and with greater number of units transfused. In contrast, a significant decline in TRALI risk was identified with older age. The study suggests a substantially increased TRALI risk with platelets transfused in combination with RBCs and/or plasma as well as possible effects of gender and race, which need further investigations. The study was based on claims data and thus limitations include potential under- or mis-recording of transfusion procedures and number of units, as well as lack of clinical detail to validate recorded TRALI.

SP344

Elevated Blood Lead Level in Packed Red Blood Cells at One Institution

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Background/Case Studies: Lead exposure is a known risk factor for developmental delay and behavioral issues in the pediatric population. Packed red blood cell (pRBC) transfusion has recently been recognized as a potential source of lead exposure. Increased blood lead levels after perinatal transfusion have been noted in premature infants. Acceptable blood lead levels differ between the pediatric and adult populations. Red blood cell donors are not tested for blood lead levels and risk of lead exposure is not part of the standard blood donation questionnaire. Although there are no current guidelines as to the transfusion threshold for lead in pRBC units designated for neonates, some studies have suggested a cutoff of 0.15 umol/L. As a blood bank of a large institution which supports a neonatal intensive care unit, we wanted to assess the lead content of our pRBC inventory. **Study Design/Methods**: Donated pRBC units were obtained from a national blood donor center. Fifteen random blood segment samples from the blood bank of one institution were analyzed for lead content using an atomic absorption spectrometer method. Low values of less than 0.05 umol/L were run in duplicate. Geometric mean was used to analyze results. Results were compared to previous findings from other studies. **Results/Findings**: The samples displayed a range of blood lead level content from 0.034 to 0.411 umol/L. Of the fifteen samples, three had values above previously suggested transfusion threshold of 0.15 umol/L (0.411, 0.188, 0.155 umol/L). The geometric mean was calculated as 0.086 umol/L. **Conclusion**: pRBC transfusion is an under recognized source of lead exposure. With an initial, small analysis of random blood segments at one institution, the pRBC lead level content levels were similar to those demonstrated in larger population studies. 20% of screened units were above the suggested threshold for a neonatal transfusion. Future studies will include using a larger sample of donors, correlation with donor characteristics to assess risk factors, and correlation with discharge blood lead levels in neonates who received a transfusion.

SP345

Platelet Transfusion Refractoriness and Delayed Platelet Recovery Associated with Anti-HPA-1b Alloantibodies in Nonmyeloablative Hematopoietic Progenitor Cell Transplantation

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Background/Case Studies: Delayed platelet recovery and platelet refractoriness have significant clinical implications post-hematopoietic progenitor cell transplantation (HPCT). We report a case of a 24-year-old female with severe aplastic anemia and HLA alloimmunization who underwent nonmyeloablative HPCT using a combination of a haploidentical allogeneic donor and unrelated cord blood on a clinical trial. She received HLA-matched platelet transfusions pre-transplant, with appropriate corrected count increments (CCIs). On day 13 post-HPCT, she developed severe thrombocytopenia, refractoriness to HLA-matched platelet transfusions, and right arm ecchymosis. No additional HLA antibodies were identified. IVIG was administered for presumed post-transfusion purpura (PTP). Sister components from one platelet donor yielded a CCI of 1,350/μL before IVIG, and 26,380/μL after IVIG administration. Anti-HPA-1b was identified in the patient's serum, and she genotyped as HPA-1a/1a. The haploidentical donor typed as HPA-1a/1a, while the cord typed as HPA-1a/1b. Her course was complicated by diffuse alveolar hemorrhage and mucosal bleeding. Nine subsequent IVIG doses were administered with variable effect on post-transfusion CCIs. Haploidentical myeloid engraftment occurred at day 15, but the patient continued to require daily HLA-matched platelet transfusions, HPA-matched when possible, with variable increments until day 68. Cord myeloid engraftment occurred on day 79. We conducted further studies to determine the cause of delayed platelet recovery in this patient. **Study Design/Methods**: We reviewed the patient chart and transfusion indices. HPA antibody identification and titration was performed by monoclonal antibody immobilization of

glycoproteins and single platelet flow cytometry. HPA genotyping was conducted by PCR with fluorescent hydrolysis probes. **Results/Findings**: HPA genotyping of selected platelet donors revealed that poor CCIs correlated with HPA1a/1b genotype in the early peri-transplant period, but poor increments were observed at later time points irrespective of HPA-1 genotype. The platelet product associated with marked increment after the first IVIG administration genotyped as HPA1a/1b. Analysis of stored plasma samples revealed that the HPA-1b antibody was present prior to transplantation (titer=8). Anti-HPA-1b titers decreased progressively post-transplant and disappeared at the time of platelet recovery. Platelet autoreactivity was not detected. **Conclusion**: Recipient-derived HPA-1b antibodies are a rare cause of protracted thrombocytopenia and platelet refractoriness after HPCT. Detection of anti-HPA antibodies in this setting should lead to careful consideration of the differential diagnoses, including PTP and pre-existing HPA alloimmunization.

SP346

Analysis of Documentation of Adverse Transfusion Events within The Discharge Summary

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Background/Case Studies: Inpatient discharge summaries deliver important information to future providers regarding a patient's presentation, diagnosis, treatment, follow-up, and any adverse events that occurred during the hospital course. These adverse events may be prevented during future admissions if they are clearly documented within the discharge summary. For example, transfusion-associated circulatory overload (TACO) may be prevented in a patient with a known history of TACO by either not transfusing blood, limiting the number of units transfused, or slowing the rate of transfusion. Limited data currently exists regarding clinician documentation of adverse transfusion events (ATEs) within the discharge summary. **Study Design/Methods**: We conducted a retrospective chart review of all reported inpatient ATEs and the discharge summaries associated with that hospital stay from January 1, 2006 to December 31, 2015 at an adult tertiary academic center. Proportions were compared using chi-square analyses. **Results/Findings**: Four hundred thirty-six potential ATEs were reported to the blood bank by the clinician. Of these, 374 events were thought to be related to the transfusion. ATEs were documented in 101/374 discharge summaries (27%). In those discharge summaries in which an ATE was documented, 17/101 (17%) had a discrepancy between how the clinician and the blood bank documented the ATE. One example of a discrepancy was that the blood bank reported a patient experienced TACO whereas the clinician documented the patient had a transfusion-related acute lung injury. The four most common discharging specialties were Hematology/Oncology, Surgery, Internal Medicine, and Pulmonary/Critical Care. They had an ATE documentation rate of 50/192 (26.0%), 17/65 (26.2%), 12/42 (28.6%), and 9/36 (25.0%) respectively. There was no significant difference in their documentation rates (p-value 0.99). The four most common ATEs that were definitively related to the transfusion included febrile non-hemolytic transfusion reactions (FNHTRs), mild allergic transfusion reactions, moderate-severe allergic transfusion reactions, and TACO. They had a documentation rate of 32/145 (22.1%), 19/66 (28.8%), 18/36 (50.0%), and 6/18 (33.3%) respectively. Moderate-severe allergic reactions were more significantly reported compared to FNHTRs (p-value 0.001) and mild allergic transfusion reactions (p-value 0.03) but not compared to TACO (p-value 0.25). **Conclusion**: Regardless of discharging specialties or type of ATE, there is significant room for improvement in clinician documentation of ATEs. Clinician education and improving how the blood bank communicates with the clinician may be useful in both increasing ATE documentation rates as well as decreasing discrepancies.

SP347

Reversability of Iron-induced Cardiomyopathy with Combined Chelation Therapy in β Thalassemia Major

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Background/Case Studies: Cardiac iron overload is the most frequent cause of death in β Thalassemia Major. The relatively mild degree of fibrosis in most autopsy studies suggests that even when advanced, the cardiomyopathy is potentially reversible. Iron deposition is reported to be greatest in the ventricular walls with less in atria and conduction system. The degree of cardiac dysfunction is considered to depend on the quantity of iron deposited in individual myocardial fibers and the number of fibers affected. Iron is stored in intracellular lysossomes in the relativity non-toxic forms of ferritin or hemosiderin but above certain concentration, NTBI (non transferin bound iron) is released and the cell begins to fail1,2,3. **Study Design/Methods**: We studied a patient with β Thalassemia Major, 40 years age, female, followed in our Center since 1996. She was transfused with 439 RBC (red blood cells) units. She started iron chelation therapy with Desferroxamin (DFO) with pump infusion (50mg/Kg/5 consecutive days a Week) since 10 years old until 2009 when she iniciated Deferasirox (DFX). She started DFX with 20m/Kg/day and increases the dose to 35mg/Kg/day 4. Combined iron quelation therarapy with DFO (50 mg/Kg, s.c. injection twice a day, 5 consecutive days a week) and Deferasirox (DFX) is being made since 2011. **Results/Findings**: Table 1- A six (6) year follow-up of transfusional and chelant therapeutics and MR controls. **Conclusion**: Transfusions are the primary therapy for Thalassemia but have significant cumulative risks. Cardiac iron overload is the most frequent cause of death in Thalassemia Major. With combined iron chelation we reached better cardiac performance as we see with results of T2*(MR technique for Measuring Myocardial Iron)3.

References:

1 Andersson LJ. Assement of cardiac iron overload in thalassemia. MD Thesis. Imperial College, London. 2002;
2 Alan R. Cohen, Renzo Galanello, Dudley J. Pennel, Melody J. Cunningham, and Elliott Vichinsky. Thalassemia, Hematology 2004;
3 Transfusion, Volume 54, Apri l2014. Transfusion complications in Thalassemia patients: A report from Centers for Disease Control and Preveentio;
4 Ali Thaer, Maria D. Cappellini, Elliott Vinchinsky, Renzo Galanello, Antonio Piga, Thomasz LawniczeK, Joan Clark, Dany Habr and John Porter. BJH, 147, 752-759. Efficacy and Safety of Deferasirox doses of >30mg/Kg per d in patients with transfusion-dependent anaemia and iron overload

SP348

Inflammatory and Cardiopulmonary Biomarker Characterization of Pulmonary Transfusion Reactions

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Background/Case Studies: We hypothesized that biologic markers of inflammation and cardiopulmonary disease could be used to distinguish transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), and Possible TRALI. **Study Design/Methods**: A prospective case series at two academic hospitals utilized active surveillance to enroll cases of TRALI, TACO and Possible TRALI as well as transfused controls without pulmonary edema. Biomarkers measured in 58 clinical samples included cardiopulmonary (BNP, GDF-15, ST-2, Cystatin C) and inflammatory (CRP, soluble TNFRII and TIMP-1) markers. Wilcoxon Rank-Sum tests were used to compare results between groups of TRALI, TACO, Possible TRALI, and control patients. **Results/Findings**: Prior to and following the onset of pulmonary edema, levels of BNP were elevated in

TABLE. A six (6) year follow-up of Transfusional and chelant therapeutics and MR controls

Date	RBC	Ferritin N (10-291ng/mL)	DFX (35g/Kg)	DFO (50mg/Kg/5 consecutive days a week)	T2* N 2Oms
2009	31	10140	YES	NO	17
2012	36	9270	YES	NO	20.14
2013	37	7485	YES	NO	28.99
2015	23	5895	YES	NO	77.26

patients with TACO in comparison to that of patients with TRALI and controls ($p < .04$ for all). BNP levels were also elevated in patients with Possible TRALI compared to TRALI ($p=0.02$) but similar to levels in patients with TACO ($p=0.96$). In contrast, Cystatin C levels were higher in patients with TACO than those of patients with Possible TRALI ($p=0.02$) and controls ($p=0.05$). TIMP-1, soluble TNFR-II and CRP levels were higher in TACO patients compared to controls ($p < 0.05$) but not different than those in patients with Possible TRALI. **Conclusion**: There is elevation of both cardiopulmonary and inflammatory markers in patients with TACO and Possible TRALI. Patients with abnormal cytokine and cardiopulmonary biomarker levels may be predisposed to developing hydrostatic pulmonary edema with transfusion. Further studies evaluating a combination of markers of inflammatory injury and cardiac stress may improve our ability to differentiate pulmonary transfusion reactions.

SP349

A Pilot Study Comparing Mortality of Intravenous Iron Therapy versus Fresh and Older RBCs in a Septic Canine Model

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Background/Case Studies: Anemia in critical illness is common and associated with poor outcomes. Standard care with allogeneic red blood cell (RBC) transfusion is effective, but carries well-known risks. Transfusion has been associated with increased morbidity and mortality in this population. To mitigate these hazards, alternative therapy with parenteral iron has been recommended, but never directly compared to transfusion therapy. Elemental iron is essential for bacterial growth and previous studies in humans and animals suggest that increasing plasma iron levels may increase infection risks. Older stored RBCs release non-transferrin bound iron (NTBI) and cell free hemoglobin (CFH), which have been associated with increased mortality in pre-clinical models of transfusion and infection. To compare these therapies directly, we investigated the effect of transfusion of RBCs stored for 7 and 21 days to two parenteral iron preparations on mortality in an anemic septic canine model. **Study Design/Methods**: Two-year-old purpose bred beagles (n= 24) were challenged intrabronchially with *S. aureus*. Shortly after bacterial inoculation, all animals underwent withdrawal of 20 ml/kg of blood to induce mild anemia. Two hours later, animals were transfused 20 ml/kg of either fresher (7-day, n=6) or older (21-day, n=6) stored universal canine RBC or treated with 7mg/kg of either intravenous iron sucrose (n=6) or ferumoxytol (a preparation with attenuated peak in serum NTBI, n=6). All animals received antibiotics, intensive care supportive measures and were followed until death or 96h. **Results/Findings**: Mortality rates were lowest in animals transfused 7-day old RBCs (50%) and in comparison increased to 83% in animals receiving 21-day old RBCs ($p=0.14$). Mortality rates were also higher in animals receiving iron sucrose (83%) or ferumoxytol (100%)($p=0.12$, iron groups compared to 7-day old blood). As in previous studies, mean plasma NTBI levels increased significantly early after transfusion with 21-day compared to 7-day old RBCs (0.5 uM vs 0 uM, $p=0.0002$). Iron sucrose resulted in greater increases in NTBI compared to both 7-day-old RBCs and ferumoxytol (2.4 uM vs 0 and 0uM respectively, $p<0.0001$). Ferumoxytol did not result in significant increases in NTBI compared to 7-day-old RBCs throughout. **Conclusion**: This pilot study suggests treatment of mild anemia with intravenous iron or 21 day old units in the setting of infection may worsen outcomes in comparison to 7 day old units. The increased serum NTBI with older units and iron sucrose could promote bacterial growth and thereby worsen outcomes during infection. Intravenous ferumoxytol therapy during infection may increase transfusion risks without raising serum NTBI levels. Additional studies powered to test this hypothesis are currently being conducted.

SP350

Feeling the Burn: The Significance of Febrile Non-Hemolytic Transfusion Reactions at Two Institutions

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Background/Case Studies: Febrile non-hemolytic transfusion reactions (FNHTR) are diagnoses of exclusion, after ruling out other causes of fever (ie- bacterial contamination or hemolytic incompatibility), and/or pyrexia from underlying condition(s). FNHTR pathogenesis stems from *product-related* inflammatory cytokines (pronounced with longer storage), and/or *host source* anti-leukocyte antibodies interacting with residual unit white blood cells. FNHTRs occur often (~1%/unit), are partly mitigated by prestorage leukoreduction, and are typically classified as non-serious events. However, the impact of FNHTRs on patients and providers may not be so trivial. Patients with FNHTR may require additional resources or disposition escalation (admission or unit transfer). The extent to which this occurs was determined across two sites. **Study Design/Methods**: Passive hemovigilance databases were reviewed at two adult-care, university-affiliated hospital transfusion services to gather known cases of FNHTR (possible to definite). Site-specific approaches to FNHTR were compared for pre-completion transfusion termination, diagnostics (microbiology, radiography), and

TABLE.

	hospital A	hospital B	p-value
annual use of cellular components (RBC: adult dose platelet concentrates; [total])/bed count	9,980: 1,316; [11,296]/605	11,014: 6,520; [17,534]/143	< 0.05
FNHTR cases in audit period (annual rate)	79 (26.3/y)	137 (68.5/y)	
audit period	2013 - 2015 (3 years)	2014 - 2015 (2 years)	
FNHTR rate (/component/year)	1 in 434	1 in 254	< 0.05
transfusion halted	49 (62%)	50 (37%)	< 0.05
patient C&S	40 (51%)	112 (82%)	< 0.05
product C&S	33 (42%)	83 (61%)	< 0.05
chest imaging	17 (22%)	25 (26%)	NS
acetaminophen	53 (67%)	71 (52%)	< 0.05
meperidine	1 (1%)	15 (11%)	< 0.05
antimicrobials (new/adjusted)	11 (14%)	69 (50%)	< 0.05
diuretics	8 (10%)	9 (6.5%)	NS
antihistamines	12 (15%)	3 (2%)	< 0.05
supplemental oxygen	12 (15%)	13 (9.5%)	NS
out- to in-patient status	1 (1%)	31 (23%)	< 0.05
ward to critical care transfer	1 (1%)	2 (1.5%)	NS

management (drug changes, disposition escalation). **Results/Findings**: Hospital A (a general hospital with trauma and cancer care) and Hospital B (a cancer and stem cell transplant center) diagnosed FNHTR at 0.04 and 0.4% (respectively) of administered cellular components (red cells or platelets). FNHTR at hospital B occurred despite the high frequency of severe neutropenia at the time of the reaction (ANC$\leq$0.5 in 55% of cases). FNHTR cases were mostly non-severe (58%) at Hospital B, and the severity profile was not significantly different from all reactions within its wider 3-hospital network ($p=0.15$). Diagnosis and management of FNHTR resulted in similar rates of chest imaging (20-25%), diuretic use (7-10%), and oxygen supplementation (10-15%). Hospital B was less likely to abort the transfusion or to give acetaminophen, and more likely to culture both patient and product, give meperidine, and admit to hospital. See Table. **Conclusion**: Auditing of FNHTR cases reveals a meaningful burden of ensuing clinical activity. This information may serve in estimating site-specific economic and clinical costs of FNHTR, and thereby promote more conservative blood utilization.

SP351

Korean Hemovigilance System – Eight Years' Experience of Operation

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Background/Case Studies: We have set up and operated a national hemovigilance system supported by the Korean Ministry of Health and Welfare but independently operated by the Korean Society of Blood Transfusion since 2007. We intended to report the eight years' experience of operation. **Study Design/Methods**: In the first year (Aug 2007-Jan 2008), we defined the scope of the reporting events and developed the reporting forms. During the next 2 years (Apr 2008-Apr 2010) of pilot study, we made a homepage of Korean hemovigilance system, recruited the participants to report and collected and analyzed the data. A national hemovigilance system operated by the Korean Society of Blood Transfusion supported by the Korean Ministry of Health and Welfare has been implemented since Aug 2010. We developed the on-line reporting system and the data has been collected on the website. In 2014, we included the participation of hemovigilance system into the criteria of blood management fee which was newly created. We have continued to encourage hospitals to participate in and report to the hemovigilance system. **Results/Findings**: The Korean hemovigilance system is a voluntary reporting system and all adverse events including transfusion reactions and incidents are reported. The numbers of participating hospitals and adverse events have increased every year and 159 hospitals reported 2,770 adverse events in 2015. The number of participating hospitals have dramatically expanded owing to the blood management fee in 2014 and the amount of transfusion of the 159 participating hospitals account for about 52.6% of total transfusions in Korea. After eight years' operation (including two years' pilot study), total 8,467 adverse events have been reported to the hemovigilance system. Overall 7,798 transfusion reactions were reported. Febrile non-hemolytic transfusion reaction (4,696, 60.2%) and allergic reaction (2,256, 28.9%) were the most frequently reported adverse reactions and 45 cases (0.6%) of transfusion-related acute lung injury were reported. There were 673 reports of incidents: near miss 569 (84.5%), incidents without adverse reactions 88 (13.1%), and incidents leading to adverse reaction 16 (2.4%). About the half of incidents (53.6%) occurred in related to blood sampling, 21.9% occurred during transfusion in the ward, and 10.4% occurred during performing pre-transfusion tests in blood bank. **Conclusion**: We have set up and operated the national hemovigilance system for eight years. It seems to work very effectively. Data from the hemovigilance system is expected to support the development of blood safety strategies in Korea.

SP352

Food and Drug Administration Updated System for Classifying Reports of Donation and Transfusion-related Fatalities

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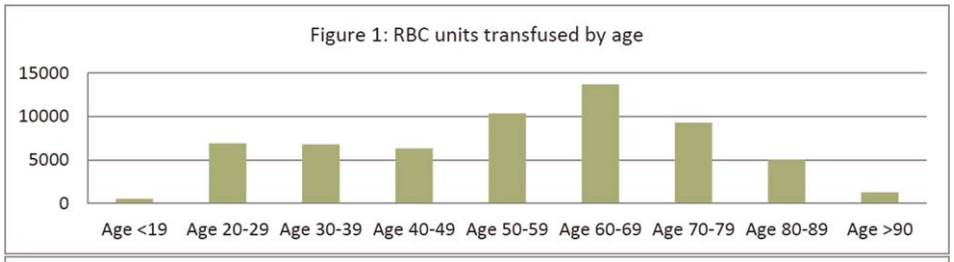
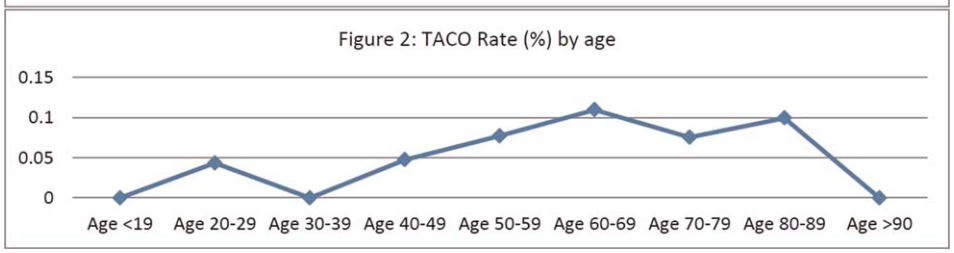
Background/Case Studies: The Code of Federal Regulations requires that fatalities related to complications from blood donation or transfusion, and from Source Plasma donation, be reported to FDA. Since 2005 FDA has released an Annual Summary of fatality reports using a case definition and imputability scale that differed from those of other hemovigilance (HV) systems. By updating its fatality classification system FDA sought to harmonize its HV efforts with other organizations, and to enhance the usefulness of its Annual Summary. **Study Design/Methods**: FDA Medical Officers assessed the HV modules of the following organizations: CDC's National Healthcare Safety Network (NHSN), AABB, International Society of Blood Transfusion (ISBT), International HV Network (IHN), British Serious Hazards of Transfusion (SHOT), and the French National Agency for Medicine and Health Products Safety (ANSM). The NHSN module pertains to transfusion-associated adverse events (AE) and includes criteria for each AE category. ISBT and IHN have a joint document on non-infectious transfusion AEs, and have issued with AABB a standard on complications related to blood donations. SHOT includes reporting of transfusion related AEs only, but will add donor AEs starting in 2016. ANSM pertains to both donation and transfusion AEs. All systems include case definitions and similar severity and imputability scales for donation and transfusion associated AEs. **Results/Findings**: FDA's previous imputability scale was limited to 3 categories: related; not related; ruled out. The updated imputability scale is consistent with those of the other HV organizations and includes 6 categories: Definite/Certain; Probable/Likely; Possible; Doubtful/Unlikely/Improbable; Ruled out/Excluded, and Not determined/assessable/evaluable. For case definition, the updated classification system adopted those of NHSN and joint ISBT/IHN/AABB for transfusion and donation AEs, respectively. A severity scale is not applicable since all reported cases are fatalities. **Conclusion**: In support of international harmonization, to provide consistency among U.S. public health agencies, and to improve clarity and utility of the information disseminated in its Annual Summary, FDA modified its approach to the review and classification of reports to the Agency of transfusion and donation related fatalities.

TABLE. Fiscal year 2015 fatality report classification

	Definite/ Certain	Probable/ Likely	Possible	Doubtful/ Unlikely/ Improbable	Ruled out/ Excluded	Not Determined/ Assessable/Evaluable
Allergy/ Anaphylaxis	2					
Bacterial contamination	3		2			
Hemolytic Transfusion Reaction (HTR)(ABO)	2					
HTR (non-ABO)	2	1	1	1		
Hypotensive reaction		1		1		
TACO	3	6	2			
TRALI	5		7	1	1	1
Donor fatality			1	12	5	2





SP353

Identifying the Target Age for Trials to Test Strategies to Decrease the Incidence of Transfusion-associated Circulatory Overload (TACO)

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Background/Case Studies: One-third of all life-threatening transfusion reactions are attributable to TACO. The incidence is between 1-5% of recipients based on active hemovigilance reports. Diuretics are often employed peri-transfusion to reduce the incidence and/or severity, although the effectiveness of diuretics is unknown. Other interventions, such as slowing the infusion rate or infusing 1 unit at a time are often promoted to reduce TACO, but again neither has been tested in clinical trials. Older age is thought to be a risk factor for TACO, however the age threshold where the risk increases is unknown and therefore the optimal age cut-off to use for purposes of clinical trial design is unclear. **Study Design/Methods**: Passive hemovigilance data for TACO was extracted from the hemovigilance system for four of our academic hospital sites for 2015. The rate of TACO for each decade of age was determined. In addition, the age distribution of transfusion recipients of all red blood cell transfusions were extracted from the transfusion information systems. Our primary objectives were: (1) To determine the risk of TACO with each decade of age; (2) To determine the number of potential recipients within that population that could be eligible for TACO intervention trials. **Results/Findings**: 60,062 RBC units were transfused at the 4 academic institutions (Figure 1). The greatest number of units were transfused to patients in their 7th decade (60-69) accounting for 23% of all units. There was a gradual increase in TACO rate by age (Figure 2). Overall, 85% of TACO cases were aged 50 or older and 66% were aged 60 or older. Patients aged 50 or older had a TACO rate 0.088% and those 60 or older had a TACO rate of 0.092%. Patients 50 or older had a 3-fold higher rate of TACO vs.those under 50 (0.09% vs. 0.03%, chi-squared, p=0.01). **Conclusion**: Large intervention trials designed to test strategies to reduce the incidence of TACO should include patients aged 50 or older to maximize the number of reactions prevented. Patients 50 and older account for two-thirds of all transfusions, and hence, if an intervention was shown to reduce the incidence of TACO, it would have a positive impact on the safety of transfusion for the majority of recipients.

SP354

Interleukin-6 Receptor-α Signaling on T cells Delays Alloantibody Evanescence in a Murine Model of Red Blood Cell Alloimmunization

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Background/Case Studies: RBC alloimmunization remains a significant clinical problem in transfusion medicine. Many patients with hematologic diseases require multiple transfusions over long periods of time. In those who are unfortunate enough to generate multiple alloantibodies, provision of compatible antigen negative RBCs can be both time and resource intensive. In rare cases, this can result in an inability to locate an otherwise life-saving therapy. Furthermore, observational clinical studies have shown that over 50% of newly developed RBC antibody responses are evanescent, often falling below the level of detection by the time the patient requires another transfusion. Thus some patients are at risk of being re-exposed to a previous RBC alloantigen, and the resulting recall alloantibody response can result in a hemolytic transfusion reaction (HTR) capable of inducing significant morbidity and occasional mortality. Despite the significant clinical consequences of red blood cell (RBC) alloimmunization, our understanding of the fundamental molecular and cellular mechanisms regulating anti-RBC antibody evanescence is limited. **Study Design/Methods**: In order to identify the impact of IL-6 signals on antibody evanescence, we have combined a recently developed murine model of RBC alloimmunization with mice that are conditionally genetically deficient in the receptor for IL-6 (IL-6Rα). Mice were transfused and antibody responses were measured over an extended period of time. **Results/Findings**: IL-6Rα signaling on T cells not only enhanced initial alloantibody production and TFH generation, it also delayed antibody evanescence in response to transfused RBCs. When T cells are unable to recieve a signal via IL-6, the resultant antibody response is short-lived (i.e. more evanescent). **Conclusion**: We have identified a cytokine whose expression regulates both initial alloimmunization as well as antibody evanescence. This suggests that IL-6Rα signaling on T cells controlls long lived plasma cell production and/or survival. Collectively, our findings support the idea that currently available biologics targeting IL-6Rα could be a viable therapeutic option for the prevention of RBC alloimmunization in select, high-risk patient populations.

Transfusion Practice: Component Management and Utilization Reviews

SP355

Detection of Anti-IgA using a Flow Cytometry (FC) Method

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Background/Case Studies: Although controversial, plasma containing IgA has been reported to cause anaphylactic reactions in IgA-deficient patients with anti-IgA (Immunohematology 2004;20:234-8). There are no FDA licensed tests in the USA for anti-IgA detection and few facilities perform anti-IgA testing. With IRB approval, our laboratory developed a FC based anti-IgA assay utilizing IgA coated red blood cells (RBC). This novel approach was taken to avoid the use of costly microbeads which has been previously reported. The FC assay is inexpensive, has enhanced stability and is easy to perform. **Study Design/Methods**: Pooled IgA coated RBCs (RBC/IgA) were prepared from 10 group O residual donor samples. The pool was washed 4x in Dulbecco's PBS (DPBS) and tannic acid (TA) (Sigma-Aldrich, St Louis, MO) treated (25ug/mL) at 37°C±1°C for 15 ±1 minute(min). The tanned RBCs were washed 4x in DPBS, incubated with a

0.5mg IgA/mL solution of human IgA (MP Biomedicals, Santa Ana, CA) at 37°C±1°C for 60 ±5 min. The RBC/IgA were stored in RBC storage solution (Immucor Inc, Norcross, GA) up to 30 days after collection. RBC/IgA were washed 4x in DPBS and 1x in DPBS with 0.6% bovine serum albumin (BSA). Diluted test/control plasma was incubated with RBC/IgA for 30 ±5 min, washed 4x in 0.6% BSA and incubated with fluorescein isothiocyanate (FITC)-labeled anti-human IgG (Jackson ImmunoResearch Lab, West Grove, PA) at lot specific optimal dilutions for 45 ±15 min. An aliquot of RBC/IgA was incubated with FITC-labeled anti-human IgA (Jackson ImmunoResearch Lab) at lot specific optimal dilutions for 45 ±15 min. The RBCs were washed and 50k RBCs were acquired from each sample by the Becton Dickinson FACScanTM (San Jose, CA) FC for analysis. RBC/IgA were evaluated for IgA coating with each run. **Results/Findings**: The FC detects fluorescence emitted from the FITC-labeled anti-IgG bound to the patients' anti-IgA bound to RBC/IgA. Adequate IgA coating of the RBC/IgA was assessed in each test run. 20 RBC/IgA pools evaluated 45x over a 21 month period had an average IgA coating of 99.46% (standard deviation (SD) 0.68). Absence of anti-IgG cross-reactivity with the RBC/IgA was confirmed in each test run, average of 0.73% (SD 1.06). A high positive control was tested 23x over 1 year and averaged 77.23% (SD 11.27); a low positive control was tested 19x over 1 year averaged 51.25% (SD 12.89). Failed test runs were excluded from analysis. **Conclusion**: This FC method using RBC/IgA coated by tannic acid yielded expected and stable positive and negative results. The tannic acid treatment method was selected as reports indicated favorable stability of tannic acid treated RBCs. This FC assay, estimated $2.23 per patient, is an inexpensive and effective and fills the void in anti-IgA testing as no licensed tests for anti-IgA are available in the USA. This study confirmed the assay's potential for clinical use.

SP356

Biocompatibility Differences between Textured and Smooth Surfaces of Platelet Storage Containers

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Background/Case Studies: A slow growth rate and strong tendency of some bacterial strains to adhere to platelet bag surfaces contribute to detection failures using current bacterial screening tests. Surfaces of the platelet bags are textured to prevent the inside faces from collapsing during heat sterilization and blood processing. This study investigated platelet and bacterial adhesion on the textured surfaces in comparison with non-textured ones. **Study Design/Methods**: Topography of three different platelet bags, MacoPharma TDV 8006XU (P15), Fenwal PL2410 (F1), and Terumo 80440 (A15) was studied using scanning electron microscopy (SEM), profilometry and atomic force microscopy. Adhesion of a biofilm-forming *S. epidermidis* strain to the surfaces of these bags was evaluated using SEM and fluorescence imaging after 24h incubation in tryptic soy broth-glucose medium at 37°C. The differences among samples were quantified by releasing the bacteria from the surfaces with sonication and determining colony forming units in the suspension(n=5). After 4h incubation on a platelet shaker at 37°C, platelet adhesion to the bag surfaces was evaluated using SEM and fluorescence microscopy(n=5). To test if trend of platelet adhesion on the surfaces was similar under the blood bank conditions, three platelet units were pooled and split into four bags: P15, F1 and two A15 bags with opposite faces up on the shaker, and platelet adhesion was evaluated after 7 days of storage(n=2). **Results/Findings**: In P15 and F1 bags, both inside surfaces are textured while A15 bags have one textured and one non-textured (smooth) surface. Bacterial adhesion was significantly ($p<0.01$) higher on the P15, F1 and A15-textured surfaces compared to the A15-smooth surface. Platelet adhesion and aggregation also occurred more extensively on the textured surfaces (not quantified). Roughness of A15-smooth surfaces was too minimal (122 ± 9 nm and 604 ± 101 nm in a 40 × 40 μm and 111 × 148 μm scanned area, respectively) for bacteria or platelet to fit in, thus reducing their contact area with the material surfaces and hence their adhesion. Topography of the different textured surfaces was also analyzed but the difference in bacterial/platelet adhesion on these surfaces cannot be solely correlated to the difference in their topography as the chemical details of the surfaces are not yet investigated. **Conclusion**: Lower bacterial adhesion to the non-textured bag surfaces due to the nanometer-scale roughness helps the bacteria to stay in a planktonic state and reduces the chance of false-negative bacteria results. Reduced platelet adhesion and aggregation on such surfaces might also contribute to preserving the platelet quality. As the textures are essential in the platelet bag design, using only one textured surface positioned above a smooth one may be an optimal combination.

SP357

***In vitro* Evaluation of Platelet Function of Platelet Concentrates Washed with Plasma-Lyte A versus Normal Saline (0.9% NaCl)**

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Background/Case Studies: Platelet Concentrate (PC) transfusions are a valued therapeutic option for bleeding and/or thrombocytopenic patients. PCs washed and suspended in normal saline (NS) have benefited the management of patients with repeated or severe allergic or febrile transfusion reactions. In addition, clinical and observational studies have produced data demonstrating washed transfusions reduce inflammatory and immunologic complications. However, suboptimal platelet function has also been observed in washed platelets. We evaluated whether use of Plasma-Lyte A, a more physiological solution, would better preserve platelet function as compared to NS. **Study Design/Methods**: Platelet rich plasma samples were aliquoted (3mL) from PC units (average storage period of 5 days) prepared for transfusion (n=21). Samples were then washed via an *in vitro* tube model in equal ratio to the standard clinical washing protocol. Briefly, samples were spun for 10 minutes at 1500xg, resuspended in 4.5mL of either NS or Plasma-Lyte A solution, spun again and resuspended in 3mL of the corresponding wash solution (n=13) or ABO identical fresh plasma (n=8). Platelet aggregation studies were then performed utilizing a Chrono-log aggregometer. ADP, epinephrine and collagen agonists were added simultaneously to induce platelet aggregation. **Results/Findings**: Baseline platelet aggregation of non-washed stored PCs averaged 40 ± 19% (normal range of 70-94%). No aggregation was detected in PCs washed and resuspended in NS. In contrast, aggregation of PCs washed and resuspended in Plasma-Lyte A averaged 29 ±13% ($p<0.001$, in comparison to NS). Resuspension in ABO-identical plasma improved platelet aggregation significantly for PCs washed in NS or Plasma-Lyte A (Table). **Conclusion**: Plasma-Lyte A significantly preserved the platelet function of the washed PCs as compared to the traditionally used washing solution, NS. Whether this effect of the transfused washed platelets is present *in vivo* is yet to be determined along with the clinical implications.

TABLE. Platelet Aggregation of Washed PCs

	Non-Washed PCs	NS-Washed PCs	Plasma-Lyte A-Washed PCs	p-value
Baseline (n=21)	40 ± 19%			
Resuspension in Same Wash Solution (n=13)		0%	29 ± 13%	<0.001
Resuspension in ABO-identical plasma (n=8)		41 ± 10%	52 ± 5%	0.03
p-value		<0.001	0.002	

SP358

Cryopreserved Platelets: Results from in Vitro and in Vivo Studies

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Background/Case Studies: Cryopreserved Platelets (CRY-PLTs) are reported to have a greater in vivo hemostatic effect than liquid-stored PLTs. Aims of this study were:

i. to evaluate the thrombin generation potential of buffy coat derived CRY BC-PLT in comparison with fresh buffy coat derived platelets concentrates;
ii. to determine the efficacy and safety of CRY-PLTs transfusion in hematological patients with severe thrombocytopenia.

Study Design/Methods: Buffy coat derived platelets were obtained from 5 buffy coats and pooled. The final PLTs concentrates were leukoreduced and transferred to a 650 mL patented cryopreservation kit which allowed mixing with dimethyl sulfoxide (DMSO 25%) in a closed system and following removal of supernatant without further manipulations. BC-PLTs were washed prior freezing, suspended in homologous plasma from 1 of the 5 donors to a final concentration of 200 mL and frozen at - 80°.CRY- BC PLTs were preserved at −80°C with 6% DMSO In vitro assays were performed before freezing and at 3,6 and 9 months after thawing . Thrombin generation (TGA) was tested in CRY BC-PLTs and compared to TG potential of fresh BC PLTs. Endogenous thrombin potential (ETP) and peak height (PH) were determined. Flow Cytometry assays for PLTs activation markers and thromboelastography were also determined.CRY-BC PLTs, were infused in five hematological patients with acute leukemia (AL) and severe thrombocytopenia (PLTs $<10\times$ 109/L) participating to the trial NCT02032134. Patients were monitored up to 7 days after infusion. Plasma from patients transfused with CRY-BC PLTs was tested for TGA pre-treatment and 24 hours after treatment **Results/Findings**: Fourty nine BC-PLTs from 245 healthy volunteer donors (145 males and 100 females, mean age: 48.16.±18.91) were prepared, cryopreserved and analyzed up to 9 months after storage. Cryopreserved PLTs show a good thrombin generation potential that is stably maintained up to 9 months after cryopreservation. Thrombin generation of CRY-BC PLTs is comparable to fresh BC-PLTs, even if slightly decreased. Infusion of CRY-BC PLT (1U) was effective in controlling mucosal bleeding (epistaxis) in two patients with AL and severe thrombocytopenia. CRY-PLT were also effective for prophylaxis in 3 patients with very low platelets count secondary to chemotherapy. In vivo, thrombin generation is stably maintained up to 24 hours after infusion of 1 Unit of CRY-BC PLTs, without any adverse effect.CRY-BC PLTs were safe and they did not determine any thrombotic event. **Conclusion**: At flow-cytometry, CRY-BC PLTs expressed higher activation markers (CD62P,CD63) than fresh BC PLTs.CRY-BC PLTs activation/deterioration is accompanied by an effective hemostatic *in vivo* function. CRY-BC PLTs are effective and safe in preventing and controlling bleeding.

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SP359

Verax PGD® Point-of-Release Testing: A Non-conventional Approach

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Background/Case Studies: We were part of a multicenter study evaluating the Verax PGD®, a point-of-release (POR) rapid assay for detecting bacterial contamination in single donor platelets (SDP). Results showed that such contamination occurs in about 1 in 3000 SDP. Since Q4 of 2012, we have used the PGD® to test SDP units implicated in transfusion reactions (TxRx) instead of in POR testing. Based on our hospital's SDP usage and TxRx rate, it was estimated that the first true positive (TP) would be detected within 5 years. Here we report the process of testing SDP units implicated in TxRx and how we utilized the PGD® to quickly work up a reaction to a day 5 SDP in a leukemia patient. **Study Design/Methods**: Our standard protocol calls for the PGD® package insert to be followed. However, all SDP units issued have a 5 ml retention sample removed and stored in the platelet incubator and the PGD® is selectively used to only test SDP units implicated in a TxRx. Additionally, any sister units in inventory are located and held in quarantine until testing is complete. If the PGD® is non-reactive, the sister unit can be released back into inventory. If reactive, the PGD® is used to re-test the unit in duplicate and if any repeat tests are reactive, the sample is considered repeat reactive (RR) and all partner units are discarded. Any remaining product is sent out for blood culture and bacterial identification. If there is bacterial growth, the PGD® is considered to be a TP. The blood supplier is notified for interdiction of any other partner units if such exist. **Results/Findings**: In August 2015 (3 years after PGD® implementation), the blood bank (BB) was notified of a TxRx (leukemia patient with symptoms of increased temperature, rigors, and chills). The PGD® was performed, resulting in a RR result in the gram-positive (G+) testing window. The patient and SDP unit were cultured and the patient was emergently given antibiotics with G+ coverage based on these results. No partner units were found in our inventory. The blood supplier was notified and a partner unit *was* found to have already been transfused a day prior (day 4) at another institution. The blood cultures (BC) from the unit and patient were found to be positive for bacterial growth in <24 hours with Coagulase Negative Staphylococcus (common skin flora). The patient transfused with the partner unit had no reaction and subsequent BC was negative. **Conclusion**: Testing SDP units implicated in TxRx rather than performing POR testing with the PGD® assay is non-conventional. However, this approach is cost effective, works well with the daily workflow of the BB, and is more sensitive than gram staining (10^3-10^5 CFU/ml vs 10^7-10^8 CFU/ml, respectively). Its rapid turnaround time is ideal compared to BC, aiding in quick decision making in regards to the patient treatment plan and whether to discard any partner units.

SP360

Epidemology of Platelet Transfusion in Hospitalized Patients: Data from an Integrated Health Care Delivery System

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Background/Case Studies: Few studies have reported the epidemiology of platelet transfusion. Our objective was to characterize inpatient platelet utilization from data available in an integrated healthcare delivery system. **Study Design/Methods**: Using comprehensive electronic medical record data from 21 community hospitals between January 2009 and August 2013, we conducted a retrospective cohort study of hospitalized adult patients receiving platelet transfusions. Principal diagnoses were calculated using ICD-9 codes. Indications for transfusion were extracted from electronic orders for platelet transfusion. Means and interquartile ranges (IQR) were calculated **Results/Findings**: 62,491 doses of platelets were transfused to 13,276 patients. The median age was 62 (interquartile range (IQR) 48-73) years, and 57% of patients were male. The platelet transfusion incidence per hospitalization increased from 1.7% in 2009 to 2.1% in 2013 ($p<0.001$). Platelet transfusion occurred in 44% of hospitalizations where platelet counts fell below 50 K/uL. The median pre-transfusion and post transfusion platelet counts were 22 K/uL (IQR 11-62) and 49 K/uL (IQR 24-101), respectively. The majority of transfused patients had non-surgical admission conditions (69%) and was in intensive care (59%) during their hospitalization. Pre-transfusion platelet thresholds were lower in medical (17 K/uL; IQR 10-38) compared to surgical (64 K/uL; IQR 32-105) patients ($p<0.001$). Most patients (72.7%) also received red cell transfusions and 36.8%

TABLE.

Principal Diagnosis	Proportion of Units TX (%)	Pre-TX Platelet Count (K/uL) and IQR	% Surgical Patients
Hematology-Oncology	35	14 (9-26)	7
Infection	18	16 (10-28)	18
Gastrointestinal	8	39 (18-67)	15
Musculoskeleta	10	60 (33-103)	35
Cardiovascular	21	80 (39-125)	50

IQR=Interquartile Range

also received plasma. 25% of transfusions were given for a platelet count > 50 K/uL and 17% for a platelet count > 100 K/uL. Clinician designated indications for transfusion where the pre-transfusion platelet count was > 50 K/uL included: "Bleeding" (39%), "Thrombocytopenia" (31%), "Procedure" (16%), and "Platelet Dysfunction" (14%). **Conclusion**: These data describe the current epidemiology of platelet utilization in a large community hospital network. Platelet transfusion occurred in a significant proportion of thrombocytopenic patients, and the incidence of platelet transfusion increased in both medical and surgical patients from 2009 to 2013. Higher pre-transfusion thresholds were seen in both medical and surgical cardiovascular admissions as well as conditions associated with bleeding. Further studies incorporating patient diagnoses and clinician designated indications for platelet transfusion will be helpful in understanding transfusion practice outside of guidelines.

SP361

How Many AB Plasma Units Were Infused? The HABSWIN Study

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Background/Case Studies: Group AB is the universal donor for plasma; these units can be given to a recipient with any plasma group. Standard practice is to select ABO group specific plasma units as the first choice for patients requiring transfusion. There are; however, many situations where group AB plasma is given to A, B or O individuals including: trauma patients whose ABO group is unknown, neonatal transfusions, prevention of outdating as AB plasma reaches its expiration date, and lack of available inventory of other plasma groups. As a result, many plasma suppliers are finding that demand for group AB plasma is exceeding collections, with the potential consequences of a shortage for those who require this group of plasma. This project explored the patterns of AB plasma utilization at hospitals around the world. **Study Design/Methods**: Hospital transfusion services collected the following information from the 2014 calendar year: Number of plasma units transfused by month or quarter (3 month period), the ABO group of the plasma units and that of the recipients. Units administered to recipients of unknown ABO group and reportedly ABO mismatched transfusions and units administered to patients of unknown blood group were excluded. The hospitals were divided into 3 categories: Small (<250 beds), medium (250-1000 beds), and large (>1000 beds). **Results/Findings**: Data was received from 15 centers in 8 countries. The majority of the respondents, 8/15 (67%), were from North America. The majority (10/15, 67%) of the hospitals were medium sized, 3/15 (20%) were small hospitals and 2/15 (13%) were large hospitals. In total, these 15 centers transfused a total of 43,369 study eligible plasma units. There were 361 (0.8%) units excluded from analysis as outlined above. Only 1496/5541 (27%) of the study eligible AB plasma units were transfused to AB recipients, whereas 21,526/26,483 (81%) of the A and B units went to group identical recipients. There was considerable variability in the proportion of AB plasma units that were transfused to non-AB recipients; this variability ranged from 56-71% at the large hospitals, 38-96% at the medium hospitals and 60-77% at the small hospitals. **Conclusion**: This is the first time that the ABO groups of plasma recipients have been investigated on a large scale. A significant proportion of AB plasma units were transfused to non-AB recipients. Whether transfusing 73% of AB plasma units to non-AB recipients is the ideal inventory management strategy remains to be determined.

SP362

Evaluation of Type-AB Plasma Usage in a Medical Referral Center for the Pacific Basin

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Background/Case Studies: Our institution is the major trauma center for the Hawaiian Islands and Pacific Basin. Due to our isolated geographic location we predominately depend on local resources as it is challenging to rapidly import blood products. As the major trauma center for the islands, we maintain thawed AB plasma at all times in case of a massive transfusion protocol (MTP) activation. Group AB plasma is considered universal plasma since it can be given to patients of any blood type. It lacks anti-A and anti-B isohemagglutinins, which may be implicated in hemolytic transfusion reactions. Universal plasma is in short supply as only 5-6% of donors in Hawaii are group AB. **Study Design/Methods**: A severe AB plasma shortage prompted a retrospective 6 month chart review of AB plasma usage from January-June 2015 to determine the utilization characteristics of this scarce resource. We reviewed all emergent and non-emergent group AB plasma transfusions. We also analyzed our data to look for the percentage of our AB and B plasma recipients that may have been adversely affected if we switched to thawed group A plasma for emergency release. **Results/Findings**: 148 group AB plasma transfusion events (522 units; range 1-49 units) were assessed during the study period. Blood groups of patients who received AB plasma were as follows: group A, 59 (40%); group AB, 23 (15.5%); group B, 20 (13.5%); and group O, 46 (31%). Plasma was transfused on an emergency basis to only 49/148 (33%) patients, and only 8/49 were group AB. In the remaining 99/148 (67%) transfusion events, thawed group AB plasma was released to prevent wastage due to expiration. Group AB patients required 167 units in both the emergent and non-emergent setting. Two group AB patients required 49 and 22 units each. During this period, 16/49 (33%) of emergency transfusion events may have been incompatible with the use of Group A plasma (8 group B and 8 group AB recipients). **Conclusion**: This analysis revealed that the majority of our thawed group AB plasma recipients were non-AB type. This raises the question whether maintenance of thawed Group AB plasma inventory is justifiable. Due to Hawaii's geographically isolated location, it is challenging to emergently transport blood products from the Continental United States. For this reason, it is imperative that we optimize the use of our limited resources. Furthermore, maintaining thawed type-AB plasma may not be feasible for our rural centers with low trauma volumes. Use of a thawed Group A plasma inventory and/or prothrombin complex concentrate (PCC) are potential alternatives.

SP363

Inappropriate Plasma Transfusion at Academic Hospitals: An Audit & Qualitative Study

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Background/Case Studies: Annually 4.7 units of plasma per 1000 population are used in Ontario, Canada. Two provincial audits found that 30% of plasma use is inappropriate. This study aims to (a) characterize the appropriateness of plasma use at five teaching hospitals, and (b) explore healthcare workers' perceptions on factors that contribute to inappropriate plasma transfusion and strategies to improve use. **Study Design/Methods**: 1. Audit (2014): 15-20 consecutive plasma orders were tracked from each site. Orders for apheresis were excluded. Charts were reviewed within 72 hours for demographics and indications for plasma. Two adjudicators determined order appropriateness via a provincial plasma audit tool. 2. Semi-structured interviews (2014-2015): Process mapping and typical case sampling identified key players in the transfusion process at each site. Interviews were recorded, transcribed and anonymized. Transcripts were coded and analyzed for themes. **Results/Findings**: Of the 90 plasma orders audited, 46 [51%] were deemed appropriate, 37 [41%] inappropriate and 7 [8%] indeterminate. The most common order settings, prescriber disciplines and levels of training were noted for the inappropriate orders [as percentages of total inappropriate orders, and of total orders in the respective category]: 19 [51%, 46%] were to the intensive care unit and 12 [32%, 31%] to the operating room; 9 [24%, 36%] were by physicians in anesthesiology, 8 [22%, 53%] in intensive care, 7 [19%, 37%] in surgery and 6 [16%, 54%] in general internal medicine; and 20 [54%, 47%] were by medical residents and 17 [46%,

36%] by staff physicians. Common reasons for inappropriate use include an international normalized ratio (INR) < 1.5; bleeding/urgent procedures with warfarin anticoagulation or vitamin K deficiency without contraindication to prothrombin complex concentrate; and the reversal of heparin or oral anticoagulants. Twenty-five interviews were done with doctors, nurses and transfusion medicine staff. Five themes of factors were found to contribute to inappropriate plasma use: knowledge gaps, action preferred to inaction, the middle-man phenomenon, time pressures and barriers to interdisciplinary collaboration. Favourable strategies for improvement include point-of-care education, gatekeeping measures, timely access to tests/consultations and reflective practice. **Conclusion**: A large proportion of plasma use at participating academic hospitals is inappropriate. Order setting, specialty and level of training do not seem to impact appropriate use. Players in the transfusion process are insightful about barriers to appropriate use and strategies for change. Improving plasma transfusion practice likely needs a multidisciplinary, respectful and empowering approach – leveraging transfusion laboratory expertise, order entry, feedback and other targeted interventions.

SP364

Blood Component Transfusions in Mass Casualty Events

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Background/Case Studies: Planning transfusion needs in mass casualty events (MCEs) is a critical part of disaster preparedness. Three RBC units (U) per admission (UPA) has been used for estimation, but additional validation would be useful. Other blood components critical to massive transfusion protocols (MTPs) have not been analyzed on this basis. **Study Design/Methods**: We searched for all English-language medical publications since 1980 of MCEs with total RBC >50U and derivable data on RBC UPA, excluding war zones and natural disasters. Blood component UPA and post-event usage rates were analyzed. We expressed platelet and cryoprecipitate (cryo) usage in doses (5 whole-blood (WB)-derived U or 1 plateletpheresis U per dose) and counted WB U as RBCs. Intergroup means of UPA were compared by two-tailed t-test ($p<0.05$). **Results/Findings**: We compiled informative reports on 18 MCEs and 2 MCE clusters from 1980-2015. The MCEs were bombings, shootings, plane crashes, structural collapses or explosion. The ratios of patients evaluated: admitted in each MCE ranged from 9.7:1 to 1:1. For all MCEs, the medians, interquartiles (IQ), and ranges of UPA were 2.5 RBC (IQ 1.4-3.8, range 0.7-6.9), 0.9 plasmas (IQ 0.5-2.1, range 0.2-3.3), and 0.3 platelet doses (IQ 0.1-0.4, range 0.04-1.1). Event-wide transfusions were provided in 10 reports (6 with plasma and platelet use). Eleven MCEs or MCE clusters (8 with plasma and platelet use) had data from trauma centers treating part of the patients. (One MCE had reports of both types.) Seven of 10 event-wide reports were from MCEs in 1980-1999, whereas 8 of 11 trauma-center reports were from 2000-2013. Compared to event-wide reports, trauma centers had similar RBC use but averaged >2 times as many plasma and platelet UPA (Table). In 6 MCEs noting cryo use, mean UPA was 0.20 doses (range 0.01-0.37). From 3-41% of RBCs were transfused uncrossmatched (median 22%) in 4 MCEs with data. In reports (n) with rates of use and followup >24hr, medians of 68% of RBC (n=7), 79% of plasma (n=5) and 78% of platelets (n=4) were given in the first 12 hr-1 day. **Conclusion**: In MCEs, blood component transfusions per admission average around 3U RBC, 1U plasma and 1/3 dose of platelets. Event-wide transfusion data across all hospitals may be more relevant for blood suppliers, whereas in trauma centers the goal of balancing RBC, plasma and platelets in MTPs may lead to more intensive plasma and platelet use. Over 68% of all blood components needed were transfused in the first 12 hr-1 day from current inventory.

TABLE. Mass Casualty Events: Mean Blood Component Units per Admission

Report Types Compared (n)	RBC	Plasma	Platelet Doses
All MCEs (20)	2.86	1.31	0.32
Event-wide transfusions (10)	2.91	0.83	0.19
Trauma centers (11)*	2.99	1.72	0.43
Event-wide vs trauma centers	p=0.92	p=0.12	p=0.09

*One trauma center was also in an event-wide report.

SP365

Utilization Survey of Red Blood Cells and Plasma in China Based on a Sampling of 25 Hospitals

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Background/Case Studies: To better understand the clinical use of RBC and plasma, the most commonly use blood products in China, we performed a blood utilization survey. Doing so, we hope to establish baseline information on blood utilization in China and to discover the usage pattern. **Study Design/Methods**: A blood utilization survey was performed by sampling data from 25 Grade 3A hospitals (tertiary hospital), one each from the 25 selected provinces in China, from January 1, 2015 to December 31, 2015. A standard data collection form was distributed to the selected hospitals by the coordinating center (Chinese Institute of Blood Transfusion). The data was prepared, verified, and submitted by each participating hospital to the coordinating center. The coordinating center compiled the data and provided analysis. The total number of hospital admission, operations and the use of red blood cells and plasma were collected for the survey (Table 1). SPSS software was performed to investigate the correlation. **Results/Findings**: The correlation coefficients of the annual admission, surgical operations with red blood cells, plasma usage are 0.917, 0.712, 0.809 and 0.677, respectively.RBC and Plasma use distribution please see data in Table 2. **Conclusion**: This is the first blood utilization survey performed in China in large scale. This data provided the baseline status of blood use in China; it can be used to guide future epidemiology study as well as clinical trials.

TABLE. Annual admission rate and RBC/Plasma use*

	x±sd	The correlation coefficients (R)
Average RBC transfused/ admission (units)	0.2589 ± 0.08552	0.917
Average RBC transfuse/ operation (units)	0.6568 ± 0.28008	0.809
Average plasma transfused/ admission(mL)	21.8160 ± 16.53207	0.712
Average plasma transfuse/ operation (mL)	54.0126 ± 46.66553	0.677

*Each unit of RBC has 200 mL of red blood cells.

TABLE. RBC and Plasma Use Distribution

	RBC (U)		Plasma (ml)	
Category	Use	Distribution (%)	Use	Distribution (%)
Surgery	282981.5	39	26620354.6	42
Medicine	172625.2	24	16965979.3	27
ICU	67129.8	9	9475729.7	15
OB & GYN	45454.3	6	1792824.1	3
Pediatric	21884.7	3	1664748.8	2
Others	133343.9	19	7005833.7	11

Notes:

1. Each unit of RBC has 200 mL of red blood cells

SP366

Blood Transfusion in Lower Gastrointestinal Bleeding: Results from a National Study in the United Kingdom

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Background/Case Studies: Gastrointestinal bleeding is a common indication for transfusion, but it is not known what proportion of this is due to lower gastrointestinal bleeding (LGIB). The aim of this multi-center observational study was to define the patient characteristics, investigations, management and the use of blood in LGIB. This report focuses on the use and appropriateness of blood transfusion. **Study Design/Methods**: All hospitals in England were asked to provide data on patients admitted with or who developed LGIB whilst an inpatient from September to December 2015. Cases were identified by clinical teams and data on transfusion and outcomes were entered into a central website until discharge, death or 28th day of admission. Continuous data are reported as median and range. **Results/Findings**: Data on 2528 cases of LGIB were provided by 138 hospitals. Red cell transfusion occurred in 666/2511 (26.5%) cases, receiving 3(1-17) units. Of these, 261/666 (39.2%) were transfused at a hemoglobin (Hb) threshold $\leq$80g/l and 36/666 (5.5%) were shocked. Shock or tachycardia was found in less than 30% of patients transfused at each Hb threshold (Table 1). FFP was used in 56/2498 (2.2%) cases; 15/56 had an INR$\geq$1.5. Platelet transfusion occurred in 44/2498 (1.8%) cases; 8/44 with a platelet count $<$30 and 21/44 were taking anti-platelet medication. **Conclusion**: The frequency of major bleeding in LGIB is very low, but despite this red cell transfusion is a common intervention. Most of the transfused population had an admitting Hb$>$70g/l and were not shocked and represent a group of patients where red cell transfusion could have been avoided. FFP and platelet transfusions were similarly over-used. This study shows there is considerable scope for improving transfusion practice in LGIB.

TABLE. Frequency of shock per Hb threshold in patients with LGIB

Admitting Hb (g/l)	Patients transfused N	Normal admitting observations N (%)	Shocked* N (%)	Isolated tachycardia** N (%)
Hb $\leq$ 70	139	106 (79.1)	12 (9.0)	16 (11.9)
Hb 71-80	122	88 (75.2)	9 (7.7)	20 (17.1)
Hb 81-90	115	82 (73.2)	5 (4.5)	25 (22.3)
Hb 91-100	100	78 (79.6)	2 (2.0)	18 (18.4)
Hb 101-110	66	45 (71.4)	3 (4.8)	15 (23.8)
Hb 111-120	50	36 (75.0)	1 (2.1)	11 (22.9)
Hb $\geq$ 121	74	53 (72.4)	4 (5.3)	17 (22.4)

*Shock defined as heart rate $\geq$100/minute and systolic blood pressure $<$100mmHg on admission. **Isolated tachycardia defined as heart rate $\geq$100/minute. Data missing in 20 cases.

SP367

Overview of the Use of Blood Products in the Hospital District of Helsinki and Uusimaa in 2011-2014

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Background/Case Studies: Higher amounts of blood products are used in Finland than in other Western European countries. However, the use has declined over the past few years, eventhoug earlier estimates suggested that the use would increase to the ageing of the population. The purpose of the study is to provide an up-to-date overview of the use of blood products and changes occured in 2011-2014. Data covering all blood transfusions within the Helsinki and Uusimaa Hospital District (HUS) in that period was analyzed. Approximately one third of all blood transfusions in the country carried out in this area. The use of red blood cells (RBC) and platelets (PLT) in comparison to population size as well as the use in different age groups was also examined. **Study Design/Methods**: Data of all blood transfusions carried out in 2011-2014 in the HUS was obtained from the centralized blood bank database of the area. Data were analyzed by means of quantitative methods by using IBM SPSS Statistics 23 software. ANOVA, Mann-Whitney U and Krushkal Wallis tests were used to calculate differences. **Results/Findings**: The research material consisted of 349,568 blood transfusions, 66% of which were red blood cell transfusions, 14.4% platelet transfusions and 19.6% fresh frozen plasma transfusions. The use of blood products declined by 11.2% during four years. Of all patients, 70.7% received only RBC products, 2.4% only PLT products and 2.7% only FFP products, while 8% were given all three types of blood products. Patients older than 65 received 45% of all blood products and 52% of RBCs. PLTs and FFP were the most frequently transfused products for patients aged 40-64. Men received 53.1% and women 46.9% of all blood products. PLT and FFP products were significantly more often transfused for men than women. The median age of RBC product recipients was 66.2 years, that of PLT product recipients was 61.4 years and that of FFP products was 58.5 years. The haemoglobin concentrations of before RBC transfusions were lower in 2014 than before. The haemoglobin and thrombocyte concentrations before blood transfusions varied between hospitals. A total of 0.7% of the population in the Hospital District area received RBC transfusions, while 0.1% received PLT transfusions. In the age group 90 or more, almost 7% of the population received RBC transfusions, while the corresponding figure for people aged 10 to 19 was only 0.1%. **Conclusion**: Detailed information on the use of blood products in different hospitals and in different demographic groups can be used for the development of blood transfusion treatment and the related guidelines, and for estimating the need for blood products in the future. The availability of up-to-date data on blood transfusion treatment may help to optimise the use of blood.

Transfusion Practice: Emergency and Trauma Practice

SP368

The Effect of Plasma Transfusion on International Normalized Ratio (INR) of Non-massively Bleeding Patients

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Background/Case Studies: The prophylactic use of FFP in non-bleeding patients has been questioned. Holland & Brooks (2006) studied the effect of FFP transfusions in non-bleeding patients with prolonged INR and found that while there was a predictable effect on INR, no clinical benefit occurred when the INR was below 2.0. The trigger INR (the INR deemed necessary to initiate treatment of bleeding with FFP) is undefined, but a consensus trigger can be approximated from the literature. An INR $\geq$ 2.0 is often used as a critical value for consideration of FFP administration in patients at risk of bleeding (Holland &Brooks, 2006) **Study Design/Methods**: This was a retrospective cross sectional study on the effect of plasma transfusion on the international normalized ratio (INR) of non massively bleeding patients. The main outcome objective of the study was to assist in the development of policies that reduce unnecessary and ineffective FFP transfusions. Two further aims are to contribute to the formulation of new policies that reduce the risk of transfusion associated infections and improve FFP inventory management. The null hypotheses was 1) that there was no significant difference between the frequency of FFP transfusion between non massively bleeding patients with an INR $<$ 2.0 and those with an INR $\geq$ 2.0, and 2) that an equal number of patients with an INR below 2.0 and $\geq$ 2.0 will achieve a pre versus post INR reduction of 25% or more. Data of FFP transfusion and INR results were collected from 234 patients issued FFP from May 1, 2014 through May 21, 2014 on odd numbered days. **Results/Findings**: A chi-square test used to determine whether there was a significant difference in the frequency of FFP transfusions between the two groups (INR $<$2.0 and INR $\geq$ 2.0) was highly significant ($p < 0.0001$). A chi-square test used to determine whether there was a significant difference in the number of patients in the two groups who had a 25% or more reduction in INR was also highly significant ($p < 0.001$). Regression analysis estimated the relationship between INR reduction and number of FFP units transfused in the INR $\geq$ 2.0 cohort to be $y = 0.3247 + 0.1609$ x. A receiver-operating characteristic (ROC) curve was used to predict the pre INR trigger that would most likely result in a 25% or more reduction in INR post FFP transfusion. The ROC curve showed this to be an initial INR $>$ 1.9 which is identical to the new guidelines issued by UMMC in October 2014. **Conclusion**: This study rejected both null

hypotheses and stresses the importance for physicians to adhere to the new FFP transfusion guideline.

SP369

One Size Does Not Fit All: An Analysis of Two Massive Transfusion Protocols in a Hospital-Based Blood Bank over Five Years

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Background/Case Studies: Massive transfusion protocols (MTP) are increasingly used by hospitals to rapidly and efficiently provide bleeding patients with optimal ratios of blood products. Initial experience at our site using a single protocol demonstrated that platelets released for non-trauma patients were often not used and subsequently wasted. This study evaluated the role of having two different MTPs at a large academic medical center, one for trauma patients and one for non-trauma patients. **Study Design/ Methods**: A retrospective cohort study was conducted of patients who received a trauma or non-trauma MTP from 2011 through 2015. The Trauma MTP coolers contained 6 units of red blood cells (RBCs), 5 units of plasma (FFP) and 1 apheresis platelet. The Non-Trauma MTP coolers contained 6 units of RBCs and 3 units of FFP; they did not receive apheresis platelets. Non-trauma MTP activations were evaluated by a transfusion medicine physician who can convert the non-trauma activation to the trauma protocol if clinically indicated. **Results/Findings**: Of 723 MTP activations between January 2011 and December 2015, there were 270 non-trauma MTPs, 371 trauma MTPs and 82 non-trauma MTP activations with conversion to trauma MTP. Of all non-trauma situations, clinicians activated a non-trauma MTP 63% of the time while 100% of true trauma situations received a trauma MTP. See table for summary data. **Conclusion**: Non-trauma protocols had higher rates of returned products and lower rates of products used outside the MTP indicating the actual product needs in non-trauma cases were well satisfied by the smaller non-trauma protocol. The non-trauma MTP led to lower rates of platelet wastage. Due to the spectrum of bleeding cases seen in large hospitals, having two MTP protocol sizes with comparable ratios of products provides efficiency to hospital blood supply while adequately meeting the diverse clinical need.

SP370

Audit of Massive Transfusion Protocol Activations in a Tertiary Level Hospital in South Australia

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Background/Case Studies: A Massive Transfusion Protocol (MTP) is an essential part of haemostatic resuscitation as laboratory parameters are not always immediately available to guide therapeutic decisions in exsanguinating patients. With an MTP clinicians can expedite therapy by the provision of blood and blood components in a very short turnaround time with the intention of stabilising the coagulation parameters thereby improving clinical outcome. With haemostatic resuscitation being increasingly applied to patients with haemorrhage other than trauma, MTP use has proportionally increased. MTP was implemented in our institution in 2013. The aim of the audit was to examine the application of MTP activations in a tertiary hospital in South Australia. **Study Design/Methods**: MTP activations between 2013 and 2015 that could be linked to a hospital admission were analysed. Data collected comprised reasons for activation, number of MTP activations including unused, partially used or completely used massive transfusion packs, blood products used and patient outcome. Massive transfusion was defined as 10 or more red cell unit transfused in a 24 hour period. **Results/ Findings**: A total of 334 activations were included: 138 (41.3%) in 2011, 125 (37.4%) in 2014 and 71 (21.3%) in 2015. Fifty six percent (186/334) of the activations were activated in Emergency Department, 24% (82/427) in the operating room and the remainder in Intensive Care Unit and other wards. MTP activations resulted in 19.5% (65) unused, 44.6% (149) partially used and 35.9% (120) complete use of massive transfusion packs. Forty eight unused (73.8%) and 52 (43.2%) of the completely used packs were activated in the Emergency Department. The top 4 reasons for MTP activation were in patients undergoing major surgery (colorectal, orthopaedics, neurosurgery) (35%), trauma (23.1%), medical patients (13.5%) and vascular surgery (12.6%). Within the 120 activations which were completely used, 85 activations had more than one massive transfusion pack ordered and 55.3% (47/85) of those activations resulted in a massive transfusion. **Conclusion**: Over one third of the MTP activations were used completely and nearly 25% of the activations were unused. Liberal MTP activations may reduce the risk of under treatment and help with rapid access of blood and blood products in patients with haemorrhage but also has the risk of exposing patients with

TABLE.

	NON-TRAUMA	NON-TRAUMA WITH SWITCH	TRAUMA PROTOCOL	TOTAL
Total of Activations	270	82	371	723
Avg. Unused RBCs	8.25 +/− 10.26	11.27 +/− 12.97	7.43 +/− 6.83	8.17 +/− 9.13
Avg. Unused FFP	3.33 +/− 5.29	7.28 +/− 11.18	9.18 +/− 6.87	6.78 +/− 7.48
Avg. Unused Platelets	–	0.64 +/− 1.04	1.3 +/− 0.97	1.19 +/− 1.01
Avg. Outside Protocol RBC Use	0.17 +/− 2.39	1.17 +/− 8.39	0.4 +/− 3.22	0.4 +/− 3.93
Avg. Outside Protocol FFP Use	4.3 +/− 1.95	16.78 +/− 10.71	13.33 +/− 15.92	10.96 +/− 11.18
Avg. Outside Protocol Platelet Use	–	2.6 +/− 1.92	2.53 +/− 2.42	2.58 +/− 2.07
Platelets not dispensed with non-trauma protocol	687	455	–	1,142
Total Platelets Transfused	271	294	744	1,309

	NON-TRAUMA	NON-TRAUMA WITH SWITCH	TRAUMA PROTOCOL	TOTAL
Total of Activations	270	82	371	723
Avg. Unused RBCs	8.25 +/- 10.26	11.27 +/- 12.97	7.43 +/- 6.83	8.17 +/- 9.13
Avg. Unused FFP	3.33 +/- 5.29	7.28 +/- 11.18	9.18 +/- 6.87	6.78 +/- 7.48
Avg. Unused Platelets	--	0.64 +/- 1.04	1.3 +/- 0.97	1.19 +/- 1.01
Avg. Outside Protocol RBC Use	0.17 +/- 2.39	1.17 +/- 8.39	0.4 +/- 3.22	0.4 +/- 3.93
Avg. Outside Protocol FFP Use	4.3 +/- 1.95	16.78 +/- 10.71	13.33 +/- 15.92	10.96 +/- 11.18
Avg. Outside Protocol Platelet Use	--	2.6 +/- 1.92	2.53 +/- 2.42	2.58 +/- 2.07
Platelets not dispensed with non-trauma protocol	687	455	--	1,142
Total Platelets Transfused	271	294	744	1,309

non-major haemorrhage to unnecessary blood components. Regular review of MTP activations helping to define the activation criteria is warranted.

SP371

Emergent Use of Group O Blood

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Background/Case Studies: Block Release of uncrossmatched group O red blood cell units (O RBCs) from the hospital-based blood bank or a mobile transport service without pre-transfusion testing is done in situations where delays in blood transfusion could be detrimental to the patient. Per institutional policy, Block Release O RBCs may be Rh- or Rh+. The most worrisome consequence of Rh sensitization is subsequent hemolytic disease of the fetus/newborn in women of childbearing age. Currently, this hospital struggles to maintain an inventory of 6 O- RBC units in the mobile transport refrigerator and 12 O- RBCs in the blood bank for emergent use. These stores represent the sole inventory for our transport service, but a minimum of 25 O- and 85 O+ RBC units are kept in the blood bank. National shortages of O- blood necessitate judicious resource management of limited O- RBC supplies. An analysis of Block Release blood usage was used to characterize Block Release O RBC disposition and quantify the incidence of emergent transfusion to Rh- women of childbearing age. **Study Design/Methods**: Retrospective RBC transfusion data was reviewed for the 2015 calendar year by cross-referencing electronic blood bank data with paper "Block Release" forms and electronic medical record identifiers. Within this data set, emergently-issued O RBC products and recipients were characterized. **Results/Findings**: In 2016, 386 O RBCs were transfused emergently. While 349 (both O+ and O-) originated from the hospital-based blood bank, 37 (O- only) were transfused from transport service stores. Of these units, 20 hospital-based patients (83 RBC units) and 9 transport service patients (16 RBC units) with an Rh- (or unknown) blood type received emergently issued blood. A total of 3 Rh- (or unknown type) females of childbearing age received Rh+ product, with one patient receiving blood in each location. **Conclusion**: Given these findings, utilization of O+ RBCs in Block Release situations would be beneficial to our blood inventory management and present minimal risk to our patient population. While debate will still arise over the definition of "minimal risk", alloimmunization rates in Rh- individuals receiving Rh+ blood in an emergent situation are estimated at 20% and these O+ units would only be used in life-threatening emergencies. While the blood bank has O+ RBCs on hand for emergent issue to male and female patients not of childbearing age, situations do arise when the O- females of childbearing age will receive O+ RBCs due to limited O- inventory. The current mobile transport system stocks only O- RBCs. Shifting our mobile transport service's Block Release inventory to predominantly O+ RBC units may improve availability of this limited resource for other deserving group-identical non-emergent patients. Future studies will be required to measure the impact of this strategic resource allocation adjustment.

SP372

Pre-emptive Administration with Fibrinogen Concentrate or Cryoprecipitate Contributes to the Better Prognosis for Survival of Severe Traumatic Patients

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Background/Case Studies: Severe traumatic patients usually have coagulopathy with critical hypofibrinogenemia and hyperfibrinolysis at early phase, resulting in impaired hemostasis, massive hemorrhage, and poor prognosis for survival. We have tried pre-emptive administration with fibrinogen concentrate or cryoprecipitate for severe traumatic patients in order to improve critical hypofibrinogenemia. **Study Design/Methods**: We retrospectively compared blood transfusion volumes and prognosis for survival in patients showing Injury Severity Score (ISS) $\geq$ 26 between 3 groups, as follows: group A (Aug. 2011-Jul. 2012; n=105), no administration with fibrinogen concentrate; group B (Apr. 2013-Mar. 2014; n=114), administration with 3g of fibrinogen concentrate when fibrinogen in patients' plasma was below 1.5 g/L; group C (Apr. 2014-Mar. 2015; n=128), immediate administration with 3g of fibrinogen concentrate at patients' arrival based upon prehospital information or trauma severity. Off-label use of fibrinogen concentrate was approved by the institutional review board in the hospital. **Results/Findings**: Approximately 80% of 54 patients (25 patients in group B and 29 patients in group C) who were administered with fibrinogen concentrate showed hypofibrinogenemia lower than 1.5 g/L. Although no significant differences were observed in blood transfusion volumes and total survival rates between 3 groups, significantly low mortality within 48 hours from the arrival at hospital was shown in group C (8.6% in group C *vs.* 22.9% in group A; p=0.005). In patients with ISS $\geq$ 41, who generally show extremely low survival rate, a significantly high total survival rate was observed in group C (80% in group C *vs.* 50% in group A; p=0.02). Impressively, 45% of survivors with ISS $\geq$ 41 were administered with fibrinogen concentrate in group C. Meanwhile, pre-emptive administration with cryoprecipitate has been tried for patients with multiple injury sites and severe head injury, because they frequently showed critical hypofibrinogenemia and hyperfibrinolysis. Twelve units of cryoprecipitate, containing ~3g of fibrinogen, were pre-emptively administered to patients who showed acute subdural hematoma on computer tomography. We observed larger reductions in FDP, dramatic improvement of hemostasis (e.g., control of oozing) at multiple injury sites including intracranial lesions, and the lower mortality (32% *vs.* 50%), in patients administered with cryoprecipitate. More importantly, patients with severe head injury without multiple injuries showed dramatically better prognosis for survival within 24 hours (0% *vs.* 56%) when cryoprecipitate was given. **Conclusion**: Pre-emptive administration with fibrinogen concentrate or cryoprecipitate for severe traumatic patients may contribute to the better prognosis for survival.

SP373

O D+ Red Blood Cells as Urgent-release Blood in Emergency Department

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Background/Case Studies: Traditionally, "universal donor" group O, D− RBC units have been used for emergent uncrossmatched transfusions. While in China, group O, D− RBCs are difficult to obtain since only about 0.4% person are Rh negative. Our institution endorses a policy for the emergency release of group O, D+ red blood cells (RBC; O+ RBC) to acute hemorrhaging patients. To determine the safety of O+ RBCs as urgent release blood, we performed a retrospective review. **Study Design/Methods**: Patients admitted to the emergency department between January 2012 and 2015 and transfused emergency-release O+ RBCs were identified. Data were collected on sex, age, mortality, length of stay, clinical status, time from requisition form accepted to O+ RBCs released, ABO/Rh, RBC transfusions, and RBC antibody screen results. **Results/Findings**: 110.5 units O+ RBCs were transfused to 60 acute hemorrhaging patients (39 male, 21 female, 14 female were under age 50). All patients accepted their own ABO/Rh RBC after the first O+ RBCs release. A total of 992 units RBCs were transfused. No one of these patients was Rh negative and no one developed alloantibody in entire hospital time. The mortality of these patients is 55% (33/60). The average time from requisition form sent to transfusion to O+ RBCs released is 5 minutes. **Conclusion**: The findings support O+ RBC as urgent released blood in emergent situation since O-

TABLE. Characteristics and outcomes of 60 patients who received at least 1 uncrossmatched O+ red blood cells

Characteristic	No. (%)
Age, mean (range) yr	35(3-79)
female sex	21 (35)
female < age 50	14(23)
car accident	33 (55)
stab wound and gun shot	10(17)
gastrointestinal hemorrhage	9 (15)
aneurysm rupture	2(3)
Uncrossmatched O+ RBC products used, mean no. (range)	5(1-12)
total RBC transfusion, mean no. (range)	16 (1-116)
time from requesition form accepted to the first unit O+ RBC released, minutes, mean(range)	3.35(1-12)
Length of stay, mean (range) d	22.8 (1-241)
Mortality	33(55)
Rh D+	60(100)
Rh D-	0(0)
alloantibody	0(0)

RBCs are extremely rare in China. More data are need for value the safety of O+ when transfused to female patient under age 50.

SP374

Rapid Reversal of Warfarin using Immediate Release of Fixed Low-dose Four-factor Prothrombin Complex Concentrate

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Background/Case Studies: Four-factor Prothrombin Complex Concentrate (4F-PCC) is FDA approved for the urgent reversal of warfarin. The package insert is based on INR value and the patient's weight. In July 2014, based on previous evidence of lower dose non-weight-based (fixed) efficacy of 3-factor Prothrombin Complex, a protocol was instituted by a multidisciplinary team at our institution to provide an immediate release of fixed non-weight-based low dose of 4F-PCC prior to the initial INR result to minimize delays in treatment: initial INR drawn at time of patient presentation, release initial fixed dose of 4F-PCC without waiting for INR results (1500 IU Intracranial hemorrhage (ICH) patients, 1000 IU non-ICH patients), vitamin K administered, repeat INR within 30 min after initial fixed dose, review initial INR result and 30 min INR if available, administer additional dose if needed (pre & post PCC INR results and clinical status). **Study Design/Methods**: Retrospective analysis of our of blood bank data of patients who presented to the ED and who were enrolled in the 4F-PCC protocol to reverse warfarin. Data was collected by Transfusion Safety Officer (TSO) to monitor and track the derivate usage, protocol adherence, and reconcile it with finance. The effectiveness was evaluated by post-PCC INR and patient clinical status. **Results/Findings**: From June 2014 -April 2016, 149 patients received 4F-PCC in our institute. 79 presented with gastrointestinal (GI) bleed, 37 with intracranial hemorrhage (ICH), and 33 with other (eminent surgery, MTP, retroperitoneal bleed and hematuria). Data are summarized in Table 1. 10(12.6%) patients in GI bleed group received more than 2 vials at presentation. 3(9%) patients in ICH group received more than 3 vials at presentation. Total of 7 Patients (3 in GI and 4 in ICH group) received a second dose of 4F-PCC. 13(8.6%) patients had presenting INR <2. No adverse consequences were observed. **Conclusion**: The optimal dose of 4F-PCC that controls hemorrhage but does not significantly increase the risk of thrombosis needs further study. Our protocol of immediate release of a fixed lower dose 4F-PCC is effective in reversing warfarin and eliminates the delays caused by weight and INR measurements. Using a lower dosing may also offer benefits in cost savings.

SP375

Massive Transfusion Event Occurrence in Trauma Versus Critical Care Patient Units

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Background/Case Studies: Prompt resuscitative transfusion practices with higher blood product ratios improve clinical outcomes in patients with massive hemorrhage. Massive transfusion protocols provide expedited delivery of blood products to these patients. We implemented a massive transfusion event (MTE) activation protocol at our institution and assessed over a 6 month time period for its efficiency in delivery and blood product utilization. **Study Design/Methods**: MTEs were reviewed from May 2015 to November 2015. For each MTE, blood products were issued in a cooler containing red blood cell (RBC): plasma (P): platelet (PLT) [6:6:1 for resuscitation units and 4:4:1 for others]. MTE activation occurred by phone, and generated an order to issue 1 or more MTE coolers for pickup. Five patient care units were compared [trauma resuscitation; non-trauma resuscitation; surgery and surgical intensive care unit (SICU); medical intensive care unit (MICU); Other]. The following MTE metrics were analyzed: MTE numbers, MTE coolers issued, location, products used and returned in first cooler, and turn-around time (TAT) from activation to dispense. Groups were compared using Student's t-Test. **Results/Findings**: There were 181 MTEs (30.2 ± 5.7 MTE per month) with 1.9 ± 1.4 MTE coolers issued per activation. The majority of MTEs were initiated in the resuscitation units (trauma and non-trauma) [110, 61%], compared to non-resuscitation units [71, 39%] (Table 1). Mean return rate for RBC, P, and PLT was 31%, 41%, and 42% respectively. Non-trauma

TABLE.

Type of Bleed	No.	Mean Pre-INR	Mean Post-INR	Post PCC INR <1.4	Post PCC INR >2	Post PCC INR $<1.4>2$	Mean PCC Dose	Dose/kg
GI	79	5.1(1.5-17.7)	1.7(0.9-4)	22(28%)	16(20%)	41(52%)	1248(1000-3646)	17(7.6-52)
ICH	37	3.1(1.4-5.7)	1.4(1.1-1.6)	23(62%)	0	14(38%)	1470(530-2650)	20(6.9-37)
Other	33	2.1(1.6-16.2)	1.8(1.2-6)	3(9%)	8(24%)	22(67%)	1187(539-2040)	16(6-28)

TABLE. Massive Transfusion Events

Location (Ratio)	Number MTE	Coolersper MTE	Products Used (1st Cooler)	Products Returned (1st Cooler)	TAT (min) (1st Cooler)
Trauma Resuscitation (6:6:1)	70 (39%)	2.4 ± 1.9	4.3 ± 2.1 (71%) RBC 4.0 ± 2.5 (65%) P 0.6 ± 0.5 (63%) PLT	1.7 ± 2.1 (29%) RBC 2.0 ± 2.4 (35%) P 0.4 ± 0.5 (37%) PLT	8.1 ± 6.0
Non-Trauma Resuscitation (6:6:1)	40 (22%)	1.7 ± 1.0	3.0 ± 2.5 (50%) RBC * 2.4 ± 2.5 (39%) P * 0.5 ± 0.5 (53%) PLT	3.1 ± 2.4 (50%) RBC * 3.6 ± 2.5 (61%) P * 0.5 ± 0.5 (47%) PLT	9.2 ± 6.0
Surgery/SICU (4:4:1)	33 (18%)	1.7 ± 0.9	3.4 ± 1.5 (81%) RBC 2.3 ± 1.8 (57%) P 0.5 ± 0.5 (55%) PLT	0.8 ± 1.3 (19%) RBC 1.8 ± 1.6 (43%) P 0.5 ± 0.5 (45%) PLT	6.5 ± 5.2
MICU (4:4:1)	30 (17%)	1.8 ± 1.2	3.2 ± 1.2 (80%) RBC 3.0 ± 1.6 (72%) P 0.7 ± 0.5 (67%) PLT	0.7 ± 1.1 (20%) RBC 1.1 ± 1.6 (28%) P 0.3 ± 0.5 (33%) PLT	5.8 ± 4.0
Other (4:4:1)	8 (4%)	1.5 ± 0.8	2.4 ± 1.9 (59%) RBC 2.6 ± 1.9 (59%) P 0.3 ± 0.5 (25%) PLT *	1.4 ± 1.90 (41%) RBC 1.4 ± 1.90 (41%) P 0.7 ± 0.5 (75%) PLT *	10 ± 8.2

* $p < 0.05$ for percentage in comparison to trauma resuscitation.

resuscitation units had a lower utilization and higher return percentage for RBC (p=0.004), P (p=0.001), and PLT (p=0.15), compared to trauma resuscitation. Other critical care patient units showed similar utilization and return rate compared to trauma resuscitation. **Conclusion: Conclusion**: The majority of MTEs occurred in resuscitation units with the highest blood usage. There was a high rate of return for all blood products, especially in non-trauma resuscitation units. Inventory management strategies should be considered to mitigate high blood product return rate.

SP376

Soluble Antigens in Plasma Allow Mismatched Transfusion without Hemolysis

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Background/Case Studies: Despite growing awareness of the importance of blood product utilization and reducing waste, product shortages are common. Plasma often falls in this category, especially in situations where a massive transfusion protocol has been initiated. Previous studies have reported success using type A plasma in place of universal type AB plasma, however, it is unclear why there is not more hemolytic reactions resulting from this practice. One explanation is the water soluble antigens present in the plasma bind to, and neutralize the soluble antibodies present in the plasma. **Study Design/Methods**: Expired units of plasma (3 type A and 4 type B units) were used to make the following dilutions: a 6:1 saline to type A plasma, 3:1 saline to type A plasma, 6:1 type B plasma to type A plasma, and 3:1 type B plasma to type A plasma. The dilutions were titrated using a type B red blood cell preparation. The titration protocol followed the CAP uniform testing procedure and read after 30 minutes of room temperature incubation, incubated at 37C for 30 minutes, washed, and read after adding anti-human globulin IgG (AHG). Both the room temperature and 37C thru AHG reactions were recorded. Serial dilutions of the samples were performed, starting from undiluted and doubling up to 1024. Reactions were graded using an AABB grading reference. The room temperature and AHG titer results were compared between the saline dilutions and the mixed type plasma dilutions using the Friedman's Test in the SAS statistical program. **Results/Findings**: The titers that resulted from the mixed dilutions (type A and B plasma) were significantly lower or showed no agglutination when compared to the type A specific saline dilutions. Both of the dilutions (3:1 and 6:1) and titration protocols (room temperature and AHG) echoed the results. The differences between the saline dilutions and mixed type dilutions were statistically significant (p value of 0.008). **Conclusion**: The use of an out of type plasma transfusion has not shown significant agglutination. Given the fact that the majority of the populations are secretors, this would provide protection from the iso-antibodies. In this fashion, the dissolved B antigens in the type B plasma absorbs/binds to the type B iso-antibodies in the type A plasma. This appears to be the mechanism that gives a protective effect against adverse outcomes in massive transfusion situations in the trauma setting when type A plasma is used instead of type AB. This protective effect is revealed with the paucity of intravascular hemolysis observed in these out of type massive transfusions.

SP377

Polytrauma and Hemorrhage in Rat Leads to MOF, Coagulopathy, Inflammation, and Metabolic Disorders

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Background/Case Studies: Battlefield injuries involve trauma to multiple organs and include hemorrhage. Polytrauma leads to a number of pathologies including multiple organ failure, coagulopathy, exaggerated inflammatory responses, as well as cardiovascular and metabolic dysfunction. Developing pre-clinical models is necessary so that resuscitation strategies can be developed to mitigate the life-threatening pathologies associated with polytrauma. To that end, we have developed a rat model of polytrauma and hemorrhage, and characterized the short term changes in lung and kidney function, coagulation, plasma cytokines as well as cardiovascular and metabolic parameters. **Study Design/Methods**: αSprague-Dawley rats (300-400g) were anesthetized with Isoflurane. Polytrauma was induced by damage to the small intestines, left and medial liver lobes, right leg skeletal muscle, and by fracturing the right femur. The rats were then bled 40% of the blood volume. In some groups, resuscitation was performed at one hour with fresh whole blood (FWB), Lactated Ringers (LR) or no resuscitation as a control. Experiment was terminated at 4hrs. **Results/Findings**: Polytrauma and hemorrhage led to a significant rise in blood urine nitrogen and creatinine over the 4hrs which is consistent with acute renal injury. There was an elevation in monocytes, macrophages, neutrophils, platelets, inflammatory cytokines and myeloperoxidase in the lung tissue, suggesting acute lung injury. There was a significant rise in prothrombin time (PT) and activated partial thromboplastin time (aPPT), and a fall in clot strength suggesting an acute coagulopathy. Both pro-inflammatory cytokines (IL-1α, IL-1β, IL-6,TNFα) and anti-inflammatory cytokines (IL-4, IL-10, IL-13, IFNγ) were significantly elevated, suggesting a systemic inflammatory response syndrome (SIRS) and a compensatory anti-inflammatory response syndrome (CARS). Plasma lactate was elevated, and HCO_3 and base excess was depressed over the 4hrs suggesting a metabolic acidosis. Limited resuscitation with FWB (half of shed blood), but not LR led to a recovery of mean arterial pressure, lactate and HCO_3, but led to little improvement of PT and aPTT. No resuscitation fluid corrected the acute renal injury, and both FWB and LR resuscitation led to transudation of fluid into the lungs (elevation of wet/dry weight ratios). **Conclusion**: We have successfully developed a pre-clinical model of polytrauma and hemorrhage that demonstrates many of the characteristics of battlefield pathologies that includes acute renal and lung injury, coagulopathy, SIRS, CARS as well as cardiovascular and a metabolic dysfunction. Resuscitation with fresh whole blood mitigated some of the pathologies, but not all. Using this model, we can improve resuscitation strategies that can mitigate these pathologies. This project was funded by MRMC

Transfusion Practice: Miscellaneous Case Reports

SP378

Detection of Peanut Allergen in Donor Component after Anaphylactic Transfusion Reaction

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Background/Case Studies: Case reports have documented circumstantial evidence of donor food allergens, specifically peanuts, causing anaphylaxis in patients, but the presence of an allergen in transfused products has not been demonstrated. **Study Design/Methods**: To verify the presence of the peanut allergen, we used the AgraStrip Peanut Kit (Romer Labs, Cheshire, UK), saline negative control, and positive peanut control (Romer Labs, Tulin, Austria). Aliquots from the transfused units of red blood cells (RBC) and platelets were assessed for the presence of peanut. We also explored the dose of peanuts needed for detection in plasma: two healthy volunteer adults ingested 23 or 46 grams of peanut butter each; serial serum peanut allergen detection was performed 4, 12, and 24 hours after ingestion. **Results/Findings**: A previously healthy 4-year-old male was diagnosed with acute lymphocytic leukemia. He had a history of a severe peanut allergy. He was sequentially transfused RBCs and then platelets. After 23 mL of the platelet transfusion, he developed periorbital swelling and hives that evolved into full body hives, periorbital edema, slight peri-oral edema, minimal wheezing, and hypoxia (oxygen saturation by pulse oximetry went from 99% to 87% on room air). The remaining vital signs were unchanged. After intravenous epinephrine, diphenhydramine, normal saline bolus, and 5 Liters of oxygen via nasal cannula, his symptoms resolved. Post-transfusion IgA was 51 mg/dL (normal 18-139 mg/dL), peanut IgE was $>$100 kUA (normal $<$0.35 kUA) and direct antiglobulin test was negative. The blood product donors were contacted for pre-donation peanut intake. The RBC donor did not recall ingesting peanuts; the platelet donor recalled eating peanut butter. We did not detect peanut in the RBC unit; however, plasma from the donor at time of donation was positive for peanut. In 2 healthy volunteers, after ingesting 23 grams of peanut butter there was no peanut identified in the serum; peanut was identified 4, 12 and 24 hours after ingesting 46 grams of peanut butter. The recipient has since been transfused 1 RBCs and 5 platelets, all saline-washed, with no allergic or other adverse reaction. **Conclusion**: We demonstrated peanuts in the plasma of a platelet donor that likely caused an anaphylactic reaction in the recipient; the first time the suspected allergen has been identified in a case of transfusion-associated anaphylaxis from donor diet. We also showed that the length of time peanut can be found in plasma after ingestion may vary with dose. Transfusion support of peanut-induced anaphylaxis from transfusions can include washed cellular blood products and directed plasma component donations from individuals abstaining from peanuts for at least 24 hours, such as those with peanut allergy.

TABLE. Variation of hemolysis percentage before and after utilization of pump and comparison between pumps

Flow rate	Shuttle (S)		Piston (P)		Peristaltic (Pe)		S vs Pi	S vs Pe	Pe vs Pi
ml/h	%	p	%	p	%	p	p	p	p
30	0.016		0.026		0.241		0.2697	0.0023	0.0007
60	0.000		0.022		0.162		0.2332	0.0003	0.0003
150	0.003		0.022		0.099		0.5078	0.0003	0.0009
300	0.013		0.011		0.055		0.8946	0.0071	0.0054
450	0.022		0.021		0.069		0.6272	0.0054	0.0092
Total	0.011	<.0001	0.021	<.0001	0.116	<.0001	0.0779	<.0001	<.0001

SP379

Quantitative Assessment of Hemolysis Secondary to Modern Infusion Pumps

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Background/Case Studies: Although most studies showed that the hemolysis induced by infusion pumps was small, there were some notable exceptions [1, 2]. Only limited data [3, 4] is available on actual infusion pumps widely used in our regional hospitals, namely a peristaltic-type, piston-type and shuttle-type pumps. **Study Design/Methods**: Hemolysis and potassium levels were compared before and after use of the three different infusion pumps. Using 90 units of packed red blood cells (RBCs), aged from 10 to 28 days, 27 measurements were taken for each pump at each different flow rate (30, 60, 150, 300 and 450 ml/h), and compared to measurements taken before using the pumps. The range of flow rates was chosen to cover pediatric and adult transfusions. **Results/Findings**: It is shown that the hemolysis of shuttle-type and piston-type pumps is small. Contrary to a previous study [4], the peristaltic-type pump produces significantly more hemolysis and was worse at low flow rates (Table 1), but the absolute value of hemolysis is still within the range recommended by the regulatory agencies in North America and Europe (less than 0.8-1%). Approximately two-thirds of the hemolysis produced by the peristaltic-type pump was secondary to the use of an anti-siphon valve recommended by the manufacturer. Potassium levels did not increase with the use of the pump. **Conclusion**: Modern infusion pumps widely used in our regional hospitals and elsewhere produce only a non-threatening amount of hemolysis during transfusion of packed RBCs. Anti-siphon valves appear to induce additional hemolysis and we recommend not using them for blood transfusion.

References:

[1] Gibson JS, Leff RD, Roberts, RJ. Effects of intravenous delivery systems on infused red blood cells. American journal of hospital pharmacy. 1984, 41(3), 468-72.

[2]. Hughes J et al. Infusion pump-mediated mechanical hemolysis in pediatric patients. Ann Clin Lab Sci. 2015; 45(2): 140-7.

[3]. Frey B, Eber S, Weiss M. Changes in red blood cell integrity related to infusion pumps: a comparison of three different pump mechanisms. Pediatric critical care medicine. 2003; 4: 465-470

[4]. Lieshout-Krikke RW et al. Effect on the quality of blood components after simulated blood transfusions using volumetric infusion pumps. Transfusion. 2011; 51(8):1835-9.

SP380

The Strengths and Weaknesses of Bedside Electronic Systems for Recording Transfusion-related Patient Observations

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Background/Case Studies: Blood product administration is associated with many risks including acute transfusion reactions. To enable detection of adverse reactions so that necessary treatment can be given, the patient should have their observations (i.e. blood pressure, temperature, pulse and respiratory rate) monitored closely before, during and after the transfusion of blood products. An electronic bedside transfusion process (BloodTrack, Haemonetics) has been used at this institution for over 10 years and enables patient observations to be recorded during the transfusion process. The trust has developed and installed an electronic bedside observations recording process, System for Electronic Nursing Documentation (SEND), with integrated track and trigger calculation and alerts. SEND has been shown to make recording observations more efficient and has demonstrated successful user uptake. **Study Design/Methods**: This study examined 200 transfusion encounters over a 3 month period on the haematology ward and in a variety of in-patient and out-patient specialties at the same hospital site. The two electronic systems were evaluated for how the user recorded patient observations when commencing transfusion, performing mid transfusion checks, end of transfusion and post transfusion. **Results/Findings**: Observations were recorded in SEND prior to commencing transfusion in 74% of episodes on the haematology ward and 46% in non-haematology areas. On the haematology ward 49% of these were duplicated in BloodTrack and 28% in non-haematology specialities. Mid transfusion observations were recorded on BloodTrack in 73% of haematology ward episodes and 60% of transfusions occurring in non-haematology specialities, 58% (haematology ward) and 42% (non-haematology ward) were recorded in duplicate. It was found that end transfusion observations were missed in 2-6% of patients using BloodTrack, 54% of recorded observations on the haematology ward were also recorded on SEND. It was observed that 75% of patients who had transfusion reactions recorded had multiple mid transfusion observations taken. SEND was used as the prime system to record observations rather than BloodTrack in 85% of observations. **Conclusion**: It was demonstrated that clinical staff had a preference to use SEND to record observations, even during transfusions where the data were subsequently entered into BloodTrack. This has highlighted that there is a need for all observations to be available in one easy to use electronic platform to enable clinical users to comprehensively review patient observations in context. Clinical users value the track and trigger score and utilise this to ensure the patient is receiving the care they need and this would add value when trying to identify whether the patient has deteriorated during blood transfusion.

SP381

Transfusion Requirements and Risk Factors of 30-day Mortality in Adult Hemophagocytic Lymphohistiocytosis

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Background/Case Studies: Hemophagocytic lymphohistiocytosis (HLH) is a rare clinical syndrome characterized by the activation of the mononuclear phagocytic system resulting in an uncontrolled hyper-inflammatory response. The clinical course of HLH is often severe resulting in end organ damage. We wanted to assess the transfusion requirements and predictors of mortality at 30 days for HLH patients. **Study Design/Methods**: We identified all adult ($\geq$18 years) patients with a diagnosis of HLH (HLH-2004 diagnostic criteria was followed) at at a large academic hospital from October 2003 through June 2014. We extracted clinical and laboratory data including transfusion requirements from the medical records. In the univariate analysis, Pearson's Chi-square/Fisher's exact test and Student's t-test were used to determine the significance for the independent clinical and laboratory variables. A multivariate analysis was performed using logistic regression. A backward step-wise (Wald) selection procedure, with significance level for removal from the model set at 0.1, was conducted. Results were considered significant at $P<0.05$ based on two-sided tests. **Results/Findings**: Seventy-three patients were identified. Their median age at diagnosis was 50 years (range, 18-82); 41 (56%) were male. Patients manifested fever (96%), cytopenias (85%), splenomegaly (60%), hypertriglyceridemia (67%), low fibrinogen (33%), elevated ferritin (100%), and hemophagocytosis (71%). Median duration of hospital stay was 18 days (range, 2-89). At 30 days from admission, 53 (73%) patients were alive. Death was attributed to sepsis in 13 patients (pts), lymphoma in 3 pts, bleeding in 2 pts, GVHD in 1 pt, and unknown in 1 pt. Transfusion requirements were as follows: RBC, 85% of patients, median 6 units (range, 1-55); platelets, 70% of patients, median 5

TABLE. Significant predictors of 30-day mortality obtained by univariate and multivariate analyses

Parameters associated with poor outcome	OR (95% CI)	P value
Univariate analysis		
Hyponatremia (sodium < 135 mmol/L)	4.69 (1.226-17.933)	0.028
Peak ferritin (ferritin > 50,000 μg/L)	0.393 (0.129-1.197)	0.095
Platelet transfusion	5.906 (1.24-28.138)	0.022
Plasma transfusion	4.295 (1.444-12.774)	0.007
Multivariate analysis		
Hyponatremia	5.121 (1.258-20.85)	0.023
Plasma transfusion	4.638 (1.469-14.642)	0.009

(1-65); plasma, 44% of patients, median 6 (1-56). Table 1 shows the significant predictors of 30-day mortality according to the univariate and multivariate analyses. Hyponatremia (OR = 5.121; 95% CI: 1.258-20.85; p = 0.023) and plasma transfusion (OR = 4.638; 95% CI: 1.469-14.642; p = 0.009) correlated with poor outcome. **Conclusion**: The transfusion requirements for adult HLH patients are high. In addition to hyponatremia, plasma transfusion is a significant predictor of 30-day mortality. However, there might be other confounders that we did not account for.

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Transfusion at the Last Period of Life

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Background/Case Studies: Transfusion of blood components is a mainstay in the treatment of many patients. When the medical team determines a care terminal patient, usually they cease clinical and active treatment. However, cares shall continue, with emphasis on improving their quality of life and maintaining their welfare until his death. Our objective was to determine the use of blood components (BC) in the patient's days before the death in a hematology service and evaluate its use related to patient age, sex, pathology or type of BC transfused. **Study Design/Methods**: We analyzed 355 deaths occurring from June 2011 to January 2016 in our hematology unit by determining the number and type of transfused BC at the previous days (−1, −2, −3) and at the exitus (0), interrelating with variables explained in the objectives looking for significant relationships. Transfusion criteria always were adjusted to the existing clinical guideline in our hospital. A descriptive study of the main demographic and clinical variables in the whole series was performed (mean, standard deviation, median and range for continuous variables) and frequencies and percentages for categorical variables. The Pearson chi-square or Fisher exact test was used to compare groups. **Results/Findings**: In all cases death was due to disease's natural progression. We excluded 39 patients due lack of data, of the remaining 316, we analyzed 180 men and 136 women, with an overall median age of 65 years [15-88]. Red blood cells (RBC) and platelets (PLT) (44%) were transfused in this pre-exitus period. Death was due to acute myeloid (n=99) or lymphoblastic (n=24) leukemia (AL), non-Hodgkin's (n=70) or Hodgkin (n=10) lymphoma, multiple myeloma (n=51), myelodisplasic syndrome (n=19), chronic lymphoblastic leukemia (n=15), severe aplastic anemia (n=6) and others (n=22). BC transfused in their overall treatment were 15 RBC [0-316] and 8 PLT [0-231]. Significant differences were observed in patients ≤65 years old transfused at −2 (RBC p=0.041; PLT p<0.001) and −3 (RBC p=0.004; PLT p<0.001) and with PLT at −1 (p<0.001). Regarding pathology, AL is the most commonly transfused, detecting significant differences between AL and RBC transfusion on day −2 (p=0.006) and PLT at days −1 (p<0.001) and −2 (p<0.001); lymphomas and myelomas, were the least transfused. No significant differences between sex and transfusion were detected. **Conclusion**: Transfusion in the days before death is not unusual and takes place in a context where in many cases support palliative measures have been initiated. Transfusion attitude in patients <65 years old is more active and common in this period of time regarding older patients. It would be necessary to reconsider whether transfusion of BC should be or not, a part of death terminal and comfort care control symptoms of patients.

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Compassionate, Investigational Use of SANGUINATE™ (PEGylated Carboxyhemoglobin Bovine) in a Jehovah's Witness Patient with Hematemesis

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Background/Case Studies: Jehovah's Witnesses (JWs) pose a clinical challenge in the setting of critical anemia. Most JWs do not accept whole blood or its main components, but many do accept hemoglobin-based oxygen carriers (HBOCs). SANGUINATE™ (PEGylated carboxyhemoglobin bovine), the only HBOC still in development, is a dual action carbon monoxide (CO) releasing/oxygen transfer agent. It was well-tolerated by 18 healthy volunteers in a phase I clinical trial, and was shown in pre-clinical trials to protect the myocardium against ischemia/reperfusion injury in diabetic and normal mice. We report the investigational use of SANGUINATE™ in a JW patient. **Study Design/Methods**: The patient was a 42 year-old female JW with systemic lupus erythematosus, and a gastroduodenal EBV+ lymphoproliferative disorder treated with rituximab, dexamethasone and cyclophosphamide over the past year. The patient, hospitalized for liver abscesses, experienced acute hematemesis with hemoglobin decreasing from 7.3 to 3.1 g/dL overnight, and was transferred to the medical intensive care unit for hemorrhagic shock. Despite fluid resuscitation, the patient required vasopressor support and was intubated for shock and encephalopathy. The gastroenterology and interventional radiology (IR) services deferred further interventions because the patient was too unstable for procedures in the absence of transfusion. Transfusion medicine obtained SANGUINATE™ (PEGylated carboxyhemoglobin bovine, Prolong Pharmaceuticals, South Plainfield, NJ), for compassionate use. Following emergency use investigational new drug approval from the FDA, emergency institutional review board approval, and patient consent, she received 6 doses (each as 500 mL bags of 40 mg/mL SANGUINATE™) over 7 days. Supportive therapy included iron, folate, vitamin B12, and daily darbepoetin alfa injections. **Results/Findings**: Following the first infusion, her shock and encephalopathy improved with decreased vasopressor requirement. Blood gas analysis demonstrated a decrease in metabolic acidosis (pH= 7.30 to 7.35) and decreased lactate (5.21 to 2.10 mmol/L). Gastroenterology performed an upper endoscopy and discovered an actively bleeding vessel in the gastric antrum. IR subsequently performed a successful coil embolization of a bleeding pseudoaneurysm of the gastroduodenal artery. The patient experienced no reactions or adverse events related to SANGUINATE™. The patient's native hemoglobin gradually trended up to baseline 2 weeks after the first infusion. On day 35 follow-up, the patient was hospitalized in a step-down unit with no further bleeding events. **Conclusion**: SANGUINATE™ stabilized (bridged) a critically-ill, anemic patient for life-saving interventions without adverse effects. Additional studies are warranted to explore the drug's safety profile and efficacy.

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Audit of Provincial IVIG Request Forms and Efficacy Documentation in Four Tertiary Care Centres in Canada

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Background/Case Studies: Despite the introduction of a mandatory IVIG Request Form in Ontario and other provinces to reduce inappropriate use, Canada is the highest per capita user of IVIG worldwide. We performed a retrospective audit of new IVIG Request Forms supplemented by chart review to determine the case mix, authenticate the information provided on request forms, and assess documentation of efficacy. **Study Design/Methods**: Three tertiary care centre sites with passive surveillance programs and one site with an active surveillance program in Ontario participated. Consecutive adult patients with a first-time IVIG request between January-December 2014 were included. The specialty of the ordering physician, the completeness of the form, documentation of diagnostic criteria for the medical condition and indication for IVIG use, and documentation of efficacy were assessed by manual form and chart review. **Results/Findings**: 178

patients were assessed. The most common indications for IVIG use were immune thrombocytopenia (24.2%) and secondary immune deficiency (20.2%); and the most frequent prescribers were hematologists (37.6%) and neurologists (10.7%). Other conditions not listed on the form represented 43 cases (24.2%), with the majority of these not indicated according to current guidelines. ITP patients had the highest amount of IVIG administered in grams, followed by other indications not listed on the IVIG Request Form as a group, then Guillain-Barre Syndrome. Most patients who received IVIG for a medical condition not known to respond to IVIG or having no indication for IVIG were at passive surveillance sites. Only 52.1% of obese patients had IVIG specifically dosed to ideal body weight and 27.0% of cases had dose verification. 32.6% of cases lacked verification of diagnostic criteria and 51.7% did not meet criteria for IVIG use, with documentation of diagnostic criteria and appropriate indications for IVIG higher in the active surveillance site. 19.1% of all patients had a discrepancy between the indication written on the form and the diagnosis in the clinical record. Documentation of efficacy was lacking with 18.7% of clinic notes after IVIG administration having no mention of efficacy, and only 26.0% denoting any subjective improvement. **Conclusion**: Our audit demonstrates a lack of compliance with IVIG Request Form requirements, inappropriate use of IVIG, and lack of documentation of diagnostic criteria and efficacy. The usage of an IVIG Request Form does not appear to be an effective tool to improve appropriate IVIG use as the information provided was often inaccurate. These findings suggest implementation of the forms and monitoring of IVIG usage needs reassessment.

Transfusion Practice: Patient Testing, RBC Alloimmunization, Case Reports, and Obstetrics

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Use of Donor Blood Group as the Historical Check Sample for Transfusion in Recipients Who Were Previously Blood Donors – 21 Years of Experience

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Background/Case Studies: For hospital based blood banks and transfusion services with access to donor blood group data, the possibility exists to use the donor's ABO and RhD blood group that was determined, when they donated blood, as an historical check sample on which to validate a current pre-transfusion sample, should the donor become a recipient. This report is a description of the use of donor blood groups as historical check samples in a regional transfusion service and hospital. **Study Design/Methods**: Data for this study was collected from a regional transfusion service/blood donor center's database. The database contains data on donors, recipients, transfusions and pretransfusion test results for an area covering 460,000 inhabitants over a period of approximately 21 years (1995-2016). Since implementation of the database in 1995, the donor blood groups have been utilized as historical checks on the current pre-transfusion blood group when donors become blood product recipients. A current sample is still required before cross-matched products can be issued and a second current sample is required for those without a historical blood group. Data on donor blood groups was matched with data on electronic and serologic cross-matches, and the number of times that a donor blood group was used to validate a recipient's current blood group was calculated. Recipients whose hospital determined blood group predated the donor blood group were excluded. **Results/Findings**: A total of 123,575 donor blood groups on 76,455 donors were identified in the database. In comparison, 564,770 recipient blood groups on 418,044 individual recipients were identified over the same period. The total number of recipients in whom at least 1 electronic or serologic cross-match was performed was 263,138 (97% electronic cross-match). In 7,525/263,138 (2.9%) of these recipients, the donor blood group provided the historical check on the current pre-transfusion sample's blood group at least once. In 16/7,525 (0.23%) of these cases, representing 16 individual recipients, the result of the current pre-transfusion blood group was discrepant with the historical donor blood group. In at least 6/16 (38%) of these cases, this discrepancy was caused by clerical errors in connection with blood sampling (a wrong blood in tube, WBIT, error). In the other 10/16 (62%) recipients the discrepancy with the donor group was attributed to the presence of D variants, weak A groups or mixed field reactions that required further serological evaluation to resolve. **Conclusion**: Using the blood group obtained during a blood donation proved to be an important recipient safety measure. The use of donor-derived blood groups detected a significant number of WBIT errors potentially preventing life threatening ABO mismatched transfusions.

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Transfusion Management of Patients with Discrepant Rh Testing

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Background/Case Studies: Classifying the D typing on patients is a crucial step in the transfusion service. Our facility performs RhD testing using two anti-D clones on an automated solid phase platform. Our solid phase platform does not interpret anti-D reactions graded less than 3+; these samples are resulted as '?' and the overall RhD type is reported as No Type Determined (NTD). At our facility, patients with NTD are classified as RhD negative, Rh Typing Problem (RHP) and RhD-negative RBCs are used for transfusion. Facility policy also prohibits manual retesting of RHP blood samples. The goal of this study is to find any validity in the SOP at our facility regarding the classification of RHP patients for patient blood management. And to discover any serologic correlation within the patient population at this facility to correctly identify the RhD status of RHP patients. **Study Design/Methods**: A total of 165 RHP samples (from 95 patients) from patients with discrepant RhD results from solid phase testing between June 1, 2015 and February 29, 2016 were investigated. Manual testing were performed on each sample, as well as a computer investigation using history from our solid phase instrument, and the facility's laboratory information system. Serologic testing were performed using four different anti-D reagents: two anti-D reagents used at our facility, and two new anti-D reagents from different manufacturers. Serologic testing also included: weak D testing, examination for mixed-field agglutination, and a complete Rh-phenotype. History check included ABO/Rh, age and gender, pregnancy, recent blood transfusion, and organ transplantation. **Results/Findings**: Of the 165 RHP samples evaluated, 59 (from 39 patients, of which 33 were current OB patients) were from females under 50 years of age. There were no organ transplant recipients. Of the seven patients who received recent RBC transfusion, three showed mixed-field agglutination. No patient samples demonstrated weak D using the tube IAT method. Rh phenotyping were performed; the most common phenotypes were C- c+ E- e+ (108 samples, 61 patients), and C+ c+ E- e+ (42 samples, 26 patients). Tube testing of specimens with various anti-D reagents were performed. Of the total specimens processed; 96 (66 patients) showed manual reactions $\geq$2+ with our facility's anti-D clone, which could be classified as D-positive. Manually, the two anti-D clones used at our facility showed an increased number of strong reactions ($\geq$2+); while the two new anti-D clones showed a larger number of weak reactions ($\leq$2+). Of the total RHP patients in this study (95), 21 patients received a total of 103 RhD-negative RBC units (4 OB patients received 13 RhD negative RBC units). **Conclusion**: The results of this study support our facility policy of the RhD classification of RHP patients and the administration of RhD-negative blood products.

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A Retrospective Review of Antibody Stimulation in Previously Sensitized Patients

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Background/Case Studies: Complete or partial antigen matching is often the recommended course of action in patients requiring chronic transfusion support. This practice can be time consuming and cost prohibitive depending on the patient's phenotype and diagnosis while the impact on the patient is often speculative. Current department practice was to only provide units that were antigen negative for identified antibodies and discuss antigen matching on a case by case basis. As part of updating the policy regarding antigen matching at a hospital based transfusion service, a review of previously treated patients was undertaken to determine immunization rates in patients with already identified antibodies. **Study Design/Methods**: Using the laboratory computer system to generate applicable data, a retrospective review of 2011 to 2015 was performed on patients with previously identified antibodies. Patients were identified who had a type and screen, an identified antibody, received a red cell transfusion, and had at least one antibody screen performed at a later date. These patients were noted and further analyzed manually. **Results/Findings**: Upon completing the review, 101 antibody screen positive patients were identified having some form of serologic follow up after receiving a red cell transfusion. Of these patients, 76 had no new antibodies upon follow up while 25 patients had further antibody

TABLE. New Antibody Specificity in Previously Sensitized Patients

anti-E	anti-Bg	Warm autoantibody	anti-C	anti-Jka	anti-Lua	anti-Fya	anti-K	anti-Wra	anti-Cw	anti-Jkb	anti-c	anti-HTLA	anti-S	anti-Kpa
8	6	4	3	3	2	2	2	2	1	1	1	1	1	1

stimulation. The most commonly encountered new antibodies seen in the 25 patients were anti-E and anti-Bg (Table 1). **Conclusion**: The department continues to only offer complete or partial antigen matching on a case by case basis with medical director review. Due to anti-E being the most commonly identified antibody in already sensitized patients, the transfusion service began requiring C, c, E, and K antigen typing on all antibody patients when first seen to possibly anticipate the generation of an antibody in these systems. While anti-E is known to be immunogenic, the high incidence of Bg antibodies prompted further investigation. It was noted that anti-Bg was detected after changing lots and has prompted discussions with the department's reagent supplier regarding their reagent red cell testing and selection policies.

Disclosure of Commercial Conflict of Interest

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Successful Transfusion of -D- Patient with a 25-year-old Autologous RBC Unit

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Background/Case Studies: The -D-/-D- phenotype, first described in 1950 by Race and Sanger, is a variant Rh phenotype where the D antigen is strongly expressed without C, c, E, or e antigens. The -D-/-D- phenotype is extremely rare. Individuals with -D-/-D- are prone to sensitization to high frequency Rh antigens such as Rh17 (Hr0 or anti-RhCcEe polypeptide) when exposed to any of the RHCE. **Study Design/Methods**: An 81 year-old type O, Rh(D)+ female in excellent performance status, Eastern Cooperative Oncology Group (ECOG) 0, was seen for surgical management of low-grade mucinous appendiceal neoplasm with pseudomyxoma peritonei. The antibody screen was reactive with all cells. Extended red blood cell (RBC) phenotyping revealed -D- phenotype. The American Red Cross (ARC) Immunohematology Reference Lab (IRL) demonstrated Rh17 antibody. Coincidentally, this patient was a former donor and well known to the ARC. The Surgery team requested four RBC units. The ARC had three autologous (AT) units (collected and frozen in 1991 and 1992 at the request of the ARC IRL) and one -D- allogeneic unit, the only one available in the US. The surgical team planned to proceed by using the AT units first, followed by the allogeneic unit, if needed. The oldest AT unit was deglycerolized and shipped the morning of surgery. **Results/Findings**: The patient successfully underwent cytoreductive surgery, including distal pancreatectomy, and splenectomy, with an estimated blood loss of 400 mL. Post-operatively, her hemoglobin (Hb) decreased from 11.2 to 6.0 g/dL. She was transfused with the oldest AT deglycerolized RBC unit with an appropriate response and no apparent adverse effects. The patient was discharged to home in good condition on post-operative day (POD) 10. Selected laboratory data are shown in Table 1. **Conclusion**: There are few reports of RBC units being successfully transfused after more than 10 years and up to 21 years of storage. This case highlights three key points: 1. An RBC unit frozen for 25 years was safely thawed, deglycerolized, and transfused. 2. Consideration should be given to keeping rare RBC units in frozen storage for an extended period of time. 3. Early and consistent communication across multiple services— the Surgical Team, Hospital Transfusion Medicine Service, and Regional Blood Center—allows for the delivery of rare, critical blood products.

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Successful Management of Severe Red Cell Alloimmunization in Pregnancy with a Combination of TPE, IVIG, and IUT

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Background/Case Studies: Antibodies to Rh/Kell antigens have been associated with severe hemolytic disease of the fetus and newborn (HDFN) necessitating intrauterine red cell transfusion. We report 5 cases of severe maternal red cell alloimmunization and HDFN successfully managed using combined immunomodulation with therapeutic plasma exchange (TPE) and intravenous immune globulin (IVIG) in early gestation, and multiple red cell intrauterine transfusions (IUT) in late gestation. **Study Design/Methods**: This is a retrospective case series of 5 women aged 28 to 34 years with histories of red cell alloimmunization who presented at 10 to 13 weeks of pregnancy. All the women had pregnancy histories of intra-uterine fetal demise or the need for early IUT, with or without fetal hydrops, due to red cell alloimmunization. The antibodies detected at presentation include anti-RhD, anti-K, anti-RhC, anti-Jk(a), and non-specific immunoglobulin G (IgG). The antibody titers were measured pre- and post-TPE. All 5 women were treated with 3 TPE procedures every other day in weeks 10-13 of pregnancy, followed by weekly IVIG infusions until 21-27 weeks of pregnancy. Following TPE, each woman was followed with serial peak middle cerebral artery (MCA) velocities using Doppler ultrasound beginning at 16 weeks gestation to detect the occurrence of fetal anemia. At the time of the indicated IUT, fetuses were administered red blood cell (RBC) units that fully matched the maternal phenotype. The delivery outcomes and newborn information were followed. **Results/Findings**: The pre-TPE antibody titers in these 5 cases ranged from 128-4096 for anti-RhD, 512-1024 for anti-K, $<$1-8 for anti-RhC, and $<$1 for anti Jk(a). A 2 to 4 fold dilution reduction in anti-D and anti-K titers and a 0 to 2 fold dilution reduction in anti-C titers were observed following TPE. The first IUT was performed between 21-27 weeks of pregnancy and the total number of IUTs for each patient ranged from 4-7. One patient developed a non-specific IgG post IUT. No new alloantibodies were identified in the other four patients at the time of delivery. All four women successfully delivered healthy infants at gestational ages ranging from 33 to 38 weeks. One of the infants required a simple red cell transfusion in his second day of life and another was treated with phototherapy for hyperbilirubinemia. Besides observation in the neonatal intensive care unit, no other complications related to maternal red cell alloimmunization were reported in the other three infants. **Conclusion**: A combined immunomodulatory regimen of TPE and IVIG in early pregnancy results in successful management of severe maternal red cell alloimmunization and HDFN. IUT with fully phenotypically-matched RBCs may help prevent further red cell alloimmunization in complex cases of HDFN.

TABLE. Pre- and post-operative laboratory data

Parameter	Pre-Operation	POD-0	POD-0, Post Transfusion	POD-1	POD-2	Discharge (POD-10)
Hemoglobin (g/dL)	11.2	6.0	8.1	7.3	7.5	7.8
Total bilirubin (mg/dL)	0.39	0.50	0.85	0.36	0.33	

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Fetomaternal Hemorrhage (FMH) and Rh Immunoglobulin (RhIG) Dosage: A Novel Consideration from a Mathematical Modeling Perspective

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Background/Case Studies: There is wide variation in RhIG dosing, as evidenced by a recent survey from the College of American Pathologists (CAP). We hypothesize this variation is due to the use of different formulas to calculate FMH based on recommendations from different manufacturers and professional societies, as well as variation in testing methodologies (flow cytometry vs. Kleihauer-Betke [KB]). Thus, we proposed a new formula to accurately estimate FMH, leading to more accurate RhIG dosing. **Study Design/Methods**: A new formula estimating FMH was developed utilizing both fetal and maternal complete blood count (CBC) parameters, and the ratio of fetal cells observed in maternal specimen based on either KB or flow cytometry results. For validation, a computer simulation of 100 women having different FMHs randomly selected between 0 to 5% (FMH_{true}) was performed using Microsoft Excel (Microsoft, Seattle, WA). Maternal blood volume (V_M) was calculated from Nadler's formula based on randomly selected weights and heights using data from the Center for Disease Control and Prevention for women between 20 & 29 years old. KB or flow cytometric results and CBC parameters were simulated using FMH_{true} for each simulation using the 95% confidence interval derived from the coefficient of variation obtained from the CAP survey for each method and CBC reference ranges for third trimester women and newborns. Estimated FMH and RhIG dose from each method was calculated using the new formula (FMH_{new}) and the formula recommended by CAP ($FMH_{current}$) and then compared with the FMH_{true} and RhIG derived from FMH_{true} for each woman by paired t-test. **Results/Findings**: FMH (whole blood in mL) can be estimated as follows: $V_{FMH}=(1/Hct_F)[F/(F+M)](RBC_M)(V_M)(MCV_F)$ where Hct_F=fetal hematocrit in fraction, F=number of fetal cell counted, M=number of maternal cells counted, RBC_M=number of red blood cells from maternal CBC (in million cells/mL), MCF_F= fetal mean corpuscular volume (in fL). Using simulated data, for both KB stain and flow cytometry method, there were significant differences in FMH estimations between $FMH_{current}$ and FMH_{true} ($p<0.0001$), leading to significant differences in RhIG doses ($p<0.0001$). However, using the new formula, for both KB and flow cytometry methods, there is no statistically difference between FMH_{new} compared to FMH_{true} ($p=0.38$ and 0.93 for KB and flow cytometry method, respectively), leading to no significant difference in RhIG doses ($p=0.51$ and 0.56, respectively). Ultimately, using the new formula prevents unnecessary RhIG exposure for the women and expense for the hospital. **Conclusion**: If provided an accurate estimation of the ratio of fetal cells in maternal sample via either KB staining or flow cytometry results, our new formula results is a better FMH estimate compared to the current formula.

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To Give or Not to Give? A Survey of Emergency Medicine Physicians' Practice for RhIG Administration during the 1st Trimester

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Background/Case Studies: Whether to give Rh immune globulin (RhIG) to D-negative women in the 1st trimester for a potential sensitizing event, such as threatened or spontaneous abortion, is controversial among obstetric, emergency medicine (EM), and transfusion medicine (TM) physicians. In a 2006 EM article the authors suggested that due to lack of scientific evidence it may be reasonable to forego RhIG administration in these 1st trimester events. However, American College of Obstetricians and Gynecologists and AABB state that RhIG prophylaxis should be considered. In addition, appropriate testing is crucial to identify if a pregnant woman is a candidate for RhIG prophylaxis and proper dosing. The aim of this study was to assess the current practice of EM physicians for RhIG ordering and related testing. **Study Design/Methods**: A 6-question survey of EM physicians was conducted via Survey Monkey™. Questions focused on provision of RhIG and related testing in D-negative women for typical 1st trimester (<12 weeks) presentations to the emergency room when the pregnant woman would be at risk for fetomaternal hemorrhage. Survey link was sent to TM physicians to forward it to their facility's EM physicians. **Results/Findings**: Responses were received from 29 EM physicians practicing in the Midwestern U.S. RhIG is routinely prescribed by 93% of the respondents for spontaneous abortion, 90% for threatened abortion, and 62% for ectopic pregnancy. The dosage routinely ordered if a D-negative woman presents with bleeding varied among the 29 respondents (24.1% order 50μg, 65.5% order 300μg, and 10.3% were unsure of the dose). When asked what testing they order in each of four potential sensitizing events - vaginal bleeding, abdominal trauma, ectopic pregnancy, and spontaneous or threatened abortion - almost every physician surveyed orders ABO/Rh type for all four events. Ordering of an antibody screen, though, was infrequent. Summary of the responses for 27 of the 29 respondents on the type of testing ordered is shown in Table 1. **Conclusion**: These preliminary findings indicate variablity in practice of the EM physicians surveyed for ordering RhIG and testing in 1st trimester senstizing events. Although RhIG is administered in the majority of cases of threatened and spontaneous abortion, administration rates are much lower for ectopic pregnancy. We believe that more work is warranted to clarify this disparity. If indeed a D-negative woman can become sensitized in the 1st trimester, an ounce of prevention will be worth a pound of cure.

Transfusion Practice: Platelet Refractoriness and Alloimmunization Management and Case Reports

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Practical Barriers in Managing Platelet Transfusion Therapy in Alloimmunized Patients

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Background/Case Studies: The management of patients who have become alloimmunized to platelet transfusion presents one of the more common, yet most troublesome situations in transfusion medicine. Several approaches have been recommended in managing platelet transfusion in these patients which include use of HLA-matched platelets, crossmatched platelets, and HLA-antigen avoidance. Three years ago our institution developed a platelet ordering algorithm very similar to those published previously. This abstract details some of the practical barriers that arise in the treatment of these patients. **Study Design/Methods**: This review included 59 patients in our bone marrow transplant program from January 2014 through March 2016 (27 months) who were deemed to be alloimmunized. These patients received 574 platelet products during this time period of which 207 (36%) were provided as HLA-matched by our blood supplier. Post-transfusion platelet counts were obtained within 1 hour of transfusion. An HLA antibody screening test or panel-reactive antibody (PRA) was generally done prior to the initiation of platelet transfusions and repeated as

TABLE.

What testing do you order on a pregnant woman in her 1st trimester (<12 weeks) with the following potential sensitizing event to determine the need for RhIG?	No Testing Done	ABO/Rh Type	Antibody Screen	Fetomaternal Hemorrhage Screen
1. Vaginal bleeding	0% (0/27)	100% (27/27)	11.1% (3/27)	0% (0/27)
2. Abdominal trauma	11.1% (3/27)	89% (24/27)	14.8% (4/27)	25.9% (7/27)
3. Ectopic pregnancy	3.7% (1/27)	96.3% (26/27)	14.8% (4/27)	3.7% (1/27)
4. Spontaneous or threatened abortion	0% (0/27)	100% (27/27)	14.8% (4/27)	0% (0/27)

necessary. **Results/Findings**: From a practical perspective even when the need for HLA-matched products is suggested by the PRA level, "A" matches were available in only 8.7% of cases and "B" matches were available in 46.7% with the remainder (44.6%) being "C" or even "D" grade matches. To determine the impact of match-grade on post-transfusion platelet increment, 24 patients with reported PRA levels of 99% were reviewed. Among these patients, the post-transfusion increments were 16 for an "A" match, 22.9 for a "B" match, and 19.6 for a "C" match. However, since there were relatively few (7) transfusions involving an "A" match, this result may be unreliable. Of 15 patients with PRA levels of 99% who received both "inventory" and HLA-matched platlets, 9 (60%) had post-transfusion increments at least 2 times greater with HLA-matched as compared to "inventory" platelets. The remaining 40% demonstrated little or no benefit of HLA-matched platelet products. **Conclusion**: From a practical perspective there are numerous obstacles in managing alloimmunized patients. First among these is the difficulty in obtaining HLA-matched platelets. In our experience only 8.7% of platelet products for our most highly immunized group were classified as "A" matches; this proportion rose to only 13.5% even when "BU" matches were included. Sixty percent of patients receiving HLA-matched platelets demonstrated an improved post-transfusion platelet increment as compared to non-matched products. Nevertheless, 40% of patient apparently failed to respond to HLA-matched platelet products. These observations serve to emphasize the ongoing difficulty in managing alloimmunized patients.

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Partnership between Transfusion Service and Blood Donor Center for Optimal Care of Platelet-Refractory Patients

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Background/Case Studies: Patients with immune-mediated platelet refractoriness are supported with cross-matched (XM) and/or HLA-matched platelets. In highly sensitized patients, finding best-matched units can be challenging. Optimal management requires close monitoring of *in vivo* response to each platelet transfusion through corrected count increments (CCIs). We work in close partnership with our blood center to identify and recruit optimal donors for each patient. **Study Design/Methods**: Each refractory patient is followed on an Excel file. A computer program extracts data on each platelet transfusion (random, XM or HLA-matched), and CCIs are calculated. The file is securely shared between the transfusion service (TS) and donor center coordinator (DCC) daily. The DCC updates the file to: 1. Add HLA type of random and XM units (if available), 2. List all donors whose units gave a good CCI (>7500) for future recruitment, 3. Review HLA type of these good donors to identify 'mismatched' antigens (Ags) to which the patient has a known antibody, and add them to the list of 'acceptable' Ags, 4. Enter upcoming donations (unit number, donation date, anticipated availability, and HLA type). **Results/Findings**: When a consultation for platelet refractoriness is received, a TS physician (MD) creates a tracking spreadsheet (for new patients) or retrieves the existing spreadsheet (for known patients). The use and sharing of patient spreadsheets facilitates rapid assessment of effectiveness of each platelet transfusion by both TS MDs and DCC. Collaboration with the blood provider allows easy access to HLA types of transfused random or XM units, information that may not otherwise be readily available to the TS. If good CCIs are obtained, mismatched HLA Ags may be classified as 'acceptable.' This process expands the donor pool and greatly assists in procurement of appropriate units for highly alloimmunized patients. Direct access to the CCIs by the DCC expedites identification and recruitment of donors whose units have historically resulted in good responses without the need for additional communication by the TS MDs. Clear information on upcoming donations allows TS MDs to easily monitor the inventory of specialized platelets for each patient so additional products can be obtained ahead of time as necessary. **Conclusion**: Close collaboration with our blood center has improved care for platelet refractory patients. Enhanced communication via sharing of patient spreadsheets enables exchange of information about platelet transfusion effectiveness and recruitment of historically compatible donors. Patient care is tailored in real time as new information is obtained from each transfusion. Additionally, access to HLA type of random and XM units helps expand the donor pool for highly refractory patients, a valuable outcome of this partnership.

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Success of Platelet Transfusions using HLA Antibody Testing

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Background/Case Studies: Our institution is a tertiary care facility supplying over 5000 single donor platelets (SDP) to inpatients and outpatients annually. The majority (>65%) of the SDPs are transfused to oncology patients and we commonly encounter patients refractory to platelet transfusion (Tx) due to HLA immunization. In order to care for these refractory patients, we developed a process that decreased cost and increased the likelihood of finding appropriate platelet products. **Study Design/Methods**: The TSO and the Tx physician monitor patients that are receiving SDPs on a daily basis. If a potential refractory patient is identified an in depth review of the patients Tx and clinical history is performed. The following measures were undertaken if our review revealed that the patient may be refractory due to HLA immunization:

- Patients were HLA typed and HLA antibody identification was performed. Platelet crossmatching was avoided as we had seen suboptimal response rates (often no increments) in our highly immunized patient population.
- Antigen typing of donors whose platelet products are currently in blood bank inventory were reviewed (if available).
- If the patient historically responded to a randomly chosen platelet product, the (referred) donor was requested to donate again.
- Regular platelet donors at our institution were HLA typed and were recruited for refractory patients if they lacked incompatible antigens (IA).
- If the above measures did not yield a suitable product, a HLA matched unit was requested from our blood supplier.

Results/Findings: Five patients with HLA antibodies were supported with 27 HLA selected SDP Tx over the last 3 quarters (Table 1). All of these patients had very high PRAs (>85%). We saw successful count increments (CI) in 91% and 81% of Tx that received SDPs with 0 or 1 IA respectively. We estimate we purchased less than half the SDPs than we would have using our previous procedures. Most (>80%) of our successful Tx were from donors that would have not been considered appropriate using traditional HLA matching. **Conclusion**: Our process allowed us to successfully care for our broadly immunized HLA refractory patients in a cost effective manner. Our strategy of using HLA antibody identification to guide SDP transfusions resulted in higher rates of successful CI than traditional HLA matching and crossmatching. Additionally, we were able to identify more donors for these patients than traditional HLA matching would have allowed. This approach further decreased cost as we only purchased HLA selected units with a very high likelihood of success.

TABLE. Platelet CI in HLA immunized patients

	Mean Pre Plt (K/uL)	Mean Post Plt (K/uL)	Mean CI (K/uL)
Transfusions (N=27)	7.15	36.37	29.22
# Incompatible Antigens			
0 (N=11)	5.64	36.82	31.18
1 (N=16)	8.19	36.10	27.85

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Efficacy by Individual Cross-matching of Platelet Concentrates in Hematological Patients with Platelet Transfusion Refractoriness

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Background/Case Studies: Multiple transfusions in hematological patients, particularly platelet concentrates (PC), may lead to allosensibilization and immunologic platelet transfusion refractoriness (PTR). The appearance of

TABLE. API and CCI in pts with and without PTR

	With matching n=98 (with refractoriness)			Without matching n=24 (without refractoriness)		
Parameter	M±m	Max	Min	M±m	Max	Min
APIx10^9/l	21,6 ± 2,4	117	−6	14 ± 2,9	53	0
CCIx10^9/l	17,0 ± 0,3	99	0	13 ± 0,8	61	0

API - Absolute platelet increment, CCI - corrected count increment, PTR - platelet transfusion refractoriness, M±m - mean value of platelet count, Max - maximal value of platelet count, Min - minimal value of platelet count

the anti-HLA and anti-HPA antibodies in patient's blood may cause non-hemolytic immune responses and lead to a complete lack of clinical effect of platelet transfusion. Due to the high polymorphism of HLA and HPA alloantigens of platelets it is advisable to make donor/recipient by cross-matching tests. **Study Design/Methods**: The aim of this study was to evaluate the efficacy by cross-matched PC transfusions in hematological patients with PTR. 19 hematological patients with PTR (more than 2 inefficient transfusions) were enrolled in the study between July 2015 and April 2016. The average age of the patients was 30 years (22-58). The ratio of men and women were: 7/12. The control group consisted of hematological patients (n=24) without PTR (without matching). The average age of the patients was 42 years (20-66). The ratio of men and women were:16/8. All the patients had multiple transfusions. Patients with PTR received cross-matched PC. The method cross-matching was carried out using analyzer Galileo-Neo (Imucor-Gamma). The efficacy of PC transfusion was evaluated by the absolute platelet increment (API) and the corrected count increment platelet (CCI) in patients with and wthiout refractoriness. **Results/Findings**: 122 PC transfusions were performed, including 98 with matching and 24 without matching. Differences between mean API, CCI values in pts with and without PTR were unreliable (see Table 1). 15 out of 17 patients demonstrated the efficacy of PC transfusions, followed by hemostasis correction and discontinuation of bleeding. Whereas 2 patients demonstrated inefficacy of transfusions despite by cross-matched PC transfusion. **Conclusion**: Implementation of individualized selection of a donor/recipient pair by cross-matching and anti-HLA/HPA detection enhances clinical efficacy and immunological safety of PC transfusion. It also increases the absolute and corrected platelets count after transfusion. If it's impossible to pick by cross-matched PC, one should bear in mind following refractotiness causes: autoimmune process of platelet, destruction by cytotoxic T-lymphocytes and non-immunological causes such as increased consumption of blood-clotting factors syndrome.

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Predicting Platelet Transfusion Efficacy Based on Platelet Activation for Better Platelet Management

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Background/Case Studies: Platelets are stored at room temperature, at which they tend to develop platelet storage lesions (PSL), and platelet activation is one of the important factors in development of PSL. It is also known to influence desialylation, phosphotidylserine externalization which lead to platelet clearance. Hence, in the current investigation, we attempted to predict transfusion efficacy based on the activation status of the transfused platelet concentrate (PC) units during storage. **Study Design/Methods**: The current investigation was separated into two models, an activation dependent model (ADM) and a PC storage age dependent model (PSDM). In the ADM investigation, platelet activation was analyzed in PCs prior to transfusions. These observations were used to predict platelet count increment (PCI) using an equation that was formulated based on the activation levels measured as median fluorescence intensity (MFI) ratio between the sample and the isotype control. In PSDM, an index was prepared based on the observed platelet activation with respect to PC storage age. Depending on the standardized index, the activation status in MFIs was speculated based on PC storage age and used for predicting transfusion efficacy similar to ADM. Predicted platelet percent recovery (PPR) were compared with measured PPR for validation. **Results/Findings**: In our investigation, we demonstrated existence of positive correlation between PC storage oldness and platelet activation with a correlation coefficient of 0.89. Furthermore, negative correlation was observed between the PPR and PC storage oldness. Similarly, negative correlation was observed between the PPR and platelet activation with a correlation coefficient of −0.71 indicating platelet activation as an important marker of quality during the storage. In ADM we observed that 27 out of 40 patients predicted PPR (67.5%) were within±10- of measured PPR. Additionally, we observed that 36 out of 40 patients predicted PPR (90%) was less than or equal to the ±10% of measured PPR, so we could predict the minimum PPR reliably. Similarly, in PSDM we observed that 31 out of 46 patients predicted PPR (67.4%) was similar to ±20% of measured PPR and 40 out of 46 patients predicted PPR (86.95%) was less than or equal to the ±20% of measured PPR. **Conclusion**: The investigation provided reliable models for predicting transfusion efficacy based on platelet activation during storage. If the prediction system is adopted efficiently, it will assist clinicians while prescribing the PC units to be transfused thereby potentially reduce the excess use of platelet components, facilitating platelet management.

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Highly Accurate Probabilistic Model for Predicting the Need for Platelet Transfusion at the Point of Admission

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Background/Case Studies: Platelets are a commonly administered blood product. Platelets are stored at room temperature and have a short shelf life, thus making their logistic supply management a difficult and arduous task. We aim to design a model to predict the need for platelet transfusion in patients admitted to the hospital in order to aid the decision making process in platelet supply. **Study Design/Methods**: Demographic, clinical information and laboratory results were extracted from the hospital's database for patients who received platelet transfusion during their hospital admission during a 4-month time period and a control group composed of random patients who had not received platelets during their admission. A total of 47 variables were compared in the two groups using binary logistic regression analysis and a predictive model was designed. For internal validation, the accuracy of the model's predictions were checked in a bootstrap sample of the data. **Results/Findings**: Sixty two patients who received platelet transfusion and 70 patients who had not received platelet transfusion during their admission were included in the study. Binary logistics regression showed high mean platelet volume (>8.55 femtoliters), extremes of age (less than one month and older than 80 years), aspirin use, hematopoietic malignancy, active bleeding, admission for chemotherapy, CABG or renal transplant, extremely premature neonate, low platelets count at admission (<30000/microliter), past history of platelet disorder, past history of platelet transfusion, NICU/PICU and hematology/oncology service admission as significant variables in the model. The model was highly accurate with a −2log likelihood of 0. One hundred iterations of bootstrapping showed the model to be perfectly accurate with the model correctly predicting the need for platelets transfusions in all cases. **Conclusion**: Our probabilistic model can decide with very high accuracy if a patient during the course of hospitalization will need platelet transfusions based on information available at admission. Interestingly, the mean platelet volume had a much greater predictive value than the admission platelet count. In the future, our model can potentially bring a measure of predictability to the platelets supply management system for our institution. The next phase of our study will test for the external validity of this model.

Transfusion-Transmitted Diseases

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Detection of Different Categories of Hepatitis B Virus (HBV) Infection in a Multi-regional Study Comparing the Clinical Sensitivity of HBsAg and HBV DNA Testing

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Background/Case Studies: Twenty two users of individual donation (ID) nucleic acid amplification technology (ID-NAT) in six geographical regions provided detailed hepatitis B virus (HBV) infection data in first time, lapsed

and repeat donations and classified confirmed HBV positive donors into different infection categories. These data were used to compare the clinical sensitivity of HBsAg and HBV-DNA testing. **Study Design/Methods**: In total 10,981,776 donations from South Africa, Egypt, Mediterranean, North and Central Europe, South-East Asia and Oceania were screened for HBV-DNA by Ultrio assay (Grifols/Hologics) and for HBsAg by chemiluminescence immunoassay (CLIA). Ten different categories of HBsAg negative window period (WP), HBsAg positive and occult HBV infection (OBI) were identified by supplemental serology, quantitative PCR and replicate multiplex and discriminatory HBV NAT test strategies. For two regions (South-Africa and Hong Kong), additional data sets using the more sensitive Ultrio Plus assay were assessed. **Results/Findings**: Overall 9455 HBV infected donors were identified of whom 223 (2.4%) were in pre- or post-HBsAg WP, 583 (6.2%) chronic OBI, 8016 (84.8%) HBsAg and HBV-DNA concordantly positive and 610 HBsAg positive without detectable HBV-DNA. Regional HBV detection rates in first time donors varied between 0.08% and 1.07% with WP NAT yield rates varying between 1:7,700 and 1:294,000 and OBI NAT yield rates from 1:3,900 to 1:59,000. HBsAg CLIA detected 97.0% of infections in first time, 62.7% in lapsed and 41.0% in repeat donors, whereas Ultrio detected 93.1%, 95.0% and 98.3% in these respective groups. Replacement of Ultrio by Ultrio Plus increased the sensitivity of HBV-DNA detection in first time donors from 91.7-95.7% to 95.4-98.1% and in repeat donors from 95.1-98.5% to 100%. Introduction of Ultrio Plus further reduced the sensitivity of HBsAg detection in first time and in repeat donors to 87.7-96.2% and 16.5-31.5% respectively. **Conclusion**: ID-NAT and serology are complementary in detecting HBV infection in first time donmors but HBV-DNA is superior to HBsAg detection in repeat donors. Currently the multi-center data base is used to model the efficacy of different testing scenarios in eliminating HBV transmission risk.

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Hepatitis B Virus Prevalence in Chinese Blood Donors: HBsAg-reactive Rates from Pre-donation Rapid Test and Post-donation Screening Test

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Background/Case Studies: Chinese blood centers (BCs) conduct a pre-donation HBsAg rapid test (RT) to collect donations only from donors with RT- result. Successful donations undergo screening tests (SC) using enzyme linked immunosorbent assay for HBsAg and other transfusion transmitted infection markers. Lack of confirmatory testing (CT) on RT+ samples makes it difficult to estimate the HBV prevalence rate among Chinese blood donors. The aim of this study is to perform HBsAg neutralization (NT) and nucleic acid tests (NAT) on pre-donation RT+ samples and post-donation SC+ samples to provide an accurate estimate of HBV prevalence among Chinese blood donors. **Study Design/Methods**: HBsAg RT is done by a lateral flow immunoassay (Colloidal Gold HBsAg Strip) on blood collected by finger stick. In Jun - Aug 2015, venous blood samples from consented donors with RT+ results at Mianyang (MY) and Chongqing (CQ) BCs were subjected to HBsAg NT and HBV NAT. HBsAg SC+ and CT results were collected from BC database. HBsAg CT+ rates for RT+ and SC+ donors were extrapolated to annual totals to derive the prevalence estimates. **Results/Findings**: 74.6% and 68.2% of HBsAg RT+ samples were NT and NAT tested with 98.9% and 97.2% CT+ rates in MY and CQ respectively (Table 1). One sample in MY and 3 samples in CQ were negative in both NT and NAT. From SC+ samples in the same period, 59.0% (62/105) and 45.5% (66/145) were NT CT+ in MY and CQ respectively. In 2015, 45,424 and 107,499 donors attempted to donate whole blood (WB) in MY and CQ; 422 (0.93%) and 667 (0.62%) were HBsAg RT+ whereas 422 (0.93%) and 710 (0.66%) were SC+ respectively. The estimated HBV prevalence was 1.27% in MY and 0.90% in CQ. **Conclusion**: The HBsAg pre-donation RT has effectively intercepted many HBV infected donors before donation. Our study is one of the first to provide an estimate of HBV prevalence by combining both pre- and post-donation HBsAg CT results. Our results and study approach will help improve understanding of the current risk of transfusion transmitted HBV infection in China and provide an investigation model for further HBV prevalence studies in Chinese blood donors.

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The Role of Anti-HBs Quantification in HBV Infection Confirmation Among Donors Deferred Because of Unneutralized HBsAg Reactivity

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Background/Case Studies: HBsAg is only marker in a certain percentage of HBV infections. Donors who are HBV DNA- and determined as HBsAg false-reactive by neutralization test have opportunities to donate blood again after a period of delay due to the lack of anti-HBc detection for its high prevalence in China. But whether these unneutralized HBsAg reactive donors can be excluded HBV infection remains a question. **Study Design/Methods**: Blood donations were routinely tested for HBV DNA by using cobas Taqscreen MPX (Roche) or Procleix Ultrio ID (Grifols) assays and HBsAg by two ELISA kits. Donors with only HBsAg ELISA-reactive unneutralized were followed up by testing HBV DNA individually, routine HBsAg ELISA and Alanine transaminase (ALT). Both archives and follow-up samples were further to detect HBsAg, anti-HBs quantification, anti-HBc, HBeAg and anti-HBe with electrochemiluminescence immunoassay (ECL, Elecsys Roche). **Results/Findings**: Among 821 HBsAg reactive excluded from 192065 donations collected in Dalian Blood Center between January 1st, 2013 and June 30th, 2015, 87(10.6%) were HBV DNA+/HBsAg+, 55(6.7%) were HBV DNA-/HBsAg+ and 679(82.7%) were classified as undetermined HBsAg-reactive. Only 173 in 679 donors associated came back to perform follow-up testing (1-4 samples/donor; range: 93-1120 days). HBV DNA was consistently undetectable and ALT was at normal level in all follow-up donors overtime. Changes in serology were observed in 10 donors while 161 had stable serological profiles (2 donors without archive serological data). Seven new HBV infected cases with HBsAg undetectable were confirmed by significant changes of anti-HBs level (2 decreased, 3 increased and 2 increased first then decreased): 2 males, 5 females; 2 first time donors, 5 repeat donors; median age 39 years (range: 22-48 years); none of them had ever received HBV vaccination. Five in seven were persistent anti-HBc+, two had anti-HBc seroconversion and one with anti-HBc+ had anti-HBe seroconversion during follow-up. Another 2 donors with obviously increasing of anti-HBs level were excluded because of HBV vaccination before blood donation. Still

TABLE. CT+ rate among pre- and post-donation HBsAg+ donors and estimated HBV prevalence in Mianyang and Chongqing

		Jun - Aug 2015				Jan - Dec 2015			
Blood Center		# of Donors	# of Samples tested by CT*	# of CT+ Donors	CT+ Rate	# of Donors	# of CT+ Donors	Total # of CT+/ Total # of Donors Presented for WB donation	Estimated HBV Prevalence (95% CI)
Mianyang	Pre-donation RT+	118	88	87	98.9%	422	417	666/45,424	1.47%
	Post-Donation SC+	109	105	62	59.0%	422	249		(1.38-1.56%)
Chongqing	Pre-donation RT+	157	107	104	97.2%	667	648	971/107,499	0.90%
	Post-Donation SC+	151	145	66	45.5%	710	323		(0.85-0.97%)

*Some samples were not tested by CT due to no consent or sample loss.

one donor was identified as HBV infection during follow-up due to anti-HBc seroconversion occurred at the third time testing more than 1 year after donation. **Conclusion**: There are still some risk of HBV infection in donors with only unneutralized HBsAg reactivity which can be decreased by anti-HBs quantification and anti-HBc detection in follow-up. Due to a high prevalence of anti-HBc+ in Chinese population, anti-HBs quantification maybe is the only useful marker to confirm new HBV infected cases among blood donors, especially for consistent anti-HBc+ donors. HBV vaccination before blood donation should be excluded.

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Performance of New Automated Assays for Hepatitis B Surface Antigen and Hepatitis B Core

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Background/Case Studies: Blood transfusion safety around the world relies on serologic screening for Hepatitis B surface antigen (HBsAg), as well as serological screening for antibodies to Hepatitis B Core antigen (Anti-HBc), to help prevent transfusion transmitted HBV infection. Sensitive HBsAg assays must be capable of coping with a wide range of mutants while exhibiting an uncompromised specificity. In addition, continued pressures on laboratory operations demand that assays perform on platforms capable of increased walk away time and enhanced automation in areas of reagent management, retest options, and commodity/waste management. **Study Design/Methods**: The performance of two new automated prototype chemiluminescence immunoassays for the detection of HBsAg and Anti-HBc were evaluated on a next generation automated platform. Precision was assessed over 5 days. Sensitivity was evaluated on 200 known positive samples and 3 commercially available seroconversion panels. HBsAg was also evaluated using 19 mutants and 8 genotypes (A-H). Specificity was evaluated on samples obtained from 2403 first time and repeat donors from the Netherlands and 200 diagnostic specimens from the USA. Results were compared to the Abbott PRISM assay for these markers. **Results/Findings**: Overall clinical sensitivity was 100% on 200 known positive samples for HBsAg and 100% on 200 known positive samples for Anti-HBc. The HBsAg assay detected 100.00% (19/19) of the mutants while the comparator detected 57.9% (11/19) mutants. All HBsAg genotypes were detected. For the seroconversion panels tested, all positive bleeds detected by the comparator assays were detected by the prototype assays. The overall resolved specificity when compared to PRISM was 100.00% (2403/2403) and 99.88% (2392/2395) for HBsAg and Anti-HBc, respectively. For HBsAg, 4 initial reactive samples were detected. Zero samples were repeat reactive. For Anti-HBc, 11 initial reactive samples were detected and all were repeat reactive. The repeat reactive rate on blood donor samples, excluding confirmed positive samples, was 0.00% (0/2403) for HBsAg and 0.12% (3/2395) for HBc. Resolved specificity when compared to PRISM on 200 diagnostic specimens was 100.00% for both assays. Precision testing over a 5 day period showed percent CVs for positive samples of less than 10%. **Conclusion**: The new automated prototype HBsAg and Anti-HBc assays provided precision and specificity comparable to the current on-market PRISM assays. Anti-HBc sensitivity was also comparable to the on-market assay. However, the HBsAg assay demonstrated a gain in sensitivity over PRISM through the detection of a wider range of mutants.

SP402

Targeted Prospective HCV "Lookback" Program: 10-Year Experience at a Large US Transfusion Service

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Background/Case Studies: Donor HCV testing has evolved over the years and currently, multi-antigen anti-HCV testing and NAT for HCV RNA are recommended for donor testing. Although the risk of transfusion-transmitted HCV infection is relatively low, transmission may still occur if a donor is tested during the "window period". The prospective FDA "lookback" program for HCV was initiated in 1999 in order to identify recipients that were possibly exposed to HCV positive blood products. The record search of prior collections must be performed up to 12 months prior to the donor's most recent negative HCV test. If indicated, a transfusion medicine physician sends a notification letter and form to the physician who ordered the transfusion. This study presents a single center's experience of the HCV "lookback" program. **Study Design/Methods**: Data from the targeted HCV "lookback" program from January 2005 to December 2015 at a large transfusion service was reviewed and classified into the following categories: no records available, discarded/not transfused/sold, autologous donations, outside of 10 year window for "lookbacks", deceased, lost to follow up, incompetent patient, agree to notify, tested positive for HCV prior to transfusion, tested negative for HCV post transfusion. The last 6 categories represent options on the HCV notification form returned by the physician of record. Prior to sending a notification form, the status of the recipient (deceased or alive) is determined by searching electronic medical records and/or the social security death index. **Results/Findings**: In total, 443 donor units were identified as HCV positive over a 10-year period; 120 (27%) of these were not followed up either because there were no records available (68), they were discarded, not transfused or sold (27), they subsequently tested negative by HCV NAT (24), they were outside the 10 year window for "lookbacks" (11), or they were autologous donations (1). Of the 323 (73%) units that were followed up further, 194 (60.1%) recipients were deceased and 19 (5.9%) could not be located. The physician of record agreed to notify the recipient in 67 cases (20.7%). Eighteen recipients (5.5%) were not notified because they had already been tested for HCV infection: 5 recipients had evidence of prior HCV infection and 13 tested negative for HCV since the transfusion. There were no cases of transfusion-transmitted HCV infection. **Conclusion**: The 10-year retrospective review of the HCV "lookback" program identified no cases of transfusion-transmitted HCV infection. The majority of recipients were deceased, with only one-fifth in the "agree to notify" category. These results call into question the appropriateness of a 12-month "lookback" period in the era of NAT for HCV RNA, due to low yield and significant secretarial and financial support required for this program.

SP403

The HIV Prevalence in the South African National Blood Service Blood Donors – With Special Reference to Men Who Have Sex With men

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Background/Case Studies: The South African National Blood Service (SANBS) collects approximately 800 000 donations annually in a country with one of the highest HIV prevalence in the world (18% in the adult population). The HIV prevalence among men who have sex with men (MSM) in South Africa is estimated as 13%- 49%. In 2014 South Africa lifted deferral on MSM donors instead applying the same risk assessment as for heterosexual donors. The number of donors who were MSM and the HIV prevalence was unknown in SANBS, hence the motivation for the study. The aim of the study was to assess the HIV prevalence in SANBS MSM and heterosexual blood donors **Study Design/Methods**: This was a descriptive cross-sectional study. A survey questionnaire was distributed over a 2 month period to all blood donors who presented and were deemed eligible to donate. The Null hypothesis was that there was no difference in the HIV prevalence between the general blood donors (0.22%) and MSM donors. In addition to the Null Hypothesis assumption the MSM sample size of 146 was determined using: The donor population size of 479 082 with 226 137 males. Precision of 5% with 95% confidence interval. The Fisher's exact test with significance level set at 0.05 was also used to assess if there was any association between HIV statuses and sexuality. **Results/Findings**: A total of 7 344 blood donors were enrolled into the study with the majority being males (n=4613, 62.92%). The age ranged from 19-89 years. Out of 7 312 participants who indicated their sexuality, 120 (1.64%) were homosexual, 7 145 (97.72%) were heterosexual and 47(0.64%) were bisexual. Amongst the males 80 were MSM only and 29 were men who have sex with men and women (MSMW) giving a total of 109 MSM (1.48%). The HIV prevalence among MSM was 0%. The HIV prevalence amongst 7132 heterosexual donors whose HIV status was verified was 0.39%. HIV prevalence was higher amongst males at 0.47% (n=20) compared to females at 0.32% (n=8). Using Fisher's exact test a p value of 1 was obtained, showing that there was no association between HIV statuses and being either heterosexual or MSM. **Conclusion**: The MSM prevalence of 1.48% is consistent with studies which estimated MSM prevalence in the South African general population at approximately 1-3%. The MSM HIV prevalence of 0% retrospectively justifies the rationale for lifting the deferral on MSM. One limitation of the study could be that the sample size of 109 MSM might not be a true representation of SANBS MSM population. This smaller sample size (the calculated sample size was 146) could have been due to some reported donor clinic staff not introducing the study to donors citing busy clinics and also to some MSM not declaring their sexuality as in South Africa there is stigma attached to being homosexual.

TABLE.

		RLU																
	n	Reactivity	<1	1-4.9	5-9.9	10-50	>50	Mean	SD	SE	CI of mean	Range	Max	Min	Median	25%	75%	Positive	PPV
HCV	428	0.5%	50	346	18	14	0	2.4	2.5	0.1	0.2	18.1	18.1	0.8	1.6	1.1	2.6	44	10.3%
Chagas	305	0.3%	80	134	36	55	0	4.0	4.2	0.2	0.5	13.6	14.3	0.7	1.4	1.0	9.1	86	28.2%
HIV	107	0.1%	4	51	5	4	43	217.0	324.9	31.3	62.0	1311.4	1311.6	0.9	3.4	1.3	416.0	37	34.6%
HTLV	147	0.2%	7	97	5	8	30	29.0	54.4	4.5	8.9	222.1	223.0	0.9	2.1	1.2	10.9	47	32.0%
Total	987	1.1%	141	628	64	81	73												

PPV = true positives/true positives + false positives

SP404

Chemiluminescence Had a High Positive Predictive Value for Human Immunodeficiency Virus But not for Hepatitis C Virus Confirmed Infection in a Blood Bank between 2012 and 2015

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Background/Case Studies: Reactivity of blood donors to infectious diseases is responsible for the annual loss of around 6% of collected blood units. This has implications on supply of blood and operating costs. The aim of this study was to establish the positive predictive value of four test from blood donations between 2012 to 2015 in a blood bank. **Study Design/Methods**: Retrospective descriptive analysis of the reactivity of infectious tests against human immunodeficiency virus (HIV), hepatitis C virus (HCV), human T-lymphotropic virus (HTLV) and *Trypanosoma cruzi* (Chagas) was performed. Confirmatory tests were performed by Western Blot (HIV), neutralization, RIBA(HCV) or indirect immunofluorescence (Chagas), conducted in a certified Public Health Laboratory. ARCHITECT i2000SR system was used for routine screening. Data collection was made from records in HEXABANK system. **Results/Findings**: 91200 whole blood donations were received during the analyzed period. The overall reactivity for the four infectious diseases screening was 1.1%. HCV showed the greatest number of reactivities, 92.5% with readings below 5 relative light units (RLU). In turn its positive predictive value (PPV) versus confirmatory test was the lowest for the four tests analyzed, 10,3%. See Table 1. By contrast, test against HIV had the lowest number of reactivities, while 51.4% of its readings were below 5 RLU. A positive correlation to higher RLU values for this test was found. HIV test PPV was 3.4 times greater than for HCV. Administrative gray zone defined by the blood bank (RLU >0,<1) was responsible for the chronic deferral of 141 donors. **Conclusion**: Chemiluminescence test for HCV has the lowest PPV of all test evaluated, while HIV test had the highest PPV. Given the HCV test unpredictability remains relevant confirmation by RIBA before issuing a behavior. In contrast, for most cases of HIV its PPV indicates a higher diagnostic value and thus an earlier definitive deferral as blood donors, diagnosis and treatment.

SP405

Performance of a New Automated Assay for HIV

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Background/Case Studies: Blood donations are commonly screened to detect the presence of antibodies (or antibody and antigen) to human immunodeficiency virus Types 1 and 2 (anti-HIV-1/2). Blood centers require very high throughput anti-HIV-1/2 assays with high specificity and sensitivity to prevent unnecessary donor deferrals while maintaining a safe blood supply. In addition, continued pressures on laboratory operations demand that assays perform on platforms capable of increased walk away time and enhanced automation in areas of reagent management, retest options, and commodity/waste management. In the response for the need for such screening assays, we have evaluated an improved automated prototype assay for the detection of anti-HIV-1/2 antibodies and HIV-1 p24 antigen. **Study Design/Methods**: The performance of a new prototype automated chemiluminescence immunoassay for the detection of anti-HIV-1/2 antibodies and HIV-1 p24 antigen was evaluated on a next generation automated platform. Precision was assessed over 5 days evaluating positive samples. Specificity was evaluated on samples obtained from random blood donors. Sensitivity was evaluated using presumed positive samples for HIV-1, HIV-2 and HIV Group O antibodies and HIV-1 p24 antigen. Seroconversion sensitivity was evaluated with 10 commercial seroconversion panels. **Results/Findings**: Precision was less than 10% CV for positive samples over 5 days. The blood donor specificity was 100% (1000/1000). Sensitivity for HIV −1 antibody positive samples was 100% (n=107); 100% for HIV group O (n=46); 100% for HIV-2 (108) and 100% for HIV-1 p24 antigen viral isolates (n=62). Seroconversion detection was better than the comparator due to the HIV-1 p24 antigen detection capability of the new prototype assay. Eight panels were detected earlier than the comparator assay and 2 panels were detected similarly. **Conclusion**: These results indicate that the new automated prototype HIV Combo assay provided acceptable performance in specificity while providing better sensitivity than the comparator due to the HIV-1 p24 antigen detection.

SP406

Validation Study of Nucleic Acid Amplification Test (NAAT) Procleix Panther System at Blood Bank Department, Prince Mohammad bin Abdul Aziz Hospital (PMAH), Riyadh, Saudi Arabia

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Background/Case Studies: Blood donor screening require highly sensitive methods that accurately detect low levels of blood-borne pathogens. The Panther Procleix system (Panther) is a multiplex transcription mediated amplification NAAT that is FDA approved for screening HBV DNA, HCV RNA and HIV RNA. In this study, our aim was to evaluate the sensitivity of Panther for detection of viral nucleic acid in blood donors and standardized positive samples. **Study Design/Methods**: Positive blood samples with known viral loads and standardized external quality control (EQA) samples were selected in this study. Briefly, 20 samples including HBV (6), HCV (9) and HIV (5) were prepared to achieve 6X, 3X, 1.5X and 0.75X limit of detection (LOD) concentrations of each viral nucleic acid. LOD concentrations were tested in 2-3 replicates and results compared with LOD specified in manufacturer's product insert. Additionally, 19 random positive samples previously tested in Roche Cobas system were compared with Panther for viral genotypes prevalent in local population. Finally, 24 EQA samples were also included to assess viral sensitivity. **Results/Findings**: We assessed the ability of Panther to qualitatively detect the target viral LOD range compared to reference LOD. Panther analytical sensitivity was found to be 100% at 6X and 3X LOD for HBV, HCV & HIV. While Panther was 100% sensitive at 1.5X and 0.75X LOD for HBV and HIV, it was 95% sensitive for HCV at 1.5X and 0.75X LOD. Previously positive samples tested by Roche Cobas S201 NAAT also correlated 100% with Panther for detection of HBV (10), HCV (6) and HIV (3). Furthermore, Panther accurately identified all 24 EQA samples (AcroMetrix) as 100% reactive. **Conclusion**: Our findings suggest that Procleix Panther NAAT has excellent analytical sensitivity for detection of HBV, HCV and HIV at lower viral loads and compares favourably with other molecular assays currently in use.

SP407

Evaluation of Deferral Algorithm and Impact of Centrifugation Speed on False Reactive Test Rate in HIV, HBV, and HCV Serological Screening

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Background/Case Studies: False reactive results (FRR) in blood donor infectious disease screening assays cause discarding of blood products and

donor deferrals as well as extra cost. An initial reactive (IR) result is run in duplicate to determine whether the sample is repeated reactive (RR). RR samples are issued for confirmation. The donor is deferred after 2-3 consecutive FRRs. After 3 years the donor can be retested and thereafter allowed to donate or permanently deferred. To enable optimization of the deferral algorithm, we analyzed HIV, HBV and HCV results of 914,610 donations collected in Finland between March 2012 and March 2016. In addition, the centrifugation program was changed to equalize sample pre-handling for all donor screening processes and the effect on FRRs was analyzed. **Study Design/Methods**: Samples were collected in K2EDTA plasma tubes, centrifuged 2500 g 8 min (until October 2014) or 1500 g 10 min (from November 2014). Samples were tested with HIV Ag/Ab Combo (HIV), HBsAg Quality II (HBV) and Anti-HCV (HCV) assays on Abbott Architect platform. To simplify the process, IR samples were rerun without an additional centrifugation step (10 min 10,000 g) recommended by the manufacturer. Donations with unclassified confirmatory or true positive results in serological assays or HIV, HBV and HCV NAT assays (Procleix Ultrio Plus or Ultrio Elite assay, Grifols) were excluded from the analysis. **Results/Findings**: After the first FRR the three subsequent donations were false reactive in 29%, 27%, 20% (HIV); 33%, 32%, 24% (HBV) and 51%, 49%, 41% (HCV) of cases. After two consecutive FRR donations 80% (HIV), 76% (HBV) and 79% (HCV) of donors were false reactive and less than 10% of results normalized to the average negative donor result level. Sum of HIV, HBV and HCV IR% rates with centrifugation program 2500g 8min (n=45457) and 1500g 10min (n=23707) were 0,60% (95% CI 0,53-0,67%) and 0,63% (0,53-0,74%), respectively. To exclude the effect of donor deferrals and donation frequency of donors, only the first donation per donor with the current assays was included. **Conclusion**: About 80% of donors having two consecutive FRR results remain false reactive for a long period of time. The centrifugation program (2500 g 8 min vs. 1500 g 10 min) does not affect the assay specificity.

SP408

Peripartum Blood Transfusion in South Africa: An Association between HIV Infection and Risk of Tranfusion

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Background/Case Studies: South Africa has a higher incidence of peripartum blood transfusion than high-income countries despite comparable rates of obstetric haemorrhage. Obstetric services consume a large (15%-20%) proportion of the country's blood supply. South Africa also has the world's largest HIV epidemic and approximately 29% of pregnant women are HIV positive. We sought to evaluate whether HIV infection was independently associated with increased transfusion incidence. **Study Design/Methods**: From March 2014 to October 2015, a large case-control study of obstetric blood transfusion was conducted at four secondary and tertiary South African hospitals serving a predominantly urban, low-income population with a high HIV prevalence. Cases comprised women who were transfused in the peripartum period; controls were non-transfused peripartum women stratum-matched 2:1 to cases by hospital. Data on obstetric, transfusion and HIV history were abstracted from medical records. Complete blood counts were performed on a subset of subjects; CD4 and HIV viral load were also obtained in those patients who were HIV positive. Bivariate and multivariate analysis was used to determine risk factors for transfusion. **Results/Findings**: We enrolled 1,200 transfused cases and 2,433 non-transfused controls. Most patients were aged 20 to 34 years and of Black race/ethnicity, 95% had at least some prenatal care and 48% had Caesarean deliveries. HIV infection was an independent risk factor for transfusion, present in 408 (38%) cases and 776 (31%) of controls (adj. OR = 1.27, 95% CI 1.01 - 1.59). Other risk factors for transfusion included obstetric haemorrhage (OR 74.23, 95% CI 56.30 - 97.88), antenatal anaemia (ORs = 23.40, 9.72 and 5.93 for antenatal haemoglobins less than 7, 7-8 and 8-9 g/dl, respectively) and whether the patient accessed antenatal care (OR = 5.17, 95% CI 3.26 - 8.18 for "unbooked" patients). Mode of delivery (Cesarean vs. vaginal), race, hospital, age category, gravidity, parity, gestational age, and birth weight did not contribute significantly to the transfusion model. Mean pre-transfusion haemoglobin (range 7.32 - 7.75 g/dl) and mean haemoglobin increment relative to the number of RBC units transfused did not differ by HIV status and varied only slightly among hospitals. **Conclusion**: After controlling for obstetric haemorrhage, both HIV infection and antenatal anaemia are independent risk factors for peripartum blood transfusion in South Africa. There was little evidence of inappropriate transfusion based on hemoglobin thresholds and a lack of hospital effect in the multivariable model. Improved assessment and treatment of anaemia and HIV disease during pregnancy could impact the incidence of peripartum transfusion in South Africa.

SP409

ABO and RhD Blood Groups and Susceptibility to HIV Infection among South African Blood Donors

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Background/Case Studies: In addition to blood group antigens playing a pivotal role in transfusion medicine, they have also been studied for their association with infectious diseases. Examples include an association of the Duffy blood group with resistance to malaria and the Pk blood group providing protection against HIV-1. Studies have shown that HIV virions incorporate ABO blood group antigens into the HIV viral envelope. Naturally occurring antibodies against ABO antigens present in human sera have been shown to neutralize ABO-expressing HIV *in vitro, but there are conflicting data on the relevance of this effect in vivo. The aim of this cross sectional study was to investigate the relationship between ABO and RhD blood groups and HIV infection among blood donors in South Africa, where HIV is hyper-endemic. If blood group polymorphisms indeed play a protective role in HIV infection, we would expect to see underrepresentation of a particular blood group among HIV infected donors*. **Study Design/Methods**: ABO, RhD and HIV test results and demographic information such as race, gender, age and geographic region were collected for first-time, whole blood donations between January 2012 and September 2015. HIV infection was defined as being repeatedly reactive for either HIV antibody using the Prism anti-HIV (Abbott, Delkenheim, Germany) and Western blot (Bio-Rad, Hercules, CA), HIV RNA using the Griffols Ultrio Plus assay (Griffols, Barcelona, Spain), or both RNA and antibody. Red blood cells were typed for ABO and RhD using the PK 7300 (Beckman Coulter, USA). Odds ratios were calculated using multivariable logistic regression analysis. **Results/Findings**: There were 397,632 first time donors of whom 4,481 (1.13%) were HIV positive. HIV infection was associated with RhD+ status (OR = 1.20, 95% CI 1.01-1.41) but not with ABO status (OR's = 1.04, 95% CI 0.98-1.10 for A, B and AB combined versus O). HIV was also strongly associated with Black (OR= 29.43) and Coloured (OR = 7.57; both vs. White) race/ethnicity, female sex (OR = 1.72) and sexually active ages (OR's 2.19 - 3.18 for ages 20-24 to 30-39 years, vs. < 20 years) as well as mobile vs. fixed collection site and geographic area. In bivariate analyses, RhD+ status was associated with non-White race/ethnicity, female sex and ages 20-39 as well as HIV infection. **Conclusion**: *There was no association between ABO blood group and HIV infection in this study. However we found an unexpected and relatively weak association between RhD status and HIV infection. Being RhD negative may offer some protection to HIV infection or our results could be due to residual confounding by unmeasured variables related to both HIV infection and RhD status. Future studies should attempt to replicate these RhD findings and/or derive biological hypotheses for this phenomenon*.

SP410

Comparative Evaluation of Two 4th-Generation HIV Combo Assays using a Genetically Diverse HIV Panel and Diagnostic Specimens

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Background/Case Studies: The 4th generation HIV antigen/antibody (Ag/Ab) combination assays have been used routinely for detection of HIV infection in blood donors outside the United States as well as hospital patients worldwide. These assays are designed to detect acute and chronic infections by simultaneously measuring HIV p24 antigen and antibody. Early detection of acute infection is dependent upon antigen sensitivity of the assay, and genetic variation of HIV strains may also impact assay performance. In this study, a genetically diverse panel of HIV virus isolates and clinical laboratory specimens were used to compare performance of two 4th generation Ag/Ab combo assays: Abbott ARCHITECT HIV Ag/Ab Combo

and Siemens ADVIA Centaur HIV Ag/Ab Combo (CHIV). **Study Design/Methods**: Assay sensitivity was evaluated using a panel of 100 unique members representing diluted HIV antigen (n=51) or antibody (n=49) samples including divergent HIV-1 and HIV-2 subtypes and groups as well as 5 seroconversion panels. Analytic sensitivity was also determined using the WHO International HIV-1 p24 antigen standard. In addition, specificity of both assays was evaluated with routine leftover patient samples (n=3020). **Results/Findings**: ARCHITECT HIV Combo detected all 51 HIV-1 and HIV-2 virus isolate dilutions, while Centaur CHIV only detected 10 strains, missing 28/35 group M, 9/11 HIV group O, 2 group N and both HIV-2 virus dilutions. In addition, analytic sensitivity of ARCHITECT HIV Combo (0.74 IU/mL) was 2.4-fold better than Centaur CHIV (1.8 IU/ml) based on WHO p24 standard. Of the 49 diluted antibody samples, 47 were ARCHITECT HIV Combo reactive whereas 34 were detected by Centaur CHIV. Two of 34 Centaur CHIV reactive antibody dilutions were not detected by ARCHITECT HIV Combo. Notably, ARCHITECT HIV Combo showed better seroconversion sensitivity than Centaur CHIV, detecting one bleed earlier in 3 of 5 seroconversion panels. Specificity evaluation in 3020 serum samples showed 2.2-fold better separation between HIV negative and positive diagnostic specimens with ARCHITECT HIV Combo than with Centaur CHIV. Equally important, Centaur CHIV had almost 2-fold higher initial reactive rate (IR) than repeat reactive rate (RR) whereas ARCHITECT HIV Combo had equivalent IR and RR, demonstrating robustness of the assay. Confirmation of discrepant samples between assays is ongoing. **Conclusion**: In comparison with the recently FDA-approved Centaur HIV Combo assay, ARCHITECT HIV Combo demonstrated more sensitive detection of p24 antigen across divergent HIV-1 and HIV-2 strains as well as superior antibody sensitivity for group O and HIV-2 infections. In addition, the ARCHITECT HIV Combo assay is more specific and reliably discriminates reactive and negative populations.

SP411

Low Hepatitis E Virus (HEV) RNA Prevalence in US Source Plasma Donors

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Background/Case Studies: HEV is a small (27-34 nm) non-enveloped, single-stranded, RNA virus that is a causative agent of hepatitis globally and of emerging concern in industrialized countries. Transfusion-transmission of HEV has been documented from blood components including pathogen inactivated platelets and plasma, but not by plasma derived medicinal products (PDMPs) that contain virus inactivation/removal steps. The prevalence of HEV in US blood donors has been studied but there is little information available regarding HEV prevalence in US Source Plasma donors. **Study Design/Methods**: A minimum of 125,000 samples from unique US Source Plasma donors were collected from donations the first time a donor visited a participating CSL Plasma center during the 3 week study period. Study samples were traceable to the donation center but were de-linked from the donors. The samples were screened for the presence of HEV RNA in 96 sample mini-pools using the Roche cobas® HEV test on the cobas® 8800 System. Reactive mini-pools were further tested and resolved to the individual donation. HEV positive samples were further analysed to determine the genotype, quantify the virus titer, and ascertain the status of IgG and IgM HEV antibodies. **Results/Findings**: Greater than 90% of FDA licensed CSL Plasma centers participated in the study representing 27 states and all geographic regions except the Northeast. Three unique HEV RNA positive samples were identified from the approximately 128,020 unique donor samples tested using the 96 mini-pool screening strategy (~0.002%). All 3 HEV positive donations came from centers located in the US Midwest region. The HEV reactive samples were determined to be genotype 3a and had relatively low virus titers of 10^3 to 10^4 IU HEV RNA/mL. All positive donations were HEV IgM seronegative, and 2/3 were IgG HEV seronegative. One sample was IgG seropositive, suggestive of a reinfection. **Conclusion**: HEV prevalence in US Source Plasma donors was very low. Virus titers of the HEV positive units were also low. Plasma manufacturing pools incorporating these units would meet the HEV RNA requirements for pooled SD-plasma; a product for which no HEV reduction occurs. PDMP processes contain virus reduction steps capable of removing HEV thereby providing additional margins of safety, and, as such, the low residual risk of HEV in a manufacturing pool for US Source Plasma does not support the addition of routine screening for HEV. cobas® HEV is not commercially available in the US.

SP412

Rapid Donor Surveillance Study Develops Tool to Assess Risk in a Statistically Valid Sample of US Blood Donors: Babesia and Hepatitis E Virus Surveys

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Background/Case Studies: The objectives of the Rapid Donor Surveillance study were to develop infrastructure to quickly survey donors for possible exposure to transfusion transmissible (TT) pathogens and other potential hazards that would threaten the blood supply, to support quantitative risk-benefit assessments for TT diseases, and to pioneer electronic survey tools that can be delivered rapidly to a large statistically robust sample of donors. **Study Design/Methods**: In a collaboration between several blood collecting organizations (BCO) and federal partners, an electronic survey instrument was developed to address TT pathogens. Survey questions were designed to address blood donor risk for pathogens of interest, including A) exposure to ticks and tick-borne infection and B) exposure to the Hepatitis E Virus. A statistically representative sample of donors was obtained by each BCO. This sample was selected from the previous year's donor population and statistically designed to be representative of the BCO's overall donor base by gender, age, geographic spread, donor status (first-time (FT)/repeat), and donation type (whole blood/apheresis). Invitations to participate in the surveys were emailed to a sample of donors by each BCO. Additional invitations were released until 1000 responses per BCO were achieved. Response data were collected and analyzed centrally. **Results/Findings**: FT donors were less likely to respond than repeat donors (1% versus 10%). For Survey A, donors aged 18-25 were 26.5% of the sampled population; they made up 8.2% of responses, and were among the least active outdoors. Donors aged 56-65 constituted 16.7% of the sample, 28.9% of responses, and were most active outdoors (32.8% were active outdoors daily or several times per week). Other than working and gardening, the types of outdoor activities engaged in by donors at home vs. when traveling to tick endemic areas aligned closely. Over 80% of responses were received within 48 hours of the invitation. Responses to Survey B indicated that 1.3% of donors reported ever having symptoms of jaundice. While 94.3% had eaten pork in the last five years, only 3.9% reported eating raw, rare or undercooked pork or pork products. **Conclusion**: The donor population expected to be heaviest users of electronic media were the least likely to respond to the email surveys. There was a strong correlation between age and likelihood of response, with donors aged 18-25 being less likely to respond than older donors; younger donors are a relatively large fraction of total donors. Such surveys and the preparations required for their success are important to assure readiness to assess evolving emerging infectious disease risks to the blood supply. The infrastructure built for these surveys should be maintained and periodically exercised.

SP413

Prevalence of Hepatitis E Virus Infection among Voluntary Blood Donors in China: A Systematic Review and Meta-analysis

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Background/Case Studies: Hepatitis E virus is one of new threats to blood safety which was usually considered to be transmitted via fecal-oral route. China is one of the hyperendemic regions where frequent outbreaks of hepatitis E are noted. However, the overall prevalence of HEV infection among mainland Chinese blood donors is not clear until now (Figure 1). **Study Design/Methods**: The peer-reviewed literatures reporting the prevalence of HEV in Chinese blood donors were identified by systematic searching of five electronic databases. The systematic review and meta-analysis were conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement issued in 2009. Data manipulation and statistical analyses were performed by Stata 12.0. **Results/Findings**: Seventeen eligible articles involving 23 independent studies were included. Pooled prevalence of HEV infection biomarkers (anti-HEV IgG, anti-HEV IgM, RNA and antigen) among mainland Chinese blood donors were 29.6%, 1.1%, 0.1% and 0.1%, respectively which were higher than the data reported in other countries (Table 1_. The analysis of HEV genotypes indicated that the most prevalent strains in Chinese blood donors were genotype 1 and 4. **Conclusion**: Mainland China is indicated with a relatively higher risk of transmission of hepatitis E through transfusion and the screening of blood donors for HEV RNA, especially in HEV-endemic areas, might reduce the potential risk of HEV infection via transfusion.

TABLE. Pooled prevalence of HEV infection biomarkers

HEV Infection Biomarkers	Number of Studies	Event Rate (%)	95% CI (%)	P Value	I2 Statistics
Anti-HEV IgG	22	29.2	26.2-32.3	0	99.10%
Anti-HEV IgM	21	1.1	1.0-1.3	0	84.10%
HEV RNA	11	0.1	0.00-0.1	0.031	49.6%
HEV antigen	8	0.1	0.00-0.1	0.337*	12.00%

*$p>0.05$.

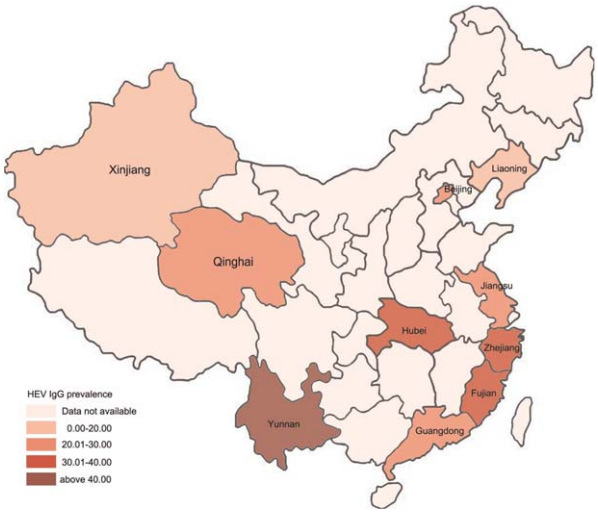

Fig. 1. Geographical distribution of HEV IgG prevalence.

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Variant Creutzfeldt-Jakob Disease Risk Deferrals: Impact of Stop-dates

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Background/Case Studies: In Canada donors were deferred for 3 months cumulative time in the UK or France or 5 years or more in western Europe since 1980 to mitigate risk of variant Creutzfeldt-Jakob disease (vCJD). Risk of exposure to vCJD was considered to be addressed in the UK and France by 1996, and elsewhere in Europe by 2007. In 2005 a stop-date for UK or France cumulative time (1980 - 1996) was introduced and in 2015 for western Europe (1980 - 2007). We aimed to evaluate the impact of introducing these stop dates on donor deferral and return. **Study Design/Methods**: Deferral for vCJD-risk travel was tracked since 2003. For each month the number of donors deferred was divided by the number of donors plus donors deferred. First time and repeat donor deferral rates were analysed separately. Autoregressive integrated moving average (ARIMA) models were constructed. Functions were fitted at the time of stop dates to determine whether or not there was a significant deviation in the time-series from that expected by the ARIMA model. This model accounted for autocorrelation between time periods, that is, the tendency for the number of deferrals for any given month to be similar to (or correlated with) that of the previous month, as well as seasonality and trend. Mean deferral rates of the series before and after the policy changes were calculated, and confidence intervals were estimated based on the Poisson distribution. Shortly after implementing the stop-date for UK and France, all previously deferred donors were sent a letter encouraging them to return to donate. **Results/Findings**: When the stop date was implemented for UK/France travel, the mean deferral rate in first time donors decreased from 2.1% (1.8 - 2.3%) to 1.1% (0.9 - 1.3%) $p<0.0001$, and in repeat donors decreased from 0.19% (0.13 - 0.25%) to 0.03% (0.02 - 0.04%) $p<0.0001$. In 2015 when the western Europe stop date was implemented the mean deferral rate in first time donors was unchanged 1.02% (0.95 - 1.09%) pre-implementation vs. 1.07% (0.99 - 1.15%) post-implementation, $p=0.46$. Among repeat donors the deferral rate decreased from 0.026% (0.022 - 0.030%) to 0.017% (0.014 - 0.021%), $p<0.002$. In total 22,341 first time and 9,691 repeat donors were deferred from 2003 to March 2016. Also 2,206 (705 first-time and 1,501 repeat) donors previously deferred for UK/France travel donors have returned and donated, peaking about 2 years post-implementation. **Conclusion**: There is a measurable benefit from the implementation of a stop date for UK/France travel, largely on future donors rather than win-back of previously deferred donors. Lack of observable impact of the western Europe stop date may be related to the long duration of cumulative time. Greater benefit of both stop dates in the future is expected as more new donors will be born after the stop date.

SP415

Performance of a New Automated Assay for HTLV I/II

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Background/Case Studies: Blood donations are commonly screened to detect the presence of antibodies to human T-lymphotropic virus Type I and/or human T-lymphotropic virus Type II (anti-HTLV I/HTLV II). Blood centers require very high throughput anti-HTLV I/HTLV II assays with high specificity and sensitivity to prevent unnecessary donor deferrals while maintaining a safe blood supply. In addition, continued pressures on laboratory operations demand that assays perform on platforms capable of increased walk away time and enhanced automation in areas of reagent management, retest options, and commodity/waste management. In the response for the need for increased specificity for such screening assays, we have evaluated an improved automated prototype assay for the detection of antibodies to HTLV I and HTLV II. **Study Design/Methods**: The performance of a new prototype automated chemiluminescence immunoassay for the detection of antibodies to HTLVI and HTLV II was evaluated on a next generation automated platform. Precision was assessed evaluating a number of known positive samples. Specificity was evaluated on samples obtained from 4929 blood donors. Sensitivity was evaluated using dilution panels comprised of three HTLV-I and two HTLV-II positive samples. **Results/Findings**: Precision was less than 5.0% for samples with values within the range of 2.00 to 6.20 S/CO. The overall resolved specificity was 100.00% (4929/2929). Multiple lots of the HTLV I/II assay showed similar dilutional sensitivity profiles. **Conclusion**: These results indicate that the new automated prototype HTLV I/II assay provided acceptable performance in specificity, sensitivity, and precision.

SP416

Performance Characteristics of a Transcription-mediated Amplification Assay on a Fully Automated System to Detect Babesia in Blood Donations

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Background/Case Studies: The Procleix® Babesia assay for use on the Procleix Panther® system is a Transcription-Mediated Amplification (TMA), qualitative *in vitro* nucleic acid test for the detection of *Babesia microti*, *Babesia divergens*, *Babesia ducani*, and *Babesia venatorum* in human whole blood specimens. The assay uses an automated whole blood sample preparation method prior to testing on the fully automated Panther system. This test is intended to screen blood donations in whole blood lysate pools of up to 16 donations. The purpose of these studies was to determine specificity, analytical sensitivity, feasibility of pooled testing, and performance in potentially problematic blood donations. **Study Design/Methods**: To assess specificity, a total of 2,210 tests from 167 unique donors were performed. For analytical sensitivity, dilutions of *in vitro* synthesized RNA transcripts for the 4 clinically relevant Babesia species were evaluated and results were subjected to probit analysis (SAS Enterprise Guide 6.1). Fresh Babesia-infected hamster whole blood with a known number of parasites was used to

determine the limit of detection (LOD) of parasites/mL. Pooling feasibility was demonstrated by serially diluting fresh Babesia-infected hamster blood to about 1 parasite/mL in multiple vials and further diluting the reactive lysates at 1:20 and 1:200 dilution. Specificity and sensitivity of the assay in samples with various blood borne pathogens, microorganisms, and cadaveric specimens were examined with and without the presence of Babesia spiked at about 3-fold the 95% LOD of the assay. **Results/Findings**: The Procleix Babesia assay on the Panther system demonstrated 99.95% specificity in normal donor specimens. The assay on the Panther system detected all four Babesia species with a 95% LOD $\leq$ 16.7 copies/mL and fresh Babesia-infected hamster blood with a 95% LOD of 1.4 parasites/mL. Dilution of the lysate, estimated at 1 parasite/mL, maintained 100% reactivity at 1:20 dilution level demonstrating the feasibility of testing pools of up to 16. Specificity and sensitivity of 100% were obtained in the cadaveric specimens and specimens with various blood borne pathogens and other microorganisms. **Conclusion**: The Procleix Babesia assay on the Panther system demonstrated high specificity and sensitivity and detected all 4 Babesia species. Dilution of fresh Babesia-infected hamster blood showed that the sensitivity in diluted lysates was equivalent to individual lysate sample testing thus demonstrating feasibility of pooled lysate screening.

SP417

Performance Evaluation of a Prototype ARCHITECT Antibody Test for *Babesia microti*

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Background/Case Studies: The ability of serologic and molecular tests to identify blood donors infected with *Babesia microti* will be important to reduce transfusion-transmitted *B. microti* infection, especially during the early weeks and months after a primary infection. Recently, the rhesus macaque model was shown to be useful to study the evolution of markers associated with early *B. microti* infection (Gumber 2016). **Study Design/Methods**: An early prototype ARCHITECT antibody test was developed using recombinant proteins derived from two *B. microti* open reading frames. Specificity of the antibody test was evaluated on a population of 2,000 volunteer blood donors (Gulf Coast Regional Blood Center, Texas), and sensitivity was evaluated on 60 samples previously characterized to have detectable parasitemia (quantitative PCR (qPCR)) and antibodies (immunofluorescence (IFA)). Additionally, serial bleeds from experimentally infected macaques were tested with the prototype antibody test and results were compared to other previously published markers (qPCR and IFA). **Results/Findings**: The specificity of the prototype test was initially determined to be 99.95% (1 reactive sample out of 2,000), confirmatory testing of the results is being performed by Quest Diagnostics (Madison, NJ). The sensitivity among 60 PCR/IFA positive samples (New York State Department of Health, Wadsworth Center, Albany, NY) was 98.33%. As compared to qPCR, the ARCHITECT assay detected 5 of 6 macaques 3-10 days later than PCR, though antibodies were detected one week earlier than PCR for one macaque. As compared to IFA, the ARCHITECT antibody test detected exposure to *B. microti* one week earlier for 5 of the 6 macaques and on the same day for one macaque. Once initially detected, antibodies were observed by both ARCHITECT and IFA antibody assays in all subsequent bleeds including those times that were intermittently negative by PCR. **Conclusion**: The early prototype ARCHITECT antibody test for *B. microti*, exhibited sensitivity and specificity values of 98.33% and 99.95% respectively on human samples. The ARCHITECT antibody test for babesia showed equivalent or earlier detection of antibodies vs. the IFA test, and detected infection equivalently or shortly after PCR.

SP418

Risk-based Decision Making: Whether to Screen Blood Donors for Babesia in a Non-endemic US State

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Background/Case Studies: Transfusion-transmitted babesiosis (TTB), usually caused by the intraerythrocytic parasite *Babesia microti*, is endemic in certain northeastern and midwestern US states. Our state is non-endemic, but a confirmed TTB case due to donor travel from an endemic region occurred in early 2015 and piqued interest in possible screening of RBC donations. Using data from cases reported to Centers for Medicare & Medicaid Services (CMS), the FDA Blood Products Advisory Committee (BPAC) suggested that a risk-reduction of about 95% across the US could be achieved by universal antibody screening and nucleic acid testing in the 5 most endemic states. There is no licensed screening test currently; testing is available only by Investigational New Drug (IND) application and there is no formal FDA guidance at this time. Multiple epidemiologic TTB studies have been reported, most of which have been relatively small and/or restricted to endemic areas. A prospective American Red Cross (ARC) IND study identified positive donors associated with TTB from unscreened units to determine risk of TTB from an unscreened donation. **Study Design/Methods**: Prospective donor screening data collected and presented by ARC were considered here to project cost implications and risk of electing against screening donors. Meetings with key stakeholders (transfusion practice committee members, infection control, risk management) took place to reach consensus following review and discussion. **Results/Findings**: The reported prospective data showed the estimated risk of a transfusion recipient developing TTB due to donor travel outside 9 endemic US states is about 1 in 10.36 million. The added cost to the customer of antibody testing every RBC donation was conservatively estimated at 10 dollars per unit. The estimated cost to prevent one case of TTB is 103.6 million dollars. At our 3 institutions, a combined 28,000 RBC units are transfused annually. Therefore, to prevent one case of TTB at our institutions it would take approximately 370 years. **Conclusion**: Despite the seriousness of a recent case of TTB, the overall risk of TTB in this non-endemic US state is extremely low and prospectively screening donors is not cost-effective or practical at this time in the absence of a formal FDA guidance. This risk-based assessment decision seems to be in line with current practices of other institutions in non-endemic US states.

SP419

Babesia Testing Investigational Containment (BTIC) Study Prevents Transfusion- transmitted Babesiosis: A Laboratory-based Donor Screening Program

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Background/Case Studies: Babesiosis is a parasitic intraerythrocytic infection caused by *Babesia microti* which is endemic in the Northeast and upper Midwest regions of the USA and transmissible by *Ixodid* ticks or by transfusion. Transfusion-transmitted babesiosis (TTB) is the most common reported transfusion associated infection. Individuals with *B. microti* infection have variable clinical findings that range from asymptomatic to mild flu-like symptoms to severe life threatening disease especially in immunocompromised patients. There is no current licensed test for the detection of *B microti*. Routine blood donor screening for babesiosis consists of a single query on the donor questionnaire; an affirmative response results in indefinite donor deferral. Asymptomatic *B. microti* infected immunocompetent individuals can transmit the infection to transfusion recipients. This study describes the first developed and implemented laboratory-based donor screening program for *B. microti*. **Study Design/Methods**: This investigational study was conducted from July 2010 - December 2015 under an approved Investigational New Drug (IND) protocol and is ongoing. Donor units intended for susceptible recipients (neonates, pediatric sickle cell, thalassemic and immunocompromised patients) were screened for B. *microti* DNA by real-time polymerase chain reaction (PCR) and for *B. microti* antibody by an indirect immunofluorescence assay (AFIA), but if not used, were transfused to other populations. Units which tested positive by PCR or AFIA ($\geq$128) or indeterminate were not transfused. Segments from all units associated with a red cell donation were saved for TTB workup. For investigative purposes, a PCR positive result or an AFIA result of $\geq$64 were considered significant for suspect TTB. Of note, some donations were double red blood cell donations. We analyzed patient specific transfusion data for TTB status. **Results/Findings**: A total of 17,302 units were screened with 100 positive results by AFIA and 2 indeterminate results. There were 8 PCR positive results with concomitant AFIA positive results and 4 PCR indeterminate results. Of the 502,069 unscreened units, 20 TTB cases were reported: 19 donors were PCR positive and of these, 3 were AFIA negative; 1 donor was PCR negative and AFIA positive. The approximate rate of TTB cases per B. microti untested units in the 5 year period is 1/25,000. No reported cases of TTB occurred with any B. microti-screened units. **Conclusion**: The presented data supports implementation of B. *microti* screening by IFA and PCR for the reduction and prevention of TTB.

SP420

Testing Strategies for *Babesia microti* in Blood Donors to Reduce Risk of Transfusion-transmitted Babesiosis in the United States

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Background/Case Studies: Human babesiosis is a tick-borne illness caused by *B. microti* parasites which reproduce in red blood cells and may be transmissible through blood transfusion from asymptomatic infected donors. Over the past decade, there have been a growing number of clinical and transfusion-transmitted babesiosis (TTB) cases in the United States. The study's objectives were to estimate risk of babesiosis in U.S. blood donors and to evaluate the effect of various blood donor testing strategies on TTB risk-reduction. **Study Design/Methods**: Based on state-level babesiosis rates among the U.S. elderly during 2006-2013 using the Centers for Medicare and Medicaid Services large databases, we developed a benefit-risk assessment model to ascertain effects of antibody-only testing as well as antibody and nucleic acid-based testing (NAT) of blood donations in the U.S. The model estimated: 1) the number of interdicted units from infected donors; 2) the percent reduction from baseline in the risk of transfusion-transmitted babesiosis (TTB) under various testing strategies; 3) the number of units lost due to false positives, and 4) the positive predictive value (PPV). The study explored how the risk estimates would change using alternative blood testing strategies of antibody-only testing and testing with both antibody and NAT in selected states or nationwide. **Results/Findings**: The results estimated that 1,200 Babesia-infected units are on average donated annually for transfusion in the U.S. The study shows a 91.4%TTB risk reduction with a PPV of about 19% following implementation of nationwide antibody-only testing strategy. Nationwide serology only plus NAT in five highly endemic states was estimated to result in 95.0% TTB risk reduction, with marginal increase to 96.0% if both tests implemented nationally. The corresponding TTB risk reduction would be about 73.7% if antibody and NAT testing were conducted only in the five US states with the highest babesiosis rates and would result in 536 units diverted annually. In contrast, nationwide testing strategies would result in about 4,118 units diverted annually. **Conclusion**: Overall, our study estimated the largest TTB risk reduction with national donor testing strategies and suggests that policy makers need to weigh benefits versus risks (e.g. donor loss, reduced PPV) before implementing donor screening nationwide. The results will inform regulatory decisions on the optimal testing strategy that could be used for reducing the risk of transfusion-transmitted babesiosis to help protect the safety of the US blood supply.

SP421

Babesia Antibody Prevalence

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Background/Case Studies: Babesiosis is a tick-borne disease with known transfusion transmission. However, no FDA approved tests are commercially available for detection of infection in donors. In May 2015, the Blood Products Advisory Committee (BPAC) recommended nationwide Babesia antibody testing as well as nucleic acid testing (NAT) in high risk areas. The BPAC report indicated antibody testing data could be used to determine applicable states for NAT screening. A large testing laboratory implemented an FDA-approved protocol using an enzyme-linked immunosorbent assay (ELISA) for qualitative detection of antibodies to B. microti. Prevalence data is presented for several collection facilities in states identified as high risk for Babesia infection. **Study Design/Methods**: Donations from voluntary donors in New Jersey (NJ) and Minnesota (MN) were tested between October 2015 and April 2016 using an ELISA based on four synthetic peptide antigens. Diluted samples were incubated in coated microwells allowing specific antibodies to bind to the solid phase. Bound antibodies were detected using horseradish peroxidase-conjugated anti-human IgG and IgM conjugate followed by addition of a chromogenic peroxidase substrate containing tetramethylbenzidene (TMB). Color development was quenched by dilute maleic acid, producing a yellow color measured at 450nm. Duplicate retests were required for initial reactive (IR) samples. Results were reported as reactive (RR) or nonreactive based on an initial nonreactive result or a final interpretation based on two of three replicates for initial reactive samples. **Results/Findings**: Of 84,928 samples tested, 306 (0.360%) were IR and 264 (0.311%) were RR. Table 1 demonstrates the difference in rates with NJ donations 0.11% higher overall than MN donations. Reactive rates fell (from 0.48% to 0.18%) during the late winter months consistent with reports of seasonal variations in infection. **Conclusion**: Although a nonreactive result does not exclude the possibility of infection and a reactive result is not definitive evidence of infection, it is clear Babesia antibodies are prevalent in the US donor population. Decreased reactivity during late winter is evident in both areas based on the limited data set available. Additional analysis of ongoing prevalence, donor follow up and transfusion transmission in endemic and non-endemic areas is required to determine efficacy of Babesia antibody screening as an effective measure to enhance safety of the US blood supply.

TABLE.

Location	# Tested	#IR	%IR	#RR	%RR
NJ	21,046	95	0.451	83	0.394
MN	63,882	211	0.330	181	0.283
Total	84,928	306	0.360	264	0.311

SP422

Prevalence of Malaria in Blood Donors from a Tertiary Care centre in North India: A 5-year Retrospective Study

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Background/Case Studies: Transfusion Transmitted malaria is a major concern in endemic countries. In India, the Drugs and Cosmetic Act, 1940 mandates the testing of all blood donations for HIV, HbsAg, HCV, malaria and syphilis. The present study was undertaken to assess the prevalence of malaria among replacement and voluntary blood donors from our centre. **Study Design/Methods**: Being an endemic country for malaria, all blood donors with history of malaria in the past 3 months or history of recent fever, were deferred according to the national guidelines. Records of all eligible donors, who donated at our centre in the year 2011-15, were retrospectively retrieved and analysed for prevalence of malaria. Screening for malaria was done by WHO approved immunochromatographic rapid diagnostic test (Malascan®) for malarial antigen and confirmed by thick and thin blood smear microscopy. **Results/Findings**: A total of 1, 08, 184 blood donors donated at our centre during the period 2011-2015. Four volunteer donors of 3,539 (0.11%) and 22 replacement donors of 1, 04, 645 (0.021%) were tested positive for malarial antigen of which 18 and 8 were confirmed to be P *falciparum* and P. *vivax* respectively, by slide microscopy. The overall prevalence of malarial antigen in blood donors, from our region is 0.024%. **Conclusion**: From the results, it can be concluded that malarial antigen testing should be continued in addition to extensive donor selection for prevention of transfusion transmitted malaria in endemic regions.

SP423

Performance of a New Automated Assay for Syphilis

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Background/Case Studies: Blood donations are commonly screened for Syphilis in order to detect the presence of antibodies to the bacterium *Treponema pallidum*. In addition, continued pressures on laboratory operations demand that assays perform on platforms capable of increased walk away time and enhanced automation in areas of reagent management, retest options, and commodity/waste management. In response to the need for increased specificity for Syphilis screening assays, an improved automated prototype assay for the detection of antibodies to *T. pallidum* was evaluated. **Study Design/Methods**: The performance of a new prototype automated chemiluminescence immunoassay for the detection of antibodies to the bacterium *T. pallidum* was evaluated on a next generation automated platform.

Precision was assessed over 5 days evaluating positive samples. Sensitivity was evaluated on 140 known positive samples. Specificity was evaluated on samples obtained from 1819 blood donors and 200 diagnostic specimens. **Results/Findings**: Precision was less than 10% CV for positive samples over 5 days. Overall clinical sensitivity was 100% on 140 known Syphilis positive samples. The unresolved specificity was 99.92% (2559/2561). Two initial reactive samples were detected. Both samples were repeat reactive. The repeat reactive rate on blood donor samples, excluding confirmed positive samples, was 0.08% (2/2561). Resolved specificity on 200 diagnostic specimens was 100% (200/200). **Conclusion**: These results indicate that the new automated prototype Syphilis assay provided acceptable performance in precision, specificity and sensitivity. Sensitivity and specificity were comparable to the comparator assay.

SP424

Evaluation of the ASI Evolution™ Automated Syphilis Analyzer

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Background/Case Studies: CDC recommends syphilis serologic screening with a nontreponemal test, such as the rapid plasma reagin (RPR) to identify persons with possible untreated infection[1]. The RPR test is dependent on good procedural technique with adequate lighting and visual acuity to interpret the presence of flocculation. The RPR test is subject to a lack of consistency and standardization between personnel interpreting results. To bring standardization and consistency to the interpretation of the RPR test, Arlington Scientific, Inc. (ASI) has developed the fully automated ASI Evolution that uses a CCD camera and mathematical algorithms to analyze the test well images and differentiate between flocculation and non-flocculation. 1.CDC, 2011. "Discordant Results from Reverse Sequence Syphilis Screening - Five Laboratories, Untied States, 2006-2010", Morbidity and Mortality Weekly, 60(05);133-137. **Study Design/Methods**: The interpretation of 197 serum specimens using the ASI Evolution were evaluated with the results by visual means.
The testing requirements were as follows:

1. All samples were qualitatively tested manually using the procedure in the ASI RPR Card Test for Syphilis package insert.
2. All samples were qualitatively tested using the ASI Evolution automated syphilis analyzer.
3. The results of the two methods were evaluated for agreement.

Results/Findings: A total of 197 serum specimens were evaluated to determine reactivity. Of the 197 serum specimens, 150 were reactive and 47 serum specimens were nonreactive visually. The ASI Evolution identified 149 of the 150 reactive serum specimens as reactive and 47 of the 47 nonreactive serum specimens as nonreactive (Table 1). A sensitivity of 99.3% and a specificity of 100% were determined. The reactive samples ranged in reactivity from minimal 1:1 titers to 1:64 titers. **Conclusion**: The data shows that the ASI Evolution gives an objective and standardized interpretation of the test results with a high degree of accuracy.

TABLE. ASI Evolution Digital Results

ASI Evolution Digital Results			
		Reactive	Nonreactive
Visual Results	Reactive	149	1
	Nonreactive	0	47

SP425

Evaluation of a Semi-automated Test System in the Detection of Rapid Plasma Reagin for Syphilis in Source Plasma Donations

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Background/Case Studies: The Rapid Plasma Reagin (RPR) Card Test for syphilis (SYP) is a nontreponemal flocculation test for the detection of reagin antibodies: a screening test for serological evidence of SYP. This test required a manual visual (VIS) result interpretation. Recently, a Semi-Automated Test (SAT) was introduced for plasma/blood donor screening. Supplemental testing with treponemal-based CAPTIA Syphilis (*T. Pallidum*)-G EIA for the detection of IgG antibodies was performed on available samples. The purpose of this study was to determine the frequency of SAT reactive (Rx) to SYP IgG positive donations. Also evaluated were a subset of the SAT results between two laboratories and SAT to VIS result interpretations. **Study Design/Methods**: Source plasma donations were evaluated using FDA licensed assays. For the subset study, SAT Rx samples (SAT-1) were then retested by an independent laboratory using SAT (SAT-2) and VIS methods. The study evaluated the SAT capability to identify Rx donations compared to VIS methods. **Results/Findings**: From January 6, to April 18, 2016: 134,607 Source Plasma (SP) donations were tested with 0.32% (433/134607) being RPR Rx. Of the 433 RPR Rx donations, 310 were available for supplemental (CAPTIA) testing of which 54% (167/310) were IgG positive. Within the 433 donations, 106 Rx donations (a subset) were re-tested. Within SAT (1 and 2): 92/106 (86.8%) donations were Rx concordant; 14/106 (13.2%) were discordant (Rx/NR). The comparison of SAT-2 to VIS: 85/106 (80.2%) concordant Rx; 10/106 (9.4%) concordant NR. Discordant results were: 7/106 (6.6%) SAT Rx/VIS NR and 4/106 (3.8%) SAT NR/VIS Rx. **Conclusion**: Within Source Plasma donors, there is a low incidence of RPR positive donations (0.32%) with an even lower number of SYP IgG positive donations 167/134,484 (0.12%). SAT concordance between two laboratories using identical samples is 86.8% and SAT concordance with VIS methods is 89.6%. Disparity between SAT results within two laboratories and between SAT and VIS results would indicate the need for further evaluation.

TABLE. Syphilis RPR Rx Donations SAT/Visual Read

SAT- 2	Visual	Total	% of Total
Rx	Rx	85	80.2%
NR	NR	10	9.4%
Rx	NR	7	6.6%
NR	Rx	4	3.8%

SP426

Reducing Transfusion-transmitted Cytomegalovirus Infection by Providing Leukocyte-reduced Blood Products Donated by Low-risk Donors

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Background/Case Studies: The high prevalence of cytomegalovirus (CMV) in the United States and around the world poses a serious challenge in manufacturing CMV-negative blood products. This is compounded by the findings of a recently published study showing the calculated risk of transfusion-transmitted CMV (TT-CMV) was up to 6.5% overall in transfused recipients and up to 0.23% via serologically untested leukoreduced cellular products. The current method of serologic testing for CMV does not completely eliminate TT-CMV due to the long window period of primary CMV infection (six to eight weeks) and risk of acquiring CMV between donations. A recent survey showed that 65% of AABB physician members consider CMV-seronegative and leukoreduced products equally effective in preventing TT-CMV; however, there is no consensus throughout the transfusion medicine community on the preferred approach to prevent TT-CMV. In addition, it is well established that CMV infection exhibits significant demographic and geographic variability. Therefore, our aim is to improve blood product safety by identifying low-risk CMV donors utilizing demographic data. **Study Design/Methods**: Using data from the National Health and Nutrition Examination Survey we studied cohorts who would be suitable blood donors. For each cohort we determined the seroprevalence of CMV and compared it to the CMV seroprevalence for all cohorts combined using Welch's *t*-test. We then determined an adjusted cost of screening for CMV-negative blood products for each cohort relative to the baseline cost of screening for these units from all cohorts combined. **Results/Findings**: The overall weighted mean CMV seroprevalence for all cohorts combined is 62.3%. Significant risk factors that have been identified in these cohorts include age, gender, and ethnicity. The lowest CMV seroprevalence is 32.6% as found in 20-29 year-old non-Hispanic White males, which is nearly 50% lower than that of the

general population. In turn, the projected reduction in the cost of finding CMV-negative units from a low-risk CMV cohort is estimated to be 34% compared to current screening approaches. **Conclusion**: We identified cohorts of blood donors with low seroprevalence for CMV based on demographic characteristics. Based on our model we predict that we can further reduce TT-CMV risk by as much as 50% with the combination of sourcing blood from these cohorts along with leukoreduction. This will provide a product comparable to the risk level of using CMV-seronegative blood products without additional testing. Alternatively, testing blood products donated by these cohorts can result in savings as much as 34% in the cost of obtaining CMV-negative units.

SP427

Prevalence of Infectious Disease Markers (IDMs) in Source Plasma and Whole-Blood Donations

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Background/Case Studies: Source plasma (SP) provides therapeutic treatment for individuals with rare and chronic diseases as well as treatment for trauma, burns and shock. Whole blood (WB) donations are used for transfusions during surgery or other medical treatment. The industry is dependent on a pool of donors in the manufacturing of these critical components. The accurate assessment of IDMs in source plasma and whole blood donors is critical to prevent the transmission of infectious agents through infusion and transfusion. Although not comprehensive for all plasma and blood donor screening, the tests included were antibodies to Human immunodeficiency virus types 1 and 2 (HIV); Hepatitis C virus (HCV); and Hepatitis B surface antigen (HBsAg). The goal of the study was to evaluate the presence of antibodies in the two different donor populations for IDMs. **Study Design/Methods**: During the period August 2015-February 2016, a total of 3,241,980 donations (2,797,492 SP; 444,488 WB) were evaluated using FDA licensed assays. Repeat reactive (RR) samples were screened using corresponding confirmatory assays (HIV, HBsAg) to define a true positive (POS); RR results were used for HCV. The incidence of infectious diseases was compared between SP and WB donations: first time (1^{st}) vs. repeat (RPT) donors. Analyses were performed using SAS 9.4. **Results/Findings**: For IDM true positive donations there was a statistical difference between WB 402/444,488 (0.09%); and SP 3014/2,797,492 (0.11%), $p=0.001$. When evaluating confirmed IDMs comparing WB 1^{st} vs RPT donations: HCV (94.2% vs 75%) and HBsAg (73.9% vs 20.8%), 1^{st} donations have significantly higher incidence, $p<0.0001$. However, there is no difference between WB 1st vs RPT donations with HIV (3.94% vs 2.08%), $p=0.3305$. For SP 1^{st} vs RPT donations: HIV (36% vs 22.4%) and HCV (98.7% vs 87.8%) show significantly higher rates, $p<0.0001$; however, HBsAg rates were similar (85.2% vs 88%), $p=0.5221$. For WB vs SP in 1^{st} donations: SP has significantly higher incidence with HIV (3.94% vs 36%) and HCV (94.2% vs 98.7%), $p<0.0001$; however, HBsAg shows no difference (73.9% vs 85.2%), $p=0.1189$. With RPT donation, there was a lower incidence of IDMs in WB vs SP: HCV (75% vs 87.8%), HBsAg (20.8% vs 88%), HIV (2.08% vs 22.4%), with HIV having the lowest rate overall. **Conclusion**: For IDMs within whole blood and source plasma donations there was an overall low incidence of RR (HCV) and POS (HIV, HBsAg) donations; 0.09% and 0.11% respectively. For first time donors, there is no difference between source plasma and whole blood donors when evaluating the incidence of HBsAg infectious disease; however, HIV and HCV are more often found with SP donors. Lastly, the lower incidence of IDMS in RPT compared to 1^{st} donations reflects the importance of donor deferral.

SP428

Prevalence of Transfusion-transmissible Infections Among Blood Donors and Strategy on Direct Laboratory Testing Cost of Blood Screening at the Ethiopian National Blood Bank Center, Addis Ababa, Ethiopia

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Background/Case Studies: Blood and its components are life saving; however, they are also associated with life threatening hazards such as transfusion transmitted infections (TTIs). Hepatitis B virus (HBV), Hepatitis C virus (HCV), human immunodeficiency virus (HIV) and syphilis are the most serious infections transmitted during blood transfusion. Serious of blood shortages especially in developing countries and reliance on unsafe family replacement or paid donors also contribute to an increased risk of TTIs. Knowing the current prevalence of TTIs among blood donors will be crucial in donor program strategy development and cost effective alternative strategies of blood screening are highly required especially in resource limited setup. **Study Design/Methods**: A retrospective analysis of blood donors' record covering the period from July 1, 2008 to July 30, 2013 was conducted. The data was collected from the Nation al Blood Bank (NBB) center Donor Data base. In addition, direct laboratory costs of parallel versus sequential strategy of blood screening were compared using the current price of the laboratory costs. Data was first exported to SPSS version 16 software for analysis. Data analysis was performed using scores and odds ratio using same software to look for an association between dependent and independent variables. P values less than 0.05 were considered significant. **Results/Findings**: A total of 173, 207 consecutive blood donors were screened between 2008 and 2013. The overall seroprevalence rate of HBV, HIV, HCV and syphilis of blood donors was 5.0%, 1.6%, 1.4% and 0.1% respectively. The HIV-HBV co-infection was higher among blood donors 135(41.79%) followed by HBV-HCV co-infection whish accounts about 103(31.89%). Significantly increased seroprevalence of TTIs was observed among Family replacement donors, factory workers, daily labors and the age group of 26-35. In this study the difference in cost between the current in use strategy (parallel) versus the newly proposed designed sequential testing algorism was 746,773.9 Ethiopian Birr. **Conclusion**: A significant percentage of the blood donors harbor TTIs. The NBB center should work on voluntary blood donor mobilization and develop culture of voluntarism. The direct laboratory cost analysis using current in use strategy (parallel) was higher than the newly designed sequential testing algorithm. Thus, the new strategy can be implemented to make screening of TTIs cost effective in NBB center.

SP429

The Blood Donors' Infectious Marker Screening and Blood Safety in Guangzhou,China

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Background/Case Studies: Background and Aims: In China,the National Regulations on Blood require double test every blood donor's transfusion-transmitted infectious agents' markers by two different regents and technicians to insure the donated blood safety. The double negative test results means the donor is qualified.Double test positive donor (any transfusion-transmitted infectious agents markers) must be eliminated and permanently shieled(not allowed to donate blood). **Study Design/Methods: Methods**: Totally 300310 blood-donors in our blood center were studied From Jan 1 to Dec 31,2015, The test subjects include blood transmitted-infectious agents' markers: HBsAg, anti-HCV, anti-HIV and anti-TP(Treponema pallidum) by ELISA and NAT,and ALT(alanine aminotransferase) by biochemical test, the ALT trigger standard is 50 u(<50U means donor qualified). chi-square x^2 Statistical analysis was performed, $p<0.05$ was considered to be significantly difference. **Results/Findings: Results**: For the 300310 tested blood-donors, the positive tests ratio(number) was 0.884%(2655) for HBsAg,0.328% (985)for anti-HCV, 0.117%(352) for anti-HIV, 0.373%(1120) for anti-TP, and 0.975%(2929) for ALT respectively. The overall unqualified donors ratio was 2.62%. Here especially emphasized that the anti-HIV positive donor's number has greatly increased comparing to the last years(data not showed here). The very high unqualified donors ratio for ALT test is because many non-pathological factors can cause ALT elevation, such as over-working,exercise, drinking etc.,so we suggested the donors taking care of such factors before donating blood.And the HBsAg infected persons are very popular in Southern China,so we do rapid preliminary screening test (RPST) before the blood donation to decrease the positive donations. **Conclusion: Conclusions**: By double testing the blood donors' blood transmitted agents' markers, we can make sure the blood and blood transfusion safety, and we have tracked the blood transfusioned patients for the last years and no blood transmitted disease case happened.

SP430

Pre-donation Counselling – Are We Doing Enough?

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Background/Case Studies: Pre-donation counselling is aimed to prevent the donation of blood by individuals who might be at risk for transfusion-

transmitted infections (TTI). Despite pre-donation counselling and notification of abnormal infectious disease screening results, some donors donate blood to seek their test results. We share our data of blood donation by donors who did not disclose their risk factors during pre-donation counselling with the intention of getting test results. **Study Design/Methods**: A retrospective study was carried out in a hospital-based blood bank in a developing country. Donor notification and counselling data of donors who were reactive for HIV, Hepatitis B, Hepatitis C and Syphilis was reviewed over a period of six months from October 2015 to March 2016. Donors who gave their consent for notification were informed about their test results through letters and telephone calls. **Results/Findings**: Out of 9529 donors who donated blood during this period, 98 donors (1.03%) were reactive for various transfusion-transmitted infections. We notified all 98 donors of their test results as all had given consent for notification in the donor questionnaire. Out of 98 reactive donors, 29 (29.6%) reported for post-donation counselling. During post donation revelations, we encountered 5 donors (17.24%) who were already aware of their test results. Two donors were on treatment for Hepatitis C and one for Hepatitis B. They donated blood again to check their reactivity status inspite of being advised not to donate at previous counselling sessions. One donor had co-infection of Hepatitis C and HIV and donated blood in order to get himself tested as he was practicing high-risk behaviour. Another young donor reactive for Hepatitis B disclosed at the time of post donation counselling that he had received a call from previous donation, but did not go for further testing and donated again to know his test results. **Conclusion**: Prospective blood donors should understand the importance of refraining from blood donation if they are at risk for any infectious disease. It is prudent to provide privacy and ensure confidentiality during pre-donation counselling to explore the motivation for blood donation. In order to increase blood recipient safety, there is need to strengthen donor counselling through information and education programs for potential donors and sensitization of camp organizers.

SP431

Compatibility of the INTERCEPT® Blood System for Red Blood Cells (RBCs) in Non-leukodepleted RBCs in SAG-M and AS-5

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Background/Case Studies: The INTERCEPT Blood System for Red Blood Cells (RBC) inactivates pathogens and leukocytes in RBC components for transfusion using amustaline to crosslink nucleic acids, preventing replication of contaminating pathogens and leukocytes. Phase 3 clinical studies evaluating transfusion safety and efficacy of leukocyte depleted INTERCEPT RBCs, are ongoing in Europe. RBC additive solutions (AS) and leukocyte reduction requirements vary with geography; this study was conducted to evaluate the quality of stored treated RBCs produced from non-leukocyte depleted RBC suspended in SAG-M or AS-5. **Study Design/Methods**: Whole blood (WB) in CPD (n=12) was separated on the day (D) of donation. For each replicate, 2 ABO matched RBC concentrates were pooled and divided in two; one half was suspended in AS-5 and the other in SAG-M. RBCs were held overnight at 1-6°C and treated with the INTERCEPT process on D1; GSH and RBCs were added to a processing solution followed by amustaline addition (20mM GSH/0.2mM Amustaline, with a 280mL RBC input). After an 18h RT hold, the RBC concentrates were centrifuged and the treatment solution was replaced with SAG-M. RBCs were stored at 1-6°C for over 6 weeks of storage (**Table 1**). **Results/Findings**: Treated RBCs contained average Hb of 51g with Hb recovery of 98 ± 1%. On D2 all indices, except Na^+, were similar regardless of AS; Na^+ was higher for SAG-M inputs. Over storage hemolysis, K^+ and lactate increased, whereas pH, ATP, Na^+ and glucose decreased. On D35 the pH and ATP were statistically significantly higher in AS-5 treated RBCs and all other indices were equivalent. All units had ATP levels >2 μM/gHb and hemolysis <1.0% on D35. **Conclusion**: The INTERCEPT Blood System for RBCs is compatible with non-leukodepleted RBC concentrates in AS-5 and SAG-M. All measured *in vitro* parameters of treated RBCs indicate suitability for clinical transfusion. INTERCEPT Blood System for Red Blood Cells is Not Approved for Clinical Use.

TABLE. RBC in-vitro function (mean±SD; n=6)

	Day 2		Day 35	
	SAG-M input	AS-5 input	SAG-M input	AS-5 input
Hemoglobin (Hb) (g/unit)	51±1	51±3	not measured	
Hematocrit (%)	67±1	67±1	68±2	69±1
Percent Hemolysis	0±0	0±0	0.1±0.0	0.1±0.1
pH at 37°C	6.75±0.02	6.75±0.02	6.24±0.02	6.26±0.01*
Total ATP (μM/gHb)	6.0±1.5	6.8±0.1	4.0±0.5	4.2±0.4*
Extracellular Lactate (mM)	5.0±0.5	5.1±0.5	23.0±1.6	22.7±1.2
Extracellular Glucose (mM)	26.6±1.1	25.3±0.9	17.3±0.7	17.1±0.9
Extracellular sodium (Na^+;mM)	148±1	146±0*	107±5	104±2
Extracellular potassium (K^+;mM)	0.7±01	0.7±0.1	43.1±2.9	43.3±1.7

* p<0.05, paired t-test

SP432

Evaluation of the Acute Toxicity of Red Blood Cells Derived from Riboflavin and UV Light-treated Whole Blood in a Canine Red Blood Cell Exchange Model

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Background/Case Studies: A medical device that uses riboflavin and UV light (R+UV) to reduce the potential infectious pathogen load and to inactivate WBC in blood products intended for transfusion is in development. Riboflavin, also known as vitamin B2, has a safe toxicological profile, and extensive in vitro and in vivo testing conducted thus far with R+UV treated blood products has demonstrated no adverse toxicological effects. To demonstrate additional safety, a canine RBC exchange (RBCX) model was used to assess tolerance to the maximum feasible dose of leukoreduced RBC (LR-RBC) derived from R+UV treated WB. Evaluation included monitoring of RBC function in addition to standard toxicology endpoints (clinical observations, hematology, clinical chemistry, urinalysis, necropsy, and histopathology). **Study Design/Methods**: Canine WB was collected in CPD anticoagulant in 450 mL collection sets to produce 8 R+UV Test and 8 Control units. Test units consisted of LR-RBC separated from WB treated with Riboflavin and 80 J/mL_{RBC} UV light. Untreated canine LR-RBC units served as the Controls. All units were stored in AS-3 at 4°C until infusion on Day 21 for the Test units and Day 18 - 21 for the Control units. To complete 1 total blood volume (TBV) RBCX, each subject underwent 4 cycles in which 25% of TBV was withdrawn at 20 mL/kg and subsequently replaced with allogeneic, type and cross matched RBC (10 mL/kg) and autologous plasma (10 mL/kg). Subjects were monitored for cardiac and respiratory parameters during the procedure and for standard toxicological endpoints over a 7-day survival period. **Results/Findings**: All RBCX procedures were completed successfully. No adverse clinical signs were seen in the Control group, while mild reactions (flushing, swelling) that resolved with limited intervention were seen in the Test group. Oxygenation levels as measured by arterial blood gases did not significantly differ between groups after breathing room air for 20 minutes following the procedure. Increases in reticulocyte counts (both absolute counts and % reticulocytes) on Day 6 trended higher in the Test group relative to the Control group, but no other test article-related findings were reported for standard toxicology endpoints. The few noted findings were independent of group, were sporadic, and were considered to be due to biologic variation, unrelated to the test article. **Conclusion**: Test and Control LR-RBCs were well tolerated and functioned as intended in this study. No toxicologically significant differences were observed between the Test and Control groups. Based upon the safety and efficacy demonstrated in preclinical testing, RBC derived from R+UV treated WB will soon be evaluated in a pivotal clinical trial in the United States.

SP433

Riboflavin and UV Light-treated Red Blood Cells Washed on Day 7 or Day 21 of Storage using the COBE 2991 Cell Processor

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Background/Case Studies: A technology that utilizes riboflavin and UV light (R+UV) to reduce the infectious pathogen load and inactivate WBC in whole blood products (WB) is currently under development. After treatment with R+UV, the WB product can be further processed into leukoreduced RBC (LR-RBC) intended for transfusion. The use of washed, LR-RBC is standard practice for some patient populations, e.g., those that are chronically transfused. The cell quality of RBC derived from R+UV light-treated and untreated WB units washed after 7 days or 21 days of storage was investigated. **Study Design/Methods**: Six standard 450 mL WB units collected in CPD were treated with R+UV and 6 units were left untreated (UT).

TABLE.

	Timepoint	% Hemolysis	p-value	pH (22°C)	p-value	K+ (mmol/L)	p-value
	D7 Pre-Wash	0.13 ± 0.02	0.235	6.85 ± 0.04	0.670	53.4 ± 7.7	<0.001*
	D7 2-4 Hr	0.21 ± 0.02	0.586	6.78 ± 0.04	0.356	2.6 ± 0.3	0.870
RB+UV	D7 24 Hr	0.31 ± 0.03	0.733	6.75 ± 0.04	0.508	13.3 ± 1.0	<0.001*
	D21 Pre-Wash	0.23 ± 0.03	0.004*	6.73 ± 0.02	0.755	69.3 ± 2.8	<0.001*
	D21 2-4 Hr	0.33 ± 0.06	0.031*	6.64 ± 0.02	0.999	3.9 ± 0.4	<0.001*
	D21 24 Hr	0.69 ± 0.24	0.014*	6.63 ± 0.02	0.979	10.6 ± 0.8	<0.001*
	D7 Pre-Wash	0.09 ± 0.02	N/A	6.88 ± 0.02	N/A	15.9 ± 0.7	N/A
	D7 2-4 Hr	0.17 ± 0.03	N/A	6.83 ± 0.01	N/A	2.4 ± 0.2	N/A
UT	D7 24 Hr	0.21 ± 0.03	N/A	6.79 ± 0.01	N/A	6.1 ± 0.4	N/A
	D21 Pre-Wash	0.13 ± 0.03	N/A	6.71 ± 0.04	N/A	38.5 ± 3.6	N/A
	D21 2-4 Hr	0.22 ± 0.02	N/A	6.64 ± 0.04	N/A	2.3 ± 0.1	N/A
	D21 24 Hr	0.28 ± 0.02	N/A	6.62 ± 0.04	N/A	4.9 ± 0.2	N/A

*Statistically significant p-value compared to Untreated Control using one-way ANOVA.

All units were processed into LR-RBC in AS-3 additive solution and subsequently stored for 7 or 21 days at 4°C. Three of the 6 R+UV and 3 of the UT units were washed in 0.9% saline using the COBE 2991 cell processor (2L wash protocol) on day (D)7 and the other half were washed on D21 of storage. The units were held in saline for 24 hours, with sampling pre-wash, 2-4 hours post-wash and 24 hours post-wash for measurement of % hemolysis, extracellular potassium (K^+) and pH. **Results/Findings**: In both R+UV and UT groups the % hemolysis increased between pre-wash and the 2-4 hours and 24 hours post-wash time points with the 24 hour post-wash showing the highest % hemolysis (Table 1). All study units reported less than 1% hemolysis. In both R+UV and UT groups the extracellular K^+ was reduced to physiologic levels for the 2-4 hour time point, but increased between the 2-4 hr and 24 hour post-wash time points. The pH at 22°C remained above 6.2 for both groups at all time points. **Conclusion**: Stored, washed R+UV treated products are acceptable for transfusion for up to 24 hours post-wash per AABB standards for an open system. Potassium concentrations were reduced to levels of no clinical concern. It is preferable that washed R+UV treated cells be transfused as soon as possible after washing.

SP434

Platelet Recovery and Survival After Whole Blood Treated with Mirasol Pathogen Reduction

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Background/Case Studies: Pathogen reduction of whole blood (WB) may reduce the risks related to transfusion and reduce costs compared to component-specific methods provided the method is efficient for its purpose and does not significantly reduce the quality of the treated WB. The Mirasol© Pathogen Reduction Technology (PRT) using riboflavin and UV light (Terumo BCT, Lakewood, USA) is a possible candidate and in this pilot study we investigated recovery and survival of platelets derived from WB stored for 24 hours after treatment. **Study Design/Methods**: 490 mL blood was collected from 13 volunteer donors and after 1 hour rest the blood was treated by Mirasol pathogen reduction procedure. 35 mL of a standardized riboflavin solution was mixed with the WB unit and then exposed to UV light for approximately 1 hour. The treated WB was stored for 24 ± 1 hour at 22 ± 2°C. WB from the storage bag (50mL) was removed to produce a platelet pellet for radiolabeling with ^{51}Cr or ^{111}In. Simultaneously, a fresh 43 mL blood sample was drawn from the donors to isolate fresh platelets, which were radiolabeled with ^{111}In or ^{51}Cr. Both fresh and stored platelets were reinfused to the donors and post-infusion samples were collected at 1.5 hours, 24 hours, 48 hours, 72 hours, 6 ± 1 days, 7 ± 1 days and 9 or 10 days according to modified BEST radiolabeling protocol. The γ radiation dose was approximately 0.6 MBq for each isotope. Samples were analyzed in a gamma counter and the data were entered into the COST program to calculate platelet recovery and survival. **Results/Findings**: The Mirasol-treated, stored mean platelet recovery was 43.02 ± 9.64%, which was 82.9% of the untreated, fresh control. The one sided 95% lower confidence limit was 75.24%. The Mirasol-treated, stored mean platelet survival of 157.1 ± 24.8 hours (approximately 6.5 days) was 82% of the untreated, fresh control. The one sided 95% lower confidence limit was 77.6%. **Conclusion**: Risk of contracting infectious diseases is a serious threat associated with blood transfusion. The Mirasol PRT has proven to be efficient in reduction of pathogen load in many *in vitro* studies and also in a clinical study evaluation of malaria transmission. The method is simple to perform and the need for equipment is limited. The handling time is approximately 2 hours and it is an advantage that the method may be applied on whole blood. Our study demonstrates sustained good quality of the platelets stored for 24 hours as the FDA acceptance criteria of recovery (66.7% of stored platelets compared to fresh control) and survival (58% of stored platelets compared to fresh control) were well met. The maximum storage time cannot be extrapolated from this investigation. In conclusion, our study indicates that platelets treated and stored in whole blood for 24 hours after pathogen reduction have qualities suitable for transfusion.

SP435

Ten Years of Experience With a Pathogen-reduction Technique In Platelets and Low Levels of Adverse Events

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Background/Case Studies: Adverse events (AE) are frequent in platelet transfusions, especially suspended in 100% plasma. The use of additive solution and a lower amount of plasma reduces side effects. We have at our blood center used platelet additive solutions for roughly 30 years. The storage situation for platelets is sadly also good for the growth of pathogens like bacteria. Due to that a pathogen reductions technique (PRT) with the aid of Amotosalen and UVA light (INTERCEPT Cerus, Amersfoort, Netherlands) was introduced at our center in 2006. That technique is in routine use in many European blood centers since many years and is recently FDA approved. During the time before the introduction of PRT the level of AE's was 1.1-1.5% annually according to our haemovigilance data. The goal of the study was to find out if the amount of AE's had changed. **Study Design/Methods**: With the aid of our computer system all platelet transfusions were detected and every patient with an AE was further analyzed by checking their charts for the circumstances around the time for the AE. **Results/Findings**: 26742 controlled transfusions were detected and a total of 54 AE's in 40 patients were found. The majority of platelets were used by hematological/oncological patients with thoracic patients coming second. The AE's were divided into allergic reactions 13, chills and fever 10, TRALI/TACO 1 and unknown 8. After checking every patient's chart that had a reported AE, 8 were exclude due to the fact that the side effect was unlikely connected to the transfusion or due to HLA antibodies and the transfusion was not HLA matched. That gives a frequency of less than 0.2% (0.17%) **Conclusion**: By adding PRT we have reduced AE from levels above 1% to less than 0.2% and at the same time no transfusion transmitted infections. The overall consumption of platelets have increased but the proportion of hematological/oncological patients has declined. The hematological patients use about the same in absolute numbers but elective surgery and especially trauma patients get so much more platelets now due to change in policy. That is an indication that the PRT platelets are doing their job but there are many other studies showing that and this was not the objective of this study.

SP436

Biological Response Modifiers in Whole-blood Products Treated with Riboflavin and Ultraviolet Light

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Background/Case Studies: A riboflavin and ultraviolet light pathogen reduction (PR) system for WB has the potential to protect the recipient against transfusion-transmitted infections and to prevent TA-GvHD by inactivating residual leukocytes. However, alterations to the RBC product due to PR may include the presence of activated platelets and inactivated leukocytes. Proinflammatory biological response modifiers (BRM) may be linked to leukocyte necrosis and/or activated platelets; the effect of PR on such BRM has yet to be characterized. **Study Design/Methods**: A total of 16 products were evaluated. Four groups (N=4) were based upon leukoreduction (LR) or non-leukoreduction (NLR) and PR or untreated (UT) status. Fresh WB was PR treated followed by packing and LR, as appropriate to group assignment. Products were stored at 2-6°C in AS-3 for 21 days (D). Cell quality (CQ) and supernatant BRM concentrations were evaluated on D0-collect (COL), D0-RBC, and on D7, 14 and 21. IL-1β, MIP-1α, RANTES, IL-2, −4, −5, −6, −8 and −13 were analyzed by Luminex MagPix. **Results/Findings**: All products met AABB CQ guidelines throughout storage. IL-2, −4, −5, −6 and −13 were at the LOD for all products at all time points. No significant differences (SD) between PR and UT were observed for IL-1β for the LR or NLR groups (Table 1). SD were observed in the LR and NLR groups on D0-RBC for IL-8, MIP-1α and RANTES and on D7 for RANTES. **Conclusion**: Activated platelets and inactivated leukocytes due to PR treatment demonstrate minimal effect on cytokines when products are stored refrigerated up to D21. In some cases, SD between PR and UT were observed at D0-RBC, however, by D14 of storage they had resolved. Additional characterization is required.

SP437

Acute Infection Following Transfusion among U.S. Elderly Medicare Beneficiaries, as Recorded by Large Administrative Databases during 2012-2014

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Background/Case Studies: Acute infections following transfusion (AIFT) are serious transfusion-related complications which can result in fever, chills, prolonged hospitalizations, sepsis, septic shock, and death. The elderly are likely to be at a greater risk for AIFT and its complications because of underlying comorbidities, high blood utilization, and declining immunity. The study objective was to assess AIFT occurrence and potential risk factors among inpatient elderly Medicare beneficiaries, ages 65 and older, during 2012-2014. **Study Design/Methods**: This retrospective claims-based study utilized large Medicare databases for the calendar years 2012-2014 in coordination with Centers for Medicare & Medicaid Services. Transfusions of blood and blood components were identified by recorded ICD-9-CM procedure and revenue center codes, and AIFT was ascertained via the diagnosis code. Our study evaluated AIFT rates (per 100,000 inpatient transfusion stays) among the elderly, overall and by calendar year, age, sex, race, blood components and number of units transfused. Fisher's exact tests were performed to compare AIFT rates, and Cochran-Armitage tests were used to ascertain AIFT occurrence trends by calendar year, age, and transfusion volume. **Results/Findings**: Among 6,050,040 inpatient transfusion stays for elderly beneficiaries during 2012-2014 study period, 138 had an AIFT diagnosis code recorded, for an overall rate of 2.3 per 100,000 stays. AIFT rates (per 100,000) varied by blood components, number of units transfused, age, and sex. AIFT rates by blood component groups were as follows: 1.9 for RBCs only, 0.9 for plasma only, 10.5 for platelets only, 3.4 for RBCs and plasma, 14.9 for RBCs and platelets, and 2.8 for RBCs, plasma and platelets. AIFT rates for age categories 65-69, 70-74, 75-79, 80-84, 85 and over were 2.5, 2.6, 2.5, 2.2, and 1.7, respectively (p=0.128). Females and males had AIFT rates of 1.9 and 2.8, respectively (p=0.032). AIFT rates by number of units transfused were: 1.6 for 1 unit, 1.9 for 2-4 units, 3.4 for 5-9 units, and 5.1 for >9 units (p<0.001). **Conclusion**: Our population-based study is the largest investigation on AIFT occurrence and potential risk factors, which shows substantially higher AIFT rates with platelet transfusions and significantly elevated AIFT risk with greater number of blood units transfused. The study suggests increased AIFT risk in males and a potential effect of advancing age on AIFT occurrence, which needs further investigation. The study was based on claims data, and thus limitations include the potential underrecording or misrecording of transfusion procedures, units, and diagnosis codes, as well as a lack of clinical details to validate AIFT diagnoses.

SP438

Inactivation of *Babesia microti* with Amustaline/GSH in Red Blood Cells

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Background/Case Studies: Babesia microti (Bm), responsible for human babesiosis, is a tick-borne intra-erythrocytic parasite endemic to portions of the northeastern and upper midwestern US. The high number of transfusion-transmitted (TT) babesiosis cases (n > 160) makes Bm the most frequently TT-parasite in the US, almost exclusively by red blood cells (RBCs). Therefore, evaluation of methods to inactivate Bm in RBCs is

TABLE. BRM Concentration (pg/mL); mean±STD

		LR					NLR				
		COL	D0 RBC	D7	D14	D21	COL	D0 RBC	D7	D14	D21
IL-1β	PR	23.5 ± 25.1	17.7 ± 2.4	11.6 ± 5.9	11.3 ± 4.7	12.1 ± 5.2	15.2 ± 6.6	8.9 ± 1.1	9.4 ± 2.7	16.7 ± 0.6	17.2 ± 2.0
IL-1β	UT	22.3 ± 18.5	17.6 ± 3.0	13.5 ± 7.5	12.8 ± 6.8	11.1 ± 7.1	43.1 ± 32.2	28.7 ± 19.5	29.4 ± 17.1	36.4 ± 25.9	35.5 ± 24.8
IL-8	PR	12.2 ± 0.0	46.2 ± 7.8*	31.6 ± 8.3	30.8 ± 9.3	28.7 ± 8.1	12.2 ± 0.0	17.2 ± 5.2	21.9 ± 4.8	33.4 ± 3.2	41.4 ± 6.5
IL-8	UT	12.2 ± 0.0	32.5 ± 4.0*	25.1 ± 8.5	21.8 ± 8.5	17.5 ± 4.8	12.2 ± 0.0	15.7 ± 5.3	21.6 ± 1.9	24.5 ± 2.2	37.6 ± 8.5
MIP-1α	PR	45.8 ± 27.4	125.2 ± 4.4	103.8 ± 16.5	103.3 ± 13.6	103.6 ± 13.3	48.5 ± 12.8	85.1 ± 23.4*	104.1 ± 10.5	131.0 ± 1.8	130.7 ± 2.9
MIP-1α	UT	54.5 ± 29.0	121.2 ± 7.4	106.8 ± 18.1	107.1 ± 17.4	93.1 ± 13.4	61.6 ± 15.6	117.7 ± 11.1*	120.6 ± 5.2	131.6 ± 2.1	133.9 ± 2.9
RANTES	PR	586.5 ± 480.6	27219.7 ± 4215.1	11612.2 ± 11307.9	11893.8 ± 10342.0	12757.7 ± 9572.0	624.3 ± 191.1	2676.1 ± 1332.9*	4539.5 ± 1938.0*	10279.4 ± 1338.0	7140.2 ± 612.7
RANTES	UT	915.2 ± 437.9	19718.4 ± 6182.1	13266.4 ± 10795.4	15807.0 ± 13774.8	13341.1 ± 9498.5	835.2 ± 350.7	8055.6 ± 4353.5*	9386.9 ± 1862.1*	12070.6 ± 580.0	6627.9 ± 241.9

*Indicates SD between PR and UT; α=0.05.

critical. In this study we evaluate the inactivation of Bm with the INTERCEPT Blood System for RBCs prepared in Optisol (AS-5) additive solution. The INTERCEPT RBC system uses the small molecule amustaline that covalently crosslinks nucleic acids of leukocytes and contaminating pathogens, preventing their replication. The process includes addition of 200μM amustaline and 20mM glutathione (GSH) and an18-24h incubation at room temperature (RT). Although inactivation is complete after 3h, the additional incubation ensures complete active ingredient decomposition. A final centrifugation and exchange of the supernatant with an additive solution provides pathogen-reduced RBCs that are ready for transfusion. **Study Design/Methods**: The study was repeated 3 times. Single RBC units were spiked with Bm-infected hamster RBCs (RBCi) to a final concentration of 106 RBCi/ml and treated with amustaline/GSHper the manufacturer's IFU. A pre-treatment (Control) sample was collected before addition of amustaline, while post-treatment samples were collected at T=3h (Test). A post-exchange sample was also collected after a complete RT incubation. Selected dilutions of the Control samples to 10-6 were inoculated into hamsters (N=6, per dilution), while the Test and post-exchange samples were inoculated neat, or at 10-1 dilution. Dilutions of the Bm Stock were also inoculated. At 3 and 5 weeks post-inoculation, hamsters were evaluated for Bm infection by microscopic observation of blood smears and 50% infectivity titers (ID50) were determined. Log reduction was calculated as [Control] ID50 minus [Test] ID50. **Results/Findings**: Parasitemia was detected in hamsters injected with 10-5 dilution of the Control samples, while no parasites were detectable in the blood smears of any hamsters receiving neat Test samples. Inactivation levels achieved in the 3 replicates of the study were >4.8, >5.0 and >4.8 log/mL. Samples taken post-exchange confirmed the inactivation results. **Conclusion**: The parasite Bm was inactivated to the limit of detection in RBC after treatment with amustaline and GSH. Inactivation of >4.9 ± 0.1 log/mL of Bm was achieved in this animal infectivity model, where pathogen reduction treatment inhibited transmission of infection. The INTERCEPT Blood System for RBC is not approved for use.

SP439

Inactivation of *Babesia microti* with Amotosalen/UVA in Platelet Concentrates Manufactured in 100% Plasma

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Background/Case Studies: A photochemical treatment process utilizing amotosalen and low energy ultraviolet A (UVA) light to inactivate pathogens and residual leukocytes in plasma and platelet components (PC) is the first pathogen reduction system approved by the FDA in the US. Initially, the system was approved for PC manufactured in 65% platelets additive solution (PAS) and now has been extended to PC suspended in 100% plasma. The objective of this study was to evaluate the inactivation of the intraerythrocytic parasite *Babesia microti* in support of that approval extension and the data below have not been reviewed by the Agency. **Study Design/Methods**: For each experiment, a single apheresis PC unit in 100% plasma was spiked with B. microti-infected hamster red blood cells (RBCi) to a final concentration of 106 RBCi/mL. Contaminated PCs were dosed with amotosalen per the manufacturer's instructions and a control sample (pre-illumination) was taken. The control sample was serially diluted to 10-6 and appropriate dilutions injected into groups of 6 hamsters per dilution, 1.5 mL per hamster, to determine pre-illumination titers. The PC unit was then illuminated and a post-treatment sample was withdrawn and injected, neat and after 10-1 dilution, into groups of 6 hamsters per dilution. In addition, serial dilutions to 10-8 of the B.microti stock were also tested by hamster inoculation. Hamsters were evaluated for development of B.microti infection at 3 and 5 week post-inoculation by microscopic observation of blood smears and 50% infectivity titers (ID50) were determined. Log reduction was calculated as [pre illumination] ID50 minus [post illumination] ID50. **Results/Findings**: In the three performed replicates, positive smears were detected in hamsters injected with up to 10-5 dilution of the pre-illuminated samples, while no parasites were detectable in the blood smears of hamsters receiving post-illumination samples. Inactivation levels achieved in the three replicates were 4.6, 4.7 and 4.3 log/mL. **Conclusion**: Photochemical treatment with amotosalen and UVA of platelet components collected in 100% plasma inactivated an average of >4.5log/mL of B. microti in this animal infectivity model. These results are comparable to the ≥4.9 log/mL inactivation achieved in platelet components manufactured in 65% PAS.

TABLE. *Trypanosoma cruzi* Inactivation in Platelets Suspended in 100% Plasma

Replicate	Log Titers ($TCID_{50}$/mL) Pre-UVA	Post UVA	Log Reduction	Log Reduction per mL
1	5.8	<0.7	>5.1	>5.1
2	5.1	<0.7	>4.4	>4.4
3	5.0	<0.7	>4.3	>4.3
4	7.5	<0.7	>6.8	>6.8
5	7.8	<0.7	>7.1	>7.1
Mean ± SD	6.2 ± 1.3	<0.7 ± 0.0	>5.5 ± 1.3	>5.5 ± 1.3

SP440

Inactivation of *Trypanosoma cruzi* with Amotosalen/UVA in Platelet Concentrates Suspended in 100% Plasma

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Background/Case Studies: A photochemical treatment process utilizing amotosalen and low energy ultraviolet A (UVA) light, developed to inactivate pathogens and residual leukocytes in plasma and platelet components (PC), is the first pathogen reduction system approved by the FDA in the US. Initially, the system was approved for Amicus PC manufactured in 65% platelet additive solution (PAS-3) and now has been extended to include Trima PC suspended in 100% plasma. The objective of this study was to evaluate the inactivation of *Trypanosoma cruzi (Tc),* a species of hemoflagellate parasite that is endemic throughout Latin America and the causative agent of Chagas disease, and was submitted in support of that approval extension. **Study Design/Methods**: For each experiment, a single apheresis PC unit in 100% plasma was spiked with *Tc* to a final concentration of ~10^6 trypomastigotes/mL. *Tc* contaminated PCs were dosed with amotosalen and a control sample (pre-illumination) was taken. The control sample was serially diluted up to 10^{-7} times and appropriate dilutions inoculated in quintuplicate onto NIH-3T3 cell monolayers to determine pre-illumination 50% Tissue Culture Infective Dose (TCID50). The PC unit was then illuminated and a post-treatment sample was withdrawn. Test samples were diluted 10^{-1} and 10^{-2} and inoculated onto NIH-3T3 cells. Cultures were monitored for trypomastigote viability, indicated by motility, and scored positive or negative for survival and replication. Pathogen reduction was calculated as the difference between the $\log_{10}$ values of mean TCID50 in pre-UVA samples and mean TCID50 in the post-UVA samples. The limit of detection (LOD) was defined for the total volume plated to be <0.7 log (0.1 mL×20 wells). This resulted in an LOD (limit of detection) of <0.7 log/mL for the post-UVA samples. **Results/Findings**: Robust inactivation of *T. cruzi* in platelets collected in 100% plasma (5 replicates) was demonstrated, as shown in Table 1. **Conclusion**: Photochemical treatment with amotosalen and UVA of platelet components collected in 100% plasma inactivated >5.5 log/mL of *T. cruzi*. These results are comparable with the ≥5.3 log/mL inactivation achieved in platelet components manufactured in 65% PAS.

SP441

Inactivation of Chikungunya Virus with Amotosalen/UVA in Platelets Concentrates Suspended in 100% Plasma

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Background/Case Studies: A photochemical treatment process utilizing amotosalen and low energy ultraviolet A (UVA) light, developed to inactivate pathogens and residual leukocytes in plasma and platelet components (PC), is the first pathogen reduction system approved by the FDA in the US. Initially, the system was approved for Amicus PC manufactured in 65% platelets additive solution (PAS-3) and now it has been expanded to include Trima PC suspended in 100% plasma. The objective of this study was to evaluate the inactivation of Chikungunya virus (CHIKV) in support of that approval extension. CHIKV is an RNA virus of the genus *Alphavirus*, a group of arboviruses

TABLE. Chikungunya virus Inactivation in Platelets Suspended in 100% Plasma

Replicate	Log Titers (pfu/mL)		Log Reduction per mL
	Pre-UVA	Post- UVA	
1	6.6	<-0.3	>6.6
2	6.6	<-0.3	>6.6
3	6.4	<-0.3	>6.4
4	6.5	<-0.3	>6.5
Mean ±SD	6.5 ± 0.1	<-0.3 ± 0.0	>6.5 ± 0.1

in the family *Togaviridae*. CHIKV has been detected in human blood products from asymptomatic infected donors. It is capable of large outbreaks that may include significant human morbidity. **Study Design/Methods**: For each experiment, a single apheresis PC unit in 100% plasma was spiked with CHIKV to a final concentration of $\sim 10^{6.5}$ pfu/mL. CHIKV contaminated PCs were dosed with amotosalen and a control sample (pre-illumination) was taken. The control sample was serially diluted up to 10^{-7} and appropriate dilutions inoculated onto Vero76 cell monolayers to determine pre-illumination titer. The PC unit was then illuminated and a post-treatment sample was withdrawn. Test samples were diluted 10^{-1} through 10^{-3} and inoculated onto Vero76 cells. The plates were incubated for 5 days at 37°C, stained with crystal violet and the plaques enumerated. Log reduction was calculated as the difference between the mean titer in pre-UVA samples and the mean titer in the post-UVA samples. **Results/Findings**: Robust inactivation of CHIKV in platelets collected in 100% plasma (4 replicates) was demonstrated, as shown in Table 1. **Conclusion**: Photochemical treatment with amotosalen and UVA of platelet components collected in 100% plasma inactivated >6.5 log/mL of chikungunya virus. These results are comparable with the ≥5.7 log/mL inactivation achieved in platelet components manufactured in 65% PAS-3.

SP442

Performance of a New Automated Assay for Antibodies to Hepatitis C

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Background/Case Studies: Serological screening for antibodies to Hepatitis C virus (HCV) in conjunction with nucleic acid testing (NAT), are used worldwide to prevent transfusion transmitted HCV infections. While NAT provides improved sensitivity and detection of HCV in the pre-seroconversion window, serological testing provides continued detection of HCV in infected individuals and individuals with resolved infections with no detectable HCV RNA. Blood and plasmapheresis centers require very high throughput anti-HCV assays with high specificity and sensitivity to prevent unnecessary donor deferrals while maintaining the safety of the blood supply. In addition, continued pressures on laboratory operations demand that assays perform on platforms capable of increased walk away time and enhanced automation in areas of reagent management, retest options, and commodity/waste management. **Study Design/Methods**: The performance of a new prototype automated chemiluminescent immunoassay for the detection of antibodies to Hepatitis C was evaluated on a next generation automated platform and compared to an on-market assay. Precision was assessed over 5 days evaluating positive samples. Specificity was evaluated on 5094 blood donor samples and 200 hospital patient samples. Sensitivity was evaluated on 200 known positive samples and 10 commercially available seroconversion panels. **Results/Findings**: Precision was less than 10% CV for positive samples over 5 days. The overall resolved specificity in a blood donor population was 100.00% (5094/5094) with an initial reactive rate of 0.00%. For hospital patients, the resolved specificity was 98.94%. Overall clinical sensitivity was 100% on 200 known positive samples for anti-HCV. Seroconversion sensitivity was better than the current on-market product as evidenced by prototype assay identifying 3 more bleeds than the on-market assay. **Conclusion**: These results indicated that the new automated prototype anti-HCV assay provided acceptable performance in specificity, sensitivity, and precision. Specificity performance of the new assay was equivalent to a current on-market anti-HCV assay while sensitivity performance indicated improvements over the current on market performance.

SP443

Riboflavin and Ultraviolet Light Treatment Reduce But Do Not Eliminate Biofilm-forming Bacteria in Buffy Coat Platelet Concentrates

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Background/Case Studies: Pathogen inactivation treatment using riboflavin and ultraviolet light (UV) illumination is effective against clinically-relevant bacteria in platelet concentrates (PCs). The predominant PC contaminant *Staphylococcus epidermidis* forms surface-attached aggregates (biofilms) in PCs, which have been linked to missed detection during routine PC screening. This study was aimed at testing the efficacy of riboflavin-UV treatment to inactivate *S. epidermidis* biofilms in buffy coat PCs. **Study Design/Methods**: Two biofilm-positive *S. epidermidis* strains (ST10002 and AZ-66) were used in this study. Biofilm and non-biofilm cells were collected from both strains and used to individually inoculate whole blood (WB) units at a concentration of $\sim 10^6$ colony forming units (CFU)/mL (N≥4). This high concentration was chosen to allow bacterial tracking during buffy coat PC production. Each spiked buffy coat fraction was pooled with 3 non-spiked ABO matched buffy coats and suspended in an autologous plasma unit to produce the PC. Riboflavin was then added to the PC pool and split into two bags: UV-treated and untreated (control). Bacterial concentration was measured before and after treatment. On days 1 and 5 of PC storage, samples were taken for *in-vitro* quality analyses monitoring platelet activation by flow cytometry (CD62P expression) and changes in dynamic light scattering. Data were analyzed using ANOVA and t-test. **Results/Findings**: Bacterial concentration was reduced during buffy coat PC production from $\sim 10^6$ CFU/mL in WB to $10^3 - 10^4$ CFU/mL in PCs ($p<0.0001$). Treatment of these PCs with riboflavin-UV did not completely inactivate bacteria. There was a ≥3.5 log reduction of *S. epidermidis* AZ-66 (≥96%), which was higher ($p<0.0001$) than the 2.6-2.8 log reduction of strain ST10002 (70-80%). No differences in *S. epidermidis* inactivation were observed in PCs produced from WB inoculated with biofilm or non-biofilm cells ($p>0.05$) for both strains. At the end of the 5-day PC storage, platelet activation and microparticle PC content measured by flow cytometry and dynamic light scattering, respectively, were increased due to UV treatment ($p<0.05$). Interestingly, platelet activation was enhanced up to 20% in PCs produced with WB inoculated with biofilm cells compared to non-biofilm cells ($p<0.05$), which should be further investigated. **Conclusion**: The efficacy of riboflavin-UV treatment is similar for *S. epidermidis* present in PCs produced from WB inoculated with biofilm or non-biofilm cells. Interestingly, treatment effectiveness was strain dependent with *S. epidermidis* ST10002 showing higher resistance to inactivation when present at high titers in PCs. These results merit confirmation with lower (real-life) concentrations of bacteria.

SP444

Evaluation of a Triple Storage Set at Two U.S. Blood Centers for Use With the Intercept Blood System for Platelets in Intersol

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Background/Case Studies: The INTERCEPT™ Blood System for Platelets is FDA approved for preparation of pathogen reduced apheresis platelets (PCs) in PAS-3 (InterSol®) up to 8.0×10^{11} platelets in 420mL. The INTERCEPT Platelet Processing Set with Triple Storage (TS) Containers (INT26) was developed for INTERCEPT treatment of PCs from single or pooled donations up to 12.0×10^{11} platelets in 650mL. The TS set allows preparation of up to 3 PCs from a single INTERCEPT treatment. Two U.S. Blood Centers evaluated *in vitro* function of PCs in PAS-3/plasma and treated using the TS set (Test) compared to published data for single-dose and double-dose INTERCEPT PCs in PAS-3. **Study Design/Methods**: Amicus® PCs were collected in 35% ACD plasma and 65% PAS-3. Twelve PCs (triple-dose donations,n=3, or pools of 2 ABO-identical donations,n=9) were INTERCEPT treated and stored as either doubles (input dose 6.7-10.0, 604-650mL, n=2) or triples (input dose 10.1-12.0, 579-648mL, n=10). On Days 5 and 7 post-donation PCs were evaluated using a panel of *in vitro* platelet function assays (**Table 1**). **Results/Findings**: After treatment, 33/34 (97%) of Test PCs had ≥3.0 $x10^{11}$ platelets/unit. Platelet dose recovery post-treatment was 90% ±4% (85%-99%) of the input dose. All Test PCs maintained pH (22°C) ≥6.5 through Day 5 and 7. *In vitro* function was retained (**Table 1**).

TABLE. Test and Control as compared to Published Data (Mean ±SD)

	Day 5 post-donation		Day 7 post-donation
In Vitro Assay (Units)	INTERCEPT Test (n=12 unless noted)	INTERCEPT Reference Range (n=63)*	INTERCEPT Test (n=12 unless noted)
Unit volume (mL)	194±36[a]	279±74	not measured[b]
Platelet count (x 10^3/µL)	1675±136[a]	1383±341	1644±147[a]
Platelet dose/ unit (x 10^{11})	3.2±0.4[a]	3.7±0.8	not measured[b]
pH (22°C)	6.8±0.2[a]	7.0±0.1	6.9±0.2[a]
Mean platelet volume (MPV, fL)	7.9±0.4[a]	8.1±0.8	7.8±0.4[a]
pCO_2 (mm Hg)	15±4	20±6	13±3
pO_2 (mm Hg)	138±17	130±21	139±15
HCO_3 (mM)	2±1	3.2±1.1	3±1
Total ATP (nmol/10^8 plts)	3.3±0.8	4.70±1.95	2.1±0.5
Morphology score	264±22	257±47	241±18
Extent of Shape Change (%)	18.4±5.0	12.2±8.1	16.3±3.6
Hypotonic Shock Response (%)	43.5±9.4	28±18	37.3 ±7.4
Sup. glucose (mg/dL)	6±10	21.5±24.0	0±0
Sup. lactate (mM)	14.2±1.4	11±2	14.5±1.2
CD62 (% expression)	35.3±10.1	36.98±16.22	37.6±7.9
Sup. LDH (IU/~10^{12}platelets)	117±23	110±24	164±27

* INTERCEPT platelets in 35% plasma/65% InterSol ;Package insert for INTERCEPT Blood System for Platelets
a. Data are n=34, measured in every unit prepared
b. Unit volume and dose were not measured after removal of samples on Day 5.

Conclusion: Amicus PCs in PAS-3 treated in the INTERCEPT TS Set retained *in vitro* function consistent with published ranges from comparable single- and double-dose INTERCEPT PCs and met AABB and FDA standard for pH (pH22°C $\geq$6.2) through Day 7 post-donation. The INTERCEPT Platelet Processing Set with Triple Storage (TS) Containers (INT26) is not approved in the US.

SP445

Monitoring the Execution of the INTERCEPT Treatment Using the Antioxidant Power of Blood Components

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Background/Case Studies: Authorities recommended quality control (QC) tests to be introduced for assessing the efficacy of pathogen inactivation in blood components. Towards this aim, polymerase chain reaction inhibition assays on mitochondrial DNA have been developed. However, these assays are rather time consuming, costly and require an instrumentation that is not always available in blood banks. As the INTERCEPT Blood system is a photochemical treatment known to generate reactive oxygen species, we sought to use the decrease of antioxidant power (AOP) of blood components to document the treatment execution. **Study Design/Methods**: An electrochemically-based miniaturized system, the EDEL technology, was used for measuring the AOP in both platelet concentrates (PCs) prepared in platelet additive solution (PAS) and plasma units. The EDEL technology has been transferred to our quality control lab for two months to measure the AOP in apheresis PCs (n = 114). Pooled plasma units (n= 6) were prepared to meet the INTERCEPT guardbands (volume of 385-650 mL). The PCs and plasma units were processed with their respective INTERCEPT processing kits according to manufacturer's recommendations. Aliquots were withdrawn from PCs or plasma units before and after INTERCEPT treatment and a few microliters were directly deposited into the EDEL sensor for the AOP measurement. The result is expressed in EDEL, an arbitrary unit (micromolar equivalent of ascorbic acid). A ΔAOP is calculated for each product, with ΔAOP = AOP (PRE-treatment) - AOP (POST-treatment). We consider that the INTERCEPT treatment is fully executed when the ΔAOP of the product is superior or equal to a $\Delta AOP_{threshold}$ of 15 EDEL. **Results/Findings**: Following INTERCEPT treatment we observed a significant decrease of the AOP in the blood components. Apheresis PCs exhibited a mean ΔAOP of 49 $\pm$ 15 EDEL. We calculated a false-negative rate of 0.9% for PCs. We also observed that untreated PCs collected from male donors exhibited a higher AOP (111 $\pm$ 12 EDEL, n = 76) compared to female donors (94 $\pm$ 14 EDEL, n = 66), with a p-value $<$ 0.0001. The method based on the measurement of a ΔAOP allows overcoming this biological variability. Plasma units showed a mean ΔAOP of 85 $\pm$ 15 EDEL confirming the completion of the INTERCEPT treatment. In addition, we showed that the presence of the photosensitizer in combination with the ultraviolet-A illumination is required to observe the AOP decrease. **Conclusion**: The measurement of the AOP of PCs and plasma units can be use to document the completeness of the INTERCEPT treatment and can easily be achieved in parallel to standard QC tests.

SP446

Establishment and Application of Bacterial Contamination Detection in Random-donor Platelet Concentrates by Flow Cytometry

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Background/Case Studies: Bacterial contamination is a major hazard associated with platelet preparations. We have established and applied an in-house flow cytometric method for detection of bacterial contamination in platelet concentrates (PCs). **Study Design/Methods**: PC samples were stained with thiazole orange, a membrane permeable dye, and detected by flow cytometry. At the evaluation phase, we designed two sets of PCs spiked studies with ten different bacteria strains in the 7 different concentrations (from 1.5X10$^{}$ to 1.5X10^6 CFU/mL). The first set was to evaluate the detection limit of our flow cytometric method. The second set was to evaluate the bacteria growth dynamics after various incubation periods mimicking the storage condition that PCs having been stored before release. The flow cytometric results were validated with an in-house PCR method which detected the DNA sequences coding for 16S rRNA. We implemented this flow cytometric method in routine contamination detection of PCs starting from Jan. 2015. Specimens of proficiency tests from College of American Pathologists (CAP) were also tested by this method. **Results/Findings**: The contamination detection limits of different bacteria by flow cytometry ranged from 1.5X10^3 to 1.5X10^4 CFU/mL. The growth kinetics varied greatly among different bacteria, with bacteria strains *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Streptococcus agalactiae* showing the most rapid growth rates. After implementation of the detection method, one false- positive result was found within the first 600 bags of routine PCs. The false-positive sample possibly resulted from contamination during sample handling. The other specimens all were negative results. The in-house PCR can detect as low as 1CFU/mL after 24 hours incubation. **Conclusion**: The detection limit of bacteria detection by our flow cytometric method was from 1.5X10^3 to 1.5X10^4 CFU/mL. The volumes of test samples are small (0.1mL for each test) and time-to-result is less than 1 hour.

SP447

Verax Platelet PGD® Test Workflow Strategy

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Background/Case Studies: Our university medical center blood bank implemented the Verax Platelet PGD® Test, which detects both gram positive and gram negative bacteria in platelet components prior to release for transfusion. As an academic center that transfuses 3000 apheresis platelets annually, and a Level 1 trauma center that must maintain an inventory of PGD®-tested platelets for emergency release, we sought to balance the need for immediate access to PGD®-tested platelets with the budgetary prerogative of minimizing the retesting of platelets prior to release. **Study Design/Methods**: We developed the following testing strategy to ensure that there are always PGD® tested platelets available. The PGD® package insert stipulates that a platelet product must be tested no more than 24 hours prior to transfusion. Each blood bank shift assesses the number of tested units available, all pending orders for platelet transfusion, including the operating room and outpatient clinics, and platelets needed to maintain the required inventory. Platelets with the shortest outdate, regardless of ABO group, are selected for testing. If needed, a technologist can test additional platelet units in batches of up to six in approximately 45 minutes. The tested platelet products are labeled with the date and time the test expires. Testing on each shift allows for differing PGD® test expiration times. The blood bank issues the units with the shortest outdates. To determine if this strategy is effective in limiting repeat PGD® testing of apheresis platelets while maintaining an adequate inventory of tested platelets, we evaluated two years of data to determine the number of times a platelet was tested before it was issued. **Results/Findings**: As shown in Table 1, over 80% of apheresis platelet products were tested only once in both years analyzed. Fewer than 2% of platelet products were PGD® tested three times. Platelet products were tested an average of $<$1.2 times. 5.39% of apheresis platelets are outdated/wasted annually. **Conclusion**: Testing in batches based on inventory and transfusion needs is effective in limiting repeat testing while maintaining sufficient inventory for immediate release. Testing all platelets in inventory every day is not necessary. Testing throughout all shifts allows for a staggered outdate of the PGD® test and the availability of tested platelets at all times. It also ensures that all staff in the Blood Bank is proficient and competent to perform the test. We are able to perform a PGD® test on every

TABLE.

Apheresis Platelets Tested	2014	2015
1X	2686 (84.6%)	2440 (81.7%)
2X	452 (14.2%)	501 (16.7%)
3X	36 (1.2%)	44 (1.6%)
Total	3174	2985
Average tests per unit	1.15	1.18

platelet issued for transfusion in our hospitals with a consistently low repeat test rate.

SP448

Brucella suis Contamination of a Platelet Pool Unit: A Second _Brucella_ spp. Case Report

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Background/Case Studies: The first reported case of a pool of whole blood (WB) derived platelets contaminated with *Brucella abortus* in the continental United States was detected in 2014. More recently, a second case of contamination with *Brucella* sp. was detected at our blood center in a WB-derived platelet pool. **Study Design/Methods**: An 8mL aliquot from a pool of 6 WB-derived platelets (Acrodose ^{TM} PL) became positive 2.45 days from inoculation time into an aerobic bottle used by the BacT/ALERT®3D. The positive sample was sub-cultured by a microbiology lab at a local hospital with a preliminary report of *Brucella melitensis*. The cultures were then sent to the Florida Department of Health (FDOH) laboratory and the final identification was *Brucella suis*. Simultaneously, cultures were performed on aliquots from each of the quarantined Red Blood Cells (RBC) prepared from the 6 WB donations involved in the contaminated pool. From this, the infected donor was identified. **Results/Findings**: The contaminated pool was not transfused and the center obtained control over all components prepared from the WB donations that made up the pool. The infected donor was identified and contacted by the center and FDOH. *Brucella* serologic report from Centers for Disease Control(CDC) revealed *Brucella* MAT (total antibody) 1280 and *Brucella* MAT (IgG titer) 40, suggesting acute infection. The donor, a 48 year old female, at a second interview stated that 9 days post-donation, she felt fatigue, neck pain, as well as headache and 7 days later developed fever. While the donor reported handling raw meats from hogs hunted by her husband back in 2014, she had not done so in the 12 months prior to her donation. Her husband has been asymptomatic. The route of transmission to the donor remains elusive. **Conclusion**: Brucellosis is a rare zoonotic disease in the continental U.S. but appears to have increasing incidence in our collection area as evidenced by this second case detected in the last 24 months. Infections with *Brucella suis* in humans occur in people handling pigs during slaughter and meat processing, including the hunting of feral swine. In both our prior and present reported cases, the bacteria survived storage at refrigerated temperatures and we were able to identify the source donor from the RBC prepared concurrently. While able to interdict the transfusion of contaminated blood components in this case, the timing for detection, as well as the known limitations of cultures in detecting low levels of bacteria in platelet components point to the importance of having appropriate procedures to remove potentially contaminated blood components as soon as detection is made. The possibility of transmission through uncultured RBC and Plasma products remains.

SP449

Septic Transfusion Reactions for Two patients from Same Platelet Collection

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Background/Case Studies: A 59 year old male patient (A) with pancreatic cancer had a transfusion reaction after receiving ~100 mL of an apheresis platelet product on the day of expiration (day 5). He experienced tachycardia, facial flushing, abdominal, back and chest pain, shortness of breath with wheezing and an increase in temperature of 1.1 C. Approximately 10 minutes prior to this transfusion, a 2nd patient (B) was transfused a ~170 of 194 mL co-component from the same apheresis platelet collection. Patient B was a 74 year old male with myelodysplastic syndrome and was receiving platelets prior to chemotherapy in the outpatient setting. This patient also experienced septic reactions including rigors, tachycardia and hypertension but no rise in temperature. Patient B symptoms were thought to be caused by a contaminated port and were only related to the transfusion after the investigation for patient A. **Study Design/Methods**: Blood cultures were collected on both patients as part of routine sepsis protocol. The platelet bag from patient A was also cultured but was not available for patient B. Lactic Acid and Procalcitonin levels were also evaluated for both patients. **Results/Findings**: The Lactic Acid and Procalcitonin results are listed below with ranges (Table 1). These results support the suspected sepsis for both patients. Gram stains for all 3 cultures were found to contain gram positive cocci in clusters. The organisms for all 3 cultures were later identified as being Staphylococcus aureus. Further genetic testing was performed and results showed that all 3 organisms were identical, that the source of the sepsis was the apheresis platelet product. The original collection and splitting process were reviewed but no deviations were found. A sample from the original collection was cultured 24 hours after the collection and remained negative 5 days after the inoculation. The products were not tested with a "point of issue" bacterial screening device. A 3rd component was given to a patient on day 3 of expiration with no adverse reactions. **Conclusion**: A transfusion reaction due to bacterial contamination of platelets occurred in two patients. Although the source of bacterial contamination cannot be identified with certainty, it is assumed that the contamination occurred at either the time of collection or during processing of the parent product. This case illustrates the use of microbiology genetic testing in establishing common origin of a bacterial contaminant, and confirms the higher risk of bacterial contamination of platelets with increased storage time.

TABLE. Lab Results

	Patient A	Patient B	Normal Range
Lactic Acid	2.6 mmol/L	3.9 mmol/L	0 to 2.0 mmol/L
Procalcitonin	0.66 ng/mL	14.0 ng/mL	</= 0.5: Sepsis not likely 0.6 - 2.0: Sepsis possible >2.0: Sepsis likely >9.9: Severe sepsis likely

SP450

A 5-Year Retrospective Study on the Use of Anaerobic Culture for Bacterial Testing of Platelets in Singapore

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Background/Case Studies: All leucocyte reduced platelets including apheresis platelets (APLR) and buffy coat derived pooled platelets (PPLT) are tested on the BacT/ALERT automated microbial detection system (bioMerieux) using both the aerobic and anaerobic cultures in Blood Services Group (BSG), Singapore, for transfusion safety. Although the simultaneous use of both cultures is not mandatory, BSG has implemented anaerobic culture to extend detection of anaerobic and facultative anaerobic bacteria. This study aims to examine the effectiveness of using anaerobic cultures for the detection of clinically relevant bacteria in platelet that could cause bacterial sepsis. **Study Design/Methods**: Test data from the period of February 2012 to February 2016 were analysed. Data includes the collation of platelet units with confirmatory bacteria results and the bacteria species isolated from the samples of: (i) culture bottles that were flagged positive by the BacT/ALERT automated microbial detection system, (ii) original platelet bags/segments and (iii) the associated blood products (when they are available). **Results/Findings**: 92,897 platelets, comprising of 35,936 (38%) of APLR and 57,501 (62%) of PPLT, were screened by BacT/Alert during the study period. 71 (0.08%) platelet units were flagged initial positive by the system of which 9 (0.001%) were interpreted as confirmed positive where there is a similar

bacteria species isolated from the culture bottle, the original platelet bags/segments and its associated blood products. Of the 9 confirmed positives, 3 units (1 APLR and 2 PPLT) were flagged initial positive for both aerobic and anaerobic cultures and the bacteria species identified includes *Bacillus* species, *Staphylococcus aureus* and Group A *Streptococcus;* 1 APLR unit was flagged initial positive for the aerobic culture only and *Serratia* species was identified; 5 units (2 APLR and 3 PPLT) were flagged initial positive only for the anaerobic culture with 4 units identified with *Propionibacterium acnes (P.acnes)* and one of the APLR units had growth of *Escherichia coli (E.coli)*. **Conclusion**: The anaerobic culture has predominantly detected *P.acnes* but the clinical significance in platelet transfusion is uncertain. However, the use of anaerobic culture is demonstrated to be effective in detection of clinically relevant bacteria, *E.coli*, (a facultative anaerobe) and has successfully prevented the transfusion of a bacteria contaminated platelet unit.

SP451

A Fatal Septic Reaction following The Infusion of a Red Cell Unit Contaminated with Aeromonas sp

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Background/Case Studies: The risk of bacterial contamination of red cell components is low but real. The infusion of a contaminated red cell unit can produce severe sepsis and even death, especially if the contaminating agent is a gram-negative bacterium. We wish to report the case of a patient who died after receiving a red cell unit contaminated with Aeromonas sp. **Study Design/Methods**: An 81 y.o. patient was transfused a 37-day old whole blood derived red cell unit as an outpatient. The transfusion was ordered because the previous day the patient had undergone a bronchoscopy to remove a bronchial clot; there had been bleeding during the procedure and the patient had some fatigue which was attributed to the low hemoglobin level (86 g/L). The patient was otherwise in fairly good health. **Results/Findings**: During the transfusion, the patient started to have rigors, dyspnea, hypertension at first then hypotension and fever. His condition worsened and eventually required intubation and transfer to the ICU. The patient died 14 hours later of what appeared to be sepsis, in spite of optimal treatment, including large spectrum antibiotics. A gram stain on the residual red cells in the bag showed abundant gram-negative rods. Within less than 24 hours after inoculation, the culture was positive for Aeromonas sp. The same bacterium was isolated from blood cultures done on the patient after the beginning of his clinical demise. Later tests confirmed the identity of the two strains, the species being A. veronii. A culture of the plasma collected as a co-component from the same whole blood unit was negative. The donor was a 64 y.o. female with no health problems and no identified risk factor for Aeromonas infection. A stool culture performed 8 weeks after the donation was negative for Aeromonas sp. An extensive investigation could not identify any potential breech of sterility involving the collection device or the processing of the unit. **Conclusion**: Aeromonas sp. can be found in the environment, particularly in brackish water. It is occasionally recognized as a cause of traveller's diarrhea and can sometimes cause severe invasive disease, especially in immunocompromised hosts. It has been previously isolated from whole blood units collected in Africa, however we do not know of any previously published case of sepsis caused by a labile component contaminated with this bacterium. The source of the contamination is not clear but might have resulted from a transient asymptomatic bacteremia in the donor.

SP452

Assay Performance of a Zika Nucleic Acid Test for Screening of Blood Donations

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Background/Case Studies: Infection with the Zika virus (ZIKV) is associated with microcephaly and neurologic disease. Most infections are asymptomatic, and blood donors may unknowingly harbor infection. ZIKV RNA was detected in 2.8% of donors during the 2013 French Polynesia outbreak, and cases of transfusion-transmission have been reported in Brazil. The U.S. FDA issued recommendations to reduce the risk of transfusion transmitted ZIKV. In areas of active transmission, blood establishments must cease collections unless donations are screened with a nucleic acid test (NAT) for ZIKV or components are pathogen reduced (PR). PR is limited to platelets and plasma products. In response, the **cobas**® Zika test, a qualitative method for detection of ZIKV RNA using polymerase chain reaction, was developed for use on the **cobas**® 6800/8800 Systems. These systems incorporate fully-automated sample preparation, amplification and detection, and ready-to-use reagents and controls. The test is intended to detect ZIKV RNA in plasma specimens from donors of whole blood and blood components. **Study Design/Methods**: The **cobas**® Zika test was designed to detect all ZIKV lineages. Most performance studies used ZIKV culture supernatant with titer assigned in copies/mL using ZIKV RNA transcript. Studies included specificity, sensitivity, limit of detection (LoD), interfering substances, matrix equivalency, and cross-reactivity. LoD and repeatability were assessed using 190 replicates across multiple concentrations, reagent lots, and days. Clinical sensitivity was evaluated by testing 25 samples confirmed ZIKV positive using published oligonucleotide sequences (Lanciotti, 2008). In addition, 5 clinical specimens were spiked into negative pooled plasma to create 250 contrived samples at various dilutions. **Results/Findings**: The 95% Probit LoD for **cobas**® Zika was 8.1 copies/mL, and the results were reproducible across multiple parameters. Specificity was 100% in 500 samples collected in a ZIKV non-endemic region. Neither ZIKV detectability nor specificity was impacted by albumin, bilirubin, hemoglobin, human DNA and triglycerides or with various anticoagulants. HIV, HBV, HCV, CHIKV, DENV serotypes 1-4, and WNV did not cross-react. Clinical sensitivity of **cobas**® Zika was 100% with 25 confirmed ZIKV positive samples from 4 countries. Reactivity was 100% with 250 contrived samples with a range of viral concentrations **Conclusion**: The **cobas**® Zika test for use on the **cobas**® 6800/8800 Systems is highly sensitive and specific for detection of ZIKV RNA. Results were submitted to the FDA, which approved the **cobas**® Zika test for use under an Investigational New Drug application. The **cobas**® Zika test and **cobas**® 6800/8800 Systems are not commercially available in the U.S. for blood screening use.

SP453

A Comparison of Potassium Concentration in Gamma-irradiated and Riboflavin- and UV-treated Red Blood Cell Products

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Background/Case Studies: The current standard of care for the prevention of Transfusion-Associated Graft Versus Host Disease (TA-GVHD) is

TABLE. Summary of parameters, mean±stdev (range)

Test Group	(mmol/L)	D0 Post-Collection	D0 Post-separation & LR	Day 1	Day 2	Day 3	Day 7	Day 14	Day 21
G Group	Na+	153.3 ± 1.7 (151.4-156.1)	140.4 ± 0.6 (139.7-141.4)	130.4 ± 3.1 (126.3-134.4)	123.3 ± 3.1 (126.3-134.4)	116.6 ± 2.9 (112.8-121.9)	105.6 ± 2.9 (102.6-111.2)	96.9 ± 2.6 (94.1-101.3)	92.8 2.6 (88.3-96.7)
G Group	K+	3.2 ± 0.2 (2.9-3.4)	2.7 ± 0.5 (2.1-3.3)	12.9 ± 2.7 (9.0-16.6)	19.2 ± 5.1 13.4-26.9)	29.6 ± 4.0 (21.5-33.6)	47.6 ± 5.6 (36.3-51.5)	60.9 ± 5.3 (50.2-66.1)	64.5 ± 6.1 (54.1-69.9)
R Group	Na+	152.8 ± 1.3 (150.6-154.9)	141.6 ± 1.3 (139.4-142.8)	127.9 ± 2.4 (130.7-127.9)	117.7 ± 2.7 (113.8-120.9)	111.9 ± 2.6 (108.2-115.1)	97.4 ± 2.8 (93.4-100.5)	88.7 ± 2.6 (85.3-91.6)	85.4 ± 3.1 (79.7-90.7)
R Group	K+	3.1 ± 0.1 (2.8-3.3)	2.4 ± 0.2 (2. −2.8)	13.9 ± 2.0 (11.8-17.3)	29.0 ± 3.4 (24.6-35.1)	35.8 ± 3.9 (30.2-41.9)	58.1 ± 4.5 (50.8-65.3)	67.5 ± 3.2 (62.7-71.5)	73.3 ± 4.1 (68.6-79.6)

gamma-irradiation (G) of blood products. Riboflavin and UV (R+UV) light treatment, developed for the reduction of microbial and viral risk by transfusion, inactivates WBC and is a potential alternative to gamma-irradiation. Both treatments elevate the potassium (K^+) load in stored RBC units. In this study, K^+ concentration was compared between gamma-irradiated (G) and R+UV-treated (R), leukoreduced (LR) RBC units over 21 days of refrigerated storage. **Study Design/Methods**: A total of 15 fresh 450 mL whole blood units collected in CPD were used for this study. On day of collection, units were transported to a local blood center for gamma-irradiation (G group, N=7) or were treated with R+UV by adding riboflavin solution and illuminating with an 80 J/mL$_{RBC}$ UV energy dose (R group, N=8). All units were processed into RBC, LR, and stored refrigerated for 21 days. In addition to testing on day of collection, K^+ and other cell quality parameters were measured on Days 1, 2, 3, 7, 14, and 21 of storage. **Results/Findings**: The K^+ concentrations were higher for the R group compared to the G group throughout storage from Day 7 to Day 21, yet the rate at which K^+ was released from the cells was similar between the 2 groups. Additionally, the measured rate of K^+ release slowed after Day 7 of storage and began to plateau by Day 21 for both groups. Significant differences were observed between the G and R groups at all time points except Day 1 for sodium (Na^+) and K^+ (Table 1), and on Days 14 and 21 for % hemolysis. All units met the standard United States guidelines for $pH_{22°C}$ (> 6.2) and % hemolysis (< 1.0%). **Conclusion**: Although the K^+ concentrations throughout storage were statistically higher for M compared to G, clinically the difference is not significant. Transfusion with stored, R+UV-treated RBC presents no greater risk than transfusion with stored, gamma-irradiated RBC.

SP454

Implementation of the INTERCEPT Blood System for Platelets in Puerto Rico to Help Safeguard Against Zika

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Background/Case Studies: INTERCEPT™ Blood System is a photochemical treatment process, licensed by the FDA for the reduction of viruses, bacteria, parasites, and leukocytes that can contaminate platelet and plasma components intended for transfusion. A large regional blood provider (Blood Center) on Puerto Rico is the first blood center in the United States or US territory to implement this technology for platelets in 100% Plasma, in an effort to help safeguard their blood supply against Zika. The potential for transfusion-transmission (TT) of Zika virus coupled with the high proportion of asymptomatic donor infections, led the FDA to release a guidance to reduce the TT risk for Zika in Feb. 2016. Puerto Rico was the first US area required to comply with the guidance. With 4 weeks to implement the Guidance, Puerto Rico had the option to suspend collections and import blood components, or obtain components locally but perform testing or pathogen reduction. **Study Design/Methods**: The Blood Center chose to implement the INTERCEPT Blood System for Platelets in order to avoid an interruption in supply. The steps necessary were to, negotiate a contract; have equipment shipped; setup GMP tracking; conduct training and perform qualification. The Blood Center requested a variance from the FDA to allow implementation of the INTERCEPT System for Trima Platelets in 100% plasma before final approval of the system. **Results/Findings**: FDA granted the variance requested. After an agreement was signed, equipment were shipped from Cerus, installation and calibration of illuminators was completed, operators were trained on the system while, in tandem, SOPs and Validation Plans were written with company support and change in product type was communicated to hospitals. Apheresis collection settings were modified to meet INTERCEPT processing parameters. In less than 2 days, product labeling and BECS-based tracking methods were created. On March 8 products were produced for PQ and were ready for administration to patients. **Conclusion**: The INTERCEPT System was successfully implemented within a week in order to help safeguard against an emerging pathogen. Longer term improvements i.e. volume adjustment, refining apheresis platform targeting and additional training was required. Beginning in mid-March 2016, for approximately 45 days, all platelet products collected in Puerto Rico were pathogen reduced. Subsequent approval of a testing IDE allows for release of certain non-pathogen reduced products however this blood center still chooses to perform INTERCEPT treatment on all apheresis platelets.

SP455

Reducing the Transfusion Transmission Risk of Zika Virus in an Area with Active Viral Circulation, Brazil

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Background/Case Studies: Brazil is experiencing the largest Zika virus (ZIKV) epidemic among the Latin American countries. The introduction of ZIKV in 2015 and the rapid spread throughout the country led to health care policies in order to pay attention to the transfusion transmission (TT) risk of this infection. Thus, the Brazilian blood banks have implemented several recommendations to reduce the TT-ZIKV risk, especially in areas where active viral circulation occurs. **Study Design/Methods**: The goal of this study is to report the actions applied and the results obtained in a non-metropolitan blood center in Southeast Brazil, where a high incidence (the third in ranking of the country) of probable cases of arbovirus infections (ZIKV, dengue, Chikungunya viruses) has been reported since December 2015. **Results/Findings**: Initially, donor educational material, history questionnaire, and deferral were updated. We have also established guidelines for the blood collection, post-donation information, blood products management and their disposition. A total of 6,011 blood donations was collected between December 2015 and April 2016. Of them, 34 (0.6%) blood donors informed one or more post-donation signs/symptoms suggestive of arboviral infection. The major symptoms observed were: fever (35.7%), maculopapular rash (28.6%), muscle pains (23.8%), conjunctivitis (4.8%), retroorbital pain (4.8%) and arthralgia (2.4%). In some of the donors who returned, ZIKV Asian genotype was confirmed by real-time PCR. **Conclusion**: Since ZIKV asymptomatic infections can be common, we endorsed that the post-donation information should not be underestimated in order to prevent TT-ZIKV. Although, critical analysis has been done during the ZIKV outbreak in Brazil, deferral of selected blood donors might be an approach to reduce the TT-ZIKV risk. Several concerns should be addressed for the surveillance of TT-ZIKV such as asymptomatic infection among blood donors, availability of approved commercial tests (serology and molecular) by the Brazilian regulatory agencies for ZIKV screening; and difficulty in confirming TT-ZIKV in endemic areas where ZIKV, dengue and/or Chikungunya viruses cocirculate. This study points out the urgent need for discriminatory and/or routine ZIKV diagnosis in order to understand the ZIKV biological and molecular characteristics in blood donors such as viral load, ZIKV persistence in blood derivatives and the use of pathogen reduction strategies to prevent TT-ZIKV. Financial support: FUNDHERP, FAPESP, CNPq.

SP456

Zika Virus Deferral Rates in Donors Within a Multiple Hospital Health System

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Background/Case Studies: Zika virus (ZIKV) is a flavivirus transmitted by *Aedes aegptis* and *A. albopictus* mosquitoes. Although there are no proven cases of ZIKV transmitted through blood transfusion, the similarity between ZIKV and other blood-borne viruses and ZIKA's detection in multiple body fluids raise the possibility of such transmission. In early February 2016, the FDA and AABB recommended a voluntary self deferral for blood donors of 4 weeks for any individual who traveled to areas with active transmission of Zika, had symptoms of ZIKV, or had had sex with a male who traveled within the previous three months to an area with active transmission of ZIKV or had symptoms of ZIKV. Based on historic travel data, AABB predicted a reduction of 2.25% of otherwise qualified donors. There are four hospital based blood collection centers within our 21-facility community hospital system. We were concerned about ZIKV deferrals at our donor collection sites due to their location in a metropolitan area with a population that has high rates of travel to ZIKV-risk areas, and we anticipated deferral rates that would exceed the 2.25% predicted. Here we report our deferral rates due to the FDA and AABB recommendations by site for February-April 2016. **Study Design/Methods**: Donors were assessed and sampled following the newly implemented ZIKV deferral guidelines. The deferral rates due to ZIKV risk were monitored at each location. Data were sent to an administrative coordinator for weekly entry into a database. **Results/Findings**: The mean ZIKV deferral rate for all our donor centers was 1.24% which is lower than the predicted deferral rate (Table 1). All sites but one had a deferral rate less than that predicted by AABB. However, the deferral rate recorded at our sites

TABLE. ZIKV Deferrals February- April 2016

Site	Total Donors	Deferrals due to ZIKV Risk	ZIKV Deferral Rate
Site 1	288	1	0.35
Site 2	427	5	1.17
Site 3	650	8	1.23
Site 4	169	5	2.96
Total	**1534**	**19**	**1.24**

may be lower than the actual number of ZIKV deferrals, since we do not capture potential self-deferrals in our statistics. **Conclusion**: ZIKV deferrals have the potential to significantly impact blood collections. The proportion of donor deferrals at our sites due to ZIKV protocol is lower than the proportion predicted by AABB. It is possible that some potential donors self-defer because they are aware of the ZIKV threat. Our data provide a starting point for our further monitoring of donor deferrals due to ZIKV in a large and highly heterogeneous urban population.

SP457

Implementation of Measures to Reduce the Risk of Transfusion Transmission of Zika Virus

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Background/Case Studies: To mitigate risk for transfusion-transmitted Zika virus (ZIKV) in areas without active transmission of ZIKV (ATZ), FDA recommended: 1) updating donor educational materials to include the risk factors for and signs and symptoms of ZIKV infection so that donors can self-defer and 2) to update the donor history questionnaire (DHQ) to assess prospective donors for a history of residence in or travel to an area with ATZ in the past 4 weeks. **Study Design/Methods**: Our organization initially posted signs on 2/1/2016 listing countries/territories identified by CDC as having ATZ and advised donors not to donate if they have been in such areas in the previous 28 days and provided every donor with an information sheet encouraging self-deferral. On 3/14/16, updated educational materials and 3 questions were added to the DHQ with corresponding deferral codes to prospectively identify donors at risk: In the past 4 weeks, (1) have you been in any of the areas on this list? (Donor given a list of ZIKV Countries.), (2) have you had a Zika virus infection? (3) have you had sexual contact with a man, who in the 3 months prior to your sexual contact, had Zika virus infection OR been in an area where Zika is present? **Results/Findings**: The number of donors who self-deferred is difficult to quantify, but was considered significant at locations near the Mexican border. The number of donors who did not self-defer but were deferred as a result of responding affirmatively to one of the three questions are listed (Table 1). Of those deferred for travel, 90% (n=338) indicated travel to Mexico, 7% to the Caribbean and 1% to Central/South America. 78% of deferred travelers resided in states bordering Mexico (Texas, New Mexico, Arizona) with 77% residing specifically in Texas border cities. **Conclusion**: Identifying donors at risk for a given infectious agent is a challenge. Posters, information sheets and educational materials encouraging self-deferral are convenient methods that can be rapidly implemented, but they lack precision. Self-deferral may provide a false-sense of security. Questions identifying deferrable risks should be implemented as soon as is feasible to further reduce risk.

TABLE. Deferral associated with Zika questions in allogenieic presentations

Category	Total Responses	Deferral per response consequence	
		Defer	% Deferred
Travel	108,166	376	0.3
Infection	108,166	0	0
Sex	108,166	147	0.1

SP458

Procleix Zika Virus Assay on the Fully Automated Panther System

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Background/Case Studies: Zika virus (ZIKV) is a mosquito-borne flavivirus that has been associated with human disease ranging from subclinical to mild illnesses. ZIKV infection has also been associated with serious and sometimes fatal cases of Guillain-Barré syndrome. Additionally, there is mounting evidence indicating that ZIKV infection can cause microcephaly and other birth defects in infants born to infected mothers. Although the primary route of infection is through the bite of a mosquito, sexual transmission and possible transfusion transmission of ZIKV have been reported. To facilitate fully automated testing for ZIKV RNA, we are developing a transcription-mediated amplification (TMA) assay for the qualitative detection of ZIKV RNA on the Procleix Panther System. The Procleix Zika Virus assay uses the same technology as the Procleix® and Aptima® nucleic acid tests, consisting of lysis and target capture of viral RNA followed by TMA and chemiluminescent detection. To mitigate the risk of false negative results, the assay targets 2 separate regions of the ZIKV genome and includes an internal control to validate each reaction. **Study Design/Methods**: Analytical sensitivity was determined by probit analysis of results from testing 20-72 replicates per level of serially diluted in vitro synthesized RNA transcript and a ZIKV positive plasma specimen that was quantified by real-time PCR and digital PCR. Specificity was assessed by testing 775 plasma blood donor samples collected from a non-endemic region in the US. All samples were tested on the Procleix Panther system. **Results/Findings**: Based on probit analysis, the Procleix Zika Virus assay showed 95% detection at 13.4 copies/mL (95% CI: 9.9-20.3) and 50% detection at 2.4 copies/mL (95% CI: 2.0-2.9) for in vitro synthesized RNA transcript, and 95% detection at 5.9 copies/mL (95% CI: 4.3-8.9) and 50% detection at 1.0 copies/mL (95% CI: 1.9-1.2) for ZIKV positive plasma. Assay specificity was 100% (95% CI: 99.5-100.0). **Conclusion**: Using the Procleix Zika Virus assay on a fully automated Panther system, we demonstrated the feasibility of detecting low levels of ZIKV RNA (95% detection at about 10 copies/mL). Specificity testing indicated that the assay is specific, with no false positive results observed in this study. Future studies will be expanded to include additional sample types and prospective, investigational screening for both surveillance and interdiction of ZIKV RNA positive blood products. Procleix Zika Virus assay on the Procleix Panther system is not FDA approved product; it is intended for investigational use only.

SP459

Analytical Performance of PCR Assays for Detection of Zika Virus RNA

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Background/Case Studies: Zika virus (ZIKV), an arbovirus transmitted by Aedes mosquitoes, has spread rapidly throughout most of Latin America during 2015-2016, with severe neurological consequences in fetuses and adults. ZIKV has the potential for transfusion transmission (TT), with high rates of viremia documented in donors during the 2013-2014 French Polynesia outbreak and several cases of probable TT recently reported in Brazil. A ZIKV PCR diagnostic test developed by the CDC received emergency use authorization (EUA) from the US FDA in March 2016. For blood screening, in April 2016 the FDA approved use of the cobas® Zika nucleic acid test (NAT) developed by Roche Molecular Systems (RMS) as an Investigational New Drug (IND). In addition, a ZIKV NAT assay is under development by Hologic/Grifols. The NAT assays are highly sensitive with 95% limit of detection (LOD) $<$ 15 copies/mL and 50% LOD $<$ 5 copies/mL. We sought to characterize the performance of the CDC PCR assay and improve its sensitivity for use as a supplemental test of ZIKV NAT. **Study Design/Methods**: ZIKV culture supernatant with quantified genomic titer provided by RMS was serially diluted to concentrations ranging from 10e5-3.16 copies/mL. RNA was extracted and amplified from 10-12 replicates using the materials specified in the CDC PCR test. Three assay configurations were compared using 1) the RNA input (5 uL) and threshold cycle (Ct) cutoff (Ct $<$ 38) specified in the protocol authorized as a diagnostic test, 2) the 5 uL RNA input with a higher Ct cutoff (Ct $<$ 40), and 3) a higher RNA input (22.7 uL) with the Ct cutoff $<$ 40. The third configuration was used to test 50 plasma blood donor samples collected from a non-endemic region in the US. **Results/Findings**: Relative to the EUA CDC PCR assay procedure and cutoff, which had a 95% and 50% LOD of 781 copies/mL and 233 copies/mL, respectively, the 95% LOD was 2.3-fold lower (347 copies/mL) and the 50% LOD was 5.5-

TABLE.

Sensitivity	5 uL RNA, Ct < 38	5 uL RNA, Ct < 40	22.7 uL RNA, Ct < 40
LOD 95 [95% CI]	781 cp/mL [387, 1222]	844 cp/mL [288, 1766]	347 cp/mL [120, 702]
LOD 50 [95% CI]	233 cp/mL [157, 344]	70.5 cp/mL [39.6, 124]	42.6 cp/mL [24, 75.1]

fold lower (42.6 copies/mL) as the Ct cutoff and RNA input increased (Table 1). Out of 50 plasma samples, 49 tested negative and 1 tested initial reactive (IR) but was negative upon re-testing. The IR-only sample was adjacent to a ZIKV RNA+ sample during initial testing; therefore cross-contamination may have led to the initial positive result. **Conclusion**: An increase in the RNA input and Ct cutoff of the ZIKV PCR assay relative to the protocol in use for diagnostic testing allows for greater sensitivity without evidence of non-specificity. These modifications of the diagnostic assay are needed for supplemental testing of reactive samples from investigational donor screening using the highly sensitive NAT assay, and may enhance sensitivity for clinical diagnosis and monitoring.

SP460

Detection of Post-transfusion Malaria in Children under 5 by a Rapid Diagnostic Test

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Background/Case Studies: Malaria is an important parasitic disease. In 2015, 214 million cases of malaria occurred worldwide, leading to 438,000 deaths. Children under 5 years accounted for 70% of the deaths. Malaria mortality rate is estimated to have decreased by 60% globally between 2000 and 2015. Treatment with artemisinin combination therapy (ACT) together with other interventions has contributed to this reduction. To prevent misuse of the artemisinins and the subsequent spread of resistant parasites, laboratory confirmation of parasitaemia is recommended before the initiation of therapy. There are however contrary guidelines in transfusion, which recommend presumptive treatment in transfusion recipients in malaria endemic regions. The rapid diagnostic test (RDT) for malaria is a tool that is increasingly replacing microscopy for malaria diagnosis although it has not been evaluated for post transfusion malaria. Effective detection will help ensure that only positive cases are treated and thereby reduce unnecessary use of ACT. This aim of the study was to evaluate the use of malaria RDT for the detection of post transfusion malaria in children under five years old at Komfo Anokye Teaching Hospital in Kumasi, Ghana. **Study Design/Methods**: The study took place between November 2014 and April 2015. Pre-transfusion blood samples from patients and the corresponding donor blood were tested for *Plasmodium* parasitaemia using RDT and microscopy. Within 48hrs of the blood transfusion, blood samples were again tested for parasitaemia by RDT and microscopy. To determine the incidence of post-transfusion malaria (defined as parasitaemic negative patients who develop parasitaemia after transfusion), 28 patients who were negative at pre-transfusion were evaluated. Their pre-transfusion, post transfusion and donor blood samples were tested for parasitaemia by PCR. **Results/Findings**: Male children formed the majority (64%) of the 179 enrolled participants. The majority (52%) of the study population were < 1 year. There were 103 patients who were not tested for parasitaemia but 17% were treated with antimalarials, which is contrary to WHO treatment guidelines. The mortality rate for participants was 11.7%. The prevalence of malaria in donor blood was 27% by RDT and 7% by microscopy. Prevalence of malaria in patients at pre-transfusion was 34% by RDT and 13% by microscopy. Out of 28 malaria negative patients at pre-transfusion, 21 received *plasmodium* positive blood and 16 went on to develop post transfusion malaria after 48hrs. The incidence of post transfusion malaria was 76.2% (16/21). Using PCR as the gold standard, the sensitivity of RDT to detect post transfusion malaria was 100%. **Conclusion**: The prevalence of post transfusion malaria in transfusion recipients is high. Malaria RDT is a sensitive tool for the detection of post transfusion malaria.

SP461

Zika Virus Outbreak in the Americas: Development of Tools to Assist Responses

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Background/Case Studies: Zika virus (ZIKV) is a Flavivirus transmitted to humans mainly by *Aedes aegypti* mosquitoes, first isolated from a monkey in the Zika Forest, Uganda, in 1947 and from a human in 1968 in Nigeria. The first ZIKV outbreak outside Africa/Asia occurred on Yap Island, Micronesia in 2007. ZIKV was next reported in French Polynesia in 2013/2014, followed by an extensive outbreak that started in Brazil in 2015, and spread through the Caribbean and the Americas. About 80% of human infections are asymptomatic, and symptomatic infections include low-grade fever, arthralgia/myalgia, headache, conjunctivitis, rash, and asthenia. ZIKV infection has been associated with severe neurological manifestations such as Guillain-Barré syndrome and with congenital abnormalities including microcephaly. There are no vaccines or specific treatments for ZIKV infection. Transmission via blood transfusion is very likely during epidemics in the absence of blood screening assays because 80% of infections are asymptomatic; two probable transfusion-transmitted ZIKV infections were reported in Brazil. About 3% of blood donations were viremic during the French Polynesia outbreak. Neurological manifestations and congenital anomalies are potential undesirable outcomes of transfusion-transmitted ZIKV that need to be prevented. Laboratory diagnosis of ZIKV is made by serology, viral isolation and nucleic acid testing (NAT), which is the most sensitive detection method. Although there is one FDA-cleared NAT for diagnostic use in clinical samples, there are no FDA-approved ZIKV blood screening assays. Our aim was to produce ZIKV-RNA Reference Reagents for use in the evaluation of existing NAT assays and development of novel ZIKV-NAT assays. **Study Design/Methods**: The ZIKV-RNA reference reagents were prepared using cultured virus stock from two strains (PRVABC59, Puerto Rico-2015, GenBank#KU501215, from CDC; and FSS13025, Cambodia-2010, GenBank#JN860885, from UTMB.), heat-inactivated and diluted in human plasma. Heat-inactivation was confirmed by back-titration and the material was further characterized by 6 well-established laboratories as follows: participants were asked to test the RNA from reagents using their NAT assay(s) in serial dilution to determine the end-point, followed by testing of half-log dilutions around that end-point to confirm titer. Estimated NAT-detectable units/mL (NDU) was calculated using Probit analysis after adjustment for the volume of reagent used for testing. **Results/Findings**: Collaborative testing produced a mean concentration of 4.4 log10 NDU/mL (range 4.2 log10 - 4.5 log10), for PRVABC59 and 4.8 log10 NDU/mL (range 4.7 log10 to 5.0 log10), for FSS13025. **Conclusion**: The ZIKV RNA Reference Reagent for NAT was established with a concentration of 4.4 log10 NDU/mL for PRVABC59 and of 4.8 log10 NDU/mL for FSS13025.

Administrative Section

Blood Management

A1-030E

Novice to Expert: Designing Transfusion Medicine Education Using an Innovative Approach

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Background/Case Studies: The Joint Commission has identified blood product transfusion as one of the most common and overused medical intervention prescribed for hospitalized patients. Many hospitals have attempted to address this concern with patient blood management (PBM) programs. Most PBM programs utilize a variety of approaches to enhance blood utilization, but education is generally considered to be the flagship element of these programs. However, the content of this education and the perception of the intended audience for that education have not been standardized. This abstract describes an approach to determining the specific educational content and the perceived need for education by the clinical staff. **Study Design/Methods**: Since it is generally acknowledged that medical school curricula provide limited transfusion medicine education, a needs assessment was designed to assess actual knowledge and self-assessed knowledge of transfusion practice. The assessment tool was embedded into an internet link and distributed from the Chief Executive's Office to attending physicians, residents, fellows and other credentialed providers. The results of the survey were used to develop educational resident conferences, departmental Grand Rounds, and eLearning mandatories. **Results/Findings**: Over 50% of respondents were hospital residents, with pediatrics and internal medicine being the most numerous; other respondents included attending physicians, fellows, nurse practitioners, and nurse anesthetists. Among clinical physician staff, 66% indicated that they had 3 or fewer hours of medical school education devoted to transfusion medicine and 78% have had no post-graduate education related to transfusion or alternatives. Of this group, 82% order blood product transfusion at least monthly. In an assessment of transfusion knowledge, significant deficits were identified in the indications for platelet transfusion, expected post-transfusion increments, indications for blood product irradiation, the use of cryoprecipitate, and the causes and identification of transfusion reactions. Importantly, however, 46% of respondents considered themselves to be "novices" or "advanced beginners" when they assessed their own knowledge, and 68% indicated that additional transfusion training would be either "very helpful" or "extremely helpful." **Conclusion**: Historically, ordering clinicians have had limited exposure to proper transfusion education and are seeking additional knowledge to aid them in the path to safe and appropriate transfusion prescribing. The needs assessment has highlighted specific knowledge deficiencies of clinicians as well as validating an overall interest in additional training in transfusion medicine. This information has been used to target a new educational approach to transfusion medicine at this institution.

A2-030E

Successful Implementation of a System-Wide Program to Reduce Platelet Wastage

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Background/Case Studies: In 2013, our healthcare system funded projects to increase value, improve efficiency and reduce costs, including a proposal from Transfusion Services for a novel model to reduce apheresis platelet (Plt) wastage due to outdating. Data analysis revealed Plt outdating in our 5 hospital system ranged from 5 - 37% (> $1 million annual loss of outdated Plt). **Study Design/Methods**: We proposed saving $700,000 annually through reduced Plt outdating by implementing a hub-and-spoke Plt sharing model. The "hub" hospital was selected based on its low outdate rate (5%) due to heavy but predictable usage by its large outpatient infusion center. The other 4 hospitals with higher wastage rates (eg, a facility that stocked, but infrequently transfused, Plt based on scheduled cardiovascular surgeries) were designated as "spokes". In the proposed model, the 4 spoke facilities would transfer all Day 4 Plt to the hub during evening shift for transfusion to the next morning's infusion center patients. In order to provide central direction and management of the project, we funded an additional 0.5 FTE Plt Utilization Coordinator to organize logistics and training. **Results/Findings**: The coordinator met with each facility in the system individually to determine: 1) the "best" time of day for each spoke to transfer Plt to the hub such that patient care and workflows were minimally disrupted; 2) minimum/maximum par levels; and 3) transport logistics between facilities requiring modification. As each spoke facility was ramped up, corresponding reductions were made to the hub facility's standing Plt orders. An unexpected benefit to the health system was realized when the Utilization Coordinator observed the processes at each of the 5 institutions, including excessive Plt ordering practices at some facilities and worked with the staff and management to implement ordering best-practices. Additionally, the project was further modified by designating the central hub as "first call" before the blood supplier should a spoke hospital have a shortage, reducing supplier upcharges for stat orders. At the end of the first year, this model reduced the Plt outdate rate to 3-14% at the 5 facilities, saving the healthcare system $720,000. **Conclusion**: Communication and ongoing review of usage patterns proved important in reaching this monetary goal. Data provided by partnering with our blood supplier also proved helpful in making facilities feel more comfortable accepting lower par levels. Partnership with both the Finance and Project Management offices provided the leverage and accountability necessary for the project success. The healthcare system was able to exceed its ambitious goal of saving $700,000 through reduced outdated Plt and become better stewards of a limited and valuable resource.

A3-030E

BloodBrief: Increasing Awareness to Influence Transfusion Practice

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Background/Case Studies: Transfusion medicine clinical practice is well established however varies from hospital-to-hospital. Introduced to hospitals in 2013, the BloodBrief aims to promote optimal utilization of blood components and products by heightening hospital awareness of issue trends over time. Each BloodBrief engages chairs of hospital transfusion committees informing hospitals of utilization of a blood component or product, highlighting 3 years of anonymized issue data, disposition data, cost (if applicable) and hospital peer comparison. To-date, BloodBrief topics include O-neg red blood cells, AB plasma, CMV sero-negative platelets and IVIG. Topics addressed and data provided continue to evolve; and distribution has been expanded beyond the initial top 50 targeted hospitals. **Study Design/Methods**: To determine effectiveness and impact of the BloodBrief, hospitals were asked to complete an electronic survey in January 2014. The evolution of the BloodBrief prompted the need to conduct a 2nd survey. Between February 12 - March 9, 2016, 77 contacts representing 100 hospitals were asked to complete the survey. Of the 100 hospitals, 89 were identified as a top 50 hospital on at least one of the last 4 BloodBriefs released since January 2015. The 11 other hospitals were chosen randomly outside of top 50 lists. **Results/Findings**: A total of 25 respondents started the 2016 survey. Of the 19 respondents that completed the entire survey, 6 represented a single hospital and 13 responded for a group of hospitals. Survey data determined these 13 respondents represented >100 hospitals. 85% of respondents, prior to reviewing a BloodBrief, were not aware how their hospital(s) ranked with other hospitals across the country (excluding Quebec). 90% indicated the BloodBrief highlighted data/information that was new (ranking within comparable hospital group, top user, 3-yr issue trends, cost). The BloodBrief influenced 85% of respondents to review transfusion practice or blood component/product demand. All BloodBrief topics prompted transfusion policy review or change (29% O-neg RBC, 21% AB plasma, 18% CMV sero-negative plts, 11% IVIG). Changes and policy review that occurred include: requirement for CMV sero-negative plts, stock other plasma groups to reduce AB plasma use, recommendations guiding use of IVIG, O-neg in uncrossed situations limited to women of childbearing age. Most hospitals opting to not review transfusion practice or policy cite use of already very strict transfusion policy. **Conclusion**: Results of the 2016 BloodBrief effectiveness survey confirm survey findings from 2014. The BloodBrief continues to be effective in promoting optimal utilization of blood components/products. Heightened hospital awareness of issue trends over time and comparisons within hospital peer groups influences hospital transfusion practice/policy.

A4-030E

Blood Management in an Orthopedic Setting

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Background/Case Studies: Transfusions are one of the most over-utilized treatments performed in any hospital setting (Choosing Wisely Campaign

TABLE. PBM Impact Measures

	FY13	FY14	FY 15
Transfusions per Discharge	0.68	0.50	0.32
Length of Stay	3.3	3.2	3.0
Blood Spend Actual	$1,083,208	$776,880	$620,028

April 2014 http://www.choosingwisely.org/societies/american-association-of-blood-banks/). Costs and risks attributed to transfusions are high and may have a significant impact on patient safety. In our institution we perform over 10,500 joint replacements and spine surgeries per year, making transfusion-associated costs very high. We implemented patient blood management (PBM) strategies aiming to reduce waste, exposure to allogeneic blood by decreasing transfusions, and transfusion associated costs while maintaining quality patient outcomes.
PBM strategies were phased in over a two fiscal year (FY) period with FY13 as baseline and FY14 and FY15 as the monitoring period. A blood utilization dashboard was created to monitor the impact and included graphic representations of transfusions per discharge, crossmatches per discharge, perioperative autologous blood recovery, and autologous and allogeneic waste rates. **Study Design/Methods**: We made the following changes: 1) revised the Maximum Surgical Blood Ordering Schedule (MSBOS) to reflect current surgical practices, minimized excessive ordering of blood products, and reduced blood inventory par levels in the blood bank to decrease potential waste; 2) assigned a hospitalist to each nursing unit as part of the Model of Care Program where continuum of care was optimized as part of an individualized care planning approach. This care plan included real time assessment of transfusion need according to hospital published transfusion guidelines; 3) implemented specific PBM strategies peri-operatively by reconstructing our cell salvage program. This ensured maximium retention of each patient's red cell mass. We also introduced the use of tranexamic acid for total hip and knee arthroplasties to reduce post-operative bleeding. **Results/Findings**: The impact of implementing PBM strategies was monitored and measured with three organization-wide metrics during FY14 and FY15 using data from FY13 as baseline.(See Table) **Conclusion**: After review of our metrics during the monitoring period, our implementation of PBM strategies achieved our stated goals of reducing the use of allogeneic blood by decreasing transfusions, making the MSBOS consistent with surgical procedures performed currently, increasing the effective utilization of our cell salvage program and implementing tranexamic acid to maintain patient red cell mass. Additionally, review of the actual blood spend metric indicated that the implementation of PBM strategies produced significant cost savings for our organization.

A5-030E

Addition of an "MTP STAT Pack" to the Massive Transfusion Protocol Improves Time from Collection to Reporting of Actionable Coagulation Data

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Background/Case Studies: A massive transfusion protocol (MTP) designed to address obstetrical hemorrhage is utilized at our institution. This MTP is designed to provide balanced transfusion ratios of blood components, but also allows for goal-directed therapy via rapid laboratory testing. Due to the need to control rapid bleeding and quickly provide blood products in obstetrical hemorrhage, routine or even STAT evaluation of the coagulation tests may not be effective. Methods to ease collection and improve laboratory turnaround times (TATs) for coagulation data allow for more accurate real-time transfusion decisions. At our institution "MTP STAT packs" were implemented to help achieve this goal. This process minimizes electronic ordering by bedside providers, allows for prioritization of MTP specimens over routine and traditional STAT orders, and provides faster results to the treating provider. **Study Design/Methods**: Of 54 MTP activations between 2012-2016, we reviewed 50 with complete data. In 2014, STAT packs were added to the MTP– STAT packs are provided on request and with each cooler of blood issued during MTP activation. The packs consist of a biohazard bag, containing one each of EDTA and 3.2% sodium citrate tubes, as well as a heparinized syringe and a neon-green MTP lab requisition form. Data pertinent to specimen collection and TATs were obtained from blood bank records and the laboratory information system. **Results/Findings**: (See Table) **Conclusion**: The integration of the "MTP STAT pack" to the massive transfusion protocol improved coagulation lab collection rate, time to collection, and laboratory turnaround times for coagulation tests during MTP activation. This reduction in processing and reporting time provides more rapidly actionable coagulation data. In our institution, this means expediting appropriate deviation from the standard MTP ratios and diminishing any critical blood component deficit. Addition of the "MTP STAT packs" are also associated with a decreased overall MTP length, possibly indicating improved time to hemostasis due to increased availability of coagulation data.

A6-030E

Impact of Factor Concentrates on Blood Product Utilization in Orthotopic Liver Transplantation

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Background/Case Studies: Orthotopic liver transplantation (OLT) is associated with relatively high blood product utilization, with excessive transfusions associated with worse outcomes. Factor concentrates (FC) including four-factor prothrombin complex concentrates (PCC) and fibrinogen concentrates are lower volume, have a theoretical lower infection risk, but have a higher cost profile relative to blood products. We noted that factor concentrate utilization is increasing during major surgical procedures, including OLT, at our institution; however, the effect of this practice on blood product utilization remains unknown. As factor concentrates can, to a certain extent, influence the coagulation status of a patient in the same way that blood products can, we sought to assess the effect of FC use on blood product utilization. **Study Design/Methods**: We conducted a retrospective single-institution matched cohort study to assess blood product utilization among OLTs utilizing FCs intraoperatively over a two-year period at a tertiary care adult academic center. Non-FC OLT controls were randomly assigned in a 1:1 matched ratio. Preoperative variables measured included age, sex, and admit severity of index score. Day of surgery transfused product data was collected from the blood bank laboratory information system. The University HealthSystem Consortium (UHC) database was used to identify patient clinical parameters. The primary endpoint was the number of plasma units

TABLE.

Lab testing during MTP	Total # MTPs	Coagulation labs requested during MTP	Time to draw of PT/PTT, mins, (range)	Time to draw of fibrinogen, mins, (range)	TAT PT/PTT mins, (range)	TAT fibrinogen mins, (range)	Time, MTP start to fibrinogen result, mins, (range)	Length of MTP mins, (range)
No MTP STAT pack	26	22 (85%)	46 (0-163)	54 (0-200)	25 (8-45)	30 (8-54)	85 (24-231)	154 (35-320)
MTP STAT pack used	24	23 (96%)	22 (0-50)	22 (0-50)	19 (11-39)	20 (11-39)	40 (16-65)	104 (40-300)
t-Test (p-value)			0.02	<0.01	<0.01	<0.01	<0.01	<0.01

TAT, Turnaround time: time from collection to result

transfused the day of surgery. The Wilcoxon signed-rank test was used to assess the null hypothesis. Secondary endpoints included number of transfused packed red blood cell (pRBC) units, platelet doses, cryoprecipitate doses, hospital length of stay (LOS), and intensive care unit (ICU) LOS. **Results/Findings**: From December 2013 to December 2015, 167 OLTs were identified at our institution. Twenty-two OLT patients received FC intraoperatively beginning in June 2015. Nineteen consecutive patients with UHC data available were included and matched in the FC and non-FC groups. Seventeen of the 19 in the FC group received both intraoperative PCC and fibrinogen concentrate. Patients receiving FCs used significantly less pRBC units (median: 18 and 11, $p=0.029$). Plasma units (median: 14 and 8, $p=0.078$), platelet doses (median: 5 and 2, $p= 0.093$), and cryoprecipitate doses (median: 0 and 0) were not statistically different. No other preoperative variables or secondary outcomes significantly differed including total hospital LOS and ICU LOS. **Conclusion**: Utilization of FCs during OLT was associated with a reduction in allogenic transfusion of pRBCs in a limited retrospective cohort of matched patients.

Management, Finance and General Marketing

A7-030F

Cost Savings in Autoimmune Hemolytic Anemia with Genotype Matched Red Blood Cells

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Background/Case Studies: Autoimmune hemolytic anemia (AIHA) is a disorder involving antibodies against self red blood cells leading to life-threatening anemia. Although the incidence is 0.8-3 per 1,000,000 per year in adults, the mortality rate can range up to 11%. These patients are particularly difficult for blood banks because underlying alloantibodies are masked by the autoantibody and cross-match compatible blood may not be possible. The current standard is to perform technically challenging and costly adsorptions to reveal alloantibodies and issue least-incompatible red blood cells. Genotype matched red blood cells, however, can provide a safe and cost effective alternative to continuous adsorptions. **Study Design/Methods**: Financial data and specimen collection information from inpatient autoimmune hemolytic anemia patients (December 2015 to March 2016) receiving the standard practice in parallel with genotype matched only red blood cells were collected. The standard practice included adsorptions (allo- and autoadsorptions) every three days and crossmatching adsorbed patient's serum to donor red blood cells. The genotyping protocol required an initial autoadsorption in parallel with a common genotype panel. Alloadsorptions were repeated every 4 weeks to identify any new alloantibodies, if the patient continued to need red blood cells. The common genotype panel targeted the most common variants in 9 blood groups. **Results/Findings**: A total of four patients with warm autoimmune hemolytic anemia were identified. All patients received antigens matched red blood cell units for RhD, RhCE, MNS, Jk, Fy, and Do after genotyping was completed. An average of 50 mL and 20 mL EDTA blood tubes were collected from each patient for autoadsorptions and alloadsorptions, respectively. Genotyping required one 7 mL EDTA blood collection. Adsorption reports were issued with a mean of 6 hours and genotyping reports were available with a mean of 30 hours. The average cost of adsorptions was $1,900 and the average cost of genotyping was $250. On a per patient basis, the average cost of a serology only work-up with a 2 unit order of red blood cells was $2,400. Genotyping with a 2 unit order of red blood cells cost on average $900. No new antibodies were identified with genotype matched RBC units. **Conclusion**: The initial cost of genotyping an autoimmune hemolytic anemia patient is an additional $250, but subsequent transfusions with genotype matched red blood cell units saves $1500 per 2 unit order of red blood cells. In patients requiring chronic transfusions, substantial cost savings can be achieved by using genotyped matched red blood cells in place of adsorbed serum. CPT-4 Code: 81403 is available for molecular typing reimbursement.

A8-030F

Direct Cost Analysis of Implementing a Rapid Turnaround Time ADAMTS13 Activity Assay In-house Shows Decision Would Result in Institutional Cost Savings

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Background/Case Studies: Thrombotic thrombocytopenic purpura (TTP) is a disease known to be caused by an acquired defect in the ADAMTS13 protein ($\leq$10% of normal activity). The purpose of this study is to perform a direct cost analysis to determine if implementing a rapid turnaround time (TAT) ADAMTS13 activity assay in-house would result in institutional cost savings. **Study Design/Methods**: This was a retrospective study from January 2010 through September 2015 that included all patients at a large academic hospital who were treated with therapeutic plasma exchange (TPE) for suspected TTP. Medical records were reviewed on these patients to determine their ADAMTS13 activity levels prior to the start of TPEs, the number of TPE procedures each patient had received, the number of fresh frozen plasma (FFP) units given for each procedure, and the final diagnosis assigned to each patient. The total expense of implementing an in-house ADAMTS13 activity assay was defined as the cost per test using the new assay minus the cost per test under the current send-out price, then multiplying the difference by the number of tests that had been sent out during the time frame of the study. This incurred expense was then compared to the cost savings that would result from reducing the number of central venous catheter placements, TPE procedures, FFP units used, and nursing labor hours. The calculation of cost savings excluded patients who had atypical hemolytic uremic syndrome (aHUS) listed in the differential and/or final diagnosis or who continued to receive TPEs despite having ADAMTS13 activity levels non-diagnostic for TTP. **Results/Findings**: There were 59 patients treated empirically for TTP using TPE. Excluding possible or definitive aHUS patients, it was concluded that 17 of these patients had TPEs halted as a direct result of their ADAMTS13 activity results. Had a rapid TAT ADAMTS13 activity assay been available in-house, it was assumed that 16 of these patients could have avoided catheter placement and TPEs altogether. From these observations and the estimated total expense of implementing an in-house ADAMTS13 activity assay, the total net savings would amount to $40,932. **Conclusion**: According to a direct cost analysis, implementing a rapid TAT ADAMTS13 activity assay in-house would result in an annual institutional cost savings of $7,119. More importantly, faster results would allow for more appropriate clinical management and patients avoiding the risks surrounding central venous catheter placement, exposure to blood products, and TPE procedures.

A9-030F

Transitioning to Pooled Cryoprecipitate: A Pediatric Perspective

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Background/Case Studies: Cryoprecipitated antihemophilic factor (cryo) is a product prepared by thawing fresh frozen plasma to 1 to 6 C and centrifuging to collect the cold-insoluble protein which precipitates in the unit. While most of the supernatant plasma is removed to a satellite bag, approximately 15 ml is used to resuspend the precipitated product prior to re-freezing. While cryo contains Factor VIII, Factor XIII, fibronectin and vonWillebrand Factor, it is most commonly used for its fibrinogen content. At our pediatric institution we previously used only single units of cryo which were then pooled to the provider's ordered dose. There was hesitation initially to transition to pre-pooled cryo as it was expected to be difficult due to limitations of the computerized ordering system, provider education and lack of data for guidance in the literature. However, due to a reduced contamination risk, cost savings and technologist time we made a decision to transition to pre-pooled cryo when possible. **Study Design/Methods**: Because of volume restrictions due to small patient size, ordering of single units up to three is permitted. However, they are transfused individually rather than technologist-pooled as had been performed previously. Under most circumstances, for orders greater than four units, pre-pooled unit(s) of 5 are issued. The institutional transfusion committee also approved allowing the technologists to modify the provider's order and round to the nearest unit of 5 based on a chart found in the Blood Bank SOP. **Results/Findings**: There is a reduction in usage of cryo pooled within our blood bank and increased utilization of pre-pooled cryo which is demonstrated in the table. In addition to the technologist time savings by not pooling, there was also a cost savings noted for the patients. While the cost per unit of cryo is higher than single units, this is offset by decreased thawing charges and elimination of the pooling charge. Had the period of 11/2012-10/2013 followed the current protocol, the cost savings to the patients would have totaled over $30,000. **Conclusion**: Transitioning to pre-pooled cryo is possible and desirable in the pediatric setting. It results in less technologist time needed to issue the product as well as cost savings in addition to decreasing contamination risk. Allowing technologists to round units into doses ensured minimal disruption to clinical care.

TABLE. Cryo Utilization and Cost

	Cost to patient per single unit		Usage	Cost to patient per single unit		Usage
	11/12-6/13	7/13-10/13	11/12-10/13	11/14-6/15	7/15-10/15	11/14-10/15
Cryo single units (add thaw charge)	$70.79	$65.77	573	$66.28	$72.82	469
Cryo hospital pooled (add thaw charge/unit + pool charge x1)	$70.79	$65.77	92	$66.28	$72.82	15
Cryo pre-pooled 5	N/A	N/A	N/A	$89.00 ($445 for pool of 5)		100
Thaw charge per unit	$95.05	$98.85		$102.80	$106.95	
Pool charge	$127.40	$132.50		$137.80	$143.35	

A10-030F

Utilization of MLT, MLS, and SBB Staff in the Transfusion Medicine Laboratory

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Background/Case Studies: Finding qualified laboratory professionals for the Transfusion Medicine laboratory can be a challenge. Both Associate-degreed Medical Laboratory Technicians (MLT) and Medical Laboratory Scientists (MLS) with a Bachelor's degree are utilized in clinical laboratory settings. Those completing the Specialist in Blood Banking (SBB) exam may work in labs performing more complex testing. We developed a survey to evaluate the perceived differences between and utilization of MLT, MLS, and SBB staff in Transfusion Medicine laboratories of varying locations, size and staffing levels across the US. **Study Design/Methods**: A survey consisting of 49 questions was electronically distributed to approximately 250 different transfusion service and reference lab facilities in all regions of the US. The survey evaluated the location (rural, suburban, urban), size of facility by number of hospital beds and utilization of MLT, MLS, and SBB staff. The survey included questions related to the difference in testing responsibilities between MLT and MLS-trained staff. Completed surveys were returned electronically and all information was entered into a database for analysis. All survey responses were anonymous. **Results/Findings**: We evaluated 155 usable surveys, representing all regions of the US. Most facilities in the Northeast, Midwest and Southwest regions reported no difference in duties and expectations between MLS and MLT staff (65%, 53% and 61%, respectively), with 10% of all facilities indicating duties depend upon training. Southeast (42%) and West (52%) facilities noted the use of no MLTs in Blood Bank staffing. The majority of facilities with <200 beds in all regions except Southeast reported staff who rotate through all areas of the lab and 56% reported no difference in duties of MLS vs. MLT staff. In hospitals with >500 beds and Blood Center/Reference Labs, 34% indicated equivalence of MLS and MLT duties, and these labs primarily have a dedicated blood bank staff. SBB-trained staff members are found in all regions and in facilities of all sizes, with most in larger facilities with dedicated Blood Bank staff. **Conclusion**: Many facilities across the US feel that MLT staff members are equivalent to MLS staff. The reduced use of MLTs in the Southeast and West regions may result from licensure requirements in these areas. As expected, smaller facilities (<200 beds) use both MLT and MLS staff who rotate through all laboratory departments, while larger facilities, providing more complex testing, have a dedicated Blood Bank staff and are less likely to equate MLT and MLS staff. The use of rotating staff and staff with less formal training can lead to less complex testing and increased reference lab usage by smaller facilities. SBB level staff work in facilities of all sizes and all geographic areas, indicating a continued need for SBB training programs.

A11-030F

Engagement of Blood Donors for Population-Scale Genomics Research

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Background/Case Studies: In January of 2015, President Obama announced the Precision Medicine Initiative, with the goal of assembling a diverse cohort of more than a million Americans for studies to improve our nation's health. The investigators proposed that blood centers and their donors contain the ideal infrastructure and participants for population-based research studies. Blood donors are diverse and already contribute blood, health data and time for the betterment of the community. Additionally, extensive blood bank infrastructure reaches deep into our communities and blood banks are trusted and nationally collaborative. **Study Design/Methods**: The IRB-approved research study began with a 13-question survey that was e-mailed to approximately 150,000 active, inactive, and deferred donors, asking if they would be interested in participating in a research study that would follow people's health over time to understand risk and disease and what type of data they would be willing to provide. More than 300 donors expressed interest in the first 10 minutes. A cohort of 70 was assembled, matching the ethnic, age, and socio-economic diversity of the community. Donors were consented by genetic counselors and blood was collected at a large community blood drive. A leading industry partner performed whole genome sequencing, including a screen targeted at healthy adults. Results were returned to the participants via a post-test genetic counseling session and access to the data was enabled via a genome visualization and education tool at an educational event. **Results/Findings**: Of the 7,177 unique donor responses collected, 71.7% would provide genetic information, 85.5% would complete surveys and 84.9% would provide information about lifestyle, whereas 48.5% would provide information from their electronic health record and only 26.8% would provide information from their social media account. After sequencing, and at the return of their results, 29/62 (46.8%) said that they participated only because of "ability to contribute to research/participate in Precision Medicine Initiative (altruistic)" and/or "general curiosity." Initial genetic analysis indicates that 16/70 (23%) are carriers or have a predisposition for hereditary hemochromatosis, 3/70 (4%) have predisposition to blood clotting, and 4/70 (6%) were carriers for other blood disorders. Only 7/70 (10%) of cohort did not have variations in the metabolism of four common medications. Two donors had likely pathogenic genetic variants in genes that indicate a predisposition for actionable cardiac disorders. **Conclusion**: The value of a blood donor's blood and altruism extends beyond transfusion medicine into population-scale research. The pilot demonstrates that blood banks are trusted entities that can be leveraged to recruit large numbers of diverse volunteers willing to participate in genomic research.

A12-030F

Impacts of Development Partners Support and Government Commitment Towards Establishing A Sustainable and Safe Blood Supply System In Ethiopia

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Background/Case Studies: Millions of lives saved each year through blood transfusions globally. However, in most developing countries including Ethiopia, people still die due to inadequate supply of blood and its product. Since year 2004 the government of USA grant called CDC Blood safety project was the sole development partner organization supporting BTS in Ethiopia. Assessing the impact of partners support and government commitment level towards establishing sustainable and safe blood service program will have major inputs for continuity of health care delivery in Ethiopia. **Study Design/Methods**: A retrospective analysis on US government CDC Blood safety grant awards in the project periods of 2004-09 and 2010-2017 and review on Ethiopian government GMS, national blood donor database records covering 2005-2015 and review on new blood service strategy implementation status was also made **Results/Findings**: The project period analysis reveals that the first project period was found challenged by government underutilization, poor GMS and delayed grant budget release, and on the

second project period, the grant level increased from 500 USD up to 3500 USD per annum following proper fund utilization rate of the government. The review on new strategy implementation status indicates that the increased government commitment level initiated by developing new strategy in 2005 and full reversion of the blood service administration from Red Cross society to the government health care system made in 2013. Funding agent support focusing on government new strategy implementations and its identified impacts on national blood service are; establishment of nationally coordinated BTS and independent government budgeted institution with initial year budget allocation of 4.5 million USD in 2015, construction of 21 new standard non-hospital-based blood bank centers furnished with standard equipment and trained man power, procurement of 46 new mini collection van enabled to increase mobile blood collection teams from 2 to 31, mobile sites from 27 to 3200, number of Hospital utilizing safe blood from 45 in 2012 to 314 in 2015 and year-round awareness creation effort. The total annual blood donation also shows increasing from 25,004 in 2004, 54,693 in 2012 to 142,345 donation in 2015 with increased proportion of voluntary donation 23%, 28% and 97.4%, respectively. **Conclusion**: Strategic development partners funding and support based on newly developed government strategy on Blood service with commitment of the government has brought a positive impact in establishing sustainable and safe national blood service program in Ethiopia. Even though the identified positive impacts mentioned are achieved, the BTS remains with multiple challenges and needs continuity of funding and more partner support and government commitment.

Collections and Product Manufacturing

A13-030G

Increasing O-negative Units Collected by Automation using Haemonetics MCS+

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Background/Case Studies: Red blood cells collected by automation, commonly referred to as "double red cells" (DRC), result in the collection of two units of red cells. Donors who are O-negative (Neg) provide the greatest impact to the blood supply because they are "universal" red cell donors. This blood center utilizes Haemonetics MCS+ technology to collect DRC, and has consistently increased the percent of O Neg DRC year-over-year (YOY) by implementing systematic, broad-based initiatives. **Study Design/Methods**: Multiple approaches were used to achieve the desired goal that 21% of DRC units would be O Neg. In the Collections Department, all new hires and operators in training receive face-to-face education about the importance of converting O Neg whole blood donors to DRC, and participate in role-play exercises around conversion. Recruiting whole blood donors to DRC at blood drives is expected. All staff receive information and recognition in the form of verbal presentations, a quarterly Traveling Trophy presentation, and emails highlighting superior performance. Donor Resources staff receive recognition when drive coordinators schedule DRC appointments for O Neg donors. Teleрecruiters focus specifically on O Neg donors to schedule them to donate DRC. Regular updates are sent to Senior Leadership informing them of O Neg DRC collections and progress on goal. Operationally, effort is made to strategically schedule devices to drives that attract a higher percentage of O Neg donors. Devices were reallocated between fixed sites and smaller mobiles to capitalize on opportunities to make DRC available to more O Neg donors. Organizationally, conversion of eligible O Neg donors to automation is tracked to identify teams or individual staff who may require improvement. Donor information sheets available at all blood drive as well as the blood center's website provide messaging to O neg donors of the value their blood donation provides to the overall blood supply. **Results/Findings**: Over a 5-year period in this blood center, percent O Neg units collected by automation increased each consecutive year. In FY11, 18.46% of the automated red cells were O Neg. As of March 2016, this has increased to 21.65% **Conclusion**: Achieving consistent increases in collection of O Neg DRC involves educating staff and donors what donation option provides the greatest benefit to patients. Consistent messaging to collections staff, donor recruitment staff, and donors themselves can result in a significant shift in how O Neg donors choose to donate. In addition, attention to how and where devices are scheduled can optimize the chances that the percentage of O Neg units collected by automation will increase.

TABLE.

Percent O Neg	FY11	FY12	FY13	FY14	FY15	FY16 YTD
	18.46	19.48	19.85	19.93	20.42	21.65

A14-030G

Maximize Apheresis Plasma Utilizing Amicus and Alyx to Increase Whole Blood Plasma for Fractionation

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Background/Case Studies: The market demand for plasma for fractionation has presented business growth opportunity in the blood banking industry requiring diversification in operations. We developed a business plan to increase apheresis plasma collected for transfusion to allow for more whole blood (WB) derived plasma to be manufactured as recovered plasma. The apheresis plasma collection strategy included the implementation of the Alyx plasma protocol and an increase in our collection of Amicus InterSol platelets. Collecting apheresis platelets in InterSol allowed for collection of more plasma units since the plasma volume needed for the platelet is reduced by 65 percent with InterSol. **Study Design/Methods**: Our business plan included the Alyx software upgrade for plasma collections and validation of the plasma protocol, expansion of Amicus InterSol collections as well as WB plasma diversion to fractionation. The increased focus of donor recruitment and on site conversion for apheresis transfusion plasma required us to diversify our collect-to-need philosophy and include the active recruitment of AB plasma donors in the mobile environment. **Results/Findings**: With the focus on the collect-to-need philosophy, we were able to develop our mobile plasma program and direct donors to the donation type most needed for their blood type. Despite a decrease in WB collections designed to level set collections to demand, we saw a 13.9% increase in WB derived plasma manufactured for fractionation. This was a direct result of the 46 percent increase in apheresis plasma collections for transfusion in 2015. Productivity of the apheresis platelet program expanded with the increase of Amicus InterSol platelet collections. The platelet split rate remained high prior to, during and post implementation of InterSol platelets averaging 115 percent split rate, in line with the Amicus non-InterSol collection sites. By recruiting for collections based on gender and ABO blood type for specific components needed we were able to keep our RH positive donors engaged through plasma donations when red cells of that type were not in demand. **Conclusion**: By increasing our apheresis plasma collections through Alyx and Amicus with InterSol, we increased our plasma product availability to our local customers while increasing our revenue opportunities through WB plasma diverted to fractionation. We were able to keep the donors of RH types not heavily in demand for red cells engaged and have the opportunity to keep them in the habit of donating platelets with concurrent plasma and plasma only.

TABLE. Percent increase over Prior Year (PY), Amicus/Alyx plasma

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
2015 over PY			16	53	109	60	64	121	76	46	17	43	46
2016 over PY	51	38	9										30

TABLE.

	Female RBC	Male RBC	Female Plasma	Male Plasma
Total Donations	476	412	27	35
Donors meeting AAP criteria	97 (20%)	374 (91%)	26 (96%)	35 (100%)
AAP performed (Conversions)	57 (59%)	226 (60%)	16 (61%)	24 (69%)
Eligible donors AAP unwilling	30 (31%)	104 (28%)	2 (8%)	8 (23%)
AAP missed opportunities of eligible donors	10 (10%)	44 (12%)	8 (31%)	3 (9%)

A15-030G

Increasing the Projection Accuracy of Right Type Collections

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Background/Case Studies: Providing the right type of product to meet patient needs has been the impetus for blood centers to optimize the collection of blood products based on the blood type of the donor (Dnr). Based on these needs, an initiative was implemented for Collections staff to convert Dnrs, depending on their blood type, from Whole Blood (WB) to automated apheresis procedures (AAP). Even with this initiative and active monitoring, the Recruitment projection of expected products often differed from what was actually obtained. **Study Design/Methods**: All group O, AB, A Negative (Neg) and B Neg Dnrs presenting at a regional blood donor center fixed site and the associated mobile collections over a one month period were evaluated. The study assessed, by blood type and gender, if a Dnr met the Hemoglobin and height/weight requirements for an AAP and if the appropriate preferred procedure was performed. Group O, A Neg and B Neg Dnrs were targeted for Double Red Blood Cells (2RBC) collection and group AB for plasma collection. If an AAP was not performed on an eligible Dnr, the reason was also tracked. **Results/Findings**: Of all group AB Dnrs presenting, 98% met eligibility criteria for automated plasma collections [Female (F)-96%, Male (M)-100%, p=NS]. The plasma conversion rate was 61% for F and 69% for M. Of all group O, A Neg and B Neg Dnrs presenting, 53% (471/888) met eligibility criteria for a 2RBC collection. However there was a statistically significant difference ($p<0.000$) between 2RBC eligibility of F Dnrs at 20% vs. M Dnrs at 91%. The 2RBC conversion rate of eligible Dnrs was 59% for F and 60% for M (p=NS). Of all Dnrs presenting and meeting eligibility for an AAP, 27% (144/532) were unwilling to undergo this type of procedure when approached. 59% (85) preferred a WB donation while 32% (46) were unable to commit the time for an AAP. 13 Dnrs declined based on an unfavorable experience during a prior AAP. The reasons provided by M and F were not statistically different. The tracking log was not completed in 7% (65/950) of the cases where an eligible AAP was not performed. Based on 16 occasions when an AAP instrument was not available, instruments were relocated to optimize APP opportunities. **Conclusion**: To increase the accuracy of projections of 2RBC collections, as well as conversion success rate, the Dnr's gender needs to be considered in addition to the blood types of scheduled donors. Reasons Dnrs report being unwilling to undergo an AAP procedure has identified areas and opportunities to develop staff talking points as well as donor educational materials.

A16-030G

Use of the Global Registration Identifier for Donors by Collection Facilities

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Background/Case Studies: In 2014 the World Marrow Donor Association (WMDA) recognized the need for a globally unique identifier for potential stem cell donors to improve electronic communication, traceability, and accuracy by standardizing donor identification in registries across the world. **Study Design/Methods**: WMDA worked with ICCBBA to create the Global Registration Identifier for Donors (GRID). It will be introduced in a number of phases over 3-5 years. The specific timeline for each phase will be determined and communicated by WMDA. The phases are: Phase 1 - Registration identifier allocation rules, GRID format, GRID eye-readable presentation, and GRID data structure for electronic transfer are defined. Guidance for registries for mapping local identifiers to the GRID is developed. (Completed) Phase 2 - The European Marrow Donor Information System (EMDIS) and Bone Marrow Donors Worldwide (BMDW) support the GRID. Use of the GRID in communication between registries/cord blood banks/donor centers is recommended but not required. (Completed) Phase 3 - GRID is a mandatory field in communication with EMDIS and BMDW. It is introduced as an optional field in the communication between registries and their donor centers. GRID is used as the key donor identifier on search reports and is integrated in forms for donor request and outcome reporting. GRID is used on labels of products from adult donors when a donor identifier is required. Phase 4 - GRID is incorporated into all registry database systems as the key identifier for the donor and cord blood products. This is done in a manner that allows any GRID to be used as the key identifier (not only those GRIDs assigned by the registry). Phase 5 - 'GRID for life' is introduced and donors transferring to other organizations retain the GRID they have previously been assigned. **Results/Findings**: Use of the GRID will impact facilities that collect products for registries because (1) communication will use the GRID rather than the current donor identifiers (e.g., the NMDP number) and (2) the GRID will appear on the label of products from adult donors. Therefore, collecting facility computer systems should store the GRID assigned to a potential stem cell donor to improve efficiency, prevent manual transcription errors, and support labeling. The WMDA is currently in Phase 3 of the GRID project. The last step of this phase includes the use the GRID on labels of products from adult donors. Therefore updating computer systems takes on some urgency. **Conclusion**: The GRID will replace the current donor identifiers assigned by registries. Computer systems for facilities that collect products for registries may need to be updated to include a field for storing the GRID since future communications will use it for identification purposes. Further, the GRID will need to appear on the labels of products from adult donors.

A17-030G

Validation of a Biuret Assay for the Testing of Plasma Production Pool Samples

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Background/Case Studies: Plasma fractionators require a total protein test to be performed on production pool samples that contain sodium citrate, Citrate Phosphate Dextrose (CPD) and Citrate Phosphate Double

TABLE.

	Comparison		Precision		
Sample Type	Mean Total Protein (g/dl)	% Decrease from Serum	Mean Total Protein (g/dl)	SD	% CV
Serum	7.29	n/a	7.2	0.030779	0.43
Heparin	7.53	n/a	7.4	0.048936	0.66
Na Citrate	6.18	15.26	6.0	0.047016	0.78
CPD	6.50	11.51	6.4	0.051299	0.81
CP2D	6.49	11.00	6.4	0.051299	0.81

Dextrose (CP2D) anticoagulants. This testing is performed as part of product quality control testing and not related to donor qualification. The Abbott Biuret assay only lists heparin as an approved plasma anticoagulant within the package insert. The aim was to validate the testing of sodium citrate, CPD and CP2D production pool samples utilizing the Abbott Biuret assay. **Study Design/Methods**: The anticoagulants sodium citrate, CPD and CP2D were assessed on how their total protein values compared to serum and heparin. Thirty donors were collected in five different tube types: serum, heparin, sodium citrate, CPD and CP2D. Total protein levels were determined using the Abbott Biuret assay on the Abbott ARCHITECT c8000 instrument. The mean total protein value was calculated for each sample type. Precision of the assay was determined by testing each sample type from one donor 20 times on the same assay run. The mean, standard deviation (SD) and coefficient of variation (%CV) was calculated for each sample type. Anticoagulant sample type tube sets from 5 donors were submitted to 5 freeze/thaw cycles and tested to determine total protein values. Anticoagulant sample type tube sets from 10 donors were stored at room temperature, 2-8°C and −20 to −35°C for different time intervals and then tested to determine total protein values. **Results/Findings**: The comparison study showed that the total protein values in the citrated anticoagulants (sodium citrate, CPD and CP2D) were 11-15% lower than in serum. Precision of the assay for all five anticoagulants had a %CV value below 1%. It was determined that samples containing these anticoagulants can be stored up to 7 days at room temperature, up to 30 days at 2-8°C and up to 2 months at −20 to −35°C. **Conclusion**: Total protein values in citrated plasma are 11-15% lower than serum which corresponds to unpublished data from the manufacturer. The precision of the assay for all five anticoagulants had a %CV value below 1%, which is well within the CLIA total allowable error (±10%) and the European Biological Goal (±3.8%). The Abbott Biuret assay can be utilized to test production pool samples containing sodium citrate, CPD and CP2D.

A18-030G

Donor Hemovigilance: Insights from Blood Donors Seeking Outside Medical Care

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Background/Case Studies: Donating blood is safe. Blood Establishments (BE) should continuously evolve their policies and procedures to minimize adverse events and improve donor experience. Since 2013, the rate of donors seeking outside medical care (OMC) has remained unchanged at a large BE but detailed information about these donors and their donations has not been studied. The cohort of donors seeking OMC from a large BE hemovigilance database was reviewed to better understand the donors' perspective and to further improve donor safety. **Study Design/Methods**: Data was collected from donors donating between January and October 2015 were collected using the joint AABB/ISBT standard donor hemovigilance data elements such as donation location, donor age, gender, donation type, history of adverse reactions, whether donor had donated blood products previously, type of injury, and if OMC was sought. **Results/Findings**: Out of 591,354 needle-in donation attempts, 2,403 donor adverse events were reported (0.41%), of which 154 (6.5%) sought OMC. Females comprised 47% of total donors and 80% of those with OMC. First time donors comprised 17% of total donors, 8.5% of donor adverse events, and 26% that had OMC. Reactions resulting in OMC occurred both on-site (86), and off-site (68). 62% of all OMC on-site reactions occurred in the donor chair. 12 donors had more than one reaction, resulting in 166 (154 + 12) unique reactions. Overall, 73% were related to vasovagal reactions (VVR), 29% were needle-related reactions (NRR), and 4% were associated with chest pain/tightness. 66% of donors who suffered VVR in our cohort were evaluated by EMS. Of those, 75% were transported by EMS to a medical facility. EMS was called by MDs, staff, family, peers, and bystanders. Of the 112 VVR that had OMC, 26 (23%) voluntarily reported potential contributing donor-related factors. Of the 448 NRR, 11% sought OMC. NRR took longer to resolve, however donors with both NRR and VVR complained about the length of time it took for symptoms to resolve. 4/6 Chest pain cases were associated with automated technology. **Conclusion**: Donating blood is safe but donors do still rarely seek OMC. A significant number of OMC was due to calling EMS, primarily for VVR. VVR without LOC or injury may still result in calling EMS due to vomiting, delayed recovery, convulsions, concerns from family and peers, and having a VVR off-site (data not shown). Although hematoma/bruise and nerve irritation/injuries are relatively common NRR types that seek OMC, there are several other types that donors and staff should look for. Potential areas of improvement were identified, including earlier involvement of MDs and adjusting educational material to reflect the results of this study. The joint AABB/ISBT standard hemovigilance definitions provided a good framework for organizing the data.

Inventory Management, Storage and Distribution

A19-030K

Estimated Financial Impact of Complying with the FDA Draft Guidance Entitled "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion"

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Background/Case Studies: In March 2016, FDA released a revised Draft Guidance for Industryintended to control the risk of bacterial contamination of platelets. We sought to evaluate the cost of 1) performing daily testing of our SDPs starting on day 4 using a "safety measure" test or 2) purchasing pathogen inactivated (PI) SDPs. The Verax PGD test and the Cerus Intercept Blood System are the 2 FDA approved methods. Since the PGD test can be used to extend dating, the cost of both 5 day and 7 day SDP inventories were evaluated. A 7 day inventory would be expected to reduce outdating. A cost of $25 and $35 per PGD test and an upcharge of $100 and $125 per PI SDP were used for the analysis. The cost per SDP was fixed at $523 per unit. **Study Design/Methods**: A 2 month audit of all SDP transfusions was performed from 2/23/16 to 4/22/16 to ascertain the shelf life at the time of issuance. The audit data was extrapolated to determine the annualized numbers of PGD tests that would be required. The cost of the 5 day standard SDP inventory in 2015 was compared to the estimated cost for a 5 day PGD tested, a 7 day PGD tested, and a PI inventory. The 2015 SDP inventory purchases, transfusions, and outdates were used as a benchmark. **Results/Findings**: 210 SDPs were issued during the audit. The annualized SDP transfusion number of 1260 closely reflected actual 2015 SDP transfusion volume of 1208. 50% of SDPs were issued on day 5, 32.9% on day 4,

TABLE. Estimated Cost of Each Type of SDP Inventory

Type of SDP Inventory	Estimated Cost (Dollars)	Estimated Number of SDPs Needed to Be Purchased
Verax PGD Tested ($35) 5 day SDP Inventory	958,000	1,700
Verax PGD Tested ($25) 5 day SDP Inventory	939,100	1,700
Verax PGD Tested ($35) 7 day SDP Inventory	792,000	1,400
Verax PGD Tested ($25) 7 day SDP Inventory	816,200	1,400
2015 Standard 5 day SDP Inventory	888,900	1,700
Cerus PI 5 day Inventory ($100 up charge per unit)	1,059,100	1,700
Cerus PI 5 day Inventory ($125 up charge per unit)	1,101,600	1,700

14.8% on day 3, and 2.4% on day 2. The age did not differ by ABORh type. The SDP outdate rate was 28% or 1.25 units per day. Using a 0.55% PGD positive test rate, 9.35 positives would be expected if 1700 tests were performed and 0.561 truly positive units would be intercepted. **Conclusion**: The cost of implementing additional measures to reduce the risk of bacteria in platelets is a significant expense with only a small safety benefit. PI SDP with an upcharge of $125 per unit would increase the inventory cost by 24%. 5 day PGD testing at a cost of $25 per test would increase costs by 5.6%. A 7 day PGD testing at $25 per test would decrease costs by 11% assuming a 15% outdate rate and no additional labor costs. PDG testing would prevent roughly 1 truly bacterially contaminated SDP from being transfused every 2 years.

A20-030K

Intensive Interdisciplinary Bone and Tissue Bank Inventory Management Reduces Mean Costs by $5269 (31%) per Month

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Background/Case Studies: Tracking and trending in the Bone and Tissue Bank (BTBk) promote transparency about availability and allocation and allow more efficient operations. With 40 operating suites and over 61,000 annual surgical procedures, tight inventory management in a major academic medical center is a labor-intensive process. While the BTBk had been housed in the Blood Bank (BBK) for many years, a full-time, AATB-certified tissue technologist (TTech) has only been closely managing the inventory since 2015. Quarterly interdisciplinary meetings of the BTBk committee, which included the BTBk tech, medical director (A BBK physician), BBK leadership, OR leadership, and surgery administration started in 2011. In an environment requiring increasing cost-containment, the BTBk was targeted for improvement. We hypothesized that adding including a highly-trained FTE dedicated to BTBk management and rigorously tracking waste in the interdisciplinary setting would reduce product wastage & returns, save money, and enable the BTBk to direct corrective actions to specific surgeons. **Study Design/Methods**: Lab developed software was used for receiving, issuing and disposing of tissue and Microsoft Excel® was used for tracking and trending. We created inventory minimum levels by tracking monthly usage and developed a guide for inventory par levels, keeping enough stock on the shelves and preventing product from expiring while in inventory. Two-group means to compare the "pre-TTech" with the "post-TTech" periods were compared with the t-test. Variances were compared using the variance ratio test using STATA. **Results/Findings**: The volume of the BTBk has grown from a mean of 783 products issued monthly in the "pre-TTech" period (from 2011-15) to 1013 "post-TTech" (2015-16; $p<0.00001$). The monthly product return-after-issue percentage decreased from 60% to only 49% (95% CI 57-62% and 46-52%; $p<0.00001$) after hiring the TTech, reflecting effective inventory education of surgeons. Mean monthly wastage costs decreased 31% from $16,853 (standard deviation (SD)=$10,062) to $11583 (SD=$4,738; $p=0.049$), corresponding to over $63,000 in annual savings. The much narrower SD in monthly wastage costs during the post-BTBk Tech period wasstatistically significant ($p=0.029$), and likely reflects a reduction in outliers attributed to practices of individual surgeons who, prior to education, were particularly wasteful. **Conclusion**: Tissue banks that are embedded within blood banks are surrounded by a culture of intense inventory scrutiny. By investing in a full-time BTBk specialist, daily monitoring, and engagement of other BTBk stakeholders on the BTBk committee, we were able to reduce monthly costs by over 30% and curb high-wastage practices using narrow inventory stocking guidelines and through interdisciplinary physician and staff education.

A21-030K

Bullwhip in the Blood Supply Chain

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Background/Case Studies: An empirical investigation of the bullwhip effect (i.e., demand amplification) in a national blood supply chain was conducted to identify the causes of bullwhip and its impact on inventory performance in terms of age at the point of transfusion and the rate of outdating. Bullwhip is known to create inefficiencies such as excess inventory and poor customer service in commercial supply chains. In the blood supply chain, availability is critical and holding surplus stock ages components and leads to time expiry, and hence an understanding of the extent of bullwhip in the blood supply chain and its causes will help hospital blood bank (HBB) and national blood service (NBS) managers identify inventory strategies to improve inventory performance. **Study Design/Methods**: Statistical methods were used to evaluate bullwhip and its impact on inventory performance for SAGM Red Blood Cell (RBC) components. Transaction data indicative of demand at different supply chain levels were aggregated into daily time buckets at hospital and aggregate national level. Demand amplification was measured using the Amplification Ratio (AR), the ratio of Coefficients of Variation (CoV) in demand (or orders) between supply chain levels. Bullwhip is indicated by a ratio greater than one. Semi-structured interviews with HBB managers were used to identify the potential causes of bullwhip. **Results/Findings**: Statistical evidence of bullwhip was found at both an aggregate and a hospital level. For example, at aggregate level, AR between transfused demand and donations for OPOS RBC is 2.21; i.e., the volatility in the demand signal more than doubles as it moves up the supply chain. Differences in bullwhip between components are evident and amplification at hospital level is more pronounced than at aggregate level, indicating that aggregation across multiple hospitals dampens the bullwhip experienced by the NBS. Order batching and order inflation were identified as the main causes of amplification in hospital order signals. Interviews revealed this behavior is driven by several factors: lack of clear responsibility, lack of understanding of inventory control, absence of an inventory control system, lack of visibility of remote stocks, and a 'just in case' mind-set. Analysis using Pearson's correlation coefficient revealed a strong positive correlation between hospital order volatility and stock-on-hand ($r=0.887$) and age at transfusion ($r=0.880$). The results also show a strong correlation ($r=0.918$) between stock-on-hand and the percentage of units discarded due to time expiry. **Conclusion**: Bullwhip is generated in the blood supply chain and is caused predominantly by 'order inflation' and 'order batching' at hospital level. Correlation analyses suggest that efforts to reduce hospital order volatility should result is less stock-on-hand, reduced outdating and a reduction in the average age of transfused blood.

A22-030K

Reducing pRBC Wastage Through the Use of Refrigerated Gel Packs during Pneumatic Tube Transport

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Background/Case Studies: To maintain the safety, purity, and potency of the blood supply in the United States, the FDA and AABB require packed red blood cell (pRBC) units to be kept within 1-6°C when in controlled storage and within 1-10°C during transportation. Blood banks employ a "30 minute rule" where a pRBC unit issued from the blood bank may be returned to inventory for reissue if it is within 1-10°C and less than 30 minutes have passed. At Beaumont- Royal Oak, approximately one-quarter of all pRBC units returned within 30 minutes of issue are found to exceed 10°C and are discarded. This rapid temperature increase can be multifactorial (body heat transfer to units during processing, exposure to room temperature in laboratory and patient care areas, and temperature variations within the pneumatic tube system). The purpose of this study is to evaluate whether the use of refrigerated gel packs during processing, pneumatic tube transport, and return of pRBC units will decrease product wastage. **Study Design/Methods**: 20 units of leukoreduced, non-irradiated pRBC units were set aside for use in both the control and experimental groups. Batches of 10 underwent processing and pneumatic tube transport with the experimental group using refrigerated gel packs (applied to every step) and the control group not using refrigerated gel packs in any step. Unit temperature was recorded at the time of removal from refrigerated storage, at the time of issue, upon arrival at the receiving pneumatic tube station, and upon return to the blood bank via pneumatic tube transport. Each batch was run two times for both groups. Second order regression was used to evaluate the data. A p-value <0.05 was considered clinically significant. **Results/Findings**: -Rate of increase in temperature per minute was found to be 3 times faster in the control group processed, transported to and returned from a patient care area at 0.35°C/min in comparison to the experimental group using refrigerated gel packs, which increased at a rate of only 0.11°C/min (p-value <0.01). Units in the control group were found to exceed 10°C at an average time of 14 minutes ($R^2=0.97$), while units in the experimental group passed 10°C after an average of 44 minutes ($R^2=0.97$) **Conclusion**: The utilization of refrigerated gel packs was found to have a clinically significant difference in the rate of temperature increase per minute compared to pRBC units without gel packs.

When considering this within the constraints of the "30 minute rule," every unit using a refrigerated gel pack met the requirements for return to inventory, while units without gel packs exceeded 10°C after an average 14 minutes. If refrigerated gel packs are implemented in the routine processing and transport of pRBCs through the pneumatic tube system, pRBC unit wastage would decrease, leading to significant cost savings.

A23-030K

Low-titer Plasma Implementation in Trauma Hospital and Effect on AB Plasma Usage

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Background/Case Studies: With only 4% of the population being Group AB, a national push has been made to reduce overall usage of Group AB by implementing use of Group A low titer plasma (LTP) during massive bleeds when the patient blood type is unknown. **Study Design/Methods**: Due to high demands, this hospital based Transfusion Service Laboratory (TSL) was keeping 10 AB plasma thawed at all times: 6 in our laboratory and 4 in off-site locations. Our facility worked with our regional blood supplier to begin collection and testing of the product, of which they consider anti-B of greater than 150 as high titer. Many times this plasma ended up being used on patients who had a known blood type, to reduce wastage. In April of 2015 our hospital began stocking LTP and amended our in-house thawed inventory to include 3 AB and 3 LTP. With decreasing the amount thawed, we also hoped to reduce the amount of AB plasma turned into regular stock inventory and used on patients with known blood types as opposed to wasting the unit. **Results/Findings**: Data was collected for comparison of June-December 2014 against June-December 2015. We saw a significant decrease in the amount of AB plasma that was issued (see Table). Had LTP not been implemented, our usage would have been 26.6% of total plasma. **Conclusion**: Bringing LTP on board reduced our total percentage of AB plasma usage, allowing the blood supplier to divert AB plasma to other facilities and our wastage was slightly decreased. Further assisting the decline of AB plasma usage is stocking liquid LTP with the extended outdate of 18 days which we now use at our off-site locations.

TABLE. Findings

Timeframe	AB plasma	Group A LTP	Total Wastage
June-December 2014	468	n/a	32
Total plasma issued June-December 2014	2235	n/a	
Percentage of total issued	20.9%	n/a	
June-December 2015	336	257	31
Total plasma issued June-December 2015	2232	2232	
Percentage of total issued	15.1%	11.5%	
Percentage of total issued during trauma (n=593)	56.7%	43.3%	

A24-030K

Transformation of Blood Product Delivery Process for Neonates

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Background/Case Studies: Discussion between the neonate care group and Transfusion Laboratory sparked the idea of improving the delivery process of blood products, specifically RBCs and Apheresis Platelets (PLT), for neonatal transfusion. The old process involved dividing an RBC into three same-volume aliquot bags which were irradiated on demand, crossmatched, labeled and issued to neonate floors. PTLs were divided for the specific volume plus a set volume for priming at the bedside. Nurses transferred either product into a syringe at the bedside and then administered blood via an infusion pump and discarded the remaining aliquot volume. This process review revealed quality improvement opportunities in the blood product delivery process. **Study Design/Methods**: Three goals were initially identified: provide blood in dose specific syringes that has been pre-filtered and labeled; reduce blood waste associated with neonate blood administration; decrease the number of donor exposures. The workflow process to create an RBC used 150 mL, 8 aliquot bags. PLTs are transferred directly to syringe with the requested volume. RBC aliquots are irradiated on demand, and then sterilely connected to DEHP-Free Administration set with 150-micron filter and a 30, 35 or 60cc syringe. A specific volume is transferred into the syringe; heat sealed, and detached midway between the syringe and filter. Computer product modification is performed to document transfer of volume into syringe and verified product code changed to the open system with four hour expiration. Labels are printed and attached to the syringe and aliquot bag. RBC syringes are crossmatched, and the compatibility label is affixed to the syringe. The fully labeled syringe is then issued for administration. This process change was implemented in March 2015. **Results/Findings**: Review of neonate RBCs and PLT transfusion data for 12 months since implementation, there has been a 31.15% reduction of RBCs usage (84 units with new process vs. 122 units would have been used with previous process) and 48.14% improvement in blood product waste (42 units in the new process vs. 81 units with the previous process). Neonates that received multiple transfusions while a unit is fresh (less than 14 days old) had more than 50% chance of getting transfused from the same unit. Efficient use of PLT was achieved with the ability to create multiple syringes from a single unit. **Conclusion**: This process change helped to improve the quality of neonate blood administration by providing: accurate volume in a syringe; enhanced efficiency and reduced waste by eliminating the transfer of blood products from aliquot bag to syringe at the bed side; reduced potential labeling errors and increased efficiency to the end user as blood products are ready for immediate use with the infusion pumps.

Quality Management

A25-030L

Using Lean Six Sigma to Decrease Delivery Time of Blood to the Operating Room

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Background/Case Studies: Delivery of blood to the operating room (OR) is an important and often complicated process. At our institution, after blood has been typed and crossed, blood delivery turnaround time is both variable and prolonged. We sought to develop a more efficient, streamlined, and consistent system using Lean Six Sigma principles that we hope can be applied to similar situations. Following a current type and cross, our institution's process for blood delivery involved ordering "Release Operating Room Blood" (RORB) in the electronic computer system. The order was then printed in the blood bank. The blood bank technician picked up the order, the computer verified the blood, and then the OR nurse was notified by phone that the blood was ready. The nurse told the anesthesia provider in the room, who then called the anesthesia technician to pick up the blood and deliver it to the OR. **Study Design/Methods**: In this project, Lean Six Sigma training was used to map out the process and guide its evaluation. The time it took from the "RORB" order to the time blood was delivered to the OR was recorded prospectively for randomized weekday adult cases that had a current type and cross and requested 4 or less units of red blood cells. These baseline times were recorded to identify the points of delayed delivery. **Results/Findings**: The time from the "RORB" order to blood being delivered to the room averaged 48.5 minutes (95% confidence interval, 28 to 69 min; N=23). The step that delayed delivery was the time between the blood bank calling the OR to the anesthesiologist called the anesthesia technician to pick up the blood. This was attributed to miscommunication between the nurses and anesthesiologists or a delay of the anesthesiologist to call the anesthesia technician. Once the steps were identified, a multidisciplinary team consisting of anesthesiologists, blood bank administrators, and nursing staff, collaborated to implement a new system. Calls to the OR were bypassed by having the blood bank call the operating room receptionist, who then directly called the anesthesia technician to pick up blood. After implementation, times for each step were recorded prospectively. The average time to delivery was decreased to an average of 23 minutes (95% confidence interval 19 to 26.7 min; N=23). A one-tailed t-test comparison of this data showed a statistically significant difference in total times after the quality improvement initiative (p=0.019). **Conclusion**: By using Lean Six Sigma principles and moving phone calls outside of the OR, there has been a decrease in the total time it takes for red blood cell delivery to the OR. Changing a single step in the process has been shown to decrease the delays in transfusion therapy and variability. We hope that the approach

used for this problem can be used in other facilities to solve similar issues with blood delivery.

A26-030L

Transfusion Documentation Practices in an Electronic Health Record at a Large Tertiary Care Hospital

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Background/Case Studies: The "Implementation Guide for the Joint Commission Patient Blood Management Performance Measures 2011" set standards for transfusion documentation in electronic health records (EHR). Two retrospective reviews were performed of transfusion documentation practices at a large tertiary care hospital shortly after implementation of a new EHR and at 1 year after to assess the frequency at which the standards were being met and to identify ways in which documentation practices may be improved. **Study Design/Methods**: The 1st review included 1592 RBC, platelet and plasma units issued for routine transfusion in a 2-week period (August-September 2014). The 2nd review was restricted to a representative set of clinical wards and included 133 RBC, platelet and plasma units transfused in a 2-week period (July 2015). High-density product use (massive transfusions, ECMO, surgery, etc) was excluded. The EHR was searched for each product by its Unique Donor Identification Number, assessing documentation method, transfusion date, start/stop time, encounter complete time and vital signs. The data was analyzed for documentation rates, stratifying by level of care. **Results/Findings**: In the 1st review, documentation was found for 1447 of 1592 (90.8%) blood products. Of these, transfusion times were recorded for 98.3%, with 42.3% of these having stop times and 92.2% having encounter complete times, a function that allows for the association of post-transfusion vitals and events with a product. The complete function only was used in 56.0% of found products. Of the products with stop times, 95.0% were shown as finished <4 hours. Of the products with complete times, only 56.3% were shown as finished <4 hours. Of routine transfusions where documentation was found, 98.8% had recorded vital signs. In the focused 2nd review, documentation was found for 127 of 133 (95.5%) products. Of these, 45.9% had stop times and 63.9% had complete times, compared to 45.2% and 85.5%, respectively, in the same group of clinical wards in the 1st review. In these wards, 98.3% of transfusions were stopped <4 hours, increased from 86.7%, while 28.2% were completed <4 hours, similar to 25.7% previously. Vital signs were documented in 93.2% of transfusions. **Conclusion**: Transfusion documentation in the EHR is variable, likely due to incompatibility between care provider workflow and the complex EHR interface. Transfusion times varied the most of analyzed parameters due to non-uniform end-time reporting. Documentation rates may also be affected by factors such as patient-to-nurse ratios, EHR training and transfusion experience. Extended exposure time to the EHR did not improve documentation practices, as suggested by review at 1 year. Improvement of transfusion documentation will require additional user training and revision of the EHR interface to suit non-uniform workflows.

A27-030L

Find the WBIT: One Year of Experience Using a Second Sample for ABO/Rh Typing

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Background/Case Studies: In 2015, the College of American Pathologists (CAP) changed its requirements for blood typing. An ABO/Rh type must now be confirmed by either comparison to a historical test performed in the same institution, a second sample drawn at a different time (a "check type"), or a validated method. These measures attempt to identify "Wrong Blood in Tube" samples, or WBITs, where the blood sample is not from the patient on the label. Unidentified WBITs carry the risk of assigning the wrong blood type to a patient and potentially transfusing an incompatible blood product. We present our hospital-based blood bank's experience identifying WBITs both before and after implementing the check type. **Study Design/Methods**: From 01/2014 to 04/2015, our blood bank technologists identified WBITs when a patient's new ABO/Rh type differed from a historical result. In 05/2015, our institution implemented the check type. Hospital staff were educated and trained, while electronic notices were sent across platforms frequently used by employees. If a patient lacked a historical ABO/Rh type in our blood bank system upon receipt of the first sample and RBC units were requested, the patient's nurse was notified that a check type was required. The nurse then ordered a blood type with an approved standing order. If a patient did not have a historical ABO/Rh type upon receipt of the first sample but no RBC units were requested, the care team was notified in the electronic medical record. If the blood types did not match, the blood bank requested a third sample and notified risk management. The nursing manager from the originating floor/unit was notified, and the manager subsequently re-educated the individual(s) involved. **Results/Findings**: Our blood bank performs an average of 4180 ABO/Rh types monthly. About 15% of these ordered at our institution are for patients without a historical type, necessitating a check type. Between 01/2014 and 04/2015, prior to instituting the check type, 18 WBITs were identified (average 1.2 events/month, or 0.029%). Between 05/2015 and 04/2016, after instituting the check type, 9 WBITs were found (average 0.70 events/month or 0.018%), 2 of which (22%) were identified using check types. The overall WBIT rate is consistent with reported national rates of 0.04%. WBITs originated most frequently from intensive care units, followed by general inpatient services, then labor/delivery service. **Conclusion**: The check type method has successfully identified WBITs in patients without a historical ABO/Rh type in our system. In the 12 months following their implementation, check type samples identified 22% of the WBITs recognized at our institution. Overall, WBIT rate fell after implementation of the check type. We postulate that this may be due to increased vigilance of nursing staff because of the check type.

A28-030L

Assessment of the Impact of Daratumumab on a Transfusion Service

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Background/Case Studies: Daratumumab (DARA) is a new monoclonal antibody (Ab) approved for treatment of refractory multiple myeloma. It is known to cause interference with Ab identification (ABID) and compatibility testing. Knowing which patients have received DARA is essential to prevent unnecessary tests (e.g. adsorption), resource wastage and delay in RBC transfusions. Treatment of samples with DTT is an inexpensive method used to remove interference, but needs technical expertise and additional time beyond routine testing. **Study Design/Methods**: Transfusion Service (TS) records of all patients on DARA were reviewed over a period of 4 months starting 12/1/15. Data about clinical team notification, DARA start date, immunohematology work ups (W/U), and RBC transfusions were reviewed. **Results/Findings**: During the study period, 29 patients treated with DARA were evaluated (3 had started DARA prior to FDA approval, as part of a clinical trial). Shortly after DARA was FDA-approved, our TS established a clinical care protocol (CCP) by which Heme/Onc providers notify us prior to starting patients on DARA, so baseline RBC phenotype/genotype and antibody screen can be obtained. Clinical providers were also asked to order testing and RBCs in advance, so transfusions would not be delayed. After establishment of this CCP, TS was notified *before* start of DARA in 24 of 25 (96%) patients. The average time from RBC order to RBC issue was 18.0 hours (n=79, range 0.9-76.3, some orders were for 2 units on the same day, and only issue time for the first unit was used in this calculation). There were no delays in transfusion, and we never transfused phenotypically matched blood due to pending ABID W/U. In order to improve turnaround time and save costs by not sending ABIDs to our reference lab, all 16 of our full-time technologists were trained to perform DTT treatment over 2 months. The training of each technologist took 4-5 hours (64-80 hours total). Since 12/1/2015, DARA patients have constituted 23% of our ABIDs. The number of ABIDs per month has increased by 19%, from an average of 51 (Jan-Oct '15) to 63 (Dec '15-March '16). The average time from sample receipt to resulting the ABID for DARA patients was 11.4 hours (n=59, range 2.1-73.9), or more accurately, 9.5 hours (n=57, range 2.1-31.3) after exclusion of two outliers from Dec '15 (73.9 and 55.9 hours). **Conclusion**: Approval of DARA has had a significant impact on our TS, resulting in 19% increase in the number of ABIDs, and their overall complexity due to introduction of DTT treatment as a new procedure. Additional resources are needed for staff training and increased workload introduced by DARA. By implementing a new multidisciplinary CCP to ensure timely notification to TS and advanced ordering of type and screen and RBCs, we have been able to prevent delays in RBC transfusions in patients receiving DARA.

A29-030L

Attention to Detail Competency for IRL Specialists – A Critical Skill Assessed

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Background/Case Studies: Two job requirements for Immunohematology Reference Lab (IRL) Specialists include 1) serologic/technical ability with problem-solving and 2) attention to detail. Our regional IRL tracks the

TABLE. IRL Audit Packet Performance 2013-2015

Year	Range of Results - Correctly Identifying Doc. Errors	Overall Average Annually
2013	85-98%	91%
2014	82-100%	96%
2015	91-99%	95%

competency of serologic/technical ability with serologic weak readings and patient case testing direct observation. However, monitoring the attention to detail of an IRL Specialist is more challenging. Our IRL instituted a review of paperwork errors, referred to as an "audit packet" to monitor the ability of the IRL specialist to have consistent, quality documentation. **Study Design/Methods**: The IRL generates an audit packet made up of common documentation errors made by IRL Specialists. A packet of 6-10 papers with a documentation error makes up the audit packet. All the IRL techs participate in the audit packet review in which they must identify the errors in the pages provided. The ability/competency of the IRL specialists was determined on their ability to consistently detect documentation errors in the audit packet. A study of the performance of the staff was completed over three years (2013-2015), to determine the threshold or pass rate for the annual competency. **Results/Findings**: Table 1 summarizes the results of the audit packets completed by IRL specialists from 2013-2015. **Conclusion**: The three-year average for the audit packet performance by the IRL specialist from 2013-2015 was 94%. There was a rise in audit packet performance from 2013 to 2014 as staff demonstrated improvement in detection of documentation errors. Using +/- 5% guidance, a competency passing threshold for attention to detail competency was established at 89%-99%. The determined threshold allows for a pass-point to be set for this competency. This data allows the IRL management to monitor the critical ability of the IRL Specialist to complete documentation correctly with high attention to detail.

A30-030L

A Validation Study Comparing Performance of Three Gel-Based Automated Analyzers for Pre-transfusion Testing in a Hospital Transfusion Service

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Background/Case Studies: Automated blood bank systems continue to be a focus of hospital-based transfusion services due to their high throughput and high capacity capabilities. Several FDA approved manufacturers are available, therefore even labs with established automation may switch platforms for various functionality, work-flow, or contract-related reasons. Validation between instruments is required; however, limited published literature exists to guide the validation process. In order to fill this information void, we report validation data comparing the Ortho ProVue, Grifols Erytra, and Grifols Wadiana platforms at a high-volume transfusion service. **Study Design/Methods**: Samples were split between the Ortho ProVue and one or both Grifols platform to validate ABO typing, direct antiglobulin testing, antibody screening, and antibody identification. Testing was performed according to the manufacturers' specifications for automated or manual testing on the respective platform utilized. In order to validate the full test menu of the transfusion service, plasma, cord blood, and pRBC links were tested. When indicated, historical ABO type was obtained from the lab information system or from pRBC unit tags attached by the local blood supplier. **Results/Findings**: Antibody screening: 66 samples were available for testing. 63 samples (45 negative, 18 positive) agreed across the platforms. 3 samples were discrepant (see Table). Antibody identification: 22 samples with antibodies were available for testing. 17 samples agreed across platforms and included identification of antibodies to E, K, s, M, D, Jka, C, and Fya antigens. 5 samples were discrepant (see Table). ABO type and DAT: There were no ABO or Rh discrepancies between gel platforms when performing forward RBC typing on plasma (65 specimens), cord blood (50 samples), or pRBC units (39 samples). Reverse ABO and Rh typing with the new reagents were compared to historical types within the LIS and revealed no discrepancies (29 samples). No discrepancies in cord blood IgG DAT results between platforms were noted (29 samples). **Conclusion**: The validation plan was executed over 3 months, and results were accepted. Overall, data generated shows agreement comparable to a similar comparison within the literature.

Education and Training

A31-030M

Effective Continuing Education in Immunohematology: Response to Unmet Training Needs

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Background/Case Studies: To maintain certification, immunohematology laboratory personnel are required to complete 12 hours of continuing education each year. Due to staffing and financial constraints, it is difficult for laboratories to sponsor attendance at educational events. In response, we have initiated a free training course, which rotates throughout the country. To design training content that targets the challenges in practice, we conducted a training needs assessment survey among blood transfusion professionals in the USA and Canada. **Study Design/Methods**: From June to November 2015, a questionnaire comprising 13 questions was distributed to 754 immunohematology professionals. Factors assessed included previous blood bank training and experience; knowledge of immunohematology laboratory methods; activities routinely performed; description of the most challenging cases and techniques; and interest in attending a free continuing education course and topics. The level of difficulty in routine workup of different cases was evaluated using a scale from 1 to 5 (with 1 being the lowest and 5 being the highest). This questionnaire was reviewed and approved for compliance. **Results/Findings**: A total of 176 responses were received. The majority of respondents (73.3%) worked in a hospital setting (blood bank, laboratory, transfusion service), and 22.1% worked in an immunohematology reference laboratory. On average, respondents had 10.4 years of experience in immunohematology laboratory practice. In 85% of cases, routine laboratory workup included red cell antigen typing, red cell antibody screen and identification, crossmatch and post-transfusion reaction investigation. Manual and automated serological methods were predominantly used, with only 5.2% performing routine molecular testing for case resolution. In both the United States and Canada, red cell antibody identification was reported as the most challenging situation (61% of respondents; scale 4-5). In the United States, the challenge was related to the identification of antibody against

TABLE. Discrepant antibody screen/identification

# samples	ProVue			Erytra/Wadiana		
	Screen	Panel	Interp	Screen	Panel	Interp
2	+	=	NOID	=	NT	=
1	=	NT	=	+	=	NOID
1	NT	+	E, S, K, M	NT	+	E, S, K
1	NT	+	K, NOID	NT	+	K
3	NT	+	NOID*	NT	+	NOID*
1	NT	+	E (w/dosage)	NT	=	=

*Historical antibodies; however, non-specific reaction patterns differed between platforms. (+, positive; =, negative; NT, not tested; NOID, no identification)

high-incidence antigen (63.3% of respondents in the USA, scale 4-5); while in Canada, workup for warm-auto antibody was reported to be more challenging (55.8% of respondents in Canada, scale 4-5). These challenges were mostly reported by professionals with less number of years of experience in the field. Interestingly, in Canada, challenges relative to the molecular basis of blood group and the indications of genotyping were mentioned by 68.8% of respondents, while only 4.9% of them declared performing molecular testing routinely. **Conclusion**: Serological techniques and methods for antibody identification remain challenging, especially among young immunohematologists. In response to these specific needs, we offer a free Transfusion Science Education Course (TSEC) program, focused on addressing these particular challenges.

A32-030M

Bringing Socrates to an Online World: Question-based Learning with Anticipated Discourse and Gamification

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Background/Case Studies: Socratic teaching, or *elenchus*, uses questions to correct assumptions and build new concepts. This approach is particularly apt in transfusion medicine, as clinicians in other fields may have limited understanding of transfusion principles. We propose a novel model of online learning that integrates Socratic principles with question based learning to improve engagement and understanding of transfusion. **Study Design/Methods**: Construction of 20 case-based questions was followed by diagramming avenues of anticipated discourse to form 80 supplements. In Articulate Storyline, elements of gamification including a brief story, animation, character feedback, and cohesive design (flat vector graphics, unified palette, music) were integrated with the content. Course navigation was moderated by tiered access; selecting the correct answer unlocked the 'Next' button and supplements. Course design was tested with focus groups of residents and medical students. The course, hosted on Amazon S3, reported 389 variables to Google Forms with Javascript. After receiving IRB approval, users were recruited to anonymously access the course at transfusiondoc.com. **Results/Findings**: Over three weeks, 20 users participated in the course to varying degrees, with 8 users completing the course. Among those who completed the course, median time to reach the correct answer ranged from 21 to 56 seconds per question. Median time to explore supplements ranged from 8 to 77 seconds per question. An average of 47 supplements was accessed per user. Self-reported improvement in comfort level corresponded to engagement with supplements; those with no improvement (n = 3) accessed 0-45% of supplements, those with some improvement (n = 3) accessed 56-82% of supplements, and those with most improvement (n = 2) accessed 98-100% of supplements. Users largely reported that the course was easy (n = 6). Most users stated that the level of gamification was appropriate (n = 4), with the remainder asking for additional gamified content. **Conclusion**: These findings speak to the significance of challenging assumptions through question-based learning, then giving users the agency to reinforce that learning through voluntary access of supplements that follow anticipated avenues of discourse. We establish that medical trainees and staff choose to extend their learning, with users investing time after required question-based learning to explore transfusion concepts. We further demonstrate that gamification-amplified user engagement with supplements corresponds to self-identified improvement in transfusion knowledge.

A33-030M

Strengthening Transfusion Practice in the Kyrgyz Republic

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Background/Case Studies: The safety of blood products remains a continuing cause of concern, particularly in developing countries. The US President's Emergency Plan for AIDS Relief supports the provision of a technical assistance program in the Kyrgyz Republic. The aim of project is to strengthen the implementation of safe blood programs and precautions against medical transmission of HIV in order to ensure a safe and adequate blood supply. Expert guidance and technical assistance is provided to the Ministry of Health (MoH) and the National Blood Transfusion Service in Kyrgyzstan in order to develop and implement a national safe blood program with sustainable outcomes. **Study Design/Methods**: In 2013 and 2015, the project conducted an assessment at the Republican Blood Center (RBC), 6 oblast blood centers, and in 17 clinical hospitals and 15 transfusion departments (TD). The TD are hospital-based blood collection, processing and transfusion sites. Assessment tools were developed based on AABB Standards and EU directives and covered such areas as organization and infrastructure, donor management, blood testing, production of blood components, quality assurance, monitoring and evaluation, transfusion and blood utilization, and education and development. Based on the assessment findings and identified gaps a detailed work plan was developed, including expected outcomes and key indicators. All activities were coordinated with the local CDC office. **Results/Findings**: Training and training of trainer (TOT) programs addressed the identified gaps, such as quality management systems, clinical use of blood products, safe blood collection, equipment validation, self-assessment and accreditation. In 2014, with support of international consultants, the Technical and Quality Standards were developed and approved by the MoH. In 2015, National Clinical Guidelines were developed based on international standards of practice and evidence-based medicine. Following a national level TOT program, a team of international and RBC key staff conducted mentoring visits to 10 regions of Kyrgyzstan for implementation of the Technical and Quality Standards and the Clinical Guidelines. More than 400 blood centers staff and clinicians were trained. Post-training statistics indicates improvements in Bishkek hospitals with a decrease in red cells usage (87.1%) and fresh frozen plasma (~10%) in 2015 compared to 2011. Transfusion of platelet concentrates increased 3-fold and cryoprecipitate by 60%. Blood component use in the oblast regions did not improve. **Conclusion**: Significant improvements in the use of blood components occurred primarily in the city of Bishkek where many changes occurred after training seminars, meetings and the provision of Standards and Guidelines. In the oblasts a continuation of efforts to monitor transfusion therapy and training of doctors in hospitals is necessary.

A34-030M

Adapting Lean Methodology to Improve Workflow in a Research and Development Laboratory

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Background/Case Studies: Introducing Lean methodology into a research environment can be a complex and difficult process. In manufacturing environments, where Lean methodology was first established, there is a clear and repetitive workload. In contrast, a typical research lab is in a constant state of flux, with changing projects and different procedures impacting equipment and facilities. Finding time to implement Lean processes is challenging when resources are dedicated to specific projects and staff are

TABLE. 5S for R&D

SORT	Remove unwanted items
SET	Give items a set location and quantity
SHINE	Label area and communicate work completed
STANDARDIZE	Implement Plan, Do, Check, Act cycle
SUSTAIN	Support staff to maintain new procedures

working to capacity. The goal of this project was to find useful ways of introducing Lean methodology into a Research and Development (R&D) Laboratory environment to improve workflow and standardize routine tasks, allowing for greater focus on research activities. **Study Design/Methods**: 5S, a workplace organization method, is perhaps the most valuable tool for 'levelling' routine tasks and creating a seamless workflow (see Table), and was adapted to fit a research laboratory environment. The creation of weekly 'action areas,' denoting a defined space such as a cabinet or bench, was introduced to provide a focus for improving workflow. Each action area was addressed based on 5S principles. "Before and after" photos of each action area were used to communicate and demonstrate to staff how effective each activity had been. Items with a high turnover were assigned minimum and maximum levels to prevent under- or over-stocking. Spaghetti diagrams were also used to map the steps taken during commonly performed tasks such as blood processing and testing to highlight inefficient workflows. **Results/Findings**: Although difficult to quantify, changes in each action area improved workflow and efficiency. Removal of unwanted items, defining set stock locations and quantities in the laboratory allowed routine tasks such as ordering, accessing consumables and performing experiments to be performed more rapidly. Introducing a stock labeling system and consistent communication through both verbal and written systems helped to engage staff and pass on information effectively. The spaghetti diagrams proved to be a quick measure to reduce inefficient movement of both staff and samples during experimentation, resulting in repositioning of stock and equipment to improve workflow. **Conclusion**: Breaking down Lean processes into achievable action areas allowed the R&D team to focus on a common problem without impacting workload. Communication was the key to introducing Lean ideology, utilizing multiple platforms to visualize and assess outcomes of each change.

A35-030M

ADaM: A Web-Based Algorithm for Anemia Diagnosis and Management

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Background/Case Studies: Anemia is defined as a reduction in red blood cell mass. In the clinical setting, the definition of anemia is a reduction of the body's oxygen carrying capacity to all organs. However, these definitions fail to acknowledge that anemia is simply the end indication of a host of disease processes. Anemia may be induced by something as easily assessed and readily corrected as poor nutrition, presenting in the form of iron deficiency anemia. Alternatively, it may be the result of a more complex process such as a hemoglobinopathy or underlying malignancy. Many clinicians remain confused with regards to the most appropriate means of how to proceed with laboratory evaluation of anemia. Many resources have been developed in the form of algorithms to help guide the diagnostic decision-making process. However, these algorithms are often cumbersome, and/or poorly readable on mobile devices. It was with this in mind that clinicians and informaticians at our institution developed the Anemia Diagnosis and Management Algorithm (ADaM), and subsequently implemented it as a web-based application readily adapted for mobile use. **Study Design/Methods**: Faculty in hematology, general internal medicine and transfusion medicine collaborated to create the diagnostic algorithm that forms the backbone of ADaM. This algorithm was written into a web application using PHP-FPM 5.3 (PHP package with a fastCGI process manager) for data processing and subsequently formatted with Bootstrap 3.3 (an open-source CSS and Javascript/jQuery library) for the front-end user-interface. The site further utilizes MariaDB 10.0 as a database engine to guide algorithmic progression. Google analytics has been applied to track user metrics. **Results/Findings**: ADaM has been implemented, tested, and deployed for use by the pathology, internal medicine and hematology services. With current data, ADaM has received a total of 1,116 sessions and 975 users, with 1,648 total page views. In preliminary testing and through user feedback, ADaM is expected to (a) serve as a powerful educational tool for the workup and diagnosis of anemia, (b) decrease user error in the diagnosis and management of different types of anemia, and (c) indirectly reduce the need for transfusion by providing timely and accurate recommendations for diagnosis and treatment. **Conclusion**: ADaM is a unique resource, allowing users to rapidly and accurately evaluate, diagnose, and manage anemia from any Wi-Fi accessible spot in the hospital. Furthermore, ADaM is an invaluable educational resource. More than an interactive decision making tree, ADaM contains hyperlinks to credible, expertly selected resources that provide additional information regarding the most likely medical conditions to be diagnosed. We believe that ADaM has the flexibility and utility to be useful to medical personnel at all levels of training.

A36-030M

Quality Culture and Ownership – Lessons Learned from the Developing World

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Background/Case Studies: Developing a sustainable blood supply and transfusion system needs quality as a culture, implemented through introduction of a quality management system (QMS). Often the idea is that, when instructions are written (SOPs), a quality system is in place; just follow the instructions. However, quality only partly depends on following operational instructions. Generally not understood is the importance of designing and implementing a quality management system, based on

1. organization and structure;
2. standards – technical and quality;
3. documentation – traceability and evidence;
4. education – continued teaching and training;
5. assessment - continued monitoring and evaluation.

To optimally understand the values of quality in transfusion medicine (TM) a culture has to be created - ownership development, commitment to and implementation of the principles. **Study Design/Methods**: Development and implementation of a quality management system was evaluated for 12 developing countries (2001-2015) in 4 WHO regions (table). Projects were based on step by step introduction of concept and principles of quality following a WHO Quality Management Training course (QMT) - modular, interactive, with improvement evaluation focused on comprehension and ownership of the contents. **Results/Findings**: Since the introduction of WHO QMT courses in all 6 UN regions, hundreds of professionals have been exposed. However, often selected trainees were not properly prepared to objectives and contents of QMT; trainers/facilitators had insufficient personal experience, enthusiasm and competence to conduct a high level management course; in-country follow up was not anticipated by leadership and therefore failed. However, a quality culture started to develop, and consistency of *fitness for purpose* and the *supplier-producer-customer chain* development as an integrated managerial and operational system, was noticed when

a. selection was based on strict criteria focused on future implementation;
b. training cadre had adequate competence and real-life experience;
c. a follow up structure for implementation by committed and competent leadership was in place.

Conclusion: Teaching of and training in principles of quality as a manageable system is important to improve blood safety, but not enough. A quality culture is needed to guarantee and sustain quality operations in blood centers and hospitals. Approach shall be holistic and supported by leadership - commitment, ownership and full understanding. The outcome then needs an active and continued in-country follow up to allow proper implementation of knowledge to build on the creation of a sustainable quality culture.

TABLE. Region and countries

Europe	Estonia, Kyrgyzstan, Montenegro, Slovenia, Uzbekistan
Africa	Rwanda, Tanzania, Uganda
Eastern Mediterranean	Jordan, Pakistan, Sudan
Western Pacific	Mongolia

Blood Management

AP1

Adoption of System-wide Delivery Goals and Establishment of a Minimum Par Level Dramatically Altered Platelet-Ordering Practices

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Background/Case Studies: Historically some blood banks, including those with active obstetric and trauma services, did not stock platelets (SDPs) and ordered them only for specific patient need, thus incurring additional delivery changes and delaying availability. By contract, our system does not pay for standing order deliveries but is charged for supplemental ($67) and emergency ($138) deliveries. Each of the system's blood banks previously determined how many SDPs to keep in inventory and the most expedient method of delivery. Our system formally adopted delivery method standards in 2014 seeking to reduce the number of emergency deliveries and to increase the likelihood that SDPs would already be in inventory when ordered, thus improving the time to issuance, especially at our smaller facilities, and established an inventory par level of at least one dose of platelets. We sought to assess compliance with taking SDPs on standing orders, thereby relying less on emergency deliveries and the impact on overall platelet purchases. **Study Design/Methods**: The number of SDPs (SDPs and SDP equivalents [1 SDP=6 RDPs] for one facility) purchased in 2015 was compared to the number in 2013 and 2014. The number of standing, emergency, and supplemental SDP orders from 2013-2015 were evaluated. The results were analyzed using the Student's t-test. **Results/Findings**: In 2015 SDPs were delivered on 3519 standing orders, 1865 supplemental orders, and 737 emergency orders. 170 more SDPs were purchased in 2015 than in 2014. The number of emergency deliveries decreased by 643 from 2013 to 2015 (p-value 0.008). The number of standing order deliveries increased by 629 from 2013 to 2015 (p-value 0.005). Although there was an increasing trend of supplemental delivery use, it was not statically significant (p-value 0.28). **Conclusion**: Implementing system wide delivery method goals and an inventory par level did not statistically change the number of SDPs purchased (6741 in 2015 vs 6741 in 2014 vs 6121 in 2013). There was however a significant reduction in the number of emergency deliveries. The additional platelet acquisition cost of $321,018 from 2013 to 2015 needs to be assessed, and the outdate rates evaluated. $88,734 was saved on emergency and $18,291 on supplemental delivery charges from 2013 to 2015.

AP2

A System-wide Analysis of Red Blood Cell Unit Purchases Following the Adoption of a Corporate-wide Blood Use Policy and Transfusion Guidelines

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Background/Case Studies: The 11 blood banks in our system had varying practices with respect to RBC transfusion guidelines. In 2010 common transfusion triggers were established and built in the CPOE but were not uniformly implemented or adhered to across all facilities. Between 2011 and 2014, AABB published RBC transfusion guidelines and others published randomized controlled trials (RCT) which supported the adoption of a more restrictive RBC transfusion practice. An interdisciplinary committee was formed to develop an evidence based guideline to reduce medically unnecessary RBC transfusions within our facilities. The guideline was officially approved by in 3Q14 and issued for immediate implementation. We seek to assess the impact of the institutional guideline on reducing RBC transfusions. **Study Design/Methods**: The total number of RBCs purchased and dollars spent on RBCs by all facilities between 2011 and 2015 was evaluated. The Student's T-test was used to assess statistical significance. **Results/Findings**: The 11 hospital blood banks purchased 44,059 RBC units in 2011, 40,644 in 2012, and 37,128 in 2013 at a cost of $232 per unit. 36,773 units were purchased in 2014 at a cost of $227 per unit. 35,558 RBCs were purchased in 2015 at a cost of $226 per unit. In 2015, the system reduced RBC purchases by 8,501 when compared to 2011 levels and saved $1.92M on RBC purchases. The savings included $51,006 from a reduction in cost per RBC unit. The reduction in RBC purchases was statistically significant using a 1-tailed Student's T-test (p-value <0.05). **Conclusion**: Although RBC purchases had begun to decrease prior to the issuance of the new institutional transfusion guideline likely as a consequence of the published RCTs and guidelines demonstrating that a restrictive RBC transfusion practice was safe, our institutional guidelines enforced the system's commitment to reducing medically unnecessary RBC transfusions. The $1.92M annual saving in 2015 due to the reduction of RBC purchases can be used for pay for other institutional purposes.

TABLE. SDP Orders by Deliveries Method

Delivery Method	Blood Bank 1	Blood Bank 2	Blood Bank 3	Blood Bank 4	Blood Bank 5	Blood Bank 6	Blood Bank 7	Blood Bank 8	Blood Bank 9	Blood Bank 10	Total Number of Deliveries by Type	Student's T-test (2-tailed) 2015 vs 2013
Standing Order Deliveries 2015	1562	378	175	252	621	49	56	27	239	160	3519	0.00476
Emergency Order Deliveries 2015	136	323	76	157	104	352	245	4	298	170	1865	0.00774
Supplemental Order Deliveries 2015	0	69	79	272	15	45	26	1	189	41	737	0.283
Standing Order Deliveries 2014	1517	417	149	238	642	68	79	24	191	154	3479	
Emergency Order Deliveries 2014	172	383	110	198	117	297	266	7	315	125	1990	
Supplemental Order Deliveries 2014	35	51	138	145	31	36	26	2	111	8	583	
Standing Order Deliveries 2013	1438	340	102	217	591	12	54	9	69	58	2890	
Emergency Order Deliveries 2013	145	439	83	304	173	348	290	9	435	282	2508	
Supplemental Order Deliveries 2013	32	50	91	99	24	27	42	14	27	58	464	

TABLE. System-wide RBC Purchases

RBC Units Purchased by Facility	2011	2012	2013	2014	2015
Blood Bank 1	7672	6054	5688	5609	5603
Blood Bank 2	7438	6314	6836	9051	9632
Blood Bank 3	4979	4954	4758	4692	4862
Blood Bank 4	4939	3947	3853	3613	3361
Blood Bank 5	3409	3720	3498	3614	2955
Blood Bank 6	3379	3342	3174	3052	2705
Blood Bank 7	3099	3081	2883	2753	2339
Blood Bank 8	2202	2460	2225	1983	1684
Blood Bank 9	2516	2342	1952	1735	1632
Blood Bank 10	3681	3613	1566	101	136
Blood Bank 11	748	817	695	570	649
Total Purchases	44,059	40,644	37,128	36,773	35,558
RBC Unit Cost	$232	$232	$232	$227	$226
Total Spending on RBCs	$10,221,688	$9,429,408	$8,613,696	$8,347,471	$8,036,108

AP3

An Algorithm for Platelet Refractoriness: Practical and Financial Implications

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Background/Case Studies: Platelet refractory patients use several fold more platelets and have nearly three-fold greater hospital expenses than non-refractory patients. Approximately 20% of refractoriness is, at least in part, immune-mediated and best supported with antigen-negative products. An algorithm to identify and characterize immune-mediated refractoriness was developed with resultant improvements in care, utilization, and cost. The algorithm's impact is highlighted by three challenging cases. Donor typing and algorithm costs are compared to national average apheresis platelet costs ($535). **Study Design/Methods**: The algorithm is initiated by a platelet refractoriness consult from the clinical or transfusion medicine service. We define refractoriness as two recent 1 hour corrected count increments of $<7.5*10^9$ platelets/L. Patient plasma is tested against 14 ABO-identical platelets using a solid-phase red cell adherence assay (physical platelet crossmatch [pXM]; CaptureP, Immucor). Patients with pXM reactivity to $\geq$2 units are supported with pXM-negative platelets while their serum is tested for class I human leukocyte antigen [HLA] antibodies by an antigen-linked bead-based assay (LABScreen, One Lambda). In cases with reactivity to $\geq$10 units, human platelet antigen [HPA] antibody testing by enzyme-linked immunosorbent assay (PAK12G, Immucor) is performed. When possible, virtual crossmatching [vXM] (enabled by upfront low-resolution HLA-A and HLA-B typing of institutional platelet donors) is then used to support characterized refractory patients. **Results/Findings**: A 79-year-old man with AML had pXM reactivity to 7 of 14 platelets; all HLA-A2-positive. Using pXM and then HLA-A2-negative vXM platelets, his platelet needs declined from daily to twice weekly. A 55-year-old woman with AML had 6 of 14 platelets reactive by pXM. Class I HLA antibody testing demonstrated multiple HLA-A and -B antibodies. Using pXM and then vXM platelets, her platelet needs fell from near daily to weekly. A 44-year-old woman with B-cell lymphoma required intrathecal chemotherapy. Her pXM showed pan-reactivity. HPA antibody testing revealed an HPA-1a antibody. She incremented with HPA-1a-negative platelets enabling treatment. The combined costs of five pXMs, a class I HLA antibody assay, and an HPA antibody assay are less than the cost of two apheresis platelets. In-house platelet donors give a median of four units yearly, thus upfront HLA typing accounts for only 10% of unit costs. **Conclusion**: This platelet refractoriness algorithm identifies immune-mediated cases and adds value after two platelet units are saved. Class I HLA typing of donors facilitates platelet vXM and represents a small proportion of apheresis platelet costs. This algorithm may facilitate critical patient care and financial discussions between hospital transfusion services and blood providers.

AP4

End-of-Life Transfusions (EOL): A Physician's Dilemma

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Background/Case Studies: In 2009 Health and Human Services (HHS) reported that significant resources are used at end of life (last 14 days). The American Hospital Association also developed a " Top five list" of hospital based interventions that should be discussed between patient's and physician's, at the top of the list is appropriate blood management. In 2011, blood management program "7 is the new 10" was put in place in a nine-hospital system to improve blood usage; within two years RBC usage dropped from 64,178 to 41, 000 units with an overall savings of $10 million. As a result hospital areas that continued to show an increase in red cell usage became apparent. One such area was the medical ICU (MICU). We reviewed blood usage of patients who died with 14 days of admission to the MICU and our physcians approach to caring for these patients. **Study Design/Methods**: To understand our physicians' approach to transfusions at EOL an online physician survey was conducted in Spring of 2014. Targeted physicians (328) included palliative care, critical care, hospitalists and internal medicine. Physicians had 6 months to complete the survey. To review blood usage, medical records of patients who died within 14 days of admission to the MICU were reviewed for demographics, code staus, performance status, frequency of transfusion and immediate cause of death. **Results/Findings**: In 2013, 15% of adult patients who expired within 14 days of admission were transfused a total of 2318 units of RBCs. 68% of these patients also had limited emergency treatment orders (LET). 104 RBCs/month were transfused to patients who had LET orders and who expired within 14 days of admission. In 2014, 180/328 targeted physicians completed the online survey. 55% of respondents treated EOL patients at least once a month. 45% stated that blood was transfused in response to patients' and family members' expectations and 17% out of fear of litigation. The respondents also agreed that current transfusion criteria did not apply to patients at EOL and that transfusion guidelines for these patients would be helpful. **Conclusion**: Results of the physician survey pointed to a need to advance discusssions about patients with poor prognosis for recovery and ethical issues related to transfusion. Our approach is multipronged; it includes developing institutional guidelines, physician education addressing fear of litigation and documentation of EOL discussion in patients' medical records. The goal is to improve transfusion practice to guide clinicians in the use of consensus driven recommendations to make ethical decisions when prescribing blood products for patients that have a poor prognosis for recovery.

AP5

Opportunities to Decrease the CT Ratio beyond the MSBOS

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Background/Case Studies: The Maximum Surgical Blood Order Schedule (MSBOS) is intended to guide the appropriate ordering of red blood cell (RBC) units pre-operatively. While our institution did not have an MSBOS, our crossmatched to transfused (CT) ratio was consistently above 2. **Study Design/Methods**: Less than a year ago, we instituted an MSBOS based on the RBC usage from the previous calendar year. For this study, we collected individual providers' CT ratios from the electronic health record on a monthly basis, from the pre-MSBOS (January-July 2015) and the post-MSBOS (August-March 2016) periods. The goal was to determine if the MSBOS had

TABLE. Number of providers in each surgical service with CT ratio greater than 2, the mean CT ratio for those individuals, and the number of RBC units crossmatched but not transfused.

	Jan-16			Feb-16			Mar-16		
	Number	Mean CT ratio	RBC Unitsnot transfused	Number	Mean CT ratio	RBC Unitsnot transfused	Number	Mean CT ratio	RBC Unitsnot transfused
ANESTH	13	4.1	79	13	4.2	69	11	3.0	51
CV	15	7.3	298	13	5.5	249	15	5.5	308
ENT	1	2.2	6	4	3.2	18	2	3.2	8
GEN SUR	6	3.6	105	10	4.5	82	7	3.2	48
NEUROSUR	2	8.5	22	4	4.1	25	3	3.7	11
OB GYN	11	5.5	75	8	6.1	50	7	3.5	29
ORTHO	13	5.8	120	13	4.1	101	13	5.5	129
URO	3	4.3	12	2	3.5	6	1	3.0	4
VASC	5	4.8	40	6	9.1	66	3	4.0	93
OVERALL	64	5.1	717	67	4.9	600	59	3.8	588

an effect on the institution's CT ratio, which also included orders for non-surgical patients. **Results/Findings**: We have noticed a downward trend ($R^2 = 0.579$) in the mean CT ratio in the period studied since the beginning of the MSBOS (2.3 in Jul-15 to 1.9 in Mar-16). In addition, the mean + 2 standard deviations (SD) of the CT ratio decreased from 8.1 to 5.5 in the same months, suggesting a narrower distribution of the data. For the 7 months before the MSBOS, the ratio was 2.3 compared with 2.1 for the 8 months since the MSBOS ($p = 0.003$ by Student's t test). When individual providers' data for Jan-Mar 2016 were analyzed, at least 59 people in each month had a ratio greater than 2. Table 1 shows that the mean CT ratios for these providers ranged from 3.8 to 5.1, translating to hundreds of units crossmatched and not transfused each month. While they may never leave the transfusion service and become available for someone else, the labor and time involved in handling adds to the overhead of the institution. We are starting to share service-specific data with the appropriate people and will continue to monitor for changes in behavior toward more realistic order practices. **Conclusion**: Preparation of a MSBOS is only the first step in the realization of a more effective blood ordering system in a large academic institution. Data collection and analysis following by feedback to the individual services is mandatory to achieve the goal of decreasing labor and risk of wastage when RBC units are crossmatched unnecessarily.

AP6

Trial of the Unnecessary Blood Transfusion Reduction in Japan

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Background/Case Studies: Blood transfusion therapy was provided with development of liver surgery and the heart surgery in large quantities in Japan from the late 1980s. The red blood cell disposal became the big problem by use of large quantities of the plasma in particular. In addition, the post-transfusion HCV infection was recognized as a social issue as a medical big side effect, too. The Japanese Ministry of Health, Labour and Welfare delivered guidelines on use of blood in sequence after 1986 and revised six times to date. Since 2016, the blood transfusion management fee introduced for the purpose of reducing blood transfusion. We report here the blood transfusion management fee acquisition situation. **Study Design/Methods**: We have sent questionnaire form to all medical institutions which supplied more than one unit of blood component from the Japanese Red Cross Blood Center in a after 2008. We have studied questionnaire answer rate and the number of the blood transfusion management fee acquisition hospitals. **Results/Findings**: The questionnaire answer rate was increased gradually 51.2% in 2015, in 2014 49.2%, in 2011 38.6%, in 2008 25.3%. The blood transfusion management fee acquisition hospitals increased rapidly from 2013. (Table) **Conclusion**: The blood transfusion management fee has been given once a month every patient. It requires to set hospital management system such as blood transfusion therapy Committee (at least 6 times per year), the placement of the blood transfusion exclusive duty doctor, the placement of the blood transfusion working full time laboratory technician and the hospital which met the ratio of FFP consumption and albumin consumption for the total red blood cell consumption a year. This system separate two phases by degree of member level. Furthermore, since 2013, this system revised and can request independently management regime fee and the ratio of FFP and albumin against red cell usage under standard rate as an additional fee. This revision enforced hospitals to get this insurance expense and acquisition hospitals increased exceeded 2,000 in 2014. The hospital which performed blood transfusion more than once a year in Japan rose to 11,000, but more than 95% has used these 2,000 hospitals. The total cost of blood transfusion and albumin use in Japan were approximately 200 billion yen (approximately 1,800 million dollars), but the management charges total sum was around 1.5% for approximately 3 billion yen. We have succeeded to reduce waste blood usage by introducing of management fee which was relatively small cost.

TABLE. Yearly changes of acqusition hospitals of blood management fee

year	2007	2008	2009	2010	2011	2012	2013	2014	2015
Tier I	138	217	260	309	336	352	515	544	
Tier II	606	733	733	850	889	917	1448	1555	
Total	744	950	1087	1158	1225	1269	1963	2099	

AP7

Strategies for Reducing Red Blood Cell Usage

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Background/Case Studies: Faced with a growing body of evidence regarding the safety and efficacy of transfusions, a decreased donor pool, and pressure to reduce costs, transfusion services are looking to reduce the number of red cell transfusions. This abstract outlines two of the methods used by a level 1 trauma center transfusion service to accomplish this goal: on-demand crossmatching (ODXM), and a set of three specific patient blood management (PBM) strategies: lowering the hemoglobin threshold for transfusion, lowering the default RBC order from 2 units to 1 unit, and adding decision support regarding red cell transfusion to the computerized physician order entry (CPOE) system. **Study Design/Methods**: Red cell inventory numbers from 2011-2015, obtained from the transfusion service's primary blood supplier, were compared year over year. ODXM was initiated in 2008; however, the earliest available data was from 2011. The three PBM strategies outlined above were implemented in 2012. Inventory numbers reflect a combination of both methods. Product wastage percentages were also

TABLE. Red Blood Cell Wastage

	Including Autologous			Not Including Autologous		
Year	RBC Wasted	Total Inventory	% Wastage	RBC Wasted	Total Inventory	% Wastage
2013	534	10482	5.1%	155	9943	1.6%
2014	336	10058	3.3%	141	9802	1.4%
2015	151	9159	1.6%	113	9072	1.2%

compared year over year for the same period, 2011-2015. For the period 2013-2015, inventory numbers were calculated including and excluding autologous units. Inventory numbers excluding autologous units were not available for 2011 and 2012. **Results/Findings**: Total red cell inventory decreased 39.61% from 2011-2015: from 15,166 units per year to 9,159 units per year. Wastage, including autologous units, decreased from 5.1% in 2013 to 1.6% in 2015. Wastage excluding autologous units decreased from 1.6% in 2013 to 1.2% in 2015. Total number of autologous units decreased from 539 in 2013 to 87 in 2015 (see Table). **Conclusion**: While it is not possible to separate what portion of the reduction in inventory is due to the implementation of ODXM and what portion is due to PBM strategies, the transfusion service saw a significant decrease in RBC inventory in the five year period studied. This suggests that either or both of the methods were effective in reducing red cell transfusions over the period studied. Wastage from 2013-2015 did not show a significant drop when excluding autologous units, but did show a significant drop when including autologous units. This suggests that wastage in the transfusion service was largely tied to autologous unit inventory, and that the ODXM and PBM strategies were not the primary drivers of the decrease in wastage. It is expected that the effects of these methods will plateau as they become the norm.

AP8

External Disaster Response at a Level 1 Trauma Hospital: A Transfusion Lab's Patient Blood Management Trials and Triumphs

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Background/Case Studies: A hospital-based Transfusion Services Lab (TSL) had the following staff available: 2 Med Techs (MLS), 2 Clinical Lab technicians (CLT), Medical Director (MD), Transfusion Safety Officer (TSO) and the Quality Assurance Specialist (QA) to assist in the trauma response. Scheduled blood shipment was an hour away from arrival and the red blood cells Rh- negative inventory is one that was not up to par level. **Study Design/Methods**: Assessment of Inventory levels and staffing assignments was initiated by Lead Technologist as soon as the Trauma Team activation was communicated to the Lab. Two off-duty technologists called in to volunteer and arrived within the hour. The 4 MLS and 2 CLTs were assigned to different stations; 2 MLS performed blood compatibility and the other 2 did donor blood type confirmation of new blood shipments. The QA supporting the 2 CLTs acted as responders to the Emergency department (ED) and ICU areas and issuing blood products by means of portable mobile refrigerators. MD and TSO assisted in the procurement of blood bank samples for crossmatching. The Lab Trauma white board was utilized to help keep track of all the activities including patient identifications or name confirmations, Patient ID numbers, portable refrigerator locations, phones assigned to responding technicians and the availability of blood bank samples were updated as they became available. **Results/Findings**: Although this was not the first disaster response with expected mass casualty the laboratory had dealt with, this is the first time that the new lab had the trauma code involving at least 20 patients arriving simultaneously and with most of the patients being young women of child-bearing age. As the patients started rolling in, it was noticed that the naming system was not one the lab was familiar with; all had the word "DISASTER" used as last name and a "Greek" first name, and this made it nearly impossible to tell the gender of the patient and how to respond appropriately with Rh positive or negative uncrossmatched units. TSL's usual massive transfusion response is to take uncrossmatched blood and plasma dedicated to a single trauma and follow that patient, but in this circumstance, TSL ended up doing more of an" a la carte" method of issuing products to patients and noting carefully who got what product type and number. **Conclusion**: With the presence of the Laboratory clinical staff in the Emergency room and the ICUs, it became easier for the personnel processing the orders in the laboratory to determine what products to issue on the basis of the gender and age and to anticipate the needs and lack thereof of blood products. The early procurement of blood bank samples sped up the testing process and helped prevent unnecessary use of uncrossmatched and universal type components. Team work and organized work flow saved lives.

AP9

How a Hospital and Blood Center Co-Developed a Successful Patient Blood Management Program

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Background/Case Studies: While both blood centers (BC) and hospitals may be knowledgeable about patient blood management (PBM), individually each may lack resources to implement. A joint venture, BC as consultant and three hospital (400+ beds) healthcare system (HCS) PBM program was implemented. **Study Design/Methods**: A working group (WG) was established that met every 2 weeks. It included from the BC: medical director, medical technologist and nurse; and from the HCS: nursing blood management coordinator (BMC), transfusion service supervisor, and lab manager. PBM project objectives were to implement kick-off meetings and engagement programs, create transfusion committee, provide nursing education, develop and implement auditing processes, and create and send nonconformance letters to physicians and nurses when compliance with informed consent, transfusion tags, transfusion thresholds and discharge instructions was not achieved. IT enhanced the computerized physician order entry system to include a clinical decision support system (CDS) that appeared when an order did not meet HCS transfusion threshold procedure criteria. CDS showed the first line of the associated transfusion threshold procedure, a link to the full procedure, the three most recent lab results (e.g., hemoglobin and hematocrit for red blood cells) and allowed the ordering physician to cancel the order after review of the information presented. **Results/Findings**: From 04/01/14 through 03/31/16, the following markers were monitored for compliance (2Q14 vs. 1Q16): present and completed consents (66 vs. 86%), present and completed flow sheets (19 vs. 90%), thresholds supported (73 vs. 98%) and discharge instructions provided (17 vs. 100%). The CDS System was implemented for four months in 2015 and 1Q16. Data are presented in the table. **Conclusion**: The collaboration of a BC and HCS PBM program resulted in increased compliance for several markers and cost-savings to the HCS.

Year	Units Transfused	Units Cancelled (% total)	Cost Savings – US Dollars ($)
2015	3567	136 (3.8%)	28,624
2016	3277	99 (3.0%)	22,280

AP10

Barriers to Blood Transfusion Documentation in Electronic Medical Records

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Background/Case Studies: Blood transfusions are critical for patients; however, they have been correlated with worse overall mortality. Electronic medical records (EMR) have the potential to provide precise documentation and tracking of transfusion to provide "meaningful use," but EMR data can suffer from completion and accuracy barriers. We performed a

TABLE 1. Blood Transfusion EMR Documentation Completion Rate

	ICU EMR Field Completion Rate #(%)	IP EMR Field Completion Rate #(%)	OP EMR Field Completion Rate #(%)	% EMR Field Completion Rate
Blood Consent Last Signed Date	36 (90%)	51 (88%)	20 (100%)	91%
Blood Donor Number	40 (100%)	58 (100%)	20 (100%)	100%
Blood Expiration Date	40 (100%)	58 (100%)	20 (100%)	100%
Blood Unit Type	40 (100%)	48 (83%)	20 (100%)	92%
Blood Product Type	40 (100%)	57 (98%)	20 (100%)	99%
Blood Product Descriptor	32 (80%)	43 (74%)	19 (95%)	80%
Patient Blood Type	39 (97.5%)	50 (86%)	20 (100%)	92%
Patient Verification	40 (100%)	57 (98%)	19 (95%)	98%
Blood and Patient ID Verified By	39 (97.5%)	58 (100%)	20 (100%)	99%
Blood Transfusion Time Started	37 (92.5%)	44 (76%)	17 (85%)	83%
Blood Administration Equipment	36 (90%)	43 (74%)	17 (85%)	81%
Blood Volume Given	7 (17.5%)	35 (60%)	17 (85%)	50%
Time Blood Stopped	23 (57.5%)	3 (5%)	9 (45%)	30%
Transfusion Duration	9 (0%)	0 (0%)	0 (0%)	0%
Blood Product Intake	16 (40%)	10 (17%)	10 (50%)	31%
Total Transfusion Events	40	58	20	118
Average	78%	71%	83%	75%
Standard Error	9%	9%	8%	9%

single-institution analysis of our EMR to identify completion and meaningful use barriers for blood transfusion related information. **Study Design/Methods**: Retrospective audit of blood transfusion EMR fields was performed in 13 hospital departments (n=118), to determine accuracy and completion rate. Process mapping for nursing documentation was performed to determine EMR pathways for nursing documentation. EMR fields were ordered based on chronological steps for documentation, and attributes such as variable type (e.g. integer vs. nominal and required vs. not required field) were recorded in a database (JMP Pro 2011, SAS Institute). **Results/Findings**: Retrospective analysis of EMR revealed a completion rate of 75% ± 8%. Approximately 50% of the fields had completion rates of <90%. EMR process mapping identified 3 separate pathways for documentation. Prospective validation of EMR pathway process map by structured interview (n=39) demonstrated that individual nursing process utilization of single and/or multiple EMR process map pathways (n=5). **Conclusion**: Blood transfusion documentation is critical for blood transfusion safety and patient blood management. This pilot study suggests value of EMR field audits, EMR process mapping, and nursing process mapping to identify weak points that may lead to incomplete blood transfusion documentation. Current and future work includes detailed analysis of field completion, metrics based on field data, and identifying barriers to improve accurate completion of transfusion-related EMR fields.

AP11

Residents' Transfusion Perceptions and Practices after Implementation of a Best Practice Alert: A Focus Group Analysis

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Background/Case Studies: While red blood cell (RBC) transfusion is common, there is substantial variation in transfusion practices among physicians, resulting in unnecessary transfusion. Numerous strategies have been used to reduce the number of transfusions not supported by guidelines. An interruptive best practice alert (BPA), designed to reduce unnecessary RBC transfusion at high hemoglobin concentrations (>8g/dl), was incorporated into the computerized physician order entry system at our large academic hospital. In spite of the alert, inappropriate transfusions continued at high rates. In order to improve blood utilization and patient safety at our institution, we investigated physicians' transfusion perceptions, practices, and impressions of the BPA. **Study Design/Methods**: After Institutional Review Board approval, internal medicine residents with at least 6 months of clinical training were recruited to participate in focus groups conducted in March 2016. Focus group questions were developed after review of the literature. Participants were shown the BPA prior to eliciting their feedback. Focus groups were audio recorded and transcribed. Two coders independently analyzed the transcripts using thematic analysis techniques, and coding disagreements were resolved through consensus. **Results/Findings**: Twenty-six internal medicine residents (14 seniors, 8 juniors, and 4 interns) participated in one of three focus groups. Most participants expressed awareness of current evidence-based restrictive transfusion thresholds. There was broad consensus among residents that active bleeding, anticipated hemoglobin drop, and attending physician's preference were reasons for transfusing outside the guidelines. Residents suggested blood bank management, education, and requiring attending transfusion justification as effective interventions to increase guideline adherence. Only one focus group offered cost as consideration in deciding not to transfuse. Fourteen participants reported receiving an alert in practice, and most believed that the BPA was futile. Physician frustration, interruptive timing, and alert fatigue contributed to perceived BPA futility. The desire to bypass ("click through") the alert was expressed in all focus groups. Conversely, some participants believed the alert decreased errors in wrong-patient transfusion orders and indirectly educated interns unaware of transfusion guidelines. **Conclusion**: Residents' transfusion perceptions and practices provided insight into barriers to transfusion guideline adherence at our institution. Modifications to our current BPA might improve efficacy and reduce physician frustration. Potential strategies to improve blood utilization include education and targeted feedback to residents and attending physicians.

AP12

Excessive Pre-operative Crossmatch Ordering on General Medicine Wards Identified by a Transfusion Best Practice Alert

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Background/Case Studies: Best practice alerts (BPA) in computerized provider order entry (CPOE) systems have been shown to reduce unnecessary blood utilization. Recent studies have shown that they may also identify inefficient transfusion ordering patterns, providing opportunities for targeted educational interventions. **Study Design/Methods**: A BPA employed at a large academic hospital was activated whenever a crossmatch order for red blood cell (RBC) units was placed in the CPOE system for a patient whose most recent hemoglobin was >8 g/dL. The alert screen displayed the hemoglobin value and a statement supporting restrictive transfusion. The provider

TABLE 1. Encounters in which a crossmatch order was placed despite a best practice alert (n = 360)*

	Transfusion within 24 hours	
Selected Transfusion Indication	Yes	No
Blood product for surgery	54	126
All other indications	105	75

*$p < 0.0001$

was given the option of canceling the crossmatch order or proceeding with the order by selecting a transfusion indication from an approved list. The alert was restricted to inpatients on general medicine wards. Alert activations that were bypassed were analyzed retrospectively to determine if the indication selected was associated with crossmatch orders that did not result in transfusion. **Results/Findings**: There were 410 encounters with the BPA in a 7-month period (April-October 2015); an "encounter" was defined as all alert activations on the same patient within 6 hours, to account for repeated crossmatch orders in a short period of time. The order was canceled in 50 (12%) encounters. Of the 360 encounters in which the BPA was bypassed, 180 (50%) carried the indication "blood product for surgery." Of these, only 54 (30%) were associated with RBC transfusion within 24 hours of the order (Table 1). Of the 180 encounters in which any indication other than "blood product for surgery" was selected to bypass the alert, 105 (58%) were associated with transfusion, a significantly higher proportion ($p < 0.0001$ by Fisher exact test). In 84 (47%) of the 180 encounters for "blood product for surgery," the crossmatch order was placed by a provider in a non-surgical specialty. **Conclusion**: Half of all RBC crossmatch orders on general medicine inpatients with hemoglobin >8 g/dL were for preoperative preparation of blood. The majority of these orders did not result in transfusion, suggesting overestimation of intra-operative transfusion needs by the ordering provider. These findings offer an opportunity for targeted education on effective ordering of crossmatches on inpatient wards, which may be incorporated into the already existing BPA.

AP13

Demand for Group O Rh(D)-negative Adult Red Cells in Scotland

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Background/Case Studies: Group O Rh(D)-negative (O Neg) red cell (RBC) components are a high value resource, as they can be used for the majority of patients irrespective of ABO group and Rh(D) status. Thus, blood banks are likely to hold a higher proportion of RBC stock as O Neg units than would be expected from the distribution of ABO and Rh(D) groups in the general or patient populations. **Study Design/Methods**: Data from the Scottish Account for Blood system were used to examine trends in adult RBC units booked into 31 hospital blood bank inventories and their final fate for the period 1st January 2009 to 31st December 2015. **Results/Findings**: Data are presented for 1,157,554 transfused RBC units and 204,015 red cell recipients. The number of patients transfused annually has reduced by 17% over 5 years. The trend is similar across all blood groups and the proportion of O Neg recipients is consistently around 9%. The number of adult RBC units booked into hospital blood banks has reduced by 16%, a trend seen in all blood groups except O Neg, which fell by 9%. Thus, the proportion of adult RBC units booked into stock as O Neg has risen slightly, to around 13%, for the last 3 years. The number of adult RBC units transfused also shows a consistent downward trend, with a reduction of 21%. The pattern of O Neg transfusion was similar but with a smaller reduction of 17%. There was a fall in the number of adult RBC units not transfused of 30%. The trend varies by group over the period, and O Neg is now the most common type to not be transfused. The number of adult RBC units to be outdated fell by 31% while for O Neg the reduction was much less at 8%. O Neg as a proportion of all outdates rose from 19% to 25% over the period and contributes the greatest absolute number of units outdated. O Neg units were among the least well used with an average transfused: not transfused ratio of 18.1. The proportion of O Neg units transfused to recipients of a different ABO and Rh(D) group rose from 26% to 29% over the period, while the proportion of cross-grouping in all other groups tended to fall. There was a significant correlation between the proportion of adult RBC units booked into blood bank inventories that are O Neg and the proportion of the latter that are cross-grouped and outdated (Table). **Conclusion**: Although overall demand for adult RBC units for transfusion to patients has fallen consistently, this has not been completely mirrored by a reduction in hospital blood bank inventories across ABO and Rh(D) groups, as might have been predicted. Blood bank demand for O Neg RBC stock is associated with an increasing trend in O Neg RBC cross-grouping and outdating.

TABLE 1. Booked in correlation

	Correlation coefficient	R2
% O Neg not transfused	0.85	0.72
% O Neg cross-grouped	0.95	0.91
% O Neg outdated	0.78	0.56

AP14

Multi-Station Process Change to Support Difficult Policy Change

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Background/Case Studies: Blood delivery to a patient in a Trauma Center Emergency Department can be an area of risk for patients. Multiple patients may be in need of blood at the same time, and there can be a risk of misidentification of the patient for the delivery of the blood product. Our transfusion service had some near-miss events with blood delivery when blood labeled and intended for one patient was brought to another patient's bedside. In July of 2013, a policy was implemented to provide only universal donor Group O red cells to ED patients. This policy was instituted to prevent patient harm in the event of an ABO type-specific unit transfusion to an unintended recipient of a major ABO-incompatible blood type. The transfusion lab staff was having a hard time remembering not to send type-specific red blood cell units to the ED, as our first thought was that type specific blood is best. **Study Design/Methods**: A group consisting of lab staff, a system engineer, and our medical director was formed to develop a process with a goal of 100% compliance with sending only Group O red blood cells to the ED. The lab staff stepped up to the challenge of putting some action in place for each step in our process, from receiving the order to dispatching the RBC. Process changes included placing a fluorescent green sticker stating "ED O Blood Only!!" on the product order with a line for tech initials at each bench (order entry, manual or automated testing, and dispatch). Initialing of the order by the tech indicated the Group O requirement was recognized. If initialing of the sticker was missed, the order was routed back as a learning opportunity. Additional visual cues were placed at the work stations and on the blood storage refrigerator. A daily report was reviewed for compliance and a weekly report was sent to the lab for 6 months following the process changes. **Results/Findings**: In a 16 week timeframe post-policy implementation, 20 non-group O RBCs were issued to the ED; in a 16+ week timeframe after process changes were implemented, 0 non-group O RBCs were issued. An average of 35 RBCs were issued per month in the 4 month timeframe after process changes. No events occurred after process changes until May of 2015, an 18-month time period. We had additional subsequent events in both July and September of 2015. We had gained new staff members since our changes implemented. In January 2016 a review of the reasons for the policy and the resulting process change was presented to staff at a lab meeting. We have had no new events in 4 months' time since the review. **Conclusion**: A multi-station process change was a good solution for supporting this policy change. The visual reminder with action required by the tech and additional visual cues were more successful than institution of the policy change alone. It helped change our ingrained thought process that type-specific blood is best.

AP15

Cost-Effectiveness of a Centralized Platelet Inventory Program in a Regional Cluster

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Background/Case Studies: Our regional cluster has five acute hospitals serving an 0.92 million population with one geographically distant donor facility. Historically, blood bank of each hospital has own inventory policy due to differences in the clinical needs, transport logistics and management. A centralized platelet inventory program is adopted here where a uni-directional transfer system was put in place to timely redirect the platelets to one larger hospital to reduce the platelet wastage, and this cost-effectiveness is studied. **Study Design/Methods**: A centralized platelet inventory program is adopted among three acute hospitals in the cluster since 1/3/2014, replacing the previous two-way transfer. No reduction in annual platelet inventory in the individual blood banks to ensure similar clinical needs are met. Data were retrieved from the Laboratory Information System from 1/1/2010 to 31/12/2015 for analysis. Using the previous period without a proper transfer system (Phase 1: 1/1/2010 to 31/12/2011) as the baseline, bi-directional transfer of platelets (Phase 2: 1/1/2012 to 28/2/2014) and this new centralized platelet inventory program (Phase 3: 1/3/2014 to 31/12/2015) were compared. Additional workload by the blood bank staff in packaging and arranging these transfers was calculated as the direct staff costs using the notional annual mid-point salary of the rank of patient care assistant and medical technologist, respectively. Consumable cost is blood bag expenditure. The total costs (direct staff and consumable costs) for different phases were computed. Effectiveness is the reduction in number of expired platelets. The cost-effectiveness ratio is compared between Phase 2 and 3. **Results/Findings**: The percentage reduction in the wastage rate is 24.1% and 71.4% for Phase 2 and 3, respectively, when compared to Phase 1. The total

average monthly cost increment is 31% and 33% and the additional average monthly cost is US$793 and US$801 for Phase 2 and Phase 3, respectively. The cost-effectiveness ratio (i.e., the total cost used to reduce each platelet unit) is US$34 and US$10 for Phase 2 and Phase 3, respectively; hence, Phase 3 is 3.4 times more effective than Phase 2. The average price of production of one platelet unit is around US$70, hence the net savings in the cluster are US$36 and US$60 for each platelet unit reduced for Phase 2 and Phase 3, respectively. The actual annual cost savings are US$12888 and US$57792 for Phase 2 and Phase 3, respectively. **Conclusion**: Despite the implementation of this centralized platelet inventory program increases the workload of the blood bank, the current cost-effectiveness study showed that there is overall net savings in the cluster when the total costs are computed. Moreover, the moral duty of reducing wastage of scarce product like platelets is worthwhile to promulgate this practice to other regional clusters.

AP16

Introduction of Thromboelastography into Transfusion Facility Workflow

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Background/Case Studies: In order to improve the management of coagulopathic patients and possibly reduce use of blood components, many hospitals are incorporating the use of thromboelastography. In some institutions these devices are considered to be used as "point-of-care" instruments, but often are incorporated into various laboratory settings. Considering overall laboratory workflows and staff availability, our institution decided to integrate these devices into our transfusion service (TS) laboratory. This abstract describes our approach to staff training and competency as well as integration of this testing into laboratory workflow to insure rapid turnaround of results. **Study Design/Methods**: Samples for testing are sent to the transfusion service by pneumatic tube system and test results are available to the ordering provider via remote viewer. In order to accommodate laboratory staff training, performing this test, and physician education in interpretation of the results, this testing was implemented in a stepwise fashion initially including pediatric cardiovascular surgery and liver transplant surgery and will soon be provided to the trauma service. Because a significant advantage of this technology is the rapid availability of results, we considered turnaround time (TAT) to be an important measure of our success in implementing this technology. TAT-1 is calculated by comparing arrival time in the transfusion service to the start time of the test. In addition, TAT-2 is calculated from sample collection time to the time of arrival in the TS. **Results/Findings**: Installation and validation of the instruments in the TS required approximately 9 weeks. Staff training was completed over 3 weeks. A change in process usually coincides with a decrease in quality, something that we controlled with extensive staff training. TAT has been calculated for the first 3 months after the implementation of this test; when possible, the reason for the delay beyond our target TAT-1 of 10 minutes is also recorded. In the first month of operation, the TAT-1 was 8 minutes (82.8% of samples were started in 10 minutes or less of receipt), which fell to 5 minutes (86.2% started in 10 minutes or less) in the second month and 7 minutes (95.2% started in 10 minutes or less) in the third month. For each of these first 3 months, the time from sample collection to arrival in the transfusion service was 17, 9, and 8 minutes, respectively. **Conclusion**: Our study suggests that thromboelastography testing can be effectively implemented into the environment of a busy TS. Staff training and comfort with the technology is suggested by the decreasing TAT-1 in successive months after implementation. The most significant delays in overall testing TAT (both TAT-1 + TAT-2) occurred in instrument availability when a test request was received and staffing levels of the TS.

AP17

Utilization of Group O Rh-negative Red Blood Cells from a Remote-Release Refrigerator System in a Level I Trauma Center

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Background/Case Studies: For patients with severe hemorrhage, early resuscitation with blood products can be key to survival. Our Level I trauma center contains a remote- release refrigerator system (RRRS), allowing Emergency Department personnel access to uncrossmatched group O Rh-negative (D-negative) packed red blood cells (RBCs). This system allows for rapid transfusion of blood products when there is insufficient time to wait for type-specific crossmatched blood. Providing D-negative blood prevents potential alloimmunization, a concern particularly for women of child-bearing age, for whom Rh (D) alloimmunization could lead to hemolytic disease of the fetus and newborn (HDFN). Importantly, group O Rh-negative RBCs also remain a precious and sometimes scarce resource. The purpose of this study is to examine the sex, age and blood type of the patients receiving group O Rh-negative RBCs in an emergency setting and identify cases where alloimmunization was potentially averted. **Study Design/Methods**: Utilization of the RRRS during trauma activation occurring from October through December, 2015 at our Level I trauma facility was monitored. The patient's age, sex, ABO/Rh type and number of RBC units used from the RRRS were recorded. **Results/Findings**: Over three months, 67 patients received group O Rh-negative RBCs from the RRRS. Of these patients, 19 were blood group A positive, 1 was A negative, 4 were B positive, 2 were AB positive, 30 were O positive, and 6 were O negative (5 undetermined). The patients used a total of 139 units of remote release O negative RBCs (mean: 2.1 units RBCs per patient). Of the 67 patients with life-threatening anemia, 48 were men, and 19 were women. The mean age was 46.3 years (range: 7-90). Of the 67 patients who received group O Rh-negative blood from the RRRS, one was an Rh-negative woman of child bearing age. **Conclusion**: Access to group O-negative RBCs via the RRS allows for early resuscitation with blood products in trauma patients while waiting for type-specific crossmatched blood and providing Rh-negative RBCs can prevent Rh-D alloimmunization. Because Rh-negative group O blood is a scarce resource, it ideally should be reserved for Rh-negative women and children with the potentially for developing Rh HDFN. Our data show that of the 67 patients who received blood from the RRRS only one patient was female, of child-bearing age, and Rh negative. Thus, in the three months covered by our study, a total of 139 group O Rh-negative RBCs were emergently transfused with only a single episode of potential Rh alloimmunization averted. In this era of group O Rh-negative blood shortages, continued monitoring of the allocation of this precious resource will be key to ensure the appropriate target population is reached.

AP18

Care in the Community-Home Transfusion by Community Paramedics

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Background/Case Studies: In 2015, Transfusion Medicine (TM), the Community Paramedic Program (CPP), and the Cancer Centre collaborated to create a pilot project to provide transfusions to patients in their home environment. Through a close partnership and strong communication, TM and CPP worked together to define eligibility criteria, referral requirements, procedures, protocols, education, and an evaluation plan. The program allows community paramedics with transfusion training to perform in-home transfusions for patients with mobility issues, thereby eliminating the need for patients to travel to acute care sites for their transfusion. **Study Design/Methods**: During the program development the following elements were discussed and evaluated to determine how to proceed. CPSA, CSTM, and CSA standards provided necessary guidance:

Patient Eligibility: Previous transfusions with no complications. Patient must suffer from a medical condition such that a trip of an hour or more would compromise the patient's health.
Product Eligibility: Red cells and platelets.
Pre-transfusion testing and product orders: Testing performed at least 24hrs prior.
Training and competency program: Created for CPP staff by RN Transfusion Safety Leader to perform transfusions.
Adverse reaction considerations.
Referral process: CPP receives the referral and reviews for need and appropriateness; referral is sent to TM for final review.
Products are picked up from the central TM Service.
The comprehensive record of transfusion is documented on the patient's medical record.
The patient receives written notification of transfusion.

Results/Findings: From Oct 2015 to April 2016, the CPP has performed 78 home transfusions on 27 different patients; 128 units of red cells and 32 platelets have been administered. To date, there has been only 1 mild allergic reaction reported. During the pilot, patient interviews were conducted and feedback was overwhelmingly positive. The cost of transfusing 2 units of red cells at a hospital Day Medicine unit is ~$400 and ~$1300 if the transfusion occurs at Cancer Centre. In contrast, the cost of a CPP transfusion visit is ~$400. **Conclusion**: This program also presents the potential cost considerations for patients and their caregivers; the cost of private transportation and time off work for caregivers, although difficult to quantify, must be considered. The true measure of success is in the comfort provided to the patients, often at a time when their lives are nearing the end.

AP19

Result Analysis of National Blood Inspection for Blood Centers in Korea (2012 to 2015)

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Background/Case Studies: In order to enhance the blood safety management of blood centers, the Korean government has taken charge of the permission of all blood centers since 2005. Korea Centers for Disease Control and Prevention (KCDC) has made biennial inspection of blood centers to supervise blood management processes at national level since 2007. The aim of this study was to show the result of blood center inspections performed in Korea from 2012 to 2015. Also, analysis data give us useful information on how to reinforce the inspection task. **Study Design/Methods**: From 2012 to 2015, KCDC had inspected annual average of 58 blood centers using the checklist in Blood Management Regulations. Inspectors consisted of the officials of Division of Human Blood Safety Surveillance in KCDC and laboratory medical specialists. We analyzed the results of inspection performed twice for each of 108 blood centers. **Results/Findings**: 108 blood centers were classified by the task characteristic. 17 were the blood centers which provided most of blood services generally in Korea, such as blood centers of Korea Red Cross Blood Services. Their annual amount of blood collection was 2,887,614 units, which was 99.9% of national annual blood collection. 3 were blood laboratory centers, and 27 were the inventory centers. 61 were the hospital blood centers in which the blood collection was only made for their own use when necessary. Ten centers failed the inspections from 2012 to 2015. Two of them closed the facilities voluntarily due to manufacturing unauthorized blood products. Eight deficiency facilities passed the re-inspection after correcting the problem. Five were classified under deficiency due to the lack of accuracy of testing. Two were unperformed guidelines review and renewal which had been done at least once a year. One of ten was conducted inadequate blood culture. **Conclusion**: In the past, the lack of specific equipments or facility like a separate interview room and a donor waiting room were the most of deficiency reasons. Regular inspection improved the blood facilities and appropriateness of blood collection. Post evaluation of inspection resulted to modify Blood management Act amendment to allow post-transfusion screening tests for NAT and anti-HTLV in some emergency situation and apheresis granulocytes transfusion. In order to enhance blood safety, KCDC offers practical education annually to the personnel who work in blood centers to strengthen their capabilities since 2014. To improve the quality management process, we will further reinforce the review of standard operating procedures of each blood center and the blood culture process. Reflecting the analysis result and the latest information, we will amend the inspection checklist of Blood management Act and keep improving the supervision process of blood centers

AP20

Utilization Audit of Using Thawed Plasma

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Background/Case Studies: In order to provide enterprise-wide standardization among some of the transfusion services, the implementation of a new Laboratory Information System (LIS) was to be used by three of its institutions. The three institutions faced many challenges in maintaining agreement for the LIS. These included product dictionaries, compatibility tables, product modifications, and nomenclature. One dilemma that was encountered was the expiration of fresh-frozen plasma (FFP) after thawing. One facility had always modified FFP to thawed FFP (TFFP), which has an expiration date of 24-hrs from thawing. The other two facilities modified FFP to thawed plasma (TP) which has an expiration date of 5-days from thawing. Majority ruled, so the decision was made that after thawing FFP the new product would be TP. The goal of this institution is to keep plasma wastage to $\leq$10%. The objective of the plasma audit was to 1) quantify the number of units that would have been issued as TFFP and 2) determine if the use of TP decreased plasma wastage. **Study Design/Methods**: This was a 7 month retrospective utilization audit from June December 2015, after the installation of the new LIS. A total of 103 plasma units were transfused. The units were categorized as being transfused within 24-hrs, 48-72 hrs, or 96-120 hrs of thawing. The patient's location was also documented for all units that weren't issued within the 24-hrs. **Results/Findings**: A total of 92 (90%) TP units were issued within 24-hours of thawing, and 11 (10%) were issued within the 5-day expiration date. Of the 11 units issued within the 5-day expiration date, (8) 73% units were issued within 48-72 hours of thawing and 3 (27%) units were issued within 96-120 hours. Also, 64% of the units issued within the 48-120 hours were transfused to the Emergency Room, Operating Room, and Interventional Radiology. The plasma wastage for 2015 was 12%, but if the FFP units were modified to TFFP instead of TP, the plasma wastage would have increased to 16%. **Conclusion**: Even though blood product wastage is inevitable and unpredictable, it is optimal to decrease the wastage rate in order to maximize the blood supply. The utilization showed the efficient use of TP, with 97% of the units being transfused within 72 hours from thawing. Overall, the audit showed that the use of TP had a positive outcome and that the implementation of using TP decreased wastage, conserved plasma, saved money and made plasma readily available for critical care areas.

AP21

Implementation of Emergency Department Blood Product Refrigerator

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Background/Case Studies: Previously, a level one trauma hospital-based Transfusion Support Laboratory (TSL) provided uncrossmatched blood products on demand to the Emergency Department (ED) via a portable blood refrigerator which was staffed by an employee of the TSL and each response took an average of 54 minutes. This level of support required increased staffing levels at all times and would often interfere with other ongoing TSL activities. The most common response was for patients that never used any uncrossmatched products. To better provide service, as well as reduce demand on TSL staff, a refrigerator was purchased by the ED which was stocked with emergency release red blood cells and thawed plasma by the TSL. The new process required training the ED staff to use the provided refrigerator first and request TSL support only on patients requiring an increased number of blood products. ED staff was assured TSL would still provide support when requested. **Study Design/Methods**: To judge the impact of the ED refrigerator on TSL workflow, workflow was compared both before and after the installation of the ED refrigerator. Two metrics were collected from the laboratory information system and paper records: the number of responses TSL made to the ED, and which responses used uncrossmatched product. ED staff was provided training by the Transfusion Safety Officer (TSO) as well as updated guidelines for requesting a physical response by TSL with the aim of minimizing TSL response for patients that did not need uncrossmatched product. After go live, TSL staff reported responses that did not use products to the TSO for investigation which lead to ED staff education. **Results/Findings**: Prior to installation of the ED fridge, TSL staff was responding to the ED an average of 2.25 times a day and the ratio of responses which did not use product with the responses that did was 1.78. This resulted in a daily loss of about two hours of staff productivity with responses that were not consistently using blood products. After installation the average number of responses dropped to 1.97 and the ratio dropped to 1.01. **Conclusion**: The installation of an ED fridge with uncrossmatched product was able to reduce the number of responses that TSL staff made however not to the point of being able to reduce staffing. It did allow for staff to focus on duties within the laboratory and better serve all patients within the hospital. When TSL staff does respond to the ED, the patients there are more likely to require blood products and a physical response is more appropriate. Continued education of the ED staff by the TSO was instrumental in the adoption of this new process and allowed for continual process development.

AP22

Reasons for Blood Transfusion Refusal May Be More Diverse Than Expected

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Background/Case Studies: Human blood is highly symbolic and meanings surrounding its use involve complex religious and cultural beliefs. It is widely understood that Jehovah's Witness members may decline transfusion of certain blood products; however, less well described are members of other spiritual belief systems that may also refuse specific transfusions. Herein, we present three non-Jehovah's Witness patients who declined blood transfusion for religious reasons **Study Design/Methods**: Medical history was collected for each patient with cultural perspective provided by a faculty member in the field of anthropology. **Results/Findings**: Patient #1, a Messianic Christian Hebrew Roots member in his 60's required pulmonary

decortication for a lung abscess. He upheld that the Old Testament forbade receiving allogeneic blood products and declined any and all allogenic transfusions (he was not a candidate for autologous blood banking (hemoglobin <11g/dL)). The surgery was performed and the patient recovered without the need for transfusion of blood products. Patient #2, a Navajo Nation member in her 30's developed an abscess after a gynecological procedure and potential blood loss from a planned surgical intervention was significant. She refused blood from anyone but family members (including in-laws) citing the necessity to limit blood donors to spiritual relatives. She ultimately responded to treatment without the need for surgery or transfusion of blood products. Patient # 3, a Navajo Nation member in her 20's, presented at 32 weeks gestation with a history of severe post-partum hemorrhage. She believed that blood products contained another person's life force and refused transfusion unless on the verge of death. She gave birth without suffering life-threatening hemorrhage and was not transfused. **Conclusion**: Blood product refusal based on religious or spiritual beliefs may be more varied and diverse than is commonly reported. Christian groups with similar interpretations of scripture to that of Jehovah's Witnesses may refuse blood transfusions based on a perceived Biblical prohibition. Members of certain Native American communities who harbor traditional beliefs may also decline blood product transfusion based on spiritual concerns. Ultimately, each patient must be approached as an individual and with "cultural humility", understanding that beliefs concerning human blood lie at the nexus of religious, historical, and cultural forces, all of which may have bearing on the patient's clinical care.

AP23

Hemoglobin-Based Oxygen Carrier Use in a Jehovah's Witness with Newly Diagnosed Acute Lymphoblastic Leukemia

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Background/Case Studies: The management of Jehovah's Witness patients with severe, symptomatic anemia is challenging, as blood transfusions are usually not an option. Hemoglobin-based oxygen carriers (HBOC) can be used as an alternative to red blood cell (RBC) transfusion in patients with acute lymphoblastic leukemia (ALL) and severe symptomatic anemia. **Study Design/Methods**: A 48-year-old Jehovah's Witness presented with increasing fatigue, weakness, dyspnea, a hemoglobin (HGB) of 4.8 gm/dL, white blood cell count of 4.9 x 10^9/L, and platelet count of 108 x 10^9/L. She refused transfusion of RBCs and platelets. She was diagnosed with ALL and started on induction chemotherapy. On day 5, her HGB fell to 3.0 g/dL; she had increased symptoms of anemia and received two units of HBOC-201 ("Hemopure," HbO2 Therapeutics). This was administered under emergency FDA Investigational New Drug (IND) and local Institutional Review Board approval, and after informed consent was obtained. On the same day, her platelet count fell to below 20 x 10^9/L, and she received antifibrinolytic treatment with aminocaproic acid to prevent spontaneous bleeding. **Results/Findings**: Chart review was performed to identify pertinent clinical information regarding the patient's status during hospitalization. With the use of HBOC-201, there was immediate resolution of the patient's tachycardia, improvement in oxygen saturation with decreased oxygen requirement, and an increase in energy. The patient completed induction chemotherapy without requiring additional units of Hemopure and was discharged. Even though the patient was stable enough only to require two transfusions, there were other advantages to having a blood substitute available. First, its availability made the clinical team more willing to proceed with appropriate chemotherapy. Second, knowing that a blood substitute was available in the case of acute decompensation made daily nursing and clinical care less stressful to the providers. **Conclusion**: This is the second report to document the use of Hemopure in the management of severe symptomatic anemia in a patient with acute lymphoblastic leukemia who refused RBC transfusion. Hemoglobin-based oxygen carriers not only are a life-saving intervention by preventing the effects of end-organ ischemia secondary to anemia but Hemopure also gives clinicians confidence to initiate and to continue treatment for a patient who does not have blood transfusion as an option.

AP24

Bilateral Ischemic Optic Neuropathy Following Cardiac Bypass Surgery Using Restrictive Transfusion Criteria

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Background/Case Studies: A 75-year-old male presented with chest pain and following a cardiac catheterization was emergently taken for 3-vessel coronary bypass. During the postoperative period, the patient experienced blurred vision and was ultimately diagnosed with bilateral ischemic optic neuropathy with total vision loss in one eye and blurred vision in the other. **Study Design/Methods**: This is a case report using physician, nursing and laboratory data from the patient chart.
Results/Findings:

Day 1: The patient's presurgical hemoglobin was 13.4 mg/dL. Cell-saver was used during surgery. Hemoglobin measured at 5.8 mg/dL after patient taken off pump. Transfused 1 - RBC, 1 - Apheresis platelet and 1 - FFP with the hemoglobin responding at 9.7 mg/dL. 300 ml shed blood transfused in ICU following transfer from OR. Hemoglobin 9.3 mg/dL.
Day 2: Hemoglobin 8.9 mg/dL (AM), blood pressure low - used pressors; fluid bolus given.
Day 3: Hemoglobin 7.6 mg/dL (AM), sinus tachycardia - Levophed for blood pressure support.
Day 4: Hemoglobin 7.6 mg/dL (AM), patient reported blurred vision, 2 - RBCs transfused in PM.
Day 5: Hemoglobin 9.5 mg/dL (Noon), vision remained blurred - opthalmologist consult.
Day 6: Hemoglobin 9.2 mg/dL (AM), vision remained blurred - temporal artery biopsy negative for arteritis.
Day 7: Discharged with probable permanent blindness in one eye and undetermined recovery of other eye.

Conclusion: As more hospitals adopt stricter blood management protocols, additional studies are needed to verify lower transfusion guidelines remain beneficial. This case illustrates a successful medical procedure that had a less than desirable effect on a patient. All medical procedures have inherent risks and each individual case encompasses many variables. It's unknown if a transfusion on day 3 could have prevented the neuropathy in this case. Larger studies are needed to track adverse events across the transfusion spectrum to determine if the rates of these events have increased since the adoption of stricter transfusion guidelines.

Collections and Product Manufacturing

AP25

Utilizing DXT Data Management System to Optimize Amicus Platelet Production

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Background/Case Studies: Cost containment needs triggered an opportunity to achieve additional operational efficiencies in our apheresis platelet program. To achieve optimal level of production, it is essential to evaluate platelet donations, identify missed opportunities and set a threshold for an achievable growth goal. We took a data driven strategic approach to manage productivity and success of the apheresis platelet program using procedural data and operational efficiency reports from Fresenius Kabi, Fenwal Amicus DXT Data Management. Amicus procedure data is transmitted from the device to DXT after completion of the procedure. DXT operational efficiency reports are generated by center management. Analysis of the data is performed regularly for strategic planning and to assure achievement of center goals. This provided a method of focus on opportunities to increase apheresis platelet productivity. **Study Design/Methods**: Amicus DXT was implemented March 2014. DXT reports provide detailed information on each procedure, including target and actual platelet product yield. This enabled the operators to plan each procedure to obtain the optimum number of platelet and plasma units from each donation. Monitoring InterSol collections and concurrent plasma is another initiative tracked using DXT reports. **Results/Findings**: Having daily procedural visibility, we increased our split rate 13.2 percent. This allowed us to collect 267 fewer procedures yet yield 182 more platelet units. With the increase of InterSol procedures our concurrent plasma unit collections grew 70.7 percent. This allowed more WB plasma to be diverted to recovered plasma and generate additional revenue for our center. Due to platelet optimization, budget goals associated with cost per unit were met. Increased productivity reduced the cost per procedure by 3.5 percent. We have potential to improve further as center managers collaborate with Fresenius Kabi team to ensure KPIs are met. Continued focus on DXT data will help increase our efficiency and overall objective of obtaining a 2.0 percent split rate or better. **Conclusion**: Our initiative to collect and provide life-saving blood components to the community at the lowest possible cost continues to be achieved. By optimizing the donor base using the data available through Amicus DXT, we continue to position ourselves to be cost efficient. The Amicus DXT was easy to implement. DXT operational efficiency reports provide the information needed to increase our platelet efficiency, educate

staff and donors to continue to serve and strengthen the bonds of the community.

AP26

Building a Major Military Blood Drive

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Background/Case Studies: The Armed Services Blood Program (ASBP) was established in 1951 and became fully operational in 1962. As a tri-service organization, the ASBP collects, processes, stores, and distributes blood and blood products to Soldiers, Sailors, Airmen, Marines, and their families worldwide on a daily basis. The challenges associated with donor recruitment mirror those faced by our civilian counterparts; however, the ASBP is restricted to federal property for collections, and the ASBP must navigate through the numerous deployments to identify and recruit qualified donors for whole blood and apheresis collection. Each year the Army Blood Program (ABP) plans and conducts a blood drive at the United States Military Academy at West Point, NY, and Cadet Summer Training (CST) at Fort Knox, KY. These blood drives are large in comparison to a "normal" blood drive, as they will produce over 3,000 units of whole blood collectively. The careful planning and strategic marketing that are vital to a successful and cost-effective "normal" blood drive are vital at West Point and Fort Knox. **Study Design/Methods**: With a donor population of 4,000 to 5,000 at West Point, six ABP Blood Donor Centers (BDCs) consolidated at West Point in December to train and collect units under one facility. With a donor population of 10,000 during Cadet Summer Training at Fort Knox, four different ABP BDCs conducted a series of blood drives between June and August. Both West Point and CST required extensive planning and logistical support. The marketing plan for West Point was different than the plan for CST. **Results/Findings**: 130 ABP employees collected 1,839 units at West Point. Four ABP BDCs conducted a total of 25 blood drives with an average of 18 employees per drive to collect 3,100 units at CST. An average of three months was used to plan and market both events, compared to an average of two weeks to plan and market a normal blood drive. Manufacturing of products was completed within the established timeframe for both drives; however, distribution was delayed beyond the units required to support operational missions. **Conclusion**: Extensive planning and marketing will have a direct impact on the support received at West Point and CST. These drives are conducted in December, June, July, and August, which are times of low national donor collections. These large-scale blood drives may not always be cost-effective; however, they provide mission support to ASBP and an opportunity to educate future leaders about the program.

AP27

Evaluation and Implementation of a New Platelet Sampling Kit

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Background/Case Studies: The SSK- 10mL is used to perform the single sampling process on apheresis platelet collections in our locations that perform bacterial detection testing. **Study Design/Methods**: Determination of platelet yield, residual WBC and BacT/ALERT testing was performed for each sample. The evaluation included documentation and assessment of the following processes: sterile welding, sampling from platelet bag, sample transfer into BacT/ALERT blood culture bottles, transfer into vacuum tubes for platelet yield and residual WBC count. The SSK-10mL was also assessed for human factors and visual inspection. Staff compared the previous platelet sampling device to the SSK-10mL device for the following: ease of use, process efficiency, and compatibility with existing SOP, workflow, visual inspection, mechanical function and overall performance. The new device was assessed for size and weight reduction. **Results/Findings**: A total of twenty apheresis platelet units were sampled using SSK-10mL. For all samples, sterile connections, sampling into the SSK-10mL, transfers into BacT/ALERT culture bottles and transfers to vacuum tubes were satisfactory. There were no leakages, or any other unfavorable occurrences. Staff preferred the ITL SSK product to the previous platelet sampling device due to ease of use, process efficiency and overall performance. The ergonomics of the design include a self-filling mechanism that does not require manipulation of a plunger, making SSK-10ml less of a repetitive motion injury risk. Time studies performed between the previous and new device were comparable. Storage requirements for the boxes of SSK-10mL were 40% less, as compared to the prior platelet sampling kit. Ordering patterns have been modified to order once, instead of twice per week streamlining the supply ordering task. The SSK-10ml weighs 13.5 g, this is 6.3 g less than the prior sampling device that weighs 19.8 g. This difference translates to 655kg less bio hazardous waste annually. **Conclusion**: In conclusion, upon completion of the evaluation, data and verbal feedback were reviewed and summarized below:

- Annual savings greater than $150,000.00
- Better ergonomics
- Critical supply space savings 40% less space needed
- Biomedical Waste disposal savings $>$ 655 kg per year
- Time efficiencies as staff competency increases

Considering all of the positive factors listed above, a decision was made to implement a system wide switch to the ITL SampLok Sampling Kit 10ml for platelet sampling at our blood center.

AP28

Implementation of Wireless VPN on Blood Mobile for using the Donor System Remotely

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Background/Case Studies: It is critical to access donor information on Blood Mobile during a drive. We used laptop download method previously. This was a daily process and required a nurse to ensure data replication and to transport the laptops to and from blood mobiles. We cannot enter data during the drives. The workflow was not efficient. The laptop download/upload method was evaluated, but the staff deemed the upload process too complex and would be error-prone if implemented. To save time and money and to make the workflow better, we implemented the wireless VPN, which allow staff to enter data to the Donor System in real time. **Study Design/Methods**: We compared advantages and disadvantages of the three methods on the Blood Mobile: laptop download, laptop download and upload, and wireless VPN. We estimated average time for laptop download method since no information is stored in database. We compared the average time used per donation using wireless VPN with that using wired connection at the Donor Center. **Results/Findings**: The wireless VPN was implemented on 4/9/2016. We calculated the whole blood donation time from donor registration in the donor system to the end of bleed from database. Table 1 shows wireless VPN has almost the same performance as the wired connection. We interviewed 5 staff at the Donor Center. They estimated that the new wireless VPN process took about 5-10 minutes longer than the laptop download method. Since wireless VPN is a newly implemented process, adjustments and optimization are ongoing. The clinical staff needs to learn how to manage computer glitches. The management team has provided more training, and more staff will be assigned for big drives. We have also adjusted staff roles and appointment slots to better match the donation times. Compared to the laptop download and the laptop download and upload methods, the wireless VPN method has many advantages. There are no laptops full of data being transported to and from blood drives. The nurse can meet at the blood drive without the need to sign out the laptops. We enhanced the security and donor safety by entering data in real time. **Conclusion**: It is challenging to implement a wireless solution for an operation remotely from the

TABLE. Comparison between Wireless VPN and Wired Connection at the Donor Center

Methods	Number of Drives (4/9-4/30)	Average Minutes per donation	Maximum Minutes per donation	Minimum Minutes per donation
Wireless VPN	17	35	89	16
Wired Connection	22	41	84	25

blood mobile. We demonstrate that using wireless VPN on the blood mobile is comparable to using wired connection at the Donor Center. It takes longer to process a donor than with the laptop download. The reasons are that any new process takes time for staff to adjust to. Data are now entered in real time. This is a more efficient workflow that provides us better security and a safer system for the donors.

AP29

Traceability of Blood Units – Reduced Costs – Increased DonorService

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Background/Case Studies: The process of blood collection must be efficient and has to meet with GMP (good manufacturing practice) standards. Traceability of all blood products is of utmost importance. Currently, at the collection sites of Sanquin Blood Bank (the Dutch national Blood Bank), extra labels are pasted by the collection staff next to the unique identification code of the donor (EIN), in order to streamline the collected products (whole blood) for the production facility. An example of these tags is "antiplatelet medication, male donor, donation time >12 minutes, not sterile donation", etc. The major advantage of these tags is less mistakes at the production site and consequently less spillage of blood products and increase of safety/quality. Apart from sticking the label on the blood product, the extra information is also put into the blood bank information system eProgesa. But, as a consequence, the pasting of (many) labels has increased the workload of the collection staff. Furthermore, there is always a risk of wrongly sticking a tag. **Study Design/Methods**: Since November 2014, the Blood Bank information system eProgesa has a new functionality that can replace the manual pasting of tags. Donor/product information will be put into eProgesa on the collection sites. The collection staff (as always) paste the unique identification number (EIN) on the products. At the end of the collection session, all EINs are scanned, which will generate a printed list with EINs. This printed list accompanies the products when shipped to the production site. At the production site the EINs are scanned from the printed list to control the number of products (to ensure that all the blood products have been shipped form collection site to production facility). Thereafter, new labels per blood product are generated that include all information that was formerly added by means of extra labels on the collection site. Currently this method is used for whole blood only. **Results/Findings**: Since pasting of labels has been abandoned on the collection site, this has led to a reduction of work load of more than 9500 hours/year, and consequently more time for the donor and other activities. Labels are no longer needed to be produced which also saves costs. By means of the printed list of EINs, traceability of shipment of blood products has been improved. The production facility, by pasting the labels on site (which they have to do anyway), can also improve efficiency, since they can better organize the streamlining of the production process. **Conclusion**: Collection of whole blood can be done more efficiently with less sticking of labels and better traceability using a new functionality in the blood bank information system. This has resulted in work load reduction and less costs. In addition, it has also improved the efficiency of the production process.

AP30

Reversible Pharmacological Targeting of RHOA Prevents Refrigerated Platelet Storage Lesion and Restores Normal Platelet Survival

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Background/Case Studies: Refrigerated storage impairs platelet survival because it causes glycoprotein-Ib (GPIb) to deglycate/desialylate and cluster, resulting in platelet removal. Platelet glycosylation depends on the location and activity of specific glycosyltransferases (GT) and sialyltransferases (ST). GPIb and GT/ST clustering depends on the formation of lipid raft (LR) microdomains, which in turn depends on the dynamics of cytoskeletal rearrangements and endocytotic internalization. We investigated whether RhoA, Rac and/or Cdc42 of the family of Rho GTPases are crucial regulators and can be targeted to prevent the cold storage lesion of platelets. **Study Design/Methods**: Activities of specific Rho GTPases were analyzed by specific effector pulldown assays. Combinations of genetic deletion of RhoA and pharmacological approaches using specific inhibitors Rhosin (RhoA), NSC23766 (Rac) and CASIN (Cdc42) were used. In vivo platelet lifespan of carboxyfluorescein ester-labeled murine or human platelets or biotinylated Rhesus monkey platelets were analyzed. Spreading, fibronectin adhesion and collagen aggregation were used for in vitro functional studies. LRs were purified by Triton-X-100/sucrose gradients. Protein expression and localization was analyzed by immunoblot and confocal microscopy of whole platelets and/or purified LRs. Statistical analysis was performed by Student's t and ANOVA tests. **Results/Findings**: Our *in vivo* and *in vitro* data indicate that RhoA and Rac, but not Cdc42, are activated upon refrigeration. Pharmacological inhibition of RhoA during cold storage results in a) restoration of platelet lifespan *in vivo* of murine platelets, 7-day stored monkey platelets, or 7-day stored human platelets followed by xenotransfusion ($p<0.01$); b) abrogation of cold-storage-dependent phagocytosis by macrophages ($p<0.01$); c) prevention of myosin activation; d) prevention of formation of GPIb-containing caveolar and planar LR ($p<0.01$); e) prevention of GPIb clustering and co-localization with endocytotic intermediates ($p<0.01$); and f) prevention of expression and/or activity of GT. The effect of RhoA inhibition is reversible, since the removal of the drug results in restoration of all relevant cytoskeletal, adhesion and aggregation activities to normal levels for platelets stored at room temperature, and specific since the effect of the RhoA inhibition is phenocopied in genetically RhoA-deficient platelets, and the addition of RhoA inhibitor on RhoA-deficient platelets does not further induce any functional or biochemical change. **Conclusion**: Reversible pharmacological targeting of RhoA is a revolutionary approach and prevents the cold storage lesion of platelets. Targeting RhoA ex vivo may radically transform the current process of platelet storage in blood banking.

AP31

Blood Service as a Manufacturer, Creating a Continuous Improvement Culture

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Background/Case Studies: The Blood Service is fully Government funded and has increasing pressure to deliver benchmarked efficiencies in the face of decreasing demand for fresh blood components. In 1996, seven regional services were merged to form The Australian Red Cross Blood Service. Each region had differing structures, processes and efficiencies. The Manufacturing Division recognised it needed to change its model, and set out to develop a standard structure to significantly shift culture and to benchmark in the top quartile internationally for productivity, whilst delivering components in full and on time (DIFOT) in >97% of cases. **Study Design/Methods**: The leadership group collated information from international counterparts and best practice manufacturers to challenge the traditional operational concepts and inform decisions. The mission of the division was redefined: our goal to become a great manufacturer and "to take pride in efficiently and reliably delivering the right products to the right place at the right time." The core characteristics of organisations that thrive in a manufacturing environment were adopted to provide context for staff. These included: be flexible to meet the changing demands of customers; work in a standardised way; do things right the first time; eliminate waste; always look for better and simpler ways of doing things; constantly measure progress; and match the skill of people to the work they do. The skill sets and structural requirements of each team were redefined according to the processes performed by that team whilst ensuring that the service could be delivered, and build a continuous improvement customer focused culture. The new mission and manufacturing principles through line of sight and transparent measurement were reinforced. **Results/Findings**: A significant change was implemented in April 2014, including a flatter structure and, fewer individual teams with focus on supervisor capability, multiskilling, and enablement to improve their own processes. Support teams were developed to remove non-core functions (e.g., maintenance, managing deviations, Quality Assurance

TABLE.

	12/13	13/14	14/15	15/16
Processing (Weighted components/ FTE)	9208	10,625	12,145	12,878
Testing (Collections/FTE)	7949	10,265	14,987	17,382
Red Cell DIFOT%	95	97.6	96.8	98.2

programs, and audits) from the Testing and Processing teams. To develop a lean culture, Lean Coordinator positions were created, supported by a national team to focus on coaching staff in lean methodologies, support initiatives from the front line and embed standard work. **Conclusion**: Utilising Manufacturing concepts within a Blood Service required a paradigm shift in thinking. Change of this magnitude required extensive planning before being communicated and is a long-term commitment to ensuring the Blood Service delivers outstanding, efficient service to stakeholders.

AP32

Optimizing the Efficiency of Blood Collection Management

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Background/Case Studies: In the Netherlands, the use of whole blood products has decreased by 26% since 2012. Therefore the need was felt for a consistent and efficient policy with regard to the planning systematics, type of donation sites, personnel, and communication. **Study Design/Methods**: Systematics to provide transparency and structure were needed to act on this decrease. Larger locations allow more frequent planning than small ones and can therefore make maximum use of their donors. So, small locations with less than 600 donors were merged to compensate for the decline in collection. This resulted in a higher donation frequency and maximum planning purposes. Potential growth, donor participation, and geographical situation defined the maintenance of fixed locations, which were therefore set at a minimum of 3,000 donors. A communication plan was written to communicate all changes. **Results/Findings**: A proportional shifting of the collection percentage (aim: 5 x 20%) was reached for all weekdays. 11 small fixed locations turned mobile and 21 locations were merged. The donation frequency for fixed sites was standardized to 1.6, and that for mobile sites to 1.1. Despite a decrease from 182 to 150 collection sites, 75% of the donors were willing to change their donation location. Because of the declining demand for whole blood, the plasma collection was increased by recruitment and by changing whole blood donors to plasmapheresis donors (+10,667 plasma donors). **Conclusion**: Implementation of an annual blood collection plan with transparency and structure resulted in one nationwide stock management on blood type level, based on hospital demand. It provides efficiency for acting on decreases and donor planning. A communication plan supports all stakeholders to organize the process. Collections are performed in a uniform way, resulting in increased efficiency and more donor service.

AP33

Effect of the New Blood Donor Guidelines on the Donation Rate in a Community Blood Center

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Background/Case Studies: The Northern California Community Blood Bank (NCCBB) is located in Humboldt County and collects between 8,000 and 10,000 blood units on an annual basis. With the new Food and Drug Administration (FDA) rule (going into effect in May 2016):

Minimum hemoglobin (Hgb) and hematocrit (Hct) requirement of 13g/dl and 39% for male donors, and
Minimum Hgb and Hct requirement of 12 g/dl and 36%, respectively, for female donors as long as additional steps are taken to ensure the adequacy of their iron status.
We decided to study the impact of these changes on our blood supply.

Study Design/Methods: This is a retrospective study performed between the months of December 2014 and November 2015. Using the Blood Bank Computer Systems (Auburn, WA), we looked into the deferral rate of donors in regards to their hematocrit (Hct) level, the number and type of missed donations. **Results/Findings**: Whole blood donations (males):

Eighty one donors attempting for 456 donations would have been deferred 167 times resulting in the loss of those products. Of 8,080 whole blood donations for the year, the loss of 167 units constitutes 1.94% loss; in another context this is also equal to 4-5collection days. Of the 81 donors, 4 would have been deferred 3 times, 12 would have been deferred twice and the remaining 65 donors would have been deferred once.
Whole blood donations (females):
Drawing female donors at Hct of 36% and 37%would have allowed an additional 82 donations, representing an additional 0.9% whole blood units.
Apheresis donations (males):
Fifty donors would be deferred resulting in the loss of 92donations. Of the 50 donors, 1 would have been deferred 7 times, 5 would have been deferred 4 times, 5 for 3 times, 11 for 2 times and 28 would have been deferred once.
Of the 3,465 platelet donations for the year, the loss of 92 donations would results in 2.66% overall.
Because these donors average 2.2 platelets per donation, the loss in platelet products would be 202 of 7273 for the year, or 2.7% of platelet products.
Apheresis donations (females)
Seven female donors were deferred for Hct at 36% and 11 at 37% respectively. Inclusion of these donations would have yielded approximately 37 platelet products, an increase of 0.51%.

Conclusion: Implementing the new requirements in male donors might result in the loss of 3-4 days of inventory in a calendar year. Drawing female donors at Hgb of 12 might counterbalance the inventory loss but might be time consuming and expensive to perform in regard to iron level monitoring.

AP34

Paperless Mobile Collections Providing Insights using Donor-ID and Fenwal DXT

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Background/Case Studies: We have been collecting blood on mobile drives using our Donor-ID computer system for donor registration, screening and phlebotomy documentation since October 2000. The computer kit on mobile drives requires our mobile staff to set up a local network to communicate with multiple laptops and wireless portable devices. In January 2016, we began replacing our mobile apheresis devices to improve blood type-specific, demand-based collections. We selected the Fenwal Alyx apheresis device to support our strategy. In addition to collecting red blood cells and plasma components, the Alyx device can communicate with our information system to support performance analytics and electronic collection records to reduce errors, save time, and improve reporting capabilities. **Study Design/Methods**: Our existing computer system, Donor-ID, is in place to support donor pre-collection activities on a mobile drive and phlebotomy documentation. Donor-ID software is loaded on a laptop acting as a local server at the mobile drive. The Fenwal DXT Data Management system, when interfaced with Alyx captures procedure data. DXT system is installed on the existing Donor-ID computer equipment, and communicates on the existing network. Our Alyx devices communicate with DXT using wireless technology, which allows for flexibility in placement on mobile blood drives. Alyx collection data gets sent to a centralized repository for reporting purposes. DXT reports provides insight to key performance indicators that include:

- Total products per collection
- Quantity not sufficient
- Device utilization
- Collection time

Results/Findings: Collection staff find the computer equipment easy to set up prior to starting a mobile event and breakdown at the end. Technicians believe the Alyx DXT system easy to use because it uses existing processes and does not add steps for data entry. Training was accomplished in less than one day. Management uses Alyx DXT reports to improve operational performance. Information technology staff find the system easy to deploy and administer because it uses the existing computers, servers, and network. The initial implementation took approximately 12 weeks, plus one day per kit. **Conclusion**: The Alyx DXT system is easy to set up and does not require IT staff at each blood drive. Data collected provides the ability to gain insight in mobile collections and improve efficiencies that support our strategy. Once all of the Alyx devices are deployed throughout the center, we intend to implement a two-way interface between Donor-ID and DXT that exchanges donor and Alyx procedure data. Donor-ID then sends the complete donation records to our primary manufacturing system, SafeTrace, to support component preparation, labeling, and distribution activities.

AP35

Challenges in Creating a Process to Use the Centers for Disease Control and Prevention (CDC) Zika Virus Website in Donor Eligibility Screening

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Background/Case Studies: With the release of FDA's Zika Virus Guidance, our facility pivoted from one donor/unit management strategy to another.

Changes included a new Zika travel risk question to the medical history questionnaire, using the CDC Zika virus website to assess travel to a Zika virus risk area, and implementation of all FDA recommendations within four weeks, a timeline granted to blood centers located in areas with no locally acquired cases of Zika virus transmission. The biggest challenges were deciding what method and how often to check the CDC website, and how to disseminate updated risk area information to historians within the context of a standardized process. **Study Design/Methods**: To ensure staff at all collection sites used similar criteria to evaluate donors' travel risk, and because real-time access to the CDC website was impossible for mobile sites due to inconsistent internet/cellular data access, a hardcopy, document controlled form listing CDC's Zika risk areas was created as a reference tool. It was initially decided that the CDC website would be checked weekly to accommodate training of all staff on the revised form. However, multiple updates to the CDC Zika virus website each week, the liabilities of retrieving and disseminating hardcopy forms, and concerns about the safety of our blood supply, made it difficult to comply with this process. Subsequent changes included daily checks of the CDC website, and an agreement with QRA and MD to approve revised forms the day before implementation. **Results/Findings**: Since it was decided that historians would review the Zika travel risk question with donors, Information Services created a way for historians to access this form electronically on the Zika travel risk question screen in the electronic medical history questionnaire. Initial complications included the form's inaccessibility on touch tablets at mobile sites, which will be corrected with the next scheduled software upgrade later this year. In the interim, mobile historians access the electronic form through the SOP downtime program. A push notification program was also created to check the CDC website every hour for updates to the Zika risk country list or California's number of locally acquired transmission cases. This notification program is currently used in parallel with our daily manual checks while undergoing validation. **Conclusion**: These changes removed the administrative overhead of retrieving and redistributing hardcopy forms multiple times a week; allowed quick dissemination of updates; and ensured historians used a standardized list of Zika virus risk areas for donor screening. We hope to further reduce staff time by replacing manual, daily checks of the CDC website with the push notification program.

AP36

Benefits of Using the Alyx DXT Data Management System to Manage a Successful dRBC and Plasma Program

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Background/Case Studies: The collection of double red blood cell (dRBC) and plasma units for transfusion using the Fenwal Alyx device was implemented in Sept 2013. The decision was made to also implement Fenwal's Alyx DXT Data Management system to have access to multiple operational efficiency reports. There was a need to increase red cell and plasma collections with a focus on right type mix and collection of dRBCs from infrequent donors. This strengthened the need for a strategic data-driven approach to manage the Alyx program using DXT. Alyx is utilized in the mobile environment. Alyx devices are connected to the DXT database when they are returned to mobile staging area. The Alyx procedural data is downloaded to DXT daily. The analysis, in the form of operational efficiency reports, is available after data download is complete. The DXT reports can then be viewed at any time, from anywhere. **Study Design/Methods**: Monthly and Quarterly Business Review meetings with blood center management team and Fresenius Kabi team members are held to monitor and track the defined Alyx KPIs. The KPI metrics tracked using DXT are device utilization, QNS rate, percent of type O dRBC collections, and collection time. The KPIs are monitored by region, by device and by phlebotomist. The metrics are regularly monitored by the center manager and senior management using the DXT reports. The analysis is used to implement process improvements, identify training needs as well as recognize those outstanding performers. **Results/Findings**: The direct result of daily insight into the mobile operations through the use of Alyx DXT efficiency reports positioned us to meet distribution demand goals in 2015. Our Alyx utilization for dRBC and plasma collections increased by 63 percent in 2015 compared to 2014. The focus on plasma collections at mobile sites from AB donors was implemented in Sept 2015 to supplement concurrent plasma collected in fixed sites. The overall QNS rate was maintained at or below the target threshold as operators who needed assistance were quickly identified and training was able to take place. **Conclusion**: Data visibility provided by the ALYX DXT was a contributing factor to Bonfils ALYX utilization improvements and overall red cell collection. Due to strong committed team work and collaboration with the Fresenius Kabi team, we are able to grow the automated red cell and plasma collections at mobile drives. Having data available immediately provided our team with the facts needed to make data driven decisions. This is reflective of the power of Alyx DXT and its capabilities.

TABLE.

	dRBC Procedures	Plasma Procedures	ALYX Utilization
2014	1997	0	200
2015	3234	56 (Q4)	325

Results:

AP37

Collection of Apheresis Pplatelets in a Mobile Environment using a Default Platelet Count

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Background/Case Studies: Our blood center has collected apheresis platelets at fixed sites using a hematology analyzer to determine the donor's pre-platelet count. We implemented a mobile platelet program using a default platelet count to increase our platelet collections. Mobile platelet drives are currently scheduled in small, rural communities in conjunction with a regularly scheduled blood drive. **Study Design/Methods**: We used a default platelet count instead of a hematology analyzer to collect apheresis platelets. A default platelet count of 240 x $10^3/\mu L$ was calculated using an average of all our plateletpheresis donors over the last 3 months. **Results/Findings**: Utilizing a default platelet count of 240 x $10^3/\mu L$, we performed 198 procedures and collected 290 platelet products and 55 concurrent red blood cell products over a 4 month period. A metric of platelets per procedure (PPD) was 1.54 compared to the PPD at fixed sites of 1.80. **Conclusion**: We implemented a mobile platelet program using a default count of 240 x $10^3/\mu L$. Our PPD was 1.54 compared to our fixed site PPD of 1.80. Factors leading to a decreased PPD at mobile sites include: on site conversions of donors, donors with time constraints and the possibility of a collection of hyperconcentrated platelets from donors with a platelet count higher than the default platelet count used to perform the procedure. Future directions include placing a hematology analyzer on the platelet mobile to get a more accurate pre-procedure platelet count which will increase platelet collections to include the collection of triple platelets which are currently not allowed to be collected from donors that are collected utilizing a default platelet count.

AP38

Implementation of Electronic Procedure Records for Automated Source Plasma Collections using Fenwal DXT and Donor-ID

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Background/Case Studies: In January 2016, we implemented a source plasma collection program as an opportunity for business growth using our existing blood donor population and programs. We selected the Fenwal Aurora plasmapheresis device to support our strategy. In addition to collecting source plasma, the Aurora device can communicate with our information system to support electronic collection records to reduce errors, save time, and improve reporting capabilities. **Study Design/Methods**: Our existing computer system, Donor-ID, is in place to support collection activities including donor registration, screening, and phlebotomy data capture. The Fenwal DXT Data Management system, when interfaced with Aurora, supports donor verification, transfer optimal plasma collection volume, and procedure data capture. The DXT system interfaces with Donor-ID to exchange donor and procedure data, preventing the need for duplicate data entry in either system. Procedure data is sent from Donor-ID through DXT to Aurora prior to donation. Procedure data is sent from Aurora through DXT to Donor-ID at the completion of the donation. Using an existing interface, the complete donation record gets passed to the primary manufacturing system, SafeTrace, to support component preparation, labeling, and distribution activities. Data from the three computer systems are sent to our existing internal data warehouse for reporting purposes. **Results/Findings**: Apheresis technicians find the Aurora DXT system easy to use because it uses their existing computers and processes and does not add steps for data entry. Training

was accomplished in less than one day. The information technology staff find the system easy to administer because it uses the existing computers, servers, and network. Our Aurora devices are connected using wired Ethernet. The complete installation, configuration, and validation took approximately 12 weeks. **Conclusion**: The Aurora devices, DXT software, and two-way interface with Donor-ID work as intended. Errors are prevented by avoiding duplicate data entry and providing decision support. In turn, this reduces time spent on error management and associated costs. Technician performance metrics and management summary metrics that are provided by DXT reports as key performance indicators, include:

- Plasma yield total, efficiency, per technician, per time unit, per location
- Number of procedures total, per technician, per time unit, per location
- Procedure times average, per technician, per location
- Device alerts per device, per technician, trends

Future plans include adding locations to grow the plasma program, using wireless device networks where beneficial, and implementing a similar interface with DXT for use with our Fenwal Alyx devices.

AP39

The Advance of Implementing the TRIMA® Accel Automated Blood Collection System for Apheresis

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Background/Case Studies: In order to be more efficient and utilize cost effectiveness appropriately we needed to maximizing the collection of apheresis products to be more beneficial to participating hospitals for the primary care of the community. The objective was to evaluate all products collected by the Trima Accel at our fixed site since Feb 2016. Products were collected and assessed for Platelet Yield for each product compared to the Haemonetics LN 9000 and number of products collected from each donor. Provide effective donor education and monitor the affects of using the Trima Accel. **Study Design/Methods**: Total apheresis products collected increased immediately bringing in the Trima Accel. There was a 50% increase in products collected in February, 61% in March, and 59% in April.
Platelets
February: Singles- 23%, Doubles- 63%, Triples- 14%
March: Singles- 26%, Doubles- 56%, Triples- 18%
April: Singles- 33%, Doubles- 37%, Triples-32%
Red Blood Cells
February - 16%
March - 8%
April - 21%
Plasma
February - 7%
March - 9%
April - 23%
For continuing successful apheresis collections, donor recruitment and collections staff provide donors with a superior knowledge of the Trima Accel's specifications and qualities to make the donation process more gratifying. Continuous monitoring was done on all products, emphasis was placed on platelet product's yield values. Each donors platelet product from the Trima Accel was compared to their product from the Haemonetics LN 9000. **Results/Findings**: On average 50% of our platelet products from the Trima Accel gave a platelet yield of 6.5 or higher producing a double product which makes us more efficient in our community and industry. Our main focus was put on platelet collections which proved successful compared to our Haemonetics LN 9000 technology which collected only 180 platelet products on approx. six procedures daily a month due to its capability. The Trima Accel collected over 200 products a month on approx. four procedures daily which included platelet, RBC, and plasma products depending on donor capabilites. There was an increased from approx. 1.0 to 2.37 product per procedure. **Conclusion**: Our findings conclude, implementing the Trima Accel increased our products collected per donor and an increase in platelet yield as compared to the previous performance on the Haemonetics LN 9000 technology. Since blood transfusion demand has decreased, to be more readily available for patients at participating hospitals, a more advanced strategically acceptable approach had to be taken by increasing our resources. The Trima Accel proved to have a shorter duration for donating platelets on average to 80 minutes as opposed to 95 minutes. Future goals include recruiting more donors based off of our current statistics proving a greater satisfaction of supporting a patient's life by donating more products in less time.

Education and Training

AP40

Utilizing Pre-tests to Gauge New Employees' Skill Level for Performing an ABO Problem Work-up

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Background/Case Studies: A disparity in tube reading and grading skills was identified due to the range of experience that new employees possess when hired. The original ABO testing training module was developed to train the standard operating procedures with the expectation that the trainee could effectively evaluate weak and mixed-field reactivity. This was challenging for some trainees, as they struggled to re-learn tube reading and grading along with the complex processes of working up an ABO problem. As a result, training would often take longer to ensure that the employee was not released to perform a task prior to mastery. New employee events related to ABO testing were also noted. The goal of this study was to reduce time for training on ABO problems and to reduce new employee events related to ABO testing. **Study Design/Methods**: A pre-test was developed to determine the skill level of the trainee prior to training in ABO testing. The test provided fifteen samples with varying ABO types and ABO problems. Using the results, the trainer tailored the training session to the trainee's skill level. If the trainee scored low, the trainer presented serology independent of the standard operating procedure until mastery. Upon mastery of the skill, the standard operating procedure was introduced. If the trainee scored high, the trainer was able to reduce the amount of wet lab case studies and focus solely on the standard operating procedures. **Results/Findings**: A two-day reduction in training time was observed with the implementation of the pre-test. A reduction in new employee ABO testing-related events was also noted. Events were reduced from 9% of the total reported new employee events to zero (see Table). **Conclusion**: By using a pre-test, the trainer was able to tailor the training session to the trainee's skill level. Reviewing serology independent of the complex standard operating procedure allowed trainees to focus on one component of the training session at a time. This reduced overall training time by reducing redundancy for trainees whose existing skills were already at mastery level and reducing complexity for those whose skills required remediation. By creating a focused training environment, the trainees more readily mastered the complex standard operating procedures leading to a reduction in ABO-related testing events.

TABLE.

	Pre-Implementation	Post-Implementation	% Reduction
% of total new employee events related to ABO testing	9%	0%	100%
Training time for ABO testing	5 days	3 days	60%

AP41

Improving Hemolysis Reading and Grading by Use of a Visual Aide

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Background/Case Studies: A critical piece of transfusion reaction testing is the hemolysis check. This can be problematic when the test is reliant on human interpretation of hemolysis visually present in a patient sample. The goal of this study was to determine the reliability of staff's visual reading and grading of hemolysis and to determine if methods to aid in reading and grading were necessary. **Study Design/Methods**: Six blind samples with various grades of hemolysis raging from negative to severe were given to each employee. The results of the blind sample test were tallied and from this it was determined that reading and grading a hemolysis sample blindly without comparison to a visual aid was difficult. Considering the impact that incorrect evaluation of hemolysis could have on a transfusion reaction work-up, a

TABLE. Results of the Blind Sample Test Before and After Implementation of the Hemolysis Visual Aid

	Pre-Implementation Blind Sample Test		Post-Implementation Blind Sample Test	
	Total	% of Total Tests	Total	% of Total Tests
False Positives	1	3%	0	0%
False Negatives	4	12%	0	0%

solution was pursued to decrease inaccurate results. A web and textbook search for an existing resource came up empty. A hemolysis grading visual aid was developed in house. This visual aid provides a pictorial representation of samples ranging from negative to severe hemolysis. After implementation of the chart the initial test was repeated. **Results/Findings**: The original test resulted in four out of thirty-three employees calling samples with mild hemolysis negative. In addition, one employee called a negative sample positive. A wide range of grading greater than ±1 from tech to tech was also observed. The second test given with the aid of the hemolysis chart demonstrated an elimination of false results. The range in grading was also notably reduced to ±1 from tech to tech (see Table). **Conclusion**: This study demonstrated that staff interpretation of hemolysis without a comparison tool was not consistent and yielded inaccurate results. The visual aid was a successful tool in reducing false negatives and positives by 100%. It also increased reliability in grading hemolysis by narrowing the rage of grading variability.

AP42

Development of a Weekly Trainer Evaluation

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Background/Case Studies: An effective trainer is essential to the success of the training program. A final training evaluation, which included an evaluation of the trainer, was given to new employees at the end of the 4-month training period. Most often, responses regarding the trainer were minimal or lacking. Using an evaluation at the end of the training period was a disadvantage to trainers as they received feedback after the completion of the training program. By evaluating at the end, new employees who had multiple trainers were challenged to remember specific details for evaluating each trainer. The final evaluation was the only resource used to gauge the effectiveness of the trainer. This could potentially compromise the training program if the trainer's skills were lacking. The goal of this study was to increase trainee response rate and provide feedback to trainers in a timelier manner. **Study Design/Methods**: An independent Weekly Trainer Evaluation (WTE) was developed. Concepts that were critical for an effective trainer to master were identified as "Skills." Some skills included: Identification and adaptation to learning style, Use of SOPs, Answering Questions, and Communication. These documented skills served as a guide and provided structure and focus for the trainees as they evaluated the trainer. A grading system for each skill was developed. The scale ranged from a score of "1" (Needs Improvement) to "4" (Excellent). Descriptors were incorporated with each score, providing meaning and objectivity to the evaluation. Trainers could also use the descriptors for reference as they looked to make improvements. The trainee completed the WTE on a weekly basis, and the scores/comments were shared with the trainer via a conversation that was guided by the points on the evaluation. **Results/Findings**: The pointed descriptors on the WTE resulted in feedback revealing that 3 tech trainers could benefit from mentoring in order to become more effective trainers. The specific area of need was also highlighted, so mentoring could focus on the particular skill that was lacking. The real-time feedback allowed mentoring to occur in close proximity to the training period when details could be more easily recalled (see Table). Identifying these opportunities for growth was particularly helpful for newer trainers. **Conclusion**: By providing an opportunity to evaluate the trainer on a weekly basis, trainee response rate increased. Modifying the evaluation from a vague essay question on the final training evaluation to a scaled grading which included descriptive skills, trainees were more readily able to give applicable feedback. This allowed trainers to make real-time changes, which were positively reflected on their evaluations.

Study Results:

AP43

Transfusion Medicine: A Platform for Effective Mentoring of High School Girls Interested in Careers in Science or Medicine

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Background/Case Studies: American high school girls lag behind boys in terms of knowledge of, and interest in, careers in fields related to science, technology, engineering, and math (STEM). Closing this gap requires, among other things, active mentorship programs that are accessible to young students and that provide first-hand examples of how STEM-related interests translate to opportunities in the workplace. Responding to that need, our Transfusion Medicine Service partnered with Girls Inc. to provide a STEM mentorship opportunity to a student in their Eureka program. **Study Design/Methods**: Our goal was to provide a platform for a sophomore in high school to learn about STEM-related career opportunities for women. Rather than a summer job, the Eureka program provides opportunities to mentor a young person considering a STEM-related career. During one month of summer vacation, our student, CA, spent 4 days with us each week exploring the Blood Bank, Stem Cell Lab, Blood Donor Center and Clinical Apheresis unit, studying theory and processes. CA worked with women leaders in our medical center, including a physician in Neurology, an engineer in the Center for Innovation and Transformational Change, a Laboratory Director in Pathology, a specialist in Quality Assurance, and the Senior Vice President of Operations. All of them shared their insights, expertise, and wisdom acquired in their personal and professional journeys. **Results/Findings**: CA compiled a daily log of her activities and lessons learned from them. She reviewed her progress every Friday with her peers and councilors at Girls Inc. She learned about blood products, blood typing, antibodies and antigens, procuring funding for equipment, reducing obstetrical hemorrhage, health care finance and billing, bone marrow harvesting and transplants, process improvement, lean manufacturing, and much more. Her energy and enthusiasm were rewarded when she was a speaker at the Million Women Mentors Summit and Gala in Washington, DC, at the end of summer 2015. She spoke about why mentors are vital to the success of young women who are interested in careers related to STEM. In addition, CA was invited to appear on Soapbox, a local television show, to explain the importance of mentoring to students interested in STEM careers. **Conclusion**: The successful partnership between Girls Inc. and our Transfusion Medicine Service illustrates the value and importance of providing mentorship to high school girls who are potentially interested in STEM-related careers. Because of our partnership with Girls Inc., CA was able to gain insight into the possibilities for women in leadership roles in science and medicine. She is extremely energized and motivated for her future endeavors.

TABLE.

	# of Responses that Lead to Opportunities for Mentoring Trainers	# of Trainees Providing Feedback	Evaluation Method
2 years prior to implementation	0	14	Final Training Evaluation
2 years after implementation	3	16	Weekly Trainer Evaluation

AP44

Use of 5S Concepts to Organize and Track Training Documentation

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Background/Case Studies: A major component of a training program is documentation and tracking of training completion. Adequate documentation of training is a primary constituent for passing regulatory and accrediting inspections. In a large lab with multiple locations, it became challenging to ensure documentation was complete and up to date. An internal audit of employee training files found 14 misfiled documents, 4 missing documents, and 1 original training document for a training that was re-created due to initially being lost. The goal of this study was to reduce misfiled and missing documentation to zero occurrences. **Study Design/Methods**: To increase efficiency during inspections and ensure documentation compliance, a system was put into place to standardize tracking of training and filing. Using 5S concepts, training documentation was sorted and a training profile was created as a checklist to track training. The profile organized training modules in the order that training should occur. To set things in order, a hanging three-ring binder was created for each employee to replace existing hanging files. The contents were divided by clearly labeled tabs. To standardize the organization of the core training documentation, a printed copy of the training profile served as a table of contents. To sustain the changes made in this study, a checklist was developed for the person filing training to ensure standardization regardless of who was filing the training documents. **Results/Findings**: By evaluating and reorganizing the approach to tracking and filing training documents, the initial goal to reduce the error rate of misfiled or missing documents to zero was met. Internal audits have revealed no findings of misfiled or missing documentation since implementation. In addition, organizing the profile in the order of training rather than by bench has added efficiency to tracking of training and hand-offs to trainers. **Conclusion**: Having an organized and easy to use tracking and filing system increased efficiency and reduced misplacement of employee training documentation. Using three-ring binders increased awareness when filing, as it is a more deliberate action to pull an employee's training binder and open it to file rather that inserting a training document into a hanging file. Using the 5S concepts added focus to each step of the process in this study. In addition to meeting the goal to reduce misfiled and missing documentation to zero occurrences, the new system has been recognized and complimented by inspectors.

AP45

Bloody Easy: An Evaluation of Transfusion Medicine Educational Resources

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Background/Case Studies: In Canada, the Canadian Standards Association (CSA) and the Canadian Society for Transfusion Medicine (CSTM) publish national standards related to Transfusion Medicine. Provincial laboratory accreditation programs present in most provinces assess compliance with these standards through a mandatory accreditation process. Included in both standards is the provision of ongoing education and competency assessment of all healthcare professionals involved in transfusion medicine activities. A library of resources aimed at providing inter-professional transfusion medicine-related content was developed to support hospitals in meeting the required standards. A comprehensive evaluation of two Bloody Easy resources; Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions (BE3) and its electronic companion Bloody Easy for Health Care Professionals eLearning program (BE online) was undertaken. The evaluation objectives were to evaluate the potential knowledge transfer and uptake of information among healthcare professionals, to evaluate the effectiveness of each resource and to evaluate the global impact of BE3 and BE online. **Study Design/Methods**: A validated methodology framework was used to evaluate both resources. A project team, developed measures to determine accessibility and usage, validity and usefulness, and support for achieving accreditation from national regulatory bodies. The methods used to collect data were Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis, records review from an online tracking tool, a survey and focus group. In order to ensure any bias could be ruled out, representation from physicians, who are the intended end-user of both resources, was necessary and therefore an ad hoc physician group was assembled and comprised of five physicians representing all types of hospitals by size (small, community and teaching) and represented all geographic regions in the province of Ontario where these resources were developed. **Results/Findings**: Record review of the completion rate of BE online revealed a low number of participants over a 4 year period despite feedback from respondents being primarily positive in regards to the program content, length and navigation. The evaluation process identified the BE3 handbook as a valued and integral resource for transfusion medicine and essential in the absence of senior staff resources. **Conclusion**: The evaluation project determined the accessibility, usage, validity and the usefulness of the BE resources and provided valuable feedback from the end-users. A number of important operational strategies for improving the revision, marketing and promotion of the resources were identified and vital to ensure uptake to those healthcare professionals that the resources were intended for, ordering and prescribing physicians.

AP46

Table-top and Simulation Exercises in Preparing for Emergencies

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Background/Case Studies: Because emergency situations do not occur frequently, staff on-site at the time of the emergency may not have experience in either observing or participating in a real emergency event. Table-top exercises and simulations provide practice in decision making, tests interactions between individuals and groups, allows for the review of plans, policies and procedures, and helps identify weaknesses. Simulations can be used to test workflow, logistics and communications. **Study Design/Methods**: A set of short emergency situations was developed to allow staff to participate in or observe others reacting to an emergency event. Events can be staged as a surprise event, or done at a preplanned time. Some exercises were table top events and did not involve the use of real materials and/or props and can be performed in a conference room away form the busy labortory. Simulation events occurred in the laboratory or work area and include moving through the actions being taken. In addition to the acutal participants in the event, observers are needed to assess the interactions and decision making processes of the participants.Scenarios should be short (10-15 minutes), have events unfolding in a series and end happily. These emergency exercise events enhance adult learning by being practical, are results oriented and build on skills that staff use every day. The minimum number of participants in an invent include the leader or initiator of the event, at least one participant and one observer. but more participants allow the test fo communications . A debrief of an acutal event can also turn into a training tool as decisions can be evaluated for effectivness and policies and procedurs updated. The topics should be selected to be relevant to the participants. For example, a water shut down may be relevant in the transfusion service if chillers and x-ray irradiation devices require water cooling. A loss of lighting is most critical in a lab with no windows whereas a fire could occur almost anywhere. **Results/Findings**: In the session held in March of 2016, there were 21 participants. Using a scale of 1-4 with 4 being the highest, the average rating for the question "Rate your overall degree of satisfaction with this session" the average score was 3.8. The participant comments included "awesome practice", "enjoyed the interactive format" and "panel was cool". Lessons learned included recognition that not all participants in table top exercises were comfotable in a decision making role. In the simulated exercises, staff were able to perform tasks using muscle memory and were more comfortable as participants. The discussion leader must be moderate harsh observer criticism and ensure that the observations are helpful. **Conclusion**: Table top exercises and simulations are valuable tools in training and instilling confidence in responding to emergency events.

AP47

Retention of Blood Bank Technologists Through Ongoing Educational Support

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Background/Case Studies: A hospital-based transfusion service laboratory (TSL) opened in 2011 and hired 15 Medical Laboratory Scientists (MLS), of which only one was a Specialist in Blood Banking (SBB). The department faculty and management in TSL made the decision to increase the number of SBB graduates by providing MLS staff opportunities to enroll in online SBB programs. This was implemented in an effort to improve employee engagement in the field of Transfusion Medicine and to maintain quality work. The department agreed to support SBB education by covering the tuition costs of an online program and providing the employee educational paid time to complete onsite orientation and clinical rotations. Additional costs including transportation and lodging were to be incurred by the employee. TSL faculty and management agreed to be mentors for MLS staff

who were enrolled in an SBB program. At the completion of the program, enrolled staff needed to be certified by the American Society for Clinical Pathology (ASCP). **Study Design/Methods**: A review of all online SBB programs available was done through the AABB professional development website. Online programs that offered 12-month distance learning were evaluated further to see if outside applicants were accepted. The cost of the program was also evaluated. Interested and qualified MLS staff applied to one year online programs. Local blood suppliers in the region were contacted to evaluate if clinical rotations could be completed at the blood centers. Each applicant's start date with the enrolled SBB program was staggered to allow TSL to have adequate staffing coverage while the employee was away completing orientation and clinical rotations. The SBB applicants were also required to do research while in the program. **Results/Findings**: A total of 4 applicants were accepted by two online SBB programs. The first applicant successfully completed and attained SBB certification in 2013. Second applicant completed the SBB program and certification in 2014. Third and fourth applicants completed the program and certification in 2016. Each employee cost the department $3000 in tuition and 160 hours of paid education time. Additional costs incurred by the employee totaled an average of $1500. The local blood centers allowed the clinical rotations for the employees at no additional cost. **Conclusion**: The department has 4 employees who are SBB graduates and ASCP certified. The SBB graduates have contributed to quality improvement through participation in data collection for the department, running cost analysis on reagents, writing equipment validation plans and assisting with revisions to policies and procedures using standards and checklist from regulatory agencies. The SBB graduates also are an additional resource for technical expertise.

AP48

Strengthening the Blood Services in Ukraine

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Background/Case Studies: The US President's Emergency Plan for AIDS Relief is supporting a five-year program to strengthen the blood services in Ukraine and to build local capacity for sustainability. Six regional blood centers, 5 hospital-based transfusion departments, the National Children's Hospital, and the Kyiv City Blood Center were selected as demonstration sites with the aim to develop them as centers of excellence. These sites would then promote improvements among the other blood centers in Ukraine. An assessment was conducted at each site in 2013, and technical assistance (TA) began in 2014. Implementation of a TA program required approval and support by the MOH in the form of a memorandum of understanding (MOU). In February 2014, the political environment in Ukraine changed with the overthrow of the president and the establishment of a new government. Representatives within the Ministry of Health (MOH) and in the Blood sector department have changed multiple times, which resulted in a delay in the signing of the MOU. The subsequent fighting in Eastern Ukraine had a direct impact that resulted in the loss of two of the demonstration sites, a regional blood center and regional hospital. **Study Design/Methods**: Training and training-of-trainer programs address gaps identified during the assessments, including recruitment of volunteer donors, donor collections, and quality management, donor testing, clinical practice, and storage and distribution. International consultants provide training both on-site and through webinars. Practical exercises promote understanding of information. Results of pre- and post-exams are used to evaluate comprehension. In addition, the aim of trainings on testing for transfusion-transmitted infections and the clinical use of blood is to provide international standards of practice and scientific and evidence-based medicine, so that local experts can develop national guidelines aligned to European requirements. **Results/Findings**: A handbook and tool kit on donor recruitment and marketing were developed, which has led to improvements in the recruitment of volunteer blood donors. Some blood centers are collecting 100% volunteer blood donations. Local quality experts are mentoring other sites, participating at national conferences, and in training activities and programs. The MOH is collaborating with representatives from the blood services, including the development of a new strategy and national blood policy. One of the national experts from a demonstrations site has recently been appointed head of the Blood Sector in the MOH. **Conclusion**: Despite national challenges, progress is being made with improving the blood services in Ukraine and key stakeholders are taking ownership. The focus for the remainder of the program which ends in 2018 is to continue building local capacity to ensure sustainability and continuous improvement.

AP49

Effectiveness of Concurrent Audits and Regular Training in Transfusion Practice in a Tertiary Care Hospital

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Background/Case Studies: Auditing the use of blood components is necessary for all transfusion services and is required by NABH, AABB, and the Joint Commission. The main purpose of auditing blood utilization is to assess the appropriate use of blood components and help to optimize their use. Different audits (prospective, concurrent, or retrospective) formats may be used, depending on the objectives and resources available. **Study Design/Methods**: A total of 6544 concurrent blood transfusion audits were done in various clinical departments, including the emergency department of the hospital over a total period of 21 months (April 2014 to December 2015). Regular training classes on blood transfusion protocols of one hour duration were organized twice a month for nursing department over a period of 16 months (July 2014 to December 2015). The main focus of concurrent blood transfusion audits was documentation of all blood transfusion details in the patient's medical records and included

- Transfusion order
- Recipient consent
- Component name
- Donation identification number
- Date and time of transfusion
- Name and signature of doctor and nurse
- Pre- and post-transfusion vital signs
- Volume transfused
- Transfusion-related adverse event
- Total transfusion time lapsed
- Transfusion indication

Results/Findings: Transfusion details that were not meeting the criteria were marked as noncompliance. % compliance was calculated by dividing the compliance audits per month with the total number of audits done in that month. It was found that % compliance increased gradually during this period with increasing training programmes and concurrent audits **Conclusion**: We found that Concurrent audits combined with regular training programmes greatly helped in evaluating transfusion practices in our hospital. Also, they permitted identification of suboptimal transfusion practices

Month/yr	% compliance
15-Dec	99.23
15-Nov	98.17
15-Oct	98.15
15-Sep	98.37
15-Aug	97.53
15-Jul	97.63
15-Jun	98.75
15-May	98.80
15-Apr	98.90
15-Mar	99.00
15-Feb	97.50
15-Jan	99.30
14-Dec	98.60
14-Nov	97.75
14-Oct	97.50
14-Sep	95.25
14-Aug	97.25
14-Jul	95.00
14-Jun	89.25
14-May	88.93
14-Apr	91.92

Inventory Management, Storage, and Distribution

AP50

Searching for the Optimal Inventory Management Strategy. . . Mission Impossible?

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Background/Case Studies: Inventory management represents a major challenge and is an integral part of blood banks operations. Our organisation

has developed an improved multi-sectoral approach allowing continuous adjustments of collection strategies in order to bring inventory levels in line with the time-fluctuating demands from hospitals. Moreover, the extension of the platelet storage time from 5 to 7 days was recently implemented by our organisation and new distribution guidelines involving inter-hospitals RBC unit exchanges were adopted in a global effort to promote optimal inventory management operations. The main objective of this study is to present the multi-sectoral approach and how it led to outstanding annual performances in terms of customer's satisfaction and product looses reduction. **Study Design/Methods**: The labile product inventory is updated each time there is a product request. Information is used to confirm product availability and to maintain a 10 days ahead inventory baseline at all time. Inventory managers meet on a weekly basis for red blood cell (RBC) and on a daily basis for platelet (PLT) units. The objective is to identify trends in customer's demands and to share concerted collection strategies to blood drives in order to ensure product availability fits customer needs. Our performance criteria regarding inventory management operations are related to waste products (n), customers satisfaction (survey, %) and cost savings ($). **Results/Findings**: Between April 1, 2015 and March 31, 2016, 219 802 RBC were distributed among 97 healthcare centres served by our organisation. Despite a variable product demand (−8.78% to −2.18%), the RBC waste rate was 0.13%, which is 0.05% lower (n = 117) than the previous year. A global performance resulting in $40 950 savings and the customer satisfaction rate was 98.38%. In the same way, our organisation distributed 39 612 PLT units to hospitals during 2015-2016 representing a 5.17% increase compared to 2014-2015. In a highly variable demand (−4.04% to 20.92%), only 3.9% (n = 419) of platelets units reached expiry date before their use, which was mostly attributed to the implementation of the 7-day platelets. The two extra days reduced products losses from 5.38% to 1.47% which represents an annual saving of $1 023 139 while fulfilling costumer expectations (97.7%). In the last 5 months only, our inventory management strategies lead to a 73% products lost reduction. **Conclusion**: Enhanced inventory management operations together with the implementation of both the 7-day platelet and the inter-hospitals RBC exchanges protocol are responsible for the improve performances in terms of product losses reduction, customer satisfaction and cost saving for our organisation during the year 2015-2016.

AP51

Strategies to Improve Quality and Security of Blood Transfusion Also Reflect on Levels of Wastage and Returned RBC

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Background/Case Studies: Transfusion safety is recognized as a global priority. In clinical or surgical setting, the highest risk of adverse events is related to errors in patient/blood product identification and the exchange of blood products, especially in the surgical environment. In this case there are two critical points, the delivery of blood components and the withdrawal of the same directly from coolers installed in the operating room (OR). In our service blood component are stored only at the blood bank and delivered to the OR only upon request, in specific transport containers. **Study Design/Methods**: Initially, transport containers were validated to maintain temperature < 10°C for 01 hour. RBC units not transfused within that time were returned to the blood bank for reissue. Returned RBC units were approved for reissue if bag integrity was not compromised and temperature of the RBC unit was <10°C at return time. Units not approved were discharged at the blood bank. From May 2012 to July 2013 baseline wastage and returned RBC levels were evaluated. **Results/Findings**: Following this initial analysis, some low-cost interventions were implemented to advance transfusion safety, which included transport containers validated to keep temperature < 10°C up to 02h; external ID tags containing patient ID, blood type, date, delivery responsible, time of delivery and maximum return time; serially numbered seals, to avoid inadvertent component manipulation; component delivery signed receipt from OR staff. Also, transfusion lab contacted surgical team 30min before maximum return time to alert about non-transfused components. Training and communication with medical and nursing staff were intensified to effective implement changes. The impact of the interventions on transfusion safety, wastage and returned RBC was measured from August 2013 to March 2016 and results were compared with baseline levels. There were neither any reports of identification errors or component exchange nor near-miss events related to patient identification within surgical setting since interventions were implemented. Furthermore RBC wastage rate decreased 55.81%, from 1.41 to 0.77, while returned RBC rate increased 90.32%, from 3.05 to 7.02. On the same period, monthly transfusions on the surgical setting decreased 17% from 30.36 to 25.25. **Conclusion**: The interventions showed to be essential to decrease the risk of exchange blood products in the surgical environment, improving the quality and the safety of transfusions, reducing wastage and increasing returned RBC for reissue.

AP52

Developing a Data-driven Research Program: An Integrated Database Network Tool Driving Education and Research Forward

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Background/Case Studies: A Data-Driven Research Program (DDRP) is being developed to access an integrated network of databases containing both administrative and health information to facilitate different types of research: health outcomes and promotion of best clinical practice; knowledge translation and continuing medical education; audit and resource utilization; vigilance and patient safety; and, documentation of clinical education achievements. Data accessible via this tool originate from the Laboratory Information System, Discharge Abstraction Data, physician rosters, diagnostic imaging, and pharmacy databases housing health and administrative information for a large academic institute. The DDRP builds on an established network of databases, which has been or is currently supporting 34 studies, originating 23 abstracts and 9 publications as of November 2015. This study was conducted to validate accuracy and completeness of the extended datasets available via the DDRP. **Study Design/Methods**: Three aspects of the DDRP were selected for validation against independent, redundant source datasets: transfusion, physician roster and pharmacy. Selected variables were extracted to compare the DDRP data with identified external sources of data. **Results/Findings**: Transfusion data from 2014 housed in the DDRP was compared to inventory lists generated by the sole supplier of blood and blood products to this large academic centre. The match rate for units of cryoprecipitate and plasma of 100%, red blood cells 99.8% and platelets 99.9%. A total of 56,258 product records were included in the analysis; 56227 matched the DDRP data yielding a 99.9% overall match rate. Physician roster data compared to the most responsible physician listed in the DDRP for 4168 patients admitted to internal medicine inpatient wards at two sites from January-June 2014 matched in 96% of cases. Pharmacy records for 2053 atorvastatin prescriptions dispensed by inpatient pharmacy from January 1 to June 30th 2014 showed a 95% match. Records on 462 inpatient orders for intravenous iron from 2010-2015 had a match rate of 90%. **Conclusion**: Data validation of the DDRP against external datasets has shown excellent concordance. This demonstrated accuracy and completeness for variables tested supports use of the DDRP for research and knowledge translation activities though on going validation will be important.

AP53

Pilot Implementation of a Cloud-Based National Blood Sourcing Program

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Background/Case Studies: When the regional blood inventory is low, it can be difficult to obtain additional blood products, especially platelets and O-negative red blood cells (RBCs), from our hospital-based blood bank's primary blood supplier. This can cause delays in patient transfusions. To address this problem, we piloted using Bloodbuy, a cloud-based application for sourcing blood products collected by qualified facilities in different areas of the United States. Using a simple web-based interface, Bloodbuy users can place blood orders that are filled by suppliers participating in the Bloodbuy network. **Study Design/Methods**: Implementation of Bloodbuy involved 1) validating that Bloodbuy could be used on existing blood bank hardware; 2) training blood bank technologists to use Bloodbuy; 3) Bloodbuy supporting the blood bank team with online order entry, fulfillment, and tracking; and 4) Bloodbuy working with the blood bank to review and monitor the program and consider modifications to the application. A single contract was executed between our hospital and Bloodbuy.

We utilized the following Bloodbuy functions: 1) set desired price ranges for ordered products; 2) browsed for available packages of products listed online; and 3) utilized automated analytic and reporting tools for administrative planning. **Results/Findings**: During the 6-month pilot program, ~40% of total RBCs were purchased using Bloodbuy. Bloodbuy products were sourced from the West, Southeast, and Northeast United States. Staff training took ~10 minutes. The order fill rate was 98%. The average turnaround time for order delivery was 2-4 hours when shipped by a regional Bloodbuy supplier. When shipped from out-of-state, the turnaround time was next-day delivery by 10:30 am. A cost savings of over $100,000 was realized in the first 45 days after implementation, representing an overall blood purchase cost savings of ~40%. There were no recalls or quality issues with the products. **Conclusion**: Bloodbuy was rapidly and easily adopted by our blood bank. By addressing the uneven geographic distribution of available blood, Bloodbuy allowed our blood bank to meet inventory needs while substantially reducing blood purchase costs.

AP54

Does Centralized Control of Platelet Logistics Reduce Wastage within a Community Hospital System?

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Background/Case Studies: A hospital system composed of 5 medium to large hospitals implemented a centralized core blood bank in 2015 to improve control, logistics, specialized blood bank guidance and testing. Prior to centralized control, platelet wastage was identified as a major focus for improvement at each of the system hospitals, which had been ordering platelets independently. A centralized logistical process for platelet redistribution was developed to combat platelet wastage. **Study Design/Methods**: The centralized process required that all orders for platelets were faxed to the centralized blood bank and reviewed by dedicated blood bank technologists for accuracy or special requirements. Operating room orders were subject to schedule limitations, prohibiting ordering of products for multiple identical procedures when they were scheduled consecutively. The laboratory information system (Cerner Millennium) inventory was reviewed for each hospital to determine if any platelets were available within the system for transfer. If none were available, then platelets would be ordered from the blood supplier. Platelets that were available from another hospital were transferred via contracted courier. The total number of platelets transfused and wasted were obtained for each hospital for 2014 prior to centralized blood bank, and 2015 after centralized blood bank. The proportion of platelets wasted was calculated, the percentage annual decrease, and the p-value comparing the annual proportions were calculated. **Results/Findings**: The total number of platelets wasted for the system in 2014 was 535 units (range 38 to 154 per hospital) and total wasted in 2015 was 297 units (range 9 to 94). The proportion of platelets wasted for the system in 2014 was 13.6% (range 9.0% to 21.7%) and the 2015 proportion wasted was 8.5% (range 4.1% to 12.1%). Each hospital showed decreases in both absolute number of wasted platelets and proportion of platelets wasted (statistically significant with exception of one hospital). **Conclusion**: The adoption of centralized platelet distribution results in substantial and statistically significant decreases in platelet wastage, and is a simple and useful strategy to dramatically reduce platelet wastage in a multihospital system with a courier system. Centralized redistribution of products should be encouraged by both hospital systems or blood suppliers that are geographically near.

TABLE.

Facility	2014 Wastage %	2015 Wastage %	% Decrease	p-value
1	10.7	6.6	39	<.001
2	18.9	12.1	36	<.001
3	13.4	11.3	16	.096
4	9.0	4.1	54	.012
5	21.7	7.7	64	<.001
Totals	13.6	8.5	38	<.001

AP55

Adoption of Centralized Platelet Inventory Program in Reducing Platelet Wastage

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Background/Case Studies: Due to the scarcity and perishability of platelets, it is very difficult for a hospital blood bank to secure a safe platelet stock level for daily operation without inevitable wastage. Most blood banks have their own inventory due to difference in clinical needs, transport logistics and management. Our regions serve around 0.92 million of population with one geographically distant blood donor facility. A well-planned platelet inventory program is adopted among three acute hospitals in the cluster. The goal of this new program is to reduce the platelet wastage and yet maintaining sufficient stock to meet the unpredictable and urgent clinical demand in all hospitals. **Study Design/Methods**: A centralized platelet inventory program is adopted in a regional cluster since 1/3/2014: systematic regular shipping of unused platelets from two smaller hospitals (A and B) to hospital C (the centralized hospital), replacing the previous two-way transfer. No change in annual platelet inventory in hospital C but there is increase in routine platelet inventory in both hospitals A and B to meet the fluctuating clinical demand. A real-time communication among the blood banks to ensure the very short shelf-life of platelets can be effectively redirected for clinical use. Data are retrieved from the Laboratory Information System from 1/1/2010 to 31/12/2015. Different periods are compared: Phase 1 (without a proper transfer system during 1/1/2010 to 31/12/2011), Phase 2 (bi-directional transfer of platelets during 1/1/2012 to 28/2/2014), and Phase 3 (centralized platelet inventory program during 1/3/2014 to 31/12/2015). Statistics by Kruskal-Wallis and one-way ANOVA (with post-hoc Tukey test) using $p<0.05$ as significance. **Results/Findings**: The cluster platelet wastage rate is: 7.7% (6.3% to 9.2%), 5.6% (4.9% to 6.3%) and 2.7% (1.5% to 3.9%) for Phase 1/2/3 respectively, all differences are statistically significance ($p=0.000$). On multivariate analyses, Phase 3 is statistically significant to have lower expired units when compared to Phase 1 or 2 ($p<0.05$); there is no statistically difference in the number of expired units in Phase 1 and 2 ($p=0.093$). No difference in the issue rate among the three periods ($p=0.802$). Significant difference in both the transfer rate and the average transfer units ($p=0.000$), with transfer rate 0.6% (0.4% to 0.9%), 3.5% (2.5% to 4.4%) and 6.5% (5.8% to 7.2%) and average transfer units are 10 (6 to 15), 59 (43 to 75) and 105 (94 to 117) for Phase 1/2/3 respectively. **Conclusion**: The adoption of centralized platelet inventory program in a regional cluster has significantly reduced the platelet wastage without change in the issue pattern and clinical needs in the individual hospitals. This well-planned inter-hospital inventory transfer can timely reshuffled the near-expired platelet units into good use.

AP56

A Successful and Sustained Statewide Red Cell and Platelet Wastage Minimisation Program

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Background/Case Studies: Blood product wastage minimisation is a stewardship obligation for all transfusion laboratories and hospitals and requires conscientious efforts to achieve this goal. High red blood cell (RC) wastage rates (5.1%) were observed in regional hospitals due to poor cold chain management or on-site RC expiry. A state-wide platelet (PLT) wastage rate of 17% was common as a result of short shelf of PLTs. The BloodMove RC and PLT programs were implemented to minimise RC and PLT wastage. The aim of this study was to evaluate the effectiveness of the two programs in achieving reduction in RC and PLT wastage. **Study Design/Methods**: The RC program included a novel cold chain modification where near expiring RCs were rotated between all state regional hospital with (10) and without (35) on-site laboratories based on a hub and spoke transfer model. An extensive education program was also commenced. The RC program was managed by a multidisciplinary team supported by a network of site nurses. Cold chain security was assured by purchase of new blood refrigerators, revalidation of blood shippers, introduction of new documentation and partnering of all blood fridges with an overseeing laboratory. The PLT program consisted of the routine transfer of near expiry Day 4 platelets from small low use city laboratories to large high use city laboratories. A common electronic Day 5 platelet inventory covering all sites was introduced for use in elective PLT transfusions by all sites prior to using available on-site fresher platelets or ordering from the supplier. **Results/Findings**: Annual RC wastage rates

decreased from 5.1% in 2011 to 0.78% in 2016. During this time zero wastage was achieved on three separate months. This annual reduction has been sustained for 48 months. PLT wastage deceased from 17% in June 2014 to 7.6% recently. This decrease has been sustained for 20 months. Currently, the monthly average number of PLTs discarded is 55 vs. 130 prior to the program commencing. Other improved key performance indicators include median number of days with zero discards per month which increased from 3 [Interquartile range (IQR) 1-4] to 10.5 days [(IQR) 9-13]) and the median number of PLTs discarded per day deceased from 4 (2-7) to 1 (0-3). **Conclusion**: Cold chain assurance and RC scheduled rotation has allowed a significant reduction in RC wastage across all regional hospitals and laboratories. PLT wastage due to expiry can significantly be reduced by routinely transferring Day 4 PLTs from low-use sites to high-use sites. Also by having access to a common Day 5 PLT inventory across multiple laboratories permits preferential use of near expiry PLTs over fresher on-site PLTs further contributing to decreased PLT wastage.

AP57

Understanding Hospital Inventory

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Background/Case Studies: In 2013, a national advisory committee on blood and blood products in Canada (excluding Quebec) made recommendations for monitoring red blood cell inventory in hospitals using an 'inventory index' with suggested minimum necessary data elements during an inventory shortage. These elements include calculating an average daily red cell demand (ADRD) using red blood cell disposition data (transfused+outdated+wasted), dividing by a specific time period (90 or 365 days), and further using the ADRD to determine an inventory index from actual inventory levels. Although recommended for use during an inventory shortage situation, the blood provider recognized the value in developing a tool using these data elements with which to engage hospitals and to better understand hospital inventory levels during times of optimal inventory. **Study Design/Methods**: All hospitals share disposition data monthly, and many hospitals share inventory levels daily via on online web-system hosted by the blood provider. These data are extracted and are used to generate an excel-based graphical tool presenting the hospital's actual red blood cell inventory over time in comparison to ADRD plotted as usage for a set number of days (ADRD x2, ADRD x3, etc.) The tool also calculates the actual inventory index. These hospital-specific inventory trend reports are developed for each blood group (subject to available data) and red blood cell totals. **Results/Findings**: The use of a hospital specific inventory trend tool facilitates collaborative dialogue between the blood provider and hospitals and highlights the amount of red blood cell inventory the hospital has in inventory generally well above any potential inventory shortage situation. This tool was leveraged to provide the basis for an automatic inventory replenishment pilot with hospitals. **Conclusion**: The hospital-specific inventory trend tool aids hospitals and the blood provider to better understand what a specific red blood cell inventory level means in consideration of actual hospital red blood cell usage over time. The tool is the foundational element to further evolve collaborative inventory initiatives between the blood provider and hospitals.

AP58

Comparative Study Between Central Blood Bank and Five Hospital Blood Banks in Tracing Packed Red Blood Cells Units

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Background/Case Studies: Transfusion safety, along with an adequate supply of blood, is the main concern of blood banks. The blood bank or transfusion service shall ensure that blood, blood components, tissue, derivatives, and critical materials used in their processing, as well as laboratory samples and donor and patient records, are identified and traceable. Traceability records for blood components are very important and should always be maintained to promote hemovigilance, contribute to improving transfusion safety, and provide complete and reliable information about the fate of a given blood component. The Central Blood Bank (CBB) in Kuwait, being accredited by the AABB, is following its regulations in tracing every component. **Study Design/Methods**: A comparative study between the CBB and five hospital blood banks (HBB) was made to assess the levels of traceability records of packed red blood cells (PRBC). A comparison between the different systems were used to record the information (manual system MS, or electronic system ES) to evaluate, which is more effective in keeping high level of traceability. A total of 1080 PRBC units were randomly chosen to be traced to its final deposition, from the year 2008 till 2013. 540 were traced in the CBB and the rest were traced in five governmental HBB (108 each). A list of units' numbers swere given to each HBB to check their own records. The results were collected from the hospitals and statistically analyzed to evaluate the current status and identify the deficiency in the traceability system. **Results/Findings**: The overall traced units were 949 out of 1080 (87.9%), while no records were found for the rest of the units. The tracing percentage was 100% throughout the five years in the CBB and two of the hospitals which is considered very high quality for transfusion safety. The percentage in the other hospitals were variable. Regarding the system used in recording the data: two hospitals are currently using the MS, H3 used MS till 2012 and ES on 2013, H4 was on MS till 2010 then shifted to ES, and H5 introduced the ES on 2011. The CBB was using ES since 2003. The traceability over the six years for the CBB, H2 and H5 is 100%. In H1 the percentage is variable ups and downs, while in the other two hospitals, once traceability reaches 100% it is maintained at that level. **Conclusion**: The overall traceability in our study is 87.9% which is similar to other study in Dutch hospitals. The percentage of traceability of PRBC over the 6 years included in this study is satisfactory in the CBB and 2 of the included hospitals, improved in other 2 HBB after introducing the ES, and not satisfactory in the last HBB. The system is not the only variable for accuracy but the personal variable and management is very important because H2 is always 100% by using MS, and H5 is 100% with both MS & ES.

AP59

A Collaborative Effort to Increase Antigen-negative Red Blood Cell Inventory for Sickle Cell Patients

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Background/Case Studies: Patients with sickle cell disease (SCD) who require chronic transfusion are often transfused O-negative red blood cells (RBC) negative for C,E,K antigens. Our service area includes hospitals with large SCD populations. Requests for C-,E-,K-negative RBC have increased, resulting in significant demand on O-negative RBC inventory. To address this issue, representatives from Donor Communications (DC), Public Relations/Marketing, Reference Laboratory, Information Services, Donor Centers, and Hospital Relations met to discuss the best approach to increase available inventory. **Study Design/Methods**: We initiated a focused recruitment effort of African American (AA) donors, since their probability is the highest of having R0 RBC phenotype. Our previous protocol requested automated phenotyping of donors on their third donation for C,c,E,e,K antigens. Beginning in April 2015, all donors who self-identified as AA were phenotyped regardless of donation history. To generate awareness and increase

TABLE.

Month	Number of Donors Phenotyped	Number of Donors with R0,K- Phenotype	Number of AA Donors with R0,K- Phenotype
JAN 2015	556	36 (6%)	26 (72%)
FEB	935	38 (4%)	18 (47%)
MAR	1009	40 (4%)	20 (50%)
APR	1023	41 (4%)	27 (66%)
MAY	1332	198 (15%)	179 (90%)
JUN	1497	201 (13%)	178 (89%)
JUL	857	114 (13%)	101 (89%)
AUG	407	115 (28%)	16 (14%)
SEP	1041	332 (32%)	38 (11%)
OCT	801	137 (17%)	124 (91%)
NOV	711	118 (17%)	108 (92%)
DEC	700	123 (18%)	110 (89%)
JAN 2016	825	147 (18%)	127 (86%)
FEB	805	137 (17%)	132 (96%)
MAR	908	167 (18%)	150 (90%)

the return rate among R0,K- donors, a specific letter, email, and phone script were created. These tools explained how the donors' blood type was in higher demand and how they could specifically help SCD patients. In October 2015 the letter was mailed once to all first time R0,K-phenotyped donors since April. In December 2015 new donors who phenotyped as R0,K- were mailed the letter on post-donation day (PDD) 11. On PDD 52 an email was sent to donors who did not schedule an appointment after receipt of the letter. On PDD 57 DC followed up with a phone call to eligible donors without an appointment. **Results/Findings**: Monthly phenotype data is summarized in the table. From 1/2/2015 to 3/31/2016 13,407 unique donors were phenotyped, 1,944 (14%) donors had R0,K- phenotype, of these 1,354 (70%) were AA donors. Since April 2015 there was an increase of 493 R0,K- donors compared to the previous 12 months. Of the donors that received the letter 83% returned at least once to donate. **Conclusion**: The results show that a multi-departmental, focused donor recruitment effort will increase antigen negative RBC inventory for patients with SCD and other conditions requiring antigen negative RBC.

AP60

A Visual Tool to Assess Platelet Refractoriness

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Background/Case Studies: Early detection of platelet refractoriness enables a prompt switch to potentially more effective crossmatched or HLA compatible platelet units. This tailored approach optimizes use of platelet inventory and decreases patient exposure to units that offer no therapeutic benefit. Determining platelet refractoriness traditionally involves the time-intensive process of manual medical record review and calculation of corrected count increments (CCI) using pre- and post-transfusion platelet counts for each transfusion event. **Study Design/Methods**: We developed a computer program that creates a graphical display to easily screen patients suspected of being refractory to platelet transfusion. The program output for an individual patient shows the temporal relationship between the number of platelets transfused and resultant laboratory platelet values. This program queries the patient's electronic medical record (EMR) in the laboratory information system (LIS) and extracts the number of platelet units transfused and platelet counts over a user-inputted time range. The program is designed so that minimal input is needed from the user, specifically the patient's medical record number and the start date and time of platelet transfusion. The date and time displayed on the x-axis is scaled correctly based on platelet transfuse and platelet result times. **Results/Findings**: A color-coded multi y-axis bar graph displaying the number of platelet units dispensed and the corresponding platelet count over time (x-axis) is generated. At a glance, the user can visualize trends in patient platelet count responses to each unit transfused in the correct chronological order. Typical execution of the program for an individual patient is a few seconds. Use of this program can quickly identify patients who do not appear to be refractory based on count increments or patients who require additional investigation and/or testing. **Conclusion**: This novel program extracts and collates EMR and LIS data to create a user-friendly, graphic representation of platelet transfusion events and platelet response for an individual patient. It provides a useful tool for rapidly identifying patients with potential platelet refractoriness.

AP61

Implementation of Psoralen-Treated Pathogen-Reduced Platelets: A U.S. Transfusion Service Perspective

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Background/Case Studies: In December 2014, FDA approved the use of psoralen-treated platelets prepared by the INTERCEPT® Blood System. In March 2016, FDA issued revised draft guidance for bacterial risk control for platelets $\geq$ four days old. The local blood supplier initiated manufacture and distribution of psoralen-treated platelets. **Study Design/Methods**: A retrospective analysis of critical steps performed to implement psoralen-treated platelets at a 1,000+-bed hospital system. **Results/Findings**: Five steps were identified: Product Review, Organizational Acceptance, Physician Education, Transfusion Lab Implementation and Nursing Education. Product Review included attendance at the April 2015 AABB Symposium on Pathogen Reduction, literature review, and evaluation of the FDA approval documents. Organizational Acceptance was primarily achieved through the institution's Transfusion Practice Committee (TPC). Factors evaluated by TPC included: review of clinical efficacy data, cost and benefit analyses, FDA draft guidance on bacterial risk control methods, and threat of emerging pathogens. TPC officially recommended implementation of psoralen-treated platelets in November 2015. Administrative approval for the anticipated budget impact was achieved. The Blood Bank requested and received AABB variance approval to use psoralen-treated platelets in lieu of irradiation as a means of preventing TA-GVHD. Intranet announcements and newsletter updates were the vehicles used to educate providers. A tie tag was created to identify psoralen-treated platelets as a replacement for irradiation and to indicate the effectiveness of CMV log kill of $\geq$ 4.9 log. Educational information was presented to nursing leaders and disseminated to all nursing staff in advance of implementation. The ordering process was not modified to indicate psoralen-treated versus 'conventional' platelets. Transfusion Service policies continued to require staff to select platelets for transfusion based primarily upon ABO/Rh and expiration date. Both were conscious decisions to facilitate an equitable utilization of a dual platelet inventory. **Conclusion**: Psoralen-treated platelets were successfully implemented as of March 1, 2016. The TPC recommendation was identified as a critical factor in achieving organizational acceptance. Clinical and laboratory leaders were identified as essential personnel to facilitate this process. For the month of March 2016, a total of 382 platelet products were transfused; 130 (34.0%) were psoralen-treated platelets transfused to a total of 55 patients between 0-87 years. No irradiation was performed on the psoralen-treated products in accordance with the AABB 30th Edition Standards 5.19.3.1. No significant adverse events with psoralen-treated products were reported.

AP62

Warming Kinetic and Clinical Impact of Returned Red Blood Cell Concentrates Without Temperature Maintenance

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Background/Case Studies: The FDA and AABB require transfusable red blood cells (RBCs) to be maintained at 1-10°C during transport. Many U.S. blood banks (BBs) follow the historical "30-minute (min) rule," which permits the acceptance of returned RBC units transported without temperature maintenance within 30 min. Our BB recently switched from the 30-min rule to direct temperature measurement. This study aims to examine the RBC warming kinetic and its clinical impact on blood recipients in a realistic clinical setting. **Study Design/Methods**: Two retrospective 7-month periods before and after the use of a thermometer (TempCheck TC-12, Hampshire Controls, Dover, NH) and a 2-month prospective audit were performed. All returned RBC units initially issued without validated containers were included. For each time period, we evaluated the time out of the BB (TOBB), the acceptance rate of the returned units, and the associated transfusion reaction frequency of reissued units, with comparisons made using proportion tests. Prospective audit aimed to evaluate the warming kinetics of returned RBC units using linear regression analysis. Prediction of temperature-based acceptance by TOBB was assessed with logistic regression. All statistical analyses were performed using STATA v14.1 with a $p<0.05$ for significance. **Results/Findings**: Per our "30-min rule" policy, 228 of 293 (77.8%) returned RBC units were accepted with a median TOBB of 14 min (IQR: 4-23 min), and the discarded units had a median TOBB of 66 min (IQR: 43-111 min). During the analyzed TempCheck periods, 139 of 215 (64.7%) returned RBC units were accepted with a median TOBB of 19 min (IQR: 11-31 min), and the discarded units had a median TOBB of 38 min (IQR: 27-68 min). There was a significant 13.1% increase ($p=0.001$) in RBC unit wastage with TempCheck use compared to the "30-min rule." Of the 76 discarded units (i.e. >10°C), 21 (28%) were returned within 30 min. The prospective audit showed a modest correlation between TOBB and return temperature ($R^2=0.43$, $p<0.001$). By logistic regression, TOBB is only a fair predictor for the temperature-based acceptance of the returned RBC units (AUROC=0.78, 95% CI=0.72-0.84). The rate of transfusion reactions associated with reissued RBCs were 4/228 (1.8%) and 0/139 (0%), before and after TempCheck implementation, respectively ($p=0.11$). **Conclusion**: Our preliminary data show that, compared to the "30-min rule" policy, temperature-based acceptance of returned RBC units is associated with a higher rate of blood wastage and reduced transfusion reaction frequency in recipients of those returned units. The "30-min rule" did not adequately predict the acceptable transport temperature of RBC units issued without validated containers. Extended study is needed to further substantiate these preliminary findings.

AP63

Temperature-regulating Material for the Shipment of Red Cells

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Background/Case Studies: After looking at how blood transportation has been done for years, areas in the processes that could be greatly improved were identified. Temperature control was the variable addressed in this evaluation. After seeing the trend of maintaining the required 1°C −10°C of red cell for a maximum of 24 hrs, the testing of a Temperature-regulating Material (TRM) began. Testing has shown a substantial increase in how long red cell units can be kept within the required temperature. **Study Design/Methods**: Packing configurations were evaluated to allow for removing the use of wet ice and introducing a TRM in its place. Calibrated temperature probes were used to record the temperature of red cell units in 1-minute intervals. Box configurations were evaluated in two groups (1-7 units, 8-14 units). Box setup for 1-7 units had 2 frozen TRM hard packs on the bottom of the box, with 2 refrigerated TRM soft packs placed on top of the hard packs. Box configuration for 8-14 units had 2 frozen TRM hard packs on the bottom of the box, 1 frozen TRM soft pack on each label-exposed red cell unit, and 2 frozen TRM soft packs on top of the red cell units. All TRM units have a toweling barrier between them and red cell units. Tests ran for approximately four days, and then data was analyzed to confirm temperatures were maintained. Data collection:

- Temperature reading of red cell units in 1-minute intervals
- TRM chilled or frozen in temperature-calibrated refrigerators and freezers
- Test run in a temperature-calibrated room
- Data was analyzed to confirm temperatures were maintained.
- Tests were performed a minimum of three times to confirm results.

Results/Findings: The area targeted for improvement was temperature control in the transportation of red cells. Results show an increase in temperature duration by 14 to 30 hours beyond the 24-hour storage. This was dependent on the number of red cell units and box configuration. **Conclusion**: Implementation of the TRM units can increase the length of time red cell units can be kept within the required 1°C to 10°C range during transportation. This increases the effectiveness for longer distance transportation under stabilized and more reliable conditions. TRM will help us remove the limitations and issues associated with using wet ice and provide a more controlled environment during transportation improving the storage temperature and duration of our delivery system to our clients and reduce the number red cell units lost due to shipping temperature excursions.

AP64

Pre-Hospital Emergency Blood Supply Process Implementation

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Background/Case Studies: In the United States, traumatic injury is the leading cause of death for people between 1 and 44 years old and among the top 5 overall causes of death for all ages. Studies suggest that early intervention with antifibrinolytics and rapid provision of blood products improve survival odds. Therefore, an efficient, sustainable process to provide antifibrinolytics and blood products in the pre-hospital environment was designed for multiple flight crews serving a large rural region. **Study Design/Methods**: Thermal insulated transport boxes originally designed for military use were selected and validated for blood transport. Irreversible temperature indicators were also selected and validated. 2 “O Neg” RBC units and 2 “A” Thawed Plasma units were selected as the “emergency inventory” for each flight crew. Each blood unit has a temperature indicator and transfusion tag affixed prior to loading each transport box at the main hospital. Medical staff developed field utilization algorithms. The paramedic team was already familiar with administering blood during hospital-to-hospital patient transfers. Each flight crew makes frequent trips (air or ground) to the main hospital, allowing boxes to be refilled or replaced regularly to prevent outdating and maintain inventory. The Lab Information System tracks the location and disposition of each blood unit, and the paramedic transport electronic health record tracks all treatments, as well as patient vital signs before, during, and after transfusions. Open lines of communication were established among the paramedic crews, the transport command center, and the transfusion service laboratory. In order to monitor and improve performance, the transport teams, transfusion service personnel, and trauma services hold review meetings on a regular basis. The implementation of this process involved the following sequence: 1) utilization of antifibrinolytics; 2) simulation of transportable blood units using saline bags; 3) replacement of saline bags with RBC units; and 4) addition of Thawed Plasma units to RBC units. **Results/Findings**: During the first 6 months of operation, 46 patients received pre-hospital transfusions which involved 42 RBC units and 33 Thawed Plasma units. This population showed improved hemodynamic stability compared to historical controls that did not have access to pre-hospital antifibrinolytics or transfusions. **Conclusion**: This process for trauma programs to provide blood and antifibrinolytic treatment options in the pre-hospital environment is easily replicable. The development of hemostasis agents, as well as storage devices and standards, to support clinically effective interventions in the pre-hospital environment is encouraged.

AP65

Tracking Blood Components Issued during Massive Transfusion Protocols

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Background/Case Studies: Massive transfusion protocols (MTPs) are designed to rapidly supply red blood cells (RBCs), plasma, platelets, and cryoprecipitate to exsanguinating patients. It can be challenging for blood banks to quantify product returns and wastage during MTPs, as final disposition of the product is typically associated with the unit rather than the patient. Previous efforts to determine transfusion, return, and wastage rates required prospective manual tracking which is cumbersome and labor-intensive. We developed a computer program to retrospectively trace the final disposition of all blood products dispensed to an individual patient during an MTP activation to determine our hospital rate of transfusion, return to inventory, and product wastage in this setting. **Study Design/Methods**: We retrospectively reviewed all MTP activations from 2/2015 to 2/2016. Using our computer program, we were able to identify all blood components dispensed to each patient during each MTP and to determine the final disposition of each unit (transfused or returned to inventory; if returned, either reissued to another patient or destroyed). **Results/Findings**: Over the study period, there were 33 MTPs with an average of 24 (±22) blood components transfused per activation. A total of 776 blood products were dispensed. Final disposition by blood component is shown in Table 1. The transfusion rate for RBCs and plasma was comparable, likely because our MTP is designed to support a 1:1 ratio of RBCs to plasma. Wastage rates were also comparable for these products, due to similar temperature requirements, to allow for return to inventory. The highest wastage rate was observed for cryoprecipitate, likely due to the 6-hour shelf-life after thawing which decreases the opportunity to reissue to other patients. **Conclusion**: Our computer program allowed us to easily trace all blood products released during MTPs over a 1-year period. We have now established our current transfusion, reissue, and wastage rates in this setting and plan to use this tool for ongoing monitoring and quality assurance efforts.

AP66

Improved Workflow Efficiencies through Remote Refrigerator Storage

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Background/Case Studies: Emergency Department (ED) Level I Trauma Centers require immediate access to group O red cells. To support this requirement, our Transfusion Service previously transported uncrossmatched group O red cells to the ED for all trauma team activations, in addition to returning the 90% of unused blood products. The transport of blood products during trauma team activations results in workflow and testing inefficiencies because the ED is located in a different building and on a different level from the Transfusion Service, which was problematic during off shifts with reduced staffing levels. To improve utilization of staff time while ensuring availability of product, our institution implemented barcode-based blood administration using BloodTrack (BT) (Haemonetics Corp. Braintree, MA) and BloodTrack Emerge (BTE) for tracking RBC in and out of a remote refrigerator (RR). BTE monitors, secures, and records O-negative and O-positive access in the emergency department. It consists of software for tracking products and a kiosk with an integrated barcode scanner which controls a magnetic lock attached to the RR. Transfusion Service staff stock the refrigerator with a designated number of O-neg and O-positive red cells. To remove a product, nurses scan into the system and follow a series of on-line prompts for removal of a product. The kiosk de-activates the lock. The nurse

TABLE. Final disposition of components issued during MTP activations

Blood Component	Transfused During MTP	Reissued to Other Patients	Destroyed
RBC	298 (69%)	95 (22%)	38 (9%)
Plasma	177 (64%)	77 (28%)	22 (8%)
PLT	26 (90%)	3 (10%)	0 (0%)
Cryo	33 (83%)	0 (0%)	7 (17%)

can then remove a product and must also scan the blood product. BTE alerts the Transfusion Service when the system has been accessed, the product has been removed, and the patient identified. BTE will also alert the Transfusion Service regarding inventory status and need to re-stock. Alerts are tracked for evidence of non-compliance with established workflows. **Study Design/Methods**: The number of blood product deliveries and the time required by staff to deliver blood to the ED were monitored before and after the implementation of BTE. Data collected included the number of alerts and the amount of transport time both pre- and post-implementation. **Results/Findings**: Implementation of BTE occurred on 10/13/2015. Pre-implementation data demonstrated an average amount of delivery time at 1335 minutes per month. Post-implementation data demonstrated an average number of minutes/month at 322, a reduction of 1013 minutes/month. The average number of trips to the ED pre-implementation was 191. The average numberof trips post-implementation was 46, a reduction of 145 trips/month. **Conclusion**: Implementation of remote refrigeration in ED with barcode-based blood administration improved workflow efficiencies to ED by 76% while ensuring availability of product and maintaining tracking requirements.

AP67

Using a Refrigerator on Wheels to Reduce Blood Wastage in the Operating Room

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Background/Case Studies: Red Blood Cell (RBC) wastage continues to be a challenge for hospitals. The 2002 CAP Q Probe data showed that RBC wastage to transfused rates ranged from 0.1% to 0.7%. Our Level 1 trauma hospital strives to keep wastage to a minimum by placing RBCs in remote-release refrigerators in remote areas. But wastage rates remained unacceptable. Our 2015 monthly wastage-to-transfused rates (Jan - July) ranged from 5.9% to11%, of which 60%-84% (25-69 RBCS) were from the Operating Room (OR). The wastage rate from OR increased by 62% from 2014 (Table). We use temperature indicators to monitor RBC storage temperature acceptabiility. We hypothesized that RBC wastage was secondary to surgical staff removing RBC units from storage to allow for product proximity to hemorrhaging patients. We undertook a process improvement project to reduce wastage by providing bedside storage. **Study Design/Methods**: We acquired a refrigerator on wheels (ROW), a compact blood bank refrigerator that can be wheeled and plugged into power in the OR (or the Transfusion Service when not needed). It can hold up to 13 RBC and/or plasma units. We piloted its use in cardiovascular surgery due to anticipated need for large transfusion volumes starting in August 2015. **Results/Findings**: The RBC wastage post-intervention (August 2015 to February 2016) decreased by 57% compared to pre-intervention (Jan-July 2015). Blood product acquisition savings was $47,760, with annualized savings of $81,463. **Conclusion**: RBC wastage decreased 57% in the seven months following use of a ROW for perioperative blood component storage, with blood product acquisition cost savings of $47,760. There was no wastage of RBC units issued by ROW during the pilot period. The ROW purchase was less than $4,000, giving us an almost immediate return on investment. Based on these results, we plan on expanding our ROW inventory by 2 more ROWs for high blood use cases.

AP68

Implementation of a New Blood Cooler and Monitoring Device and its Effect on Reducing Red Blood Cell Wastage

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Background/Case Studies: The overall blood components wastage rate in a two-year tracking period in US hospitals is reported to be from 1.3 to 2.1%. Over a three-year period before implementation of a new blood cooler and tracking system, the wastage at our institution averaged 0.64% of 26,403 issued red blood cell (RBC) products. Approximately 95% of wasted RBC units were either “dispensed but not administered” individual units- that were out of blood bank for more than 20 minutes, or the most common reason for RBC product waste, “blood left in the cooler for too long” units that were packed in a picnic-style cooler plus ice block. **Study Design/Methods**: The amount of units wasted during a 3-year period before the

TABLE.

	RBC Transfusions Total	Number of RBCs Wasted in OR	Wastage/ Transfused Rate (OR)	Total Acquisition Cost (wasted RBCs)	Acquisition Cost per Month (wasted RBCs)
2014 (Jan - Dec)	8969	323	5.8%	$77,520	$6,460
Pre-intervention (Jan - Jul 2015)	5606	359	6.4%	$84,240	$12,309
Post-intervention (Aug 2015 - Feb 2016)	5458	152	2.8%	$36,480	$5,211

TABLE 1. Total RBC issued and transfused before and after implementation of new blood cooler and tracking device

Year	Number of units issued	Number of units transfused	Number of units wasted (out too long)	Wastage rate (out too long)	Estimated wastage cost ($)
2010-2012-(before)	79,209	78,662	509	1.93%	94,165.00
2013-2015 (after)	68,205	67,836	115	0.51%	21,275.00

implementation of the new cooler and the tracking system was compared to the amount wasted after implementation. The blood bank database was used to quantify and categorize total RBC units issued for transfusion throughout the hospital. Radio frequency identification (RFID) tags were used with special software to monitor blood cooler tracking. The blood coolers were validated for 10 hours at 1-6C. When coolers near the 10-hour expiration, the software alerts blood bank to call the location and have the coolers returned. The number of wasted RBC units and cost of wasted RBC units that were due to "blood left in the cooler for too long" were determined. In addition, RFID tracking provided real-time location monitoring of the blood coolers throughout the institution. **Results/Findings**: The implementation of the blood cooler and tracking device reduced mean yearly RBC wastage by four-fold from 0.64% to 0.17%. The saved RBCs corresponded to a total cost savings during the 3-year period of $72,890 after implementation (Table 1). Most other blood product wastage after implementation was not attributable to improved tracking and extended storage, such as cooler lid left open or unit expired. The visibility of tracking the blood coolers in real time for all hospital locations and the software monitoring each cooler for the 10-hour expiration on the blood bank monitor reduced blood wastage. Data about the movement of the blood coolers within the hospital became a rich source of information to aid in assessing blood utilization and improving blood delivery. **Conclusion**: The implementation of the new blood cooler and tracking system reduced the average cost per year of total RBC wastage. The cost to implement this initiative may be small compared to the total cost of blood wastage, and the significant return on investment may be reproducible in other institutions.

AP69

Process Improvement for Transfusion Turnaround Time

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Background/Case Studies: Our facility provides blood products for a Long-Term Acute Care (LTAC) facility, and there have been many concerns regarding turnaround time (TAT) for red blood cell (RBC) transfusions. A goal was set by the facility of having 90% of STAT orders available for a courier within 90 minutes of sample/order receipt. Antibody-positive samples or patients with a history of antibodies were not included in the TAT. Automation used does not have STAT capabilities, and the usual TAT for testing on the instrument is ~45 minutes. **Study Design/Methods**: TAT data were not being monitored by the transfusion service (TS), and no automated data collection existed; therefore, it was unclear if the goal was being met or not. Manual Collection of data started in March 2015. Data included date and time of receipt, completion of testing, and issue in the computer system. The data showed inconsistencies (March 91%, April 67%, May 67% and June 85%). Discussions with frontline staff showed that they did not know that a TAT goal existed. Data were reviewed for trends, and it was discovered that many of the failures that had occurred were at the time of shift change (1300 to 1500) and that Mondays and Thursdays were the busiest days of the week. Goals were discussed with all staff who performed testing so that everyone understood how to prioritize samples and that there is a 90-minute TAT expectation. Scheduling was updated so that there was more of an overlap of staff for the afternoon times when failures had been noted. **Results/Findings**: The last 6 months showed a 96% acceptable TAT (see Table). Monthly data were only at 75% in December, but this was due to a low number of samples being received (8). Overall TAT was much improved and the client had seen great improvement with blood products being available quickly. **Conclusion**: There were several things that contributed to the failure to meet the 90-minute TAT. The awareness of the goal by the frontline staff was the first step at meeting the goal. Evaluating the data enabled some fine tuning of the process and ultimately led to meeting the client's expectations. Newer automation that is being evaluated has a faster TAT of ~26 minutes and STAT handling capabilities. It is hoped that when we move to this technology, the TAT will be even better.

TABLE.

	# Samples	# met goal	% Completed
Mar-15	11	10	90.9%
Apr-15	11	6	66.7%
May-15	21	14	66.7%
Jun-15	15	11	84.6%
Jul-15	5	5	100.0%
Aug-15	18	17	94.4%
Sep-15	13	13	100.0%
Oct-15	15	15	100.0%
Nov-15	14	14	100.0%
Dec-15	8	6	75.0%
Last 6 months	73	70	95.9%

AP70

Cost Savings in an Increasing Cost Environment

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Background/Case Studies: To ensure we are meeting the needs of the patient and providing quality care at an affordable price, the department of Transfusion Medicine tasked each work unit to a 2% cost reduction. A Value Creation Collaborative group was established. The group included Inventory Specialists from each work unit to meet this goal. **Study Design/Methods**: Top expenses were evaluated. Expected daily use of reagents was calculated. The calculated expected daily use was then compared to the actual daily use to identify the amount of waste for each reagent. A main culprit identified was the automated analyzer screen strips. Most often, when antibody screen tests were run, a full strip was loaded, but less than a full strip was used for testing, thus creating waste. A tool was built to show full strip use. In addition to reagent cost reduction, the group requested frontline technologists to help share cost-reduction ideas. A tool was created to provide a single location to gather ideas in the labs. This tool allowed the staff to submit ideas and see the progress of their ideas. The tool also included a space to identify ideas that were not feasible to use at this time. This allowed the group to provide an explanation to staff about why an idea could not be used. Keeping everyone engaged until we met our goal was an expected challenge. To maintain staff engagement, celebration points were planned as progress was made. Celebrations were planned for both the total dollars saved by the ideas and the total number of ideas submitted. The Value Collaboration met monthly to review our progress and setbacks. This partnership between work units allowed the group to learn from each other and see ideas that they may not have thought about. **Results/Findings**: There was a decrease in the automated screen strip waste from a weekly average of 24% ($354 per week) to 15% ($204 per week). This was a reduction of $150 per week and approximately $7,800 per year. By including frontline technologists to collect cost-saving ideas, 60 ideas were discovered. Ideas included eliminating call hours during fully staff hours, removing unnecessary stickers used for computer downtime, removing weak D testing for historically weak D patients, recycling copper wafers, and recycling used paper for scratch paper. By implementing 42 of the submitted improvement ideas, a total of $24,717 in savings was obtained. This allowed us to exceed our goal of reducing costs; the total reduction was 3.6%. **Conclusion**: The Value Collaboration group and technologist involvement were instrumental in our work unit meeting the set goal and improving our overall cost while maintaining quality. Team collaboration exceeded our original expectations and increased discovery of novel ideas for cost reduction.

TABLE. Cost Savings Results

Total Ideas submitted	Total Ideas Implemented	Total % reduction	Total Dollars Saved
60	42	3.6	$24,717

AP71

Opening a New Transfusion Service Laboratory: A Blueprint from Planning to Going Live

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Background/Case Studies: A quaternary care center transitioned from a centralized transfusion service operated by the regional blood center to a

hospital-based transfusion service laboratory (TSL), with goals of improving turnaround time, reducing costs, and providing immediate bedside consultation. **Study Design/Methods**: This is a descriptive analysis of the development of a hospital-based transfusion service. **Results/Findings**: This 500-bed quaternary care center provides an estimated 30,000 blood components per year. Patient services include solid organ and hematopoietic stem cell transplant, cardiothoracic and neurosurgery, interventional radiology, adult extracorporeal membrane oxygenation, specialized intensive care, and high-risk obstetrics. The planning of the laboratory started approximately 18 months prior to its opening. A project committee was charged with planning, design, development, testing, validation, and implementation. Team members included project managers, laboratory manager, compliance analyst, information technology (IT) representatives, electronic health record (EHR) analysts, nurses, and laboratory medical directors. The space for the laboratory was 4,499 square feet, and it took approximately 6 months to build and an additional 2 months to complete equipment installation and validation. Test and blood product orderables were developed in conjunction with clinical teams and EHR analysts. This was followed by laboratory information system (LIS) development and validation. Two LIS system validations were performed: internal validation by laboratory medicine IT and external validation by an independent contractor. The regional blood center provided historical data points that included blood typing, antibody identification, and required component attributes and processing for all patients at this institution tested during the last 15 years; this electronic file was uploaded to the LIS before going live. These historical data were critical for supporting hematopoietic stem cell transplant patients and patients requiring special component processing. Laboratory capabilities at the time of opening included basic and intermediate complexity immunohematology testing (group typing, antibody identification, direct antiglobulin test, antibody titers, and eluates); more complex testing is currently sent to a local red blood cell reference laboratory. Secondary processing capabilities include syringe aliquoting, irradiation, volume reduction, and washing. Standard operating procedures were written at the same time these tests were validated. **Conclusion**: A multidisciplinary team, careful planning, validation, testing, and implementation resulted in the successful opening of a new TSL. Whether a hospital-based transfusion service performs more efficiently than a centralized system is yet to be determined.

AP72

Florida Hospital Transfusion Service Goes Wireless!

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Background/Case Studies: Florida Hospital Transfusion Service in Orlando, piloted a study to test the use of an External Remote Wireless Thermometer System (ERWTS) to replace the commonly used Temperature Chart System. After comparing a number of companies, the laboratory decided to evaluate the AeroScout and Mobile View System from Stanley Healthcare. AeroScout System uses a Wi-Fi Sensor Tag (T5 Series) to monitor temperature and humidity. Data is collected and wirelessly sent to an electronic database for easy access and storage. T5 Sensor Tags were placed throughout the Blood Bank Department **Study Design/Methods**: The Transfusion Service Department took a total of 6 months of data collection and comparison before the ERWTS was fully validated and went live. The data collection and comparison was based on 3 different criteria. For the refrigerators, platelet incubators, and freezers, we used the AeroScout history report, the AeroScout alarm event report, and the Equipment Temperature Chart. For the waterbaths, heating block incubators, and room temperature, we used the AeroScout history report, the AeroScout alarm event report, and the weekly average result of collected temperature data. Following our SOP, it was established that the AeroScout asset device and the chart or temperature documented in our QC should have a temperature agreement when compared to each other to have a "PASS" Validation. For refrigerators, freezers, platelet incubators, and room temperature, the reading needed to agree within +/- 2.1 degrees Celsius, and for the waterbaths and heating blocks, it needed to agree within +/- 1.1 degrees Celsius. **Results/Findings**: We began the comparison by observing the AeroScout history report for each asset and comparing that to the paper chart for each instrument or the weekly average result of collected temperature data. Once those two criteria were compared, we reviewed the AeroScout alarm event. If there was an alarm that was generated, we looked at either the instrument chart or weekly average result and the AeroScout history report to see if there was an outlier either high or low confirming the alarm. If all 3 criteria matched, that was considered a "PASS" result, and if one of the criteria did not match, that was considered a "FAIL." Four weeks of data was collected for the final validation. **Conclusion**: Once the validation was completed and all the SOP's were reviewed and signed, we went live with the remote wireless thermometers and removed all paper charts from their instruments. Charts are still available for all instruments as a backup system in case AeroScout is down for over 4 hours, according to AABB standards. The AeroScout Mobile View allows the technologists to view any alarm and to write a corrective action. As a result of this study, the Blood Bank Technologists do not have to change charts on a weekly basis and check temperatures daily, saving valuable time.

AP73

A Review of an Emergency Remote Blood Refrigerator

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Background/Case Studies: In 2005, the Andrew Anderson Emergency Center opened at Rhode Island Hospital in Providence, Rhode Island. The Center is currently one of the nation's busiest and the only level one trauma center in Southeast New England. The Center serves 110,000 people annually and transfused 3,662 units in 2015. The opening of the Center posed a problem for the expeditious transport of blood, due to its location. The Center was relocated two buildings away from the blood bank, taking approximately 10 minutes to get blood to the patient. After seven years of preparing coolers and trauma packs, the Blood Track Emerge by Haemonetics was installed in the Critical Care Unit of the Center with scanning and tracking capabilities. This puts the components right in the trauma room, giving immediate access. This retrospective review of the data in 2015, experience of a downtime, and nursing input was performed to determine the efficiency and functionality of the system. **Study Design/Methods**: In 2015, 396 red cell components were removed for 215 patients from the Blood Track Emerge via an emergency release function and transfused within minutes. A random review of significant trauma cases showed that components were removed in as quickly as two minutes after admission. Additional cases revealed components removed in under the 10 minute transportation time from the blood bank proving the refrigerator effective in providing components in trauma situations. During the second half of 2015, the Blood Track Emerge refrigerator was out of service on various occasions. The downtime proved to be a burden to all staff. Although no transfusion was delayed, the blood bank had to prepare trauma coolers and carry the trauma beeper which is programmed for every potential trauma regardless of the need for blood. This process was cumbersome for the staff. The nurses in the Emergency Center find the Blood Track Emerge a fast and reliable source of safe components with the ability to obtain blood quickly even in the most trying trauma situations. The blood bank is assured that the tracking and tracing of the components are performed by the refrigerator as required by regulatory agencies. **Results/Findings**: The data and evidence shows that the Blood Track Emerge has proven to reduce time needed for transportation of blood to the patients with little burden to the blood bank or the Emergency Center staff. **Conclusion**: The Rhode Island Hospital trauma surgery website states: "Trauma kills more people between the ages of 1 and 44 than any other disease or illness. Nearly 100,000 people of all ages in the U.S. die from trauma each year, roughly half of them in automobile crashes" The Blood Track Emerge has proven to be useful in providing components in trauma and emergent situations and has aided the blood bank and Emergency Center staff in the critical first minutes of a patient's arrival to the hospital.

Management, Finance, and General Marketing

AP74

Dismantling the Elephant in the Room: Embracing a Culture Change

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Background/Case Studies: A work unit's culture is measured as effective or ineffective based on emotional, intellectual, and behavioral aspects. Biannual questionnaire metrics on discretionary effort and engagement for a perioperative team of 15 employees indicated that this work unit was struggling with low morale and burnout. Efforts to fix teamwork, communication, and trust with a typical Human Resources (HR) toolbox had superficial results. Building and sustaining a quality culture required a different set of lenses to dismantle and avoid aversion to the elephant in the room- change. **Study Design/Methods**: Team Engagement (TE) and Plan Do Study Act (PDSA) models were employed to disrupt the status quo and embed a quality culture. A baseline measurement utilizing a culture of safety survey identified working strengths to capitalize as an anchor as well as, areas to aim for

improvement. The key aspect was disrupting the hierarchy within the work unit: the employees were allowed to be the drivers of the change while management provided support and empowerment to "fail on purpose" in a "safe" risk-taking environment. Successes and failures for each Small Test of Change (STC) were shared with graphs and open dialogue with team members. Series of STC for an idea then moved into a standardization phase for implementation into practice. **Results/Findings**: In the past three years, over 24 significant changes have occurred with the help of STC. The culture of quality excellence and transparency is evident in every process, exchange, and behavior. Successful changes include:

- Acquired the testing responsibility of Perioperative Glycemic Monitoring in the operating room - 40% increase in glucose testing without requiring an increase in staff.
- Staffing model change to add some 10 hour shifts to provide coverage for longer procedures - overtime hours decreased 63%.
- Improvement in bi-annual employee engagement and discretionary survey scores (see image)

Conclusion: Disassembling a culture that was adverse to change and improving moral and burnout takes courage, resilience and time. STC uses successes and failures as the working gears to drive change. Failing and moving forward quickly was difficult to assimilate in a highly regulated environment with procedures and policies. As small successes increased and were sustained, an emotional change was evident. The elephant became smaller as employee empowerment drove the change to share ideas and celebrate success.
Employee Engagement/Discretionary Survey Scores.

TABLE.

Questionnaire	Percent Positive			% Change
	2011	2013	2015	
My work unit continuously improve service	67	79	93	+28%
My work gives me a sense of achievement	75	64	86	+13%
My work unit will speak up that will affect patient care	33	64	86	+62%
My work /personal life is balanced	33	64	75	+56%

AP75

A Practical Approach to Project Management in a Busy Transfusion Lab

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Background/Case Studies: In a large transfusion lab with two campuses, there are often many projects (PJs) running their course at any given time. These PJs are led by a management team member (MTM) and can include the involvement of technologists at the bench level. The need for a more efficient method of managing PJs was identified, as there was a lack of planning and communication, timelines were unknown, and roles were ill-defined. Coupled together, these issues led to significant delays and decreased quality of completed PJs. The goal of implementing project management (PM) concepts was to create a streamlined process whereby PJs would be planned, executed, and completed in an orderly and concise manner. **Study Design/Methods**: As new PJs were identified, staff members were chosen by MTMs based on their knowledge, skill, and workload. The role of Project Lead (PL) was assigned to an MTM by leadership and included responsibility for the timeline, identifying problem issues, and execution of tasks. Depending on the size of the PJ, an adequate number of members were identified and assigned to perform specific tasks. The PL and their team were then tasked to complete three basic, lab-developed PM forms including a charter, a stakeholder analysis, and a decision log. The charter was used to define the scope and objectives of the PJ. The stakeholder analysis was used to identify individuals involved in or affected by the PJ, and the decision log was used to document important decisions that were made and who made them throughout the course of the PJ. These documents were presented at a standing, bi-weekly PM meeting. This meeting additionally served the purpose of producing regular updates from each PL on the status of their PJs while allowing for discussion on relevant issues. PJs were initially tracked on a spreadsheet; however, an institutional PM database was later identified for use. **Results/Findings**: A survey (SV) was sent out nine months after implementing this PM process, and results showed that 100% of participants felt that there was an improvement in how PJs were managed. Additional SV results showed that 60% of participants felt that PJs were completed in a more efficient manner and 90% felt that the PM tools that were introduced were beneficial in helping them plan their PJs. Lastly, 100% of participants felt that communication had improved through the PM bi-weekly meeting, as they felt they were regularly informed and updated on the status of all PJs taking place within the busy Transfusion Laboratory. **Conclusion**: By introducing basic PM tools and concepts into our laboratory, significant improvements were made in the areas of planning, organization, and communication regarding PJs. Likewise, the implementation of a standing PM meeting has allowed for increased efficiency as well as accountability and communication.

AP76

Operational Excellence Used to Improve Test Result Reporting Time

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Background/Case Studies: Blood donor collection centers are highly dependent on the timely release of test results in order to label blood products for transfusion. Multiple factors can influence the laboratories' ability to report results. As a means to improve performance, a large multisite donor screening organization implemented Operational Excellence (OE). OE is a known journey of continuous improvement which will drive organizational improvement. Within this organization, the Shingo Model was used along with the application of universally accepted OE principles, management system alignment, and improvement techniques. The organization adopted the slogan "Everyone, Everywhere, Everyday" as a guide to continuous improvement. **Study Design/Methods**: In February 2014, executive personnel were introduced to OE. Next, an OE assessment was conducted to evaluate where the organization stood in supporting the behaviors of OE and established goals. Leaders were then trained in OE Leader, which included an overview of OE, Cultural Operating System, and Role of the Leader, Coaching Routine, Expectations, and Self-Assessment. Policy Development occurred to identify the metrics that aligned with business goals. The OE overview and huddle concepts were presented to all employees. In July 2014, daily huddles were initiated; a short meeting (labs and key assay vendors) in which daily and weekly metrics are tracked, problems and opportunities for change are defined, action items reviewed, and escalation implemented as needed. One focal point of the daily huddle was to monitor the daily release of % results reported on time and identify means to improve the labs capability. **Results/Findings**: Between January 2014 - March 2016, the laboratories average result on time reporting were evaluated. At 6 months before OE was introduced, the labs performance was 86.8% with a 92.0% goal. Post OE, for the remainder of 2014, a 2.9% improvement was shown. This continued in 2015 for another 2.5%. Quarter 1 of 2016 is at 93.7%. **Conclusion**: The implementation of OE and its 10 guiding principles has shown a marked increase in our ability to improve our service to clients. The successful application of OE in relation to specific performance improvement implies applying OE principles to other areas of CTS is likely to enhance our ability to improve the client experience. Using correct principles and new paradigms accelerated the flow of value, alignment and empowerment of employees, and transformation of the organization's culture.

TABLE. Percent Test Results Reported on Time

Period	2014	2015	2016
1st Quarter	87.9%	91.6%	93.7%
2nd Quarter	88.0%	92.5%	NA
3rd Quarter	89.7%	92.3%	NA
4th Quarter	90.8%	93.3%	NA

AP77

Applying Innovative Marketing Principles to Maintain Morale and Engagement During BECS Implementation

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Background/Case Studies: While traditionally considered an IT and laboratory project, BECS implementation is actually an enterprise level, resource and time intensive endeavor. Maintaining employee morale and engagement is critical to successful implementation. Employing professional marketing techniques this project used creative and innovative approaches to sustain project focus, strategic alignment and team cohesiveness, and ultimately drive success. **Study Design/Methods**: Designated an organizational strategic goal, the project was branded to help establish and maintain a clear,

consistent and compelling vision of the purpose, goals, and benefits. A graphic icon was developed and used throughout all communication platforms supporting strategic alignment. A name and logo were created for the core implementation team, recognizing their key roles. Regularly published project-specific newsletters showed incremental progress featuring articles authored by director project champions to demonstrate and garner support for ongoing effort. Using the same tactics as for donor recognition and rewards, milestones were professionally packaged, celebrated and distributed on two levels. Executive management personally conferred rewards to the core team, who in turn engaged all staff in 1:1 marketing with milestone promotional items. In the intense two months prior to go-live, a large scale interactive poster provided the format both to channel the focus with a highly visible daily countdown calendar and humanize the effort with staff generated content incorporating humor and accomplishments. Go-live weekend was a branded experience that created tangible demonstration of leadership commitment and support, as well as a venue for organization wide team engagement. The conceptualized theme of a championship team included a locker room, mascot, and café. More than just staff meals, the Go-Live Café had a dedicated location, published menus, and set hours of operation reinforcing genuine care. **Results/Findings**: The scope and length of the project challenged employee stamina and morale. The project impacted 91% of staff, required a 3-month embargo of paid time off, and increased overtime by 155%. Despite these challenges, the marketing strategies proved effective. In fact, the remaining non-impacted staff wanted to participate and volunteered to work the entire 4 day go-live weekend, creating a high-energy atmosphere. Final data migration validation was completed and approved in 1/3 less time than projected. **Conclusion**: The new BECS implementation was successful and surprisingly smooth. The key team survived intact and the entire organization emerged stronger and more cohesive with newfound confidence.

AP78

Building a Transfusion Dashboard in an Electronic Medical Record (EMR)

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Background/Case Studies: Clinicians often call the Transfusion Service (TS) to ask about lab testing, including expiration of T&S, if a blood type verification (BTV) is required, and if blood products are ready, especially for patients going to the OR. At our institution, patients are required to have a BTV and a current T&S to receive crossmatched blood products. For inpatients, a T&S is valid for 72 hours, and for outpatients having elective surgery, a T&S is valid for 29 days as long as they have not been pregnant or transfused in the 3 months prior to date of collection. Though all of this information is available in our EMR, clinicians had difficulty accessing this information in a timely manner, since it was separated in the EMR, and it often required multiple clicks and prior knowledge of where to find it. Sometimes transfusion orders were placed without active T&S or BTV, and this led to more work for TS staff with reminder calls and blood product delay, even on the day of surgery. Since our institution moved to another EMR, EPIC systems, we leveraged this transition time to build a homepage within the patient's chart in the EMR to house all relevant transfusion medicine information. **Study Design/Methods**: Anesthesiologists, nurses, hematologists, and clinical informaticists explored workflows and brainstormed about content for this patient-centric real-time dashboard in the EMR. We modeled our dashboard from work done in another EMR, Cerner, at Seattle Children's, and to our knowledge this is the first Transfusion Dashboard built in EPIC systems. Our information technology team spent about 12 months to tackle issues with interface of different information systems and meaningful display of data. It went live in May of 2015 after many iterations and accuracy assessment. The report includes: patient allergies, current consent, T&S and expiration, BTV, blood products ordered & ready, relevant hematology laboratory values including CBC and coagulation studies, and required premedications prior to blood product administration. As a proxy of successfully providing valuable information, we will measure the number of requests from TS to the OR for T&S or BTV on the day of surgery for 3 months prior to go-live of this report, and for a 3 month period after this report was available to clinical staff. We will assess the anticipated decrease in requests with simple descriptive statistics. **Results/Findings**: Feedback for our Dashboard has been overwhelmingly positive, especially among OR staff who can easily ascertain if a new T&S is required prior to surgery, or if appropriate blood products are ready. We hypothesize that TS staff will make less requests for T&S and BTV for those patients on the OR schedule after this report went live. **Conclusion**: We built a clinically valuable Transfusion Dashboard to give clinicians all relevant data to avoid delay in transfusion.

AP79

Assessment of Serological Techniques and Reference Laboratory Usage in the Transfusion Medicine Laboratory

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Background/Case Studies: In the Transfusion Medicine Laboratory, we must often do more with less, requiring streamlining of testing processes and increased use of reference laboratories for more complex testing. We developed a survey to evaluate current serological testing methods among Transfusion Medicine laboratories across the United States of varying locations, size, patient populations, and staffing levels. This survey was used to evaluate the variations in methods used and the extent of testing to determine if differences depend on region, size, or type of facility, and to analyze the perceived delay in patient treatment due to referral testing. **Study Design/Methods**: A survey consisting of 49 questions was prepared and electronically distributed to approximately 250 different transfusion service and reference laboratory facilities across the United States. The survey evaluated the type of facility (teaching, non-teaching, or reference laboratory), size of facility by number of hospital beds, extent of testing, testing methods, and sample referral frequency, and perceived delays, according to location (region and rural vs. urban). Completed surveys were returned electronically and all information was reviewed and entered into a database for analysis. All survey responses were anonymous. **Results/Findings**: A total of 176 completed surveys were returned, representing all regions of the United States. All facilities surveyed perform type-and-screen and 94% also perform simple antibody identification, while 75% of facilities perform some complex antibody identification. Gel or solid-phase testing is frequently utilized in laboratories of all sizes (91%), with 15% of facilities with fewer than 200 beds reporting no use of tubes in routine testing. However, 14% of labs in the West and Southwest regions reported no use of gel or solid-phase testing. Many facilities utilize Reference Laboratories for resolution of complex serological cases (94% of facilities with fewer than 500 beds). Most facilities (62%) note a delay of up to 24 hours when specimens are sent to the Reference Laboratory, with 20% noting a delay of more than 1 day. Delays are more common in the Northeast and Southeast regions, with 43% and 26%, respectively, reporting delays of more than 1 day. **Conclusion**: Survey responses represented differing facility size and locations throughout the US. Facility size, by bed number, most influenced the methods employed and extent of testing in various regions and localities. Facilities with larger number of beds reported greater diversity in techniques compared to others. While manual and automated gel and solid phase are widely used, some areas still use only tube testing for routine procedures. The complete elimination of tube testing by some facilities may result in increased use of reference labs, ultimately delaying transfusion by 1 or more days.

AP80

Engaging Young Blood Donors through an Essay Contest

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Background/Case Studies: Finding new ways to interest people in blood donation is a perpetual challenge for blood collectors, and it is particularly difficult to capture the attention of younger audiences. In targeting messages to a particular age segment, it is important to find voices, narratives, and themes that are authentic and relatable. Soliciting testimonials from students can provide content and spokespersons for marketing and communications aimed at their peers. By surfacing such stories that carry emotional power and situational relevance, the blood center is better equipped to connect with young donor prospects. **Study Design/Methods**: We ran an online essay contest for eight weeks seeking submissions from high school, technical school, and college students on the topic, "How has blood donation changed your life?" The 1st, 2nd, and 3rd place prizes were $1000, $500, and $300, respectively. We publicized the opportunity both on our website and via our blood drive coordinators who work in educational institutions. We used a customized software program to manage entries, capture author details, secure copyrights, facilitate judging, and tally ratings. A panel of five recruiters served as judges, using thematic relevance, emotional impact, publishability, originality, and effort as criteria. **Results/Findings**: Our contest yielded a total of 75 entrants from 56 different schools (36 high schools, 16 colleges, and 4 technical schools). We had a broad based response, with

no institution having more than three submissions and only four reaching that mark. Females were better represented than males by a ratio of 51 to 24. Blood drive experiences were shared from the perspective of the donor (45 essays), coordinator/sponsor (11), or both (10). Twenty-one essayists highlighted their first time giving. A blood recipient's view was offered by 47 writers who related stories of self/author (19), family member (28), and friend/other (11); and eleven of these linked together patient combinations. The most common theme explored was the inspirations and motivations to become a blood donor; and 21 submissions described overcoming fear of needles (5), anxiety (9), or both (7). Surprisingly, five of the contributors mentioned donor reactions or adverse events. In the near term, a welcome side benefit of the contest has been opening relationships with schools that did not previously have blood drives with our blood center, but had students who participated. Several new drives have been booked via these contacts. There has not been enough time lapsed yet to evaluate changes in the essayists' donation behaviors as a result of the contest. **Conclusion**: An essay contest is a viable way to solicit a wealth of testimonials from young donors about the importance of giving blood. As such, it represents a new recruiting tool for mining content, building awareness and strengthening relationships.

AP81

Much Ado About Nothing: Preparations Before and Lessons Learned After the Papal Visit

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Background/Case Studies: The World Meeting of Families occurred in Philadelphia on 9/22/15-9/25/15 and culminated in a visit from Pope Francis on 9/26/15-9/27/15. The papal visit was designated as a National Special Security Event, with millions of visitors anticipated. Security measures implemented around the papal visit included widespread road closures and public transportation restrictions. The hospital system cancelled all elective procedures and outpatient transfusions from 9/25/15 through midday on 9/28/15. Upon resumption of outpatient transfusions, extended hours were offered to accommodate the backlog of patients. **Study Design/Methods**: In anticipation of the above events, the hospital blood bank and hospital blood donor center made significant efforts to prepare for large crowds, transportation challenges, and emergency situations. **Results/Findings**: The blood bank discussed blood product availability and logistical issues with blood suppliers. Red cell inventory was maximized in the weeks leading up to the papal visit in anticipation of possible delivery delays. When possible, HLA-matched platelets and antigen negative red cell units were ordered in advance for the chronically transfused. Additional platelet units were requested for delivery prior to the planned disruptions in transportation and once elective procedures and outpatient transfusions resumed. Blood product transportation between the system's two hospitals was complicated by road closures, necessitating coordination with hospital command centers and law enforcement. Blood bank staffing was increased to weekday levels for the duration of the papal visit, with twelve-hour shifts and personnel sleeping in house, as necessary. In case of communication failure, medical coverage was redundantly available by cellular telephone, landline telephone, and text pager. Portable 800 Megahertz radios were also available to blood bank staff and blood suppliers. In case of computer server failure, sufficient downtime forms were available. An 8/25/15 broadcast email encouraged employees to include blood donation in their papal preparations. In subsequent weeks, the hospital blood donor center collected 6 apheresis platelet units and 240 whole blood units. These donations included those from 73 first-time blood donors. Although the papal visit was highly anticipated, the event was largely uneventful. Blood inventory and staffing were adequate, and transportation challenges were satisfactorily overcome when additional platelet units were required. **Conclusion**: The papal visit preparations were a learning experience and provided excellent training for large-scale, planned events, as well as verified internal/external disaster plans. As always, cooperation between the blood bank and blood suppliers is essential, as are internal efforts to ensure adequate staffing and inventory.

AP82

World Blood Donor Day: How Sanquin and WHO Joined Forces to Create a Global Message

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Background/Case Studies: "Just imagine . . . that the people you've saved, know who you are."

On June 14, 2016, we celebrate World Blood Donor Day. This year The Netherlands is host of the global event. 2020 is the target year for all countries to obtain 100% of blood supplies from voluntary unpaid donors. In a unique partnership, Sanquin and WHO co-produced the global campaign with a greater reach and higher production values than we have had before. The objectives of WBDD were the following:

- thank blood donors for their life-saving gift and highlight the theme of blood connecting us all
- Create wider public awareness of the need for regular, unpaid blood donation, and inspire those who have not yet donated blood to start donating, particularly young people in good health
- Promote and highlight the need to share life by donating blood
- Focus attention on blood services as a community service, and the importance of community participation for a sufficient, safe and sustainable blood supply
- Persuade ministries of health to show their appreciation to regular voluntary unpaid donors and commit to self-sufficiency in safe blood and blood products based on 100% voluntary, unpaid donations

Study Design/Methods: The theme of this year is "Blood connects us all." By thanking blood donors, it highlights "sharing" and "connection" between blood donors and patients. In addition, the slogan "Share life, give blood" was adopted to draw attention to the contribution voluntary donation systems have in encouraging people to care for one another and promote community cohesion. The campaign aims to highlight stories of people whose lives have been saved through blood donation, to motivate regular blood donors to continue giving blood, and motivate people in good health who have never given blood to begin doing so. **Results/Findings**: The results of this effort include the following:

- A global unified message to thank blood donors,
- A global message to raise awareness for realizing 100% of the blood supplies from voluntary unpaid donors.
- A unique partnership with WHO, in which we were united in sharing the message of WBDD.
- Interest from all over the world in using the campaign and embracing the idea of working together on a campaign for WBDD.
- Giving countries with less means the opportunity to have professional campaign materials.
- Concrete numbers of viewers, countries who used the campaign, etc, will be available after June 14, 2016.

Conclusion: When Sanquin and WHO joined forces, they created a partnership that has not been seen before by WHO anda WBDD host country. Working together to create a global campaign with one message - to raise awareness for voluntary and non-remunerated blood donation and save blood for all. This collaboration has been so successful plans are already being made for next year's campaign.

AP83

A Pilot Study to Assess the Effectiveness of Pre-Donation ABO Rh Blood Typing in Improving Public Engagement and Donor Recruitment in Uganda

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Background/Case Studies: Pre-donation ABO Rh blood typing (referred to here as "What's Your Type?" activity; hereafter WYT?) is commonly deployed as a donor recruitment tool in the US, Canada and Europe. However, it is largely unknown in low-HDI countries.

This project - a collaboration between a charity, a leading European blood collector and the blood authorities in Uganda, Africa - introduced WYT? activity on a pilot basis in the capital city, Kampala. The pilot period is March-June 2016, with evaluation of outcomes scheduled for July 2016. **Study Design/Methods**: The essential elements of introducing WYT? activity are i/operational design that integrates WYT? with routine donor recruitment and blood collection activity and enables data collection for analysis and evaluation ii/provision of ABO Rh testing components (lancets; antisera; trays etc) iii/provision of marketing and promotional materials ("point of sale" elements to communicate the WYT? proposition; posters; blood group confirmation cards etc.) iv/design and delivery of training.

An online data-capture tool was developed as part of the pilot to track progress against the pilot target of 1,500 individuals typed and also to enable analysis of the impact of WYT? activity.

Outcomes will inform whether a WYT? approach should a/be routinely adopted by the blood authorities as a business-as-usual activity in Kampala b/whether WYT? should be extended to other locations within Uganda c/whether the WYT? approach could be recommended to other countries in Africa and beyond. **Results/Findings**: At the time of abstract submission no

outcome data is available, but analysis to be conducted in July 2016 will provide measurable outcomes against the following:

- the total number of individuals typed and average per WYT? Event
- the number of new businesses and community groups engaged through WYT? activity
- the conversion rates for attendees at a WYT? event going on to make one or more voluntary blood donations
- the accuracy of ABO Rh types given to individuals at a WYT? event, determined by cross-referencing the laboratory-determined ABO Rh results of those who subsequently become blood donors
- the most productive types of WYT? event (open or closed to the general public) and location (churches, businesses, healthcare facilities etc) to better inform future approaches.

Additionally, data will be used to challenge or validate current assumptions about the prevalence of ABO Rh types in Kampala. **Conclusion**: If WYT? activity can be shown to add value in low-HDI countries as a cost effective engagement and donor recruitment tool, it will be an important finding with implications for blood services around the world.

AP84

Progress in the Development of the Afghanistan National Blood Safety and Transfusion Service

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Background/Case Studies: In 2009, the Afghanistan National Blood Safety and Transfusion Service (ANBSTS) was established with responsibility for the development and coordination of blood transfusion services nationally. The ANBSTS established five Regional Blood Centers: Kabul, Mazar-a-Sharif, Herat, Jalalabad, and Kandahar. **Study Design/Methods**: The initial activities involved establishing 1) facilities, 2) structure and function of the ANBSTS, 3) human resources, 4) training, 5) blood donation, 6) quality systems, and 7) mentoring. **Results/Findings**: Facilities have been upgraded and power is dependable. Human Resources: There are 130 staff members and three medical officers at the Kabul Regional Blood Bank: 7 in management, 12 administrative, 3 professional, 59 technical, and 48 Support staff. An additional 26 technical staff work in 7 Kabul hospital branches. The Regional Blood Bank in Herat has 9 staff, Jalalabad 16 staff, Mazar-a-Sharif 7 staff, and Kandahar has 12 staff. Training: Thirty training sessions have been held, including but not limited to the following: biohazard safety, writing of SOPs, introduction to quality, quality management, clinical aspects of quality, introduction to infectious disease testing, blood safety and transfusion, transfusion-transmissible diseases, WHO donor screening guidelines and donor selection, blood collection, risks of blood donation, blood donor motivation, the ABO system, basics of blood bank immunohematology, antibody screening, compatibility and AHG testing, other blood group systems, transfusion reactions, Good Manufacturing Practices, component therapy, techniques of transfusion, and patient and sample identification. Regional workshops were conducted in Jalalabad and Mazar-a-Sharif. Separate trainings were held for 100 physicians, nurses, and midwives covering transfusion therapy, complications of transfusion, and prevention and management of peripartum hemorrhage. Blood Donation: About 30% of blood is collected from VNRD and the remainder from family replacement donors. There is good progress in increasing the blood supply (see Table). Blood Processing: Blood is routinely tested for ABO, Rh, HIV, HBV, HCV, and syphilis. Transmissible disease testing is done with rapid test reagents. Efforts are underway to implement ELISA. ABO and Rh typing have been converted from the tile method to the tube. Components: Equipment and procedures are now in place to prepare components. **Conclusion**: The ANBSTS now has a trained capable staff and quality operations. From 1997 to 2015, there was a huge increase in blood collections. There is a cadre of physicians, nurses, and midwives trained in transfusion medicine.

TABLE.

Year	Total Units	Year	Total Units	Year	Total Units
1997	17,947	2002	24,789	2013	78,761
2000	25,880	2008	35,662	2014	64,126
2001	13,751	2012	49,887	2015	142,887

AP85

WHO Eastern Mediterranean Region: Blood Safety and Availability

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Background/Case Studies: WHO has been at the forefront of the movement to improve blood safety and availability as mandated by successive World Health Assembly resolutions of 1975 and the Regional Committee resolution off 1987. However, many countries in the Eastern Mediterranean Region (EMR) still face major challenges in ensuring availability, safety, quality, accessibility, affordability, and clinical efficacy of blood. In addition, humanitarian emergencies and armed conflicts in the region have increased the demand for blood and made delivery of these lifesaving products challenging and complex. **Study Design/Methods**: Data on blood safety and availability were collected (1 January to 31 December 2013) from EMR countries through a WHO Global Database on Blood Safety (GDBS)-linked survey. Data entry and analysis were conducted using Microsoft Office Access (2010 version). **Results/Findings**: Findings indicate gaps in all key element areas of a national blood system (NBS), such as leadership and governance, coordination and collaboration of NBS, provision of safe blood, patient blood management and clinical transfusion, and quality system and management. In 2013, about 7 million units of whole blood were collected. Blood donation rates were 0.6 to 28.9/1000 population. The proportion of voluntary non-remunerated blood donation (VNRD) was 65.8%, with 34.7% first-time donors. Half of the EMR countries have NBS. However, despite the existence of these NBSs and their vital role in the implementation of essential interventions for Reproductive, Maternal, Newborn and Child Health, delivery on Universal Health Coverage, and achievement of the EMR 2012-2016 strategic public health priorities, overall, inadequate attention has been given to blood services as an essential part of the national health system. The WHO EMR Office developed a 10-year (2016-2025) Regional Strategy for Blood Safety through broad consultation with NBS providers, regional and international organizations, and experts. This addresses the identified GDBS gaps with the aim of improving the health of nearly 660 million people in the 22 EMR countries. It will guide countries to develop and strengthen NBSs to ensure the continuity, sufficiency, sustainability, and security of national supplies of safe and efficacious blood to meet each nation's need. **Conclusion**: The strategy will play an important role in integrating NBSs into the healthcare system as a crosscutting service: to support the implementation of WHO resolutions and Executive Board Decisions on safety, quality, and availability of blood (WHA28.72, WHA58.13, WHA63.12, EM/RC34/12); on Guiding Principles on Human Cell, Tissue and Organ Transplantation (WHA63.22); on Principles for global consensus on the donation and management of blood, blood components and medical products of human origin (EB136.2); on Hepatitis (WHA67.6); on Sickle-cell anaemia (WHA59.20); and on Thalassemia and other haemoglobinopathies (EB118.R1).

AP86

Improving Blood Management System (BMS) Efficiency at the Egyptian National Blood Transfusion Services (ENBTS) through Implementing Reliability, Availability, and Serviceability (RAS) Testing

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Background/Case Studies: RAS testing is an essential step in the application of the BMS that was initially implemented as a pilot between Tanta Regional Blood Transfusion Centre RBTC and Cairo (NBTC) at Egyptian blood banks. RAS testing is a type of non-functional testing performed using Test Cases (TC). A TC is a method to verify compliance against specific requirements; A TC acts as the starting point for any test execution.

Availability Results				
State	Number of TCs		First Run Result Percentage	Final Result percentage
	High Severity	Medium Severity		
Passed	12	2	45.2%	74.2%
Fail	11	1	38.7%	9.7%
Pending	5	0	16.1	16.1%
Total TCs #	28	3		

Serviceability Results				
State	Number of TCs		First Run Result Percentage	Final Result percentage
	High Severity	Medium Severity		
Passed	14	0	33.3%	76.2%
Fail	3	2	57.2%	23.8%
Pending	2	0	9.5%	0.0%
Total TCs #	19	2		

1.Reliability:which reflects the ability of a system to perform its required functions under stated conditions for a specified period of time, it is divided into:
–Avoidance
–Detection
–Repair
2.Availability:to reduce and eliminate downtime; The BMS divided availability into two levels:
–High availability(duplicity)
–Continuous Availability(single point of failure)
3.Serviceability:early detection of faults that can decrease or avoid system downtime.
Study Design/Methods: A)Using dynamic testing (white box technique) TCs were generated by qualitative values to comply with IEEE 829 specifications, to ensure effective testing, All of the providing company's documents were implemented in order to determine the scope of RAS testing, which includes coverage rate of TCs, item description, site, reference, severity, results, impact) **Results/Findings**: The following are results for TCs executed for the pilot project at Pre-GoLive stage. Reliability: The IT Team Generated 109 TCs, that are ready to run;at the next cycle of project. Availability: The executed TC illustrated how the efficiency of availability increased from 45.2% to 74,2%, by an average of 29% Table(1) Chart(1) Serviceability: The executed TC illustrated how the efficiency of serviceability increased from 33.3% to 76.2%, by an average of 42.9% Table(2) Chart(2) **Conclusion**: Any efficient system cannot operate without RAS testing, This was clearly illustrated by our study that showed how testing Serviceability and Availability had a direct impact on raising the efficiency of the BMS system from 40.4% to 75.0% (on average, 34.6%). This highlights how it is fundamental in converting the BMS system from a traditional to a highly efficient Ideal system. Such an increase in efficiency is advantageous, as it can avoid downtime, can cause auto-detection and auto-repair of errors, and greatly reduces effort and cost for administration and system support, respectively. It also constitutes a building block when considering future scalability and Key Performance Indicators (KPI) preparation.

AP87

Enhancing the National Blood Transfusino Serrvices Through Speech-Recognition Technology

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Background/Case Studies: The Egyptian national blood transfusion services (ENBTS) is currently engaged in a ground breaking process that aims to automate all of its manual work by using the blood management system (BMS). The ENBTS implements information systems through the BMS. The blood donation process usually consumes a great deal of time and effort from both donors and medical staff; this can be overcome by introducing a concrete information system that allows donors and blood donation centers to use speech recognition, which permits text dictation and voice commands interchangeably. **Study Design/Methods**: The Blood Donation System based on automatic speech recognition consists of 5 layers, namely, input speech, preprocessing, speech feature extraction, and classification scheme. The input layer represents a dataset of short length voice that is focused on the voice signal. Those voices are fed to preprocessing layer, in which voice localization algorithms are applied. And then a voice detection algorithm is applied to extract and isolate the noise from the background. Finally, the voice localization is applied based on specific threshold to extract the signal. The feature extraction stage seeks to provide a compact representation of the speech waveform. This form should minimize the loss of information that discriminates between words, and it provides a good match with the distributional assumptions made by the input speech. In the blood bank, medical transcriptionists listen to voice recordings that physicians and other healthcare professionals make and convert them into written reports. They may also review and edit medical documents created by using speech recognition technology. Transcriptionists interpret medical terminology and abbreviations in preparing patients' medical histories, discharge summaries, and other documents. **Results/Findings**: In this section, the evaluation of NBTS BMS with speech recognition, and a comparison of their performance are given. The system model is tested using cross validation and the evaluation is based on: (i) Accuracy, which is the correct classified records, over all records, (ii) true positive rate (TPR) where improve performance to 96.2% **Conclusion**: Developing NBTS through a speech recognition system, is a revolutionary idea that if utilized can be of great value in the blood bank in saving time and effort spent on documentation. It will also include donors with special needs in the donation pool, and have great community impact.

TABLE. Improve National Blood Donation System

Input Speech	with out Speech Recognition	with Speech Recognition
N=100	82.8%	91.3%
N=400	85.2%	93.9%
N=600	84.4%	95.8%
N=800	88.2%	95.6%
N=1000	86.2%	96.2%

Quality Management

AP88

The Management of a Quarantine or Recall When a Significant Number of Blood Products Are Involved

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Background/Case Studies: When issues arise within a blood manufacturing facility that could have a negative impact on a large number of blood components regarding safety, quality, or efficacy, a process needs to be in place to escalate the event and manage a quarantine or recall quickly to prevent transfusion. The ability to execute as expediently as possible with no impact to patients was the key criteria. **Study Design/Methods**: A procedure was created that identifies key personal and outlines their roles and responsibilities within a cross-functional recall committee. This committee is responsible for obtaining and assessing all information regarding the event, making decisions throughout the process including the final disposition, ensuring the recall or quarantine activities can be executed, and developing appropriate communication and the management of the inventory. The process also utilized the ability to electronically quarantine in-house components by individual component type or by collection date. A supporting procedure outlines a process to electronically identify implicated components by product type, collection date and the distribution location; generic

scripts were created based on potential scenarios. Templates were created for consignee notification and reconciliation of implicated components as well as a supporting document that includes aspects to take into consideration while working through the process **Results/Findings**: An event which occurred in March 2016 triggered the Recall Committee to convene. As all required information was not available to determine the impact on products, a decision was made to electronically and physically quarantine all in-house products and all red blood cells distributed to consignees. The scripts previously created by the Information Technology department were utilized and within 1.5 hours the data including component type, unit identification number, collection date, blood group, issued date and the consignee location were available for 1051 implicated red blood cells. Notification was provided to all hospitals within the same day the issue was raised, and replacement inventory was en route to both the manufacturing location and the impacted hospitals. The ongoing investigation and the follow-up testing resulted in the eventual release of all quarantined product. **Conclusion**: The creation of a process to recall or quarantine a significant number of blood components does result in efficiently removing suspect components from transfusable inventory. The defined cross-functional team brings all lines of expertise to the table to determine the potential risk to a patient, to manage the execution of a quarantine or recall while maintaining an adequate blood supply to the hospitals.

AP89

Processing 15 Liters of Whole Blood Leads to Adequate Peripheral Blood Stem Cells for Transplantation

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Background/Case Studies: Our current practice is to process 20L of whole blood during a peripheral blood stem cell collection. This has led to prolonged collection times, increased risk of citrate toxicity, and additional patient discomfort. We performed a study to determine 1) if processing 15L of whole blood would lead to a significant difference in CD34+ cell yields, 2) the number of patients who would meet goal at 15L compared to 20L after the first day of collection, and 3) the additional length of time necessary to process 20L. **Study Design/Methods**: We performed a retrospective review of patient charts from 2012 to 2016. 129 peripheral blood stem cell collections had CD34+ cell counts obtained during the collection. CD34+ cell counts were obtained at 15L of whole blood processed as well as at 20L of whole blood processed for 60 collections. Of these, 33 collections performed on the first day were included in the analysis. Demographic information, CD34+ cell yields (cells/kg), fraction of cells collected at 15L, number of patients that met the minimum goal of $5x10^6$ CD34+ cells/kg, additional length of time to process 20L, and collection efficiency (CE2 formula) were determined. Mean values were compared using the paired Student's t test. $P<0.05$ was considered statistically significant. **Results/Findings**: 33 collections on adult patients (5 allogeneic, 28 autologous) performed on day 1 were analyzed. A significantly higher amount of CD34+ cells/kg was collected after processing 20L compared to 15L of whole blood (mean 7.33 x 10^6/kg vs 5.96 x 10^6/kg, $p<0.0001$). The fraction of CD34+ cells/kg collected at 15L compared to 20L was 79%. 14 collections met goal after 15L of whole blood was processed. Four additional collections met goal after 20L of whole blood was processed. 15 collections did not meet goal after the first day and needed additional days of collection. An additional 82 minutes was necessary to process 5L more of whole blood (mean 263min vs 345min, $p<0.0001$). The mean collection efficiency was 39%. **Conclusion**: Processing 15L of whole blood during a peripheral blood stem cell collection resulted in the majority of collections reaching the minimum goal of $5x10^6$ CD34+ cells/kg and shortened the collection time significantly.

AP90

Assessment of Documentation Errors Following Nursing Quality Improvement Actions

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Background/Case Studies: AABB standard 5.29.1 (30th Ed) requires that a patient's transfusion be fully documented in their medical record. Such documentation shall include: transfusion order, patient consent, component name, donation identification number, date and time of transfusion, pre- and post-transfusion vital signs, amount transfused, ID of the transfusionist, and, if applicable, transfusion- related adverse events. To comply with standards, it is important to determine if transfusions are being documented as required. **Study Design/Methods**: In January 2015, an assessment of compliance with AABB standards was performed by physical examination of electronic medical records, and it was compared to the same assessment conducted in 2014. Error rates were calculated for the four following items normally documented by nursing staff: 1) unit number missing or incorrectly recorded, 2) transfusion start time missing or incorrectly recorded, 3) pre-vital signs not documented or incomplete, and 4) ten-minute vital signs not documented or incomplete. Errors for each of the four items were totaled for a composite patient error rate. Specifically, these measures were compared for patients who underwent blood transfusions from January 1-31, 2015, to those from April 1-30, 2014, at two hospital-based transfusion services. The blood transfusion records for 2015, consisting of 1,190 medical inpatients and 290 outpatients, were examined and the above documentation errors recorded. A total of 162 nurses at 43 issue locations generated these transfusion records. The blood products transfused included 1,029 RBCs, 374 Platelets, and 71 FFP/Cryo. A Chi-square test was used to compare error rates in 2014 versus 2015. **Results/Findings**: The medical inpatient comparison showed that 75% of the records had no documentation errors, a significant improvement from 70% in 2014 ($P=0.003$). Unit number missing or incorrectly recorded showed significant improvement, with an error rate of 10% versus 23% in 2014 ($P=0.003$). Pre- and 10-minute vital signs showed significant worsening with P values of <0.001 and 0.003, respectively. Of the pre-vital sign errors, 41% were a result of partial recording of vital signs. Start time showed no change. The outpatient comparison showed that 74% of the records had no documentation errors, a significant improvement from 61% in 2014 ($P=0.003$). Unit number recording error showed no change. Pre-vital sign documentation showed significant improvement with an error rate of 18% versus 27% in 2014 ($P=0.014$). Ten-minute vital signs showed no change. **Conclusion**: These data showed increased compliance with AABB documentation standards. Improvement in inpatient records resulted from unit number documentation and that in outpatient records from pre-vital sign documentation. The audit showed a need for improvement of completeness of vital sign documentation for medical inpatients.

AP91

Trends in Recombinant Factor VIIa Usage Before and After Introduction of Prothrombin Complex Concentrate

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Background/Case Studies: Four-factor prothrombin complex concentrate (4F-PCC) was approved for use in acute bleeding for reversal of vitamin K antagonists (VKA) by the US Food and Drug Administration (FDA) in 2013, resulting in the ability to reverse vitamin K-dependent anticoagulant activity without the use of fresh-frozen plasma (FFP). The aim of this study was to evaluate the trends in rFVIIa usage before and after the introduction of 4F-PCC at a tertiary care medical center. **Study Design/Methods**: Administration of rFVIIa during the time period of February-December 2013 (pre-4F-PCC) was compared to February-December 2014 (post-4F-PCC). Information was obtained from two separate de-identified datasets: blood bank and pharmacy. The rFVIIa database included indication, classified as on- vs. off-label use. Off-label use was further classified into subcategories: anticoagulant-associated bleeding, uncontrolled intraoperative or postoperative bleeding, neurological bleeding, and other uncontrolled bleeding. The 4F-PCC database included dosage information and release date. For purposes of this analysis, the following assumptions were made: 1) The patient received the product released by the pharmacy, and 2) 4F-PCC was used for reversal of warfarin. The number of patients who received rFVIIa was compared to the number of patients who received 4F-PCC. Data were analyzed using descriptive statistics, and comparison was with a t-test for unequal variance using a statistical significance threshold of $P<0.05$. **Results/Findings**: There was a 53% decrease (55 vs. 26 patients) in rFVIIa usage following introduction of 4F-PCC, with a decrease in mean monthly usage from 4.5 to 2.4 patients/month ($P<0.01$). On-label use remained unchanged (6 patients/year). The largest areas of decreased use of rFVIIa were in perioperative and neurological bleeding (Table 1). A total of 65 patients received 4F-PCC from February 2014-December 2014. **Conclusion**: Although reversal of warfarin was not specifically listed as a reason for rFVIIa administration in the majority of cases, there was a significant decrease in usage with the introduction of 4F-PCC. The categories showing the greatest decrease in use (perioperative and neurological bleeding) are acute settings in which recent anticoagulation use may greatly impact incidence and severity of bleeding. The decreased clinical use of rFVIIa

TABLE. Comparison of rFVIIa administration from February to December

Category	2013	2014	% Change
On-Label Use	6	6	0%
Anticoagulant associated	4	1	−75%
Perioperative Bleed	27	12	−56%
Neurological Bleed	12	2	−83%
Other	6	5	−17%

suggests that the introduction of 4F-PCC has provided an alternative to rFVIIa for treatment of uncontrolled bleeding.

AP92

Using a Computer Program to Improve Platelet-Refractory Patient Management and Resident Satisfaction

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Background/Case Studies: Management of platelet-refractory patients is challenging and time-consuming for transfusion service physicians. During initial evaluation of patients suspected of platelet refractoriness, the corrected count increments (CCI) and timing of post-transfusion platelet counts help assess the response to individual platelet transfusions. These will identify patients who may have immune versus non-immune refractoriness; cross-matched (XM) and/or HLA-matched platelets mainly benefit the former group. For immune-refractory patients, close monitoring of the effectiveness of each individual specialized platelet transfusion is important for continuous optimal care. Manual data acquisition and analysis become tedious, time-consuming and error-prone when a large number of patients are supported. At our institution, laboratory medicine residents acquire and analyze data from platelet-refractory patients. Manual data extraction was inefficient and a source of resident dissatisfaction. Additionally, many competing training and clinical service duties limited our residents' ability to dedicate adequate time to this process, with a potential negative impact on patient care. **Study Design/Methods**: A Python script was created to extract necessary data from the blood bank laboratory information system (LIS) (Table). The user enters medical record numbers of all desired patients for simultaneous processing and also specifies *x* number of days to analyze (T-*x*). The resulting data are copied to an Excel spreadsheet used to follow each individual patient, and CCIs are calculated for each platelet transfusion. **Results/Findings**: Previously, information from each platelet transfusion was gathered from the electronic health record and/or LIS and manually entered into individual spreadsheets tracking each platelet refractory patient. This process would typically take 20-40 minutes per patient, depending on the extent of data being reviewed, and it was error-prone. In comparison, with the computer program, extraction and analysis of up to 60 days' data for all patients take less than five minutes. Rapid access to accurate data has improved patient care. Sharp reduction in time spent on manual data extraction has significantly increased resident satisfaction, as more time can now be devoted to other areas of training and clinical service, which enhances the learning experience. **Conclusion**: By using a computer program, platelet transfusion data can be extracted more efficiently and accurately, providing optimal evaluation and improved care of new and ongoing platelet-refractory patients. The saved time has increased resident satisfaction and enhanced transfusion medicine training.

AP93

Tracking and Trending Nonconforming Blood Products at a Hospital-based Donor Center

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Background/Case Studies: A process was needed to recognize, track, and trend collected blood products that failed to meet quality parameters for intended transfusion, both before and after the product has been labeled. The goal was to develop a system to accomplish this with an aim to better understand the reasons for nonconformance, and to provide a standardized process for handling nonconforming products. **Study Design/Methods**: Examples of nonconforming products are apheresis platelets with a yield below $3x10^{11}$, leukoreduction failure, particulate matter, clots, lack of swirling, positive infectious disease markers, and positive culture results. Whole blood component nonconformance included hemolyzed plasma, leukoreduction failure, clots, particulate matter, and positive infectious disease markers. In order to track these and provide a clear roadmap for how to handle each category of nonconforming product, forms were developed for use by staff both preand post-labeling. The forms were placed into use in September 2014. Each form details the reason for the nonconformance and outlines the steps to take to investigate and notify appropriate personnel. Nonconforming products are discussed at daily morning rounds, and a decision is made as to their disposition. Completed forms are routed to the Quality Specialist for compiling, trending, and possible preventative action. **Results/Findings**: Over a period of eighteen months (September 2014 through March 2016), nonconforming products were tracked and sorted by product type and types of nonconformance. Apheresis platelets and plasma post filtration accounted for the majority of nonconformance. Twenty-five platelets had yields below $3x10^{11}$, half of these were due to infiltrates. Fifteen had a positive blood culture or rapid bacterial detection test, 13 were false positives. Five were not swirling at daily inspection. Thirty-three plasma were hemolyzed after leukoreduction filtration. Positive infectious disease markers only accounted for 4 nonconforming products, and particulate matter or clots for another 4 (2 platelets, 2 plasma). **Conclusion**: Separating out how nonconforming blood products are handled from the general deviation reporting process has led us to better understand the types of nonconformance that lead to product discard and the frequency of these events. Addition to the form of the steps to take for each nonconformance type streamlined and standardized the process for handling these products.

AP94

Previous Records Check – Activate your Archive

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Background/Case Studies: The purpose of the project is to simplify the Previous Records Check process by eliminating the need to reference archive files (pre-2006) by moving the archive into the live computer environment. Since ABO records need to be maintained for 10 years, and problem files are indefinite storage, 2016 was the ideal time to move the problem archive file to the live database. Current "Comparison with Previous Records" requires that multiple databases be reviewed for each order received in the Transfusion Service. Evaluation includes ABO and Rh, difficulty in blood typing, clinically significant antibodies, significant adverse events to transfusion, and special transfusion requirements. This is an extremely cumbersome process that relies on manual recognition and matching of data and has resulted in FDA-reportable errors when specific attributes or antibodies have not been immediately recognized. **Study**

TABLE.

Data Extracted from LIS		
Transfused Platelet Units	Patient	Calculated Data
1. Issue date and time 2. Donor identification number (DIN) 3. Component type (random, HLA- or XM-compatible) 4. ABO/Rh 5. Platelet count	1. Most recent platelet count before issue time 2. First platelet count after issue time	1. Time interval between unit issue and post-transfusion platelet count (by program) 2. CCI (by Excel)

Design/Methods: A Fee for Service request was made to Sunquest requesting that all Blood Bank Administrative Archive Inquiry files be exported to a workable Excel format. Patient data prior to version 6.4 (2005) are archived in this file. The exported files contain the patient's name, medical record number, DOB, age, hospital ID number, transfusion history, blood type, antigen/antibody, and problems and comments sections. Current AABB record retention requirement 5.14.5(3) was observed, and, when present, the following information was transferred from Archive to the Production environment: comments, phenotyping, problems, antibodies, and attributes. After the data entry process was completed, the resulting information was verified for accuracy. **Results/Findings**: Out of 22 hospital sites, 18 sites had an archive file that required data entry. Once the data were sorted, they required formatting to allow ease of entry. Because the download files were in all capital letters, we could not use translation codes, since r'r would look the same as R'R. Instead, we used expanded definitions for data entry. Download files were only delimited to field. A single field might include antibodies, comments, and adverse events. We needed to break this information down further to allow it to be sorted more easily. After completion of data entry, data review was required. A 95% confidence limit was our level of comfort for data review. **Conclusion**: The following list includes a number of decision points and challenges discovered along the way that will help in planning future projects:

- Time
- Patient confidentiality
- Confidence limits for data review
- IT resources
- Capital expenditures
- Staff impact

As we are completing the data entry, we have discovered that much of the information in the Archive files has already been moved to the live environment, exposing duplication of effort by the staff in performing a review of archive records.

AP95

Computerized Physician Order Entry Improves Compliance with Attestation Documentation for Uncrossmatched Blood

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Background/Case Studies: Patients experiencing bleeding emergencies may require blood transfusion before compatibility testing can be completed. In these situations, the records must contain a signed statement from the requesting physician, indicating that the situation was sufficiently urgent to require emergency release of uncrossmatched blood. In April 2012, our hospital implemented the use of computerized physician order entry (CPOE). Orders placed for emergency release of uncrossmatched blood using CPOE automatically include the required attestation statement. Prior to CPOE (and currently when orders are placed verbally), the physician's attestation is obtained by physician signature on the emergency release paperwork or by electronic co-signature of an attestation statement entered into the electronic medical record by the Transfusion Medicine Service. **Study Design/Methods**: We conducted a retrospective review of blood bank and medical record documentation for all patients requiring emergency release of uncrossmatched blood during three separate six-month periods: 1) July-December 2010 (pre-CPOE), 2) July-December 2012 (early after CPOE implementation), and 3) July-December 2015 (established CPOE system). We measured and compared compliance with attestation documentation, the method of attestation documentation, and the time required for attestation completion. **Results/Findings**: Results are shown in Table 1. Implementation of CPOE was associated with improved compliance with attestation documentation (47% pre-CPOE, 100% post-CPOE; $p<0.0001$). Use of CPOE significantly reduces the time to completion of attestation documentation (30 days pre-CPOE, 3 days post-CPOE; $p<0.0001$), as the attestation is captured automatically when the order is placed. The frequency with which physicians use CPOE to order emergency release of uncrossmatched blood has increased over time (38% early CPOE, 68% established CPOE; $p<0.0001$). **Conclusion**: Use of CPOE for emergency release of uncrossmatched blood increases compliance with documentation of physician attestation and decreases the time required for completion. Utilization of CPOE increases over time, perhaps as physicians gain experience with this method of obtaining blood during bleeding emergencies.

AP96

A Multicenter Evaluation Comparing a New Automated Immunohematology Instrument with the ProVue

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Background/Case Studies: Automated analyzers in hospital transfusion services have become more user-friendly, especially to generalists working in the blood bank. The Ortho VISION® Analyzer (Vision) is an automated in vitro immunohematology instrument which uses ID-MTS™ gel card technology with digital image processing. The new instrument has a continuous, random-sample access with STAT priority processing. The efficiency and ease of operation of the instrument were evaluated by transfusion services at five medical centers. **Study Design/Methods**: De-identified patient samples were tested on the ORTHO ProVue® Analyzer (ProVue) and again on the new instrument, thus mimicking the regular daily workload pattern. Turnaround times of different test profiles were collected and compared. To evaluate the ease of use, operators rated key features of the analyzer on a scale of 1 to 5 (1 low - 5 high). **Results/Findings**: A total of 507 samples were tested on both instruments at the five trial sites. The mean turnaround times (TATs) were 31.6 minutes (SD=±5.5) with Vision and 35.7 minutes (SD=±8.4) with ProVue, which renders a 12% reduction. The comparison of TATs for test profiles between Vision and ProVue are shown in Table 1. Antibody identification with eleven panel cells was performed on 134 samples on Vision; TAT was 43.2 minutes (SD= ±8.3). The installation, operator training, configuration, maintenance, and validation processes on the instrument are all streamlined to provide a short implementation time. The average rating of training, quality control, maintenance, serial dilution, remote result review, and efficiency features by the operators was 4.1 to 4.8. Three opportunities for improvement were identified: flexibility when editing QC results, a more adaptable maintenance schedule, and more printing options. The capabilities to perform serial dilutions, to accept pediatric tubes, and to review results by e-Connectivity® are enhancements over the ProVue. **Conclusion**: Vision provides shorter TATs compared to ProVue. Every site participating in these field trials described a very positive experience using Vision.

TABLE.

	PERIOD 1 JULY-DEC 2010 (N=64)	PERIOD 2 JULY-DEC 2012 (N=53)	PERIOD 3 JULY-DEC 2015 (N=82)	p value
ATTESTATION DOCUMENTED	30 (47%)	53 (100%)	82 (100%)	<0.0001
AVERAGE TIME TO DOCUMENTATION (DAYS)	30 (2-115, SD26)	13 (0-84, SD22)	3 (0-42, SD7)	<0.0001
TYPE OF ATTESTATION DOCUMENTATION				
SIGNED PAPER FORM	0	8 (15%)	3 (4%)	
SIGNED NOTE IN EMR	30 (100%)	25 (47%)	23 (28%)	
CPOE	0	20 (38%)	56 (68%)	<0.0001

TABLE. TATs of different test profiles

Test profiles	Number of samples performed	Vision Turnaround Time	ProVue Turnaround Time
All Test Profiles (ABO, Rh, T&S, Cord, DAT, panels, crossmatch)	507	31.6 SD ± 5.5	35.7 SD ± 8.4
Type and Screen	381	32.2 SD ± 4.5	37.0 SD ± 7.4
ABO and Rh typing (forward and reverse)	61	27.5 SD ± 5.6	32.4 SD ± 9.8

AP97

Managing QC; Can U.S. Blood Banks Track QC in Real Time?

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Background/Case Studies: As information technology and automation advance, blood banks and transfusion services are seeking easier, more thorough ways to manage quality control (QC) for the identification of shifts and trends for internal quality control (QC) performance. Although multiple options are available to track and trend QC, there are currently few options that provide real-time, intra- and potentially inter-laboratory comparison and correlation for blood banks and transfusion services. The Unity Real Time® (URT) software, widely used worldwide to track and trend QC performance, can provide a potential model for future capture of automated and manual QC results, allowing for real-time tracking and trending of all methods, reagents, and automation available in the United States. **Study Design/Methods**: A multidisciplinary team developed a questionnaire to capture information on blood bank and transfusion service performance of QC. A standardized reporting template was established from customer input so that methods, automation, reagents and frequency of QC could be collected. Data entry screens were built to mimic site-specific worksheets currently in use. Electronic barcode scanning and software interfaces were developed to eliminate/minimize manual data entry and to ensure accurate reporting of QC. Levy-Jennings charts were also developed for graded reaction analysis for shifts and trends. **Results/Findings**: QC was collected on 10 analytes, including forward and reverse ABO typing and antibody screen results. Following the AMIRUT template (Table 1), >100 possible variables were standardized and captured in Unity Real Time®, using both manual and electronic data entry. This allows the accurate and timely tracking and trending of QC as required by various regulatory and accrediting agencies worldwide. Variables are identified in the table. **Conclusion**: The Unity Real Time® software, with well-defined and validated manual and electronic data entry systems, resulted in obtaining a clean analytic dataset demonstrating the ability for blood banks to easily track and trend QC performance required by various regulatory/accrediting agencies. URT currently has the capability to allow intra-laboratory reagent and method comparison, but with a standardized reporting format and participating laboratory permission, this software can potentially be expanded to allow inter-laboratory QC comparison, a significant improvement in the evaluation of reagent and method QC performance.

TABLE. AMIRUT Template

Code	Variable	Description
A	Analyte	Antisera/Reagent Red Cell evaluated
M	Method	Slide, Tube, Gel, or Microplate
I	Instrument	Manufacturer: Analyzer
R	Reagent	Antisera/Cell Source (manufacturer or in-house)
U	Unit	Qualitative
T	Temperature	20-25C 37C 4C

AP98

Quality Approach to Investigate Donor ABO/Rh Discrepancies

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Background/Case Studies: When a donor's ABO/RH does not match historical typing, a laboratory investigation is initiated. Many discrepancies can be attributed to test system limitations and red cell antigen subgroups or variants. Once serological reasons are ruled out, the focus shifts to the collection process to determine if there was a mix-up in paper-work, specimens, data entry, or labels. Our facility used a 2-pronged approach, retesting 9 products collected before and after the index case and then interviewing the staff involved. Interviews with staff rarely provided useful information because it was difficult for them to recall details for a particular collection event several days afterwards. Our goal was to establish a new approach for prompt, tailored investigations that would resolve the case quickly and yield useful information for process improvement. **Study Design/Methods**: The BECS flags records when the current donation blood type does not match historical. Deviations are entered into our Quality (QMS) software to track investigation, RCA and CAPAs. Data from the QMS were reviewed and analyzed by a cross-functional working group that included the labs, collections, and quality. A review of 2 years of data led to "most probable," scenarios given our particular work environment, processes, and process controls. This allowed us to develop tailored investigational pathways to eliminate unnecessary investigation steps and speed up resolution. **Results/Findings**: While the facility has many process control points in place to prevent matching errors, they do still occur occasionally, particularly on busy mobile drives with crowded conditions. We identified 4 main types of mismatches that occur:See Table. By identifying the most probable points of failures, we can target staff interviews to gather timely information that helps resolve the case and leads to process improvement. In addition, we found that retesting 9 units collected before and after the index case is not useful for resolving AOB/Rh discrepancies. Instead, we adopted a time-based approach (+/- 30 minutes from start bleed time) to identify units that could have been implicated in the mix-up. **Conclusion**: Use of a logic tree to facilitate investigations based on most probable cause has reduced non-value-added retesting and provided for faster resolution of these cases.

Results/Findings:

TABLE.

Switch Type	Test Results	Point of Failure
1) Computer Record	Bag = Tube Bag and Tube ≠ Historical	Registration – visit attached to wrong donor's record
2) Donor, paperwork	Bag = Tube Bag and Tube ≠ Historical	Bedside – donors switch beds but leave paperwork and/or supplies behind
3) Test Tube	Bag = Historical Tube ≠ Historical	Bedside – side-by-side donors, pick up wrong label or wrong tube
4) Blood Bag	Tube = Historical Bag ≠ Tube Bag ≠ Bag Label	Bedside – side-by-side donors, pick up wrong label or wrong bag

AP99

Retrospective Analysis of the Utilization of an Early Candidate Pre-surgical Process in a Large Transfusion Service

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Background/Case Studies: In 2002, a hospital-based transfusion service developed an Early Candidate Pre-Surgical Sample (PSS) process designed to allow patients to be drawn well in advance of surgery. Potential benefit of the PSS process was twofold, in that it was intended to decrease potential travel costs by eliminating the need for a return trip the day before surgery for sample collection and to increase patient safety by ensuring that type-and-screen (TS) testing is completed prior to entering the operating room. This mitigates delays in providing blood products due to antibodies and other unexpected complexities encountered during testing. The PSS policy implemented allows patients who have not been pregnant or transfused in the preceding 3 months (AABB BBTS Standard 5.14.3.2-30th Ed) to have their TS drawn up to 56 days prior to surgery. If these criteria are not met, the patient needs to return within 3 days of surgery for their surgical sample (TDSS) to be drawn. The purpose of this analysis was to begin an evaluation into possible modifications to the process to increase its efficacy. **Study Design/Methods**: For a physician to order a PSS, besides meeting pregnancy and transfusion criteria, the patient's surgery should be greater than 3 days from sample draw. If not, then the physician should request that the TDSS is drawn. A one month assessment of the PSS process was conducted for the month of January 2016. The PSS drawn were provided from an electronic report and compared to the surgical date in the institution's surgical listing system to assess if the appropriate samples were ordered. **Results/Findings**: The transfusion service received 538 samples designated as PSS. Of these, 4%(21/538) did not have a surgical date listed; 39%(209/538) were drawn within 3 days of surgery and were not true PSS; 54%(292/538) were drawn 4-56 days from surgery which captured the true patients eligible for the PSS, and 3%(16/538) were drawn greater than 56 days from surgery. Further subcategorization of true PSS shows that 5%(14/292) of PSS were redrawn prior to surgery for various reasons. **Conclusion**: The results indicate that the PSS process has been a potential benefit for 52%(278/538) of eligible patients who were drawn as true PSS and did not get redrawn prior to surgery. The results also indicate room for improvement in physician education in knowing when to order the PSS based on the patient's surgical date. Further analysis of this data may include evaluating the effects of the overutilization of the PSS such as risks and benefits of a patient having an active sample beyond their surgical date. Analysis may also include the effects on testing prioritization and the process complexity of the PSS compared to the TDSS.

AP100

Blood Bank STAT Turnaround Time: Tracking Our Steps, Improving Our Process

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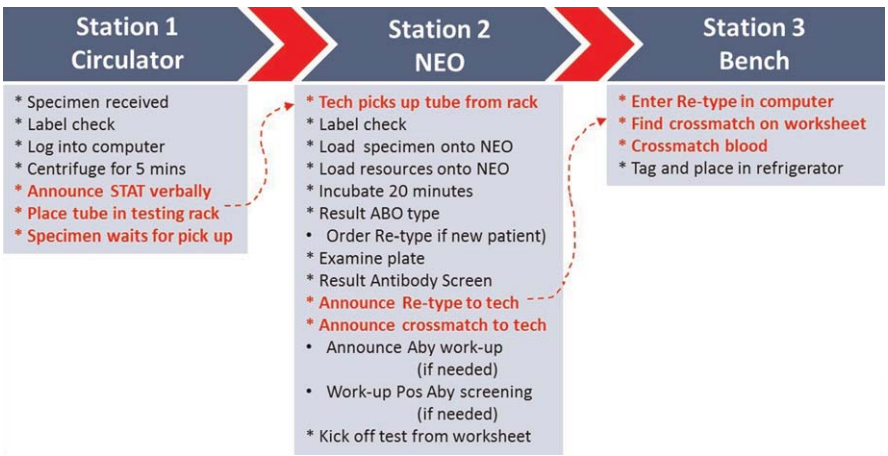
Background/Case Studies: Monitoring of STAT type and screen turnaround times (TATs) is a key indicator in a blood bank quality management program. Current internal guidelines state that a STAT type and screen result will be available within 75 minutes. A recent audit showed a failure rate of 24%, delaying transfusions and potentially impacting patient safety. **Study Design/Methods**: Process mapping established 25 unique steps in our type and screen procedure. Key communication steps were determined for time stamping. A highly visible time-tracking card was developed to serve as both an awareness prompt and an avenue to record the predetermined critical communication steps. Pre-intervention and post-intervention data was collected to evaluate the effectiveness of the quality improvement(QI) effort. **Results/Findings**: STAT type and screen turnaround times for new or previous patients decreased by 28% and 26%, respectively. The average turnaround time from login to type and screen is 68.3 minutes for new patients and 60.8 minutes for previous patients during post-intervention period. Our post-intervention performance met the 75 minute turnaround goal suggested by the current guidelines. **Conclusion**: Understanding workflow and finding the root cause(s) of a problem is critical to the success of QI initiatives. Communication gaps and non value-added steps were identified as major causes of delay in our process. A simple yet effective visual cue narrows gaps, improves the overall turnaround time and brings our practice up to standard.



25 Steps in the Process of Type and Screen with Crossmatch

AP101

Error Management After a Merger

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Background/Case Studies: With the merging of three uniquely diverse blood centers and the standardization of operational and quality processes system-wide, the Quality Assurance (QA) department was tasked to unify the newly created organization on a single system for error management with the goal of monitoring the company processes for continuous improvement. **Study Design/Methods**: Prior to merging, one of the three centers was actively using SmartCAPA™ from Pilgrim with errors categorized based on AABB Quality System Essentials(QSE) (center #1). The other two centers used either SmartCAPA™(#2) or a homegrown database(#3) with categorization based on legacy processes. The newly formed group determined that the final blood center error management process would be handled using the Pilgrim SmartSolve® Nonconformance and CAPA management applications and base the categorizations on the established QSEs (see table). The QA sections for centers #2 and #3 updated their legacy systems to categorize using the established QSE, beginning the incremental change to standardization and preparation for total integration into a single unified process. **Results/Findings**: Planning, analysis of design and user requirements were determined in the first quarter(Q) of 2015 and build was completed by the end of 2nd Q. Information for elements to capture and the final QSE categorization list was submitted and inserted into the appropriate tables by Q3 of 2015. Qualifications were completed in Q4 2015 using the procedures (SOP) drafted. A soft rollout of the application was performed in February 2016 to allow QA users to determine any additional SOP revisions needed. Operations reported errors via a manual form which were then entered by QA staff into the system. Operational staff began to use the system in March of 2016, discontinuing the use of the manual form. Monitoring

TABLE. High-level Process Categorization (QSE)

Biovigilance
Blood Administration
Blood Collection
Cellular Therapy/Patient Services
Compatibility Testing/IRL
Component Processing
Donor Suitability/History Review
Donor Testing/Donor Advocacy
Quality Program
Storage, Distribution, Transportation

by QA noted a need to review categorization of errors with operational users. Only one occurrence was logged via the Information Technology help desk of user error. **Conclusion**: Standardization of three diverse error management systems into a single process was accomplished by following a series of process steps; defining the user requirements, establishing common definitions and categories, implementing in stages and monitoring for effectiveness.

AP102

Comparing Operational Efficiencies of Two Pretransfusion Analyzers

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Background/Case Studies: Various studies have been performed on blood bank automation, with few comparing potential operational efficiencies. The purpose of this study was to evaluate the pretransfusion testing capabilities of the Ortho Vision against the Bio-Rad TANGO infinity regarding LEAN process flow. **Study Design/Methods**: A minimum of 20 runs of up to 6 samples per run were observed for each analyzer (Ortho Vision, Bio-Rad TANGO infinity) at two facilities performing approximately 13K Type & Screens (T&S) annually. Each process was mapped in detail by direct observation using Process Modellar APP (iPAD). The evaluation started at sample centrifugation completion and ended with results sent from analyzer to Lab Information System (LIS). Each was evaluated for quality (process steps, maintenance tasks), speed (operator/total cycle time), and cost (testing/maintenance personnel hours recaptured). Time studies were analyzed using Minitab v17, and statistical significance was assessed using the paired t-test, with p values of <0.05 considered significant. **Results/Findings**: Detailed process steps and maintenance tasks were evaluated/compared (Table, Part A). Time studies focused on operator time, total cycle time (operator + analyzer testing), and maintenance time (Table, Part B). Since the Ortho Vision is a relatively new analyzer on the market, many interfaces are still in the process of being established. The interface was not live at the Vision study site. The Vision operator and total cycle times thus demonstrated a significant difference (delay) in times when compared against the TANGO infinity ($p = 0.002$), which was interfaced. When the steps associated with LIS activities were eliminated, there was no significant difference in either the operator or total cycle times between analyzers ($p = 0.001$). Evaluating the total number of maintenance tasks required annually appeared to be similar (difference of <1 task/day); however, the times associated with performing maintenance was significantly less for the TANGO infinity (10.8 hrs) than for the Ortho Vision (117 hrs). **Conclusion**: This study supports that LIS interfaces do provide a significant improvement operator and total cycle times at facilities performing 13K T&S annually. Eliminating time associated with operator intervention for LIS functions, the TANGO infinity demonstrated no significant improvement over the Ortho Vision for routine testing; however, significant efficiencies and cost avoidance was demonstrated on the TANGO for maintenance activities.

TABLE.

A: Quality	TANGO infinity	Vision (No LIS)	Vision
Testing Steps	25	44	29
Maint Tasks	2017	2201	
B: Speed (min)			
Operator	1.5	6.5	1.5
TCT	34.3	43.8	34.3
Maint/Yr	649	7020	

AP103

Analysis of Crossmatch Bench Events and the Efficacy of Secondary Review in aHospital-based Transfusion Lab

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Background/Case Studies: In 2015, the total number of tests performed by a large hospital-based Transfusion Lab (TL) with two work sites was 155,791. Considering the high volume of complex tests performed, it's not unexpected that deviations occur, despite all of the safety layers in place. These layers include electronic double checks and hard stops, along with a secondary review process performed by a second tech on any associated paperwork, and management reviews of all submitted paperwork. In 2015, there were 841 events reported in TL, with 337 of those events originating within the lab. For the events originating in TL, 22% (75/337) were initiated at the crossmatch bench. **Study Design/Methods**: A retrospective review of all TL events from 2015 was conducted and events were categorized into their originating benches. Those occurring at the crossmatch bench were further subcategorized into testing categories and by whom the error was detected (self-identified by testing tech, secondary review tech, management review, Reference Lab, or caught upon subsequent review of patient). **Results/Findings**: After additional investigation, 8 of the 75 crossmatch events were removed from this analysis due to extraneous circumstances that made them outliers. The 67 events remaining were then broken down into the major test categories for analysis (see table). Events were then categorized by who detected the error. The only processes that generate paperwork (Antibody Identification (ABID) and antigen typing) are secondary reviewed by another tech trained on the process. Twenty-five events were related to ABID or antigen typing and of those 25 events, 13 (52%) were undetected by the secondary reviewer while 12 (48%) were caught by the secondary reviewer. It is important to note however, that there are instances where deviations are detected at secondary review but an event is not written. **Conclusion**: After reviewing the event data from 2015, it appears that secondary tech review is not the most effective means to identifying testing errors. Ideally, eliminating the paperwork and putting electronic checks in place would negate the need for a secondary review. As a result of these findings, TL is investigating electronic options that can safely replace the paperwork currently being generated in several processes.

*Electronic and serologic crossmatches

TABLE. Crossmatch Event Analysis

Test name	Number of Events	Events as a % of Tests Performed	% of Crossmatch Events
DCT	5	0.17% (5/2956)	7.5% (5/67)
ABO	16	0.02% (16/66396)	24% (16/67)
ABYS	5	0.01% (5/49802)	7.5% (5/67)
XM*	4	0.01% (4/34686)	6% (4/67)
ABID	14	1.5% (14/920)	21% (14/67)
Antigen Typing	11	1.1% (11/1031)	16.4% (11/67)
All Tests Performed At Crossmatch Bench	67	0.04% (67/155791)	

AP104

Improving Blood Management: Nondestructive Quality Assessment of Platelet Concentrates in Mini-bags

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Background/Case Studies: According to Canadian regulatory standards, about 1% of pooled platelet concentrates (PCs) produced is held for destructive quality testing on day 6 of storage, one day after expiry, resulting in the loss of some 2,000 PCs from inventory for quality testing. Here we present a pilot concept that would potentially eliminate this discard. An aliquot would be removed at the time of production from the PC into a separate mini-bag followed by storage until QC testing at expiry. **Study Design/Methods**: Both rectangular (R) and pencil-like (P) shaped mini-bags with a capacity of 17 mL or 25 mL were designed to maintain a comparable surface to PC volume ratio with the current CBS bag and welded in-house using the current storage bag material (MacoPharma, Lille, France). The PC fill volume and air bubble size were optimized by assessing common platelet quality parameters, such as platelet count (ADVIA), to determine yield, as well as pH, glucose, and lactate using a blood gas analyzer, and platelet activation and response to ADP monitoring CD62P expression by flow cytometry. **Results/Findings**: For the 17-mL and 25-mL containers, PC volumes between 8-12 mL and 8-20 mL were tested in combination with an 0-mL, 1-mL, and 2-mL air bubble. All bags with no air bubble showed poor platelet quality, demonstrating the necessity of a bubble. As pH is one of the QC measures, its value was used as a read-out to evaluate the different PC fill volumes. For the R17 and P17 bags, an 8-mL fill with a 1- or 2-mL air bubble revealed pH values of about 6.2, while a 12-mL volume independent of the air bubble size was <7.1 compared to a pH of 7.3 in the original PC on day 6 of storage. This result displayed an ideal range which was confirmed for 10 mL + 2 mL and 11 mL + 1 mL fill + air bubble volume, respectively. This observation was supported by glucose and lactate levels of 9 mM and 24 mM in the mini- bag vs. 10 mM and 18 mM in the original bag, respectively. Additionally, platelet activation and response to ADP were 57% and 15% for R17 bags vs. 52% and 13% for P17 bags, respectively. For the R25 bag, the in vitro quality was not close to the original storage bag, and, although the P25 mini-bag showed acceptable results for a PC fill volume of 17 mL or 20 mL with a 2-mL air bubble, the smaller volume in P17 bags was more suitable, as it does not jeopardize the volume and hence the yield of the original bag. **Conclusion**: Here we generated two shapes and sizes of mini-bags for storage and quality testing of PC aliquots and optimized the PC fill volume and air bubble size to mimic in vitro quality parameters as closely as possible to the original PC unit. Once this concept is validated in a blood production setting, implementation of a separate mini-bag as a nondestructive sampling method would avoid the loss of PCs solely for QC testing.

AP105

WBC $<7x10^6$/mL Correlates with CD34+ <10/mcL in Hodgkin Lymphoma and Most Types of Non-Hodgkin Lymphoma

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Background/Case Studies: Autologous stem cell transplantation is an integral part of the treatment regimen for Non-Hodgkin Lymphoma (NHL), Hodgkin Lymphoma (HL), and other malignancies. CD34+ cell enumeration is routinely used to determine when to initiate apheresis collection. However, CD34+ enumeration is relatively expensive and time-intensive. We aimed to determine disease-specific white blood cell (WBC) concentrations that would predict a CD34 count of at least 10 CD34+ cells/mcL. **Study Design/Methods**: We analyzed concomitant WBC and CD34+ measurements in a total of 249 patients who underwent autologous stem cell collection between Jan 2014 and Feb 2016. We focused on 19 patients with HL or NHL with at least one WBC measurement $<10x10^6$/mL early in their mobilization. **Results/Findings**: 14 patients with NHL (excluding primary CNS lymphoma) underwent a total of 18 CD34+ measurements while WBC$<10x10^6$/mL. In 3 cases, the concomitant CD34+ concentration was >10/mcL (Case #1: WBC$=6.7x10^6$/mL and CD34=11/mcL; Case #2: WBC$=7.1x10^6$/mL and CD34=10/mcL; Case #3: WBC$=7.7x10^6$/mL and CD34=16/mcL). With the exception of two patients who never mobilized, both the WBC and CD34+ concentrations were always higher the following day. WBC$<$or$=7x10^6$/mL was predictive of concomitant CD34 $<$ 10/mcL (91%; n=10/11). For 5 HL patients, there were 8 CD34+ measurements when WBC was $<10x10^6$/mL. In 3 instances, concomitant CD34 was >10/mcL (Case#1: WBC$=9.7x10^6$/mL and CD34=14/mcL; Case #2: WBC$=8.7x10^6$/mL and CD34=15/mcL; Case#3: WBC$=7.6x10^6$/mL and CD34=17/mcL). In every case where WBC$<10x10^6$/mL, both the WBC and CD34 counts were higher the following day. WBC$<7x10^6$/mL was associated with CD34+$<$10/mcL (n=3). In striking contrast, pediatric patients with neuroblastoma always had a CD34+>10/mcL even when their WBC was $<10x10^6$/mL (n=9). An adult patient with primary CNS lymphoma achieved CD34 concentration of >400/mcL despite a WBC of $5x10^6$/mL. **Conclusion**: Most patients with HL and NHL (excluding primary CNS lymphoma) will not have a collectable CD34+ count until their WBC count is $>7x10^6$/mL. It may be reasonable to defer CD34+ enumeration for such patients until their WBC is $>7x10^6$/ml. This may decrease CD34 enumerations for the laboratory and, more importantly, reduce the time that these cancer patients spend in apheresis clinic awaiting the results of testing. While further study is needed, consideration should be given to performing CD34+ enumeration for pediatric patients with neuroblastoma and adults with primary CNS lymphoma regardless of their WBC concentration.

AP106

Patient Blood Management – Prophylactic Uses of Platelets and Fresh-Frozen Plasma: A Retrospective Audit

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Background/Case Studies: Transfusion of blood and blood products are a common practice in the field of medicine. With 1.7 million units of red blood cells, over 275,000 units of platelets and 280,000 units of fresh-frozen plasma (FFP) were transfused annually in the UK, there is a significant demand on these resources. Patient blood management is a multidisciplinary, multimodal approach to ensure that blood and blood products are only used according to best clinical evidence, and focuses on the means to minimise unnecessary or inappropriate transfusions. This audit focuses on the prophylactic and pre-procedural uses of platelets and FFP. This audit aims to examine the current practice in the Royal Free Hospital against the national guidelines published by the National Institute of Health and Care Excellence (NICE), and provides recommendations to improve compliance. **Study Design/Methods**: A retrospective study method was used by collecting data concerning prophylactic platelets and FFP transfusions provided by the blood bank laboratory in the electronic document records management system. **Results/Findings**: A total 42 transfusion encounters were collected from a one-month period in 2015. 38 of these were for prophylactic uses. 30 adult patients with similar gender ratio were involved in the audits. 23 encounters received platelets, 13 received FFP, and 2 received both. We found that the total rate of compliance with the guidelines was 32%. Only 21% of patients with no procedure performed were transfused platelets at platelet count <10 x10^9/L, and only 42% of patients who had procedures were transfused FFP with international normalised ratios (INRs) $\geq$1.5. In particular, the mean dosage given to the patients was 7.6 ml/kg, which was half of the recommended dosage of 15 ml/kg. The mean decrement of INR was 0.2 ± 0.8, suggesting that FFP transfusion only lead to minimal changes. **Conclusion**: In common with other audits, we found the compliance with the guidelines is incomplete, suggesting there is still substantial room for improvement. Whilst guidelines are readily available on the hospital intranet, it is clear that many transfusions are prescribed without reference to them. Optimising practice will require education, regular audits, and feedback sessions.

TABLE. Summary of demographics of audit

Total Number of Samples	38 (Excluded 4)
Number of Males/Females	16/14
Mean Age (Range)	57 ± 15 (22-79)
Mean Weight	79.4 ± 14.4 kg
Number of Platelet Transfusions	23
Number of FFP Transfusions	13
Number of Transfusions with Both Platelets and FFP	2
Rate of Compliance	32%

AP107

Simple and Effective Competency Assessment Tracking Using Readily Available Software

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Background/Case Studies: Competency assessment (CA) for all analytes tested in a laboratory is a requirement of the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Consequences of failure to comply with competency requirements may include invalidation of test results, a need for patient evaluation, and notification of patient physicians. In addition to Test System (TS) competency, CLIA-role competency (e.g., competency as General Supervisors) must be assessed for individuals deemed competency assessors. Many regulated critical tasks (CTs) are not tests under CLIA; nonetheless, good laboratory practice dictates that CA should also be performed for these tasks. Our service currently has 623 annual competencies to perform (187 Test System, 399 Critical Task, and 37 assessor competencies). Utilizing commonly available software, we developed a tool that informs management of the overall and individual technologist competency completion rate, so that timely intervention, if needed, may be initiated. **Study Design/Methods**: Criteria for a successful tool were that it 1) captures all categories of competency assessments for both annual and six-month competencies; 2) allows individuals to be added/removed as needed; and 3) accommodates insertion of additional competencies as new TS/CTs are identified. A spreadsheet was utilized, personnel listed in rows, and competencies listed in columns. A competency is defined as complete when all required elements for that TS/CT are successfully performed. A "1" (one) is entered into the matching cell when a competency is completed. If a TS/CT is not applicable to an individual, the cell is blacked out, making it simple to determine what competencies still need to be completed and which are not required using the same spreadsheet for everyone. Supervision monitors completion rates and reports individual and overall metrics to each technologist and to transfusion medicine and laboratory quality review meetings. Personnel have responsibility for meeting quarterly completion targets. **Results/Findings**: We have been using this competency assessment tracking tool since 2013. Supervisory personnel are able to easily maintain the spreadsheet, which was developed by quality assurance. Using built-in calculations, the completion percentage is instantly updated and CA status relative to established targets is kept current, allowing supervisory staff and technologist to be proactive in addressing gaps. **Conclusion**: This tool provides an effective and simple way of generating CA metrics without the need for specialized software. In the four years since implementation, all required CAs have been completed in a timely manner, demonstrating the effectiveness of having a robust tracking and evaluation method.

AP108

Implementing an ABO Blood Group Verification Protocol

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Background/Case Studies: The mislabeling of blood samples sent to the transfusion service for type and screen or crossmatch represent a significant patient safety hazard. Recent studies have suggested that the overall mislabeling rate is up to 1.4%, with wrong-blood-in-tube (WBIT) occurring in 0.04%. It has further been reported that mislabeled specimens are implicated in up to 35% of events in which there is potential or actual patient harm. Given the potential severity of this largely preventable event, considerable attention is now focused on specimen labeling. As one approach to reducing the risk of WBIT, the 30th Edition of AABB Standards now requires testing a second current sample, comparison with previous records, or the use of an electronic identification system. **Study Design/Methods**: Since the implementation of a validated electronic patient identification system is expected to require 1-2 years, a two-sample patient ABO verification system has been implemented. We have modeled our system on that previously described in the literature; however, modifications have been made to enhance the reliability of the system and improve the turnaround time. When patient blood samples are identified that require ABO verification, a collection kit is immediately supplied to the patient's nursing station that contains an order form, instructions, pre-printed labels, and a unique collection tube. Second, in order to reduce unnecessary patient phlebotomies and reduce the turnaround time for the availability of type-specific blood, we have supplemented our approach by the use of a laboratory computer program that identifies additional, separately collected patient blood samples already present in other clinical laboratories. This abstract presents the results of our initial 3 months after the implementation of this protocol. **Results/Findings**: During the first 3 months following the implementation of the "2-sample" ABO verification, there were 8309 physician orders requiring ABO testing. Of these, 5367 (64.6%) were patients with a previous ABO result in blood bank records. The remaining 2942 required ABO verification. Of these, 787 could be tested using blood samples identified in other clinical laboratories at this hospital, and 698 were ultimately cancelled by the clinical staff as unnecessary. Thus, of the 2942 samples initially thought to require a second, or verification, ABO group, only 1457 were actually repeated. **Conclusion**: The implementation of a "2-sample" ABO verification protocol has been completed with little difficulty, largely due to the use of a prepared "collection kit" and the use of patient blood samples acquired from other clinical laboratories. This has been accomplished with minimal delay in the provision of blood and only a minimal increase in the use of group O blood.

AP109

Benefits of Monitoring Transfusion Reaction Rates

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Background/Case Studies: Monitoring of transfusion reactions was initiated beginning in 2013 in order to enter into the NHSN database for three of our 15 hospital locations. Monitoring of transfusion reactions is concurrently being done for all hospital sites. Allergic reactions are monitored. **Study Design/Methods**: Transfusion reactions are categorized based on the NHSN criteria. Transfusion reactions are recorded based on hospital site. System totals are quantified and % transfusion rate calculated using the total number of transfusions. Site transfusion rates are compared against the system transfusion rates and reviewed monthly. **Results/Findings**: The most common type of transfusion reaction is the Allergic transfusion reaction followed by the Febrile Nonhemolytic Transfusion Reaction. Nonspecific transfusion reactions were the third most commonly seen reaction. As staff became more comfortable with NHSN categories, fewer reactions were classified as Nonspecific. Allergic and Hypotensive transfusion reactions increased over time. Cumulative transfusion reaction rate is 0.29%, ranging between 0.19% - 0.89%. In 2015, one of our sites reaction rates dropped to 0.0%. In follow up, we learned nurses were reporting reactions to the patient's physician, but not reporting to Transfusion Services. **Conclusion**: Monitoring transfusion reaction rates will allow early recognition and follow up with nursing to ensure reactions are reported to transfusion services. Including reporting to nurse quality departments may help to raise awareness of recognition of transfusion reactions. Experience with the NHSN categories will improve recognition of the type of transfusion reaction.

AP110

Impact of Administrative Transfusional Audits on Records' Traceability and Prevention of Financial Losses

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Background/Case Studies: Internal audits are essential tools for continuous improvement and detection of near-miss events. Electronic medical records systems (EMRS) are effective to maintain traceability of transfusion records, although their implementation can be labor-intensive. Detailed documentation is required for transfusion payments by healthcare funders as evidence of adequate transfusion practices. Information transfer from an existing EMRS to a new system can be the highest-risk error point in that process. In such cases, data errors are responsible for payment refusals and traceability breakages, which can result in judicial rulings and financial losses. **Study Design/Methods**: In May 2014, we started implementing a new blood bank EMRS (BB-EMRS) that resulted in one or more transcription points either between EMRS or from EMRS to physical records, since systems are not fully integrated. We evaluated the results of administrative transfusion audits from Jan 2013 to Dec 2015 and its impact on refusals from healthcare plans. Transfusion records were manually audited 24h after transfusions and accounted for 19 parameters, grouped in 06 categories. **Results/Findings**: Results from administrative audits are summarized on Table 1. We observed an increase of 21,75% in overall nonconforming parameters (NC) rate from 2014 to 2015. On the same period, NC related to BB-EMRS increased 148% which represents 21,06% of total events. The most frequent NC in all categories was related to the time of transfusion which must be manually inputted on both EMRS and physical records. Since NC represents near-miss events we could estimate annual financial savings of US$51.600,00 (R$121.260,00); US$92.400,00 (R$244.860,00) and US$112.500,00 (R$443.250,00), with a mean transfusion cost of US$150,00 and the Brazilian Real quote for the period. **Conclusion**: There were no traceability breakages and 100% of refusals were reverted after further evaluation from healthcare plans. Although NC rate is less than 0,5%,

TABLE. Results of administrative transfusional audits from 2013 to 2015

	2013	2014	2015
Overall transfusions	8407	9750	9056
Parameters audited	159.733	185.250	172.064
NC parameters - all categories	344 (0,22%)	616 (0,33%)	750 (0,44%)
Relative frequency	1:464	1:301	1:229
MOST FREQUENT CATEGORIES (%)			
Hospital EMRS report	55	45	36
Transfusion request	20	43	58
BB-EMRS input	NA	16	42

auditing of transfusion process prevented substantial financial losses and judicial rulings by avoiding traceability breakages and reverting payment refusals.

AP111

Analysis of a Massive Blood Transfusion Protocol in a Hospital-based Blood Bank

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Background/Case Studies: A massive blood transfusion (MBT), or massive transfusion protocol (MTP), is essential for fast, efficient delivery of large amounts of blood products, particularly for hospitals with traumas and complex surgeries. This study was a review of the MBT in place at a Level 1 Trauma Center since 2008 to identify areas of strength and opportunities for improvement. Originally for the trauma service, the MBT can now be activated by any physician and expires after 24 hours or when no longer needed. One round of products consists of six red blood cells (RBCs), six plasma units, one platelet, and cryoprecipitate if requested. Once begun, the lab has a stay-ahead plan of one full round continually maintained in the lab to reduce preparation time between rounds. With the frequency and amount of products involved, reviews such as this can be invaluable for increasing efficiency without compromising patient safety. **Study Design/Methods**: Data was collected for the 2015 year on patients with an MBT noted in the Laboratory Information System (LIS) profile (n=137). The information from the Electronic Medical Records and LIS was analyzed using Excel. For the purposes of this study, the MBT officially began when the first round of products was either ordered or issued uncrossmatched. **Results/Findings**: MBTs were initiated an average of three times per week (the most was nine in a single day). The data shows a low elapsed time from product request to issue and a high patient survival rate within the first 24 hours of MBT activation (see Table). One opportunity for improvement was related to the low number of products used: only 47% of MBTs used the full first round of RBCs. Possible reasons for activating an MBT versus ordering STAT ala carte products may include misunderstandings of the stay-ahead process or the idea that an MBT is faster than STAT products. **Conclusion**: The MBT process at this institution has been an essential part of the rapid response to hemodynamically unstable patients for 8 years. This retrospective review of MBTs in 2015 showed both areas of success (time to issue; survival rate) and areas with opportunity for improvement (product usage). Further study may identify reasons for low usage as well as the impact of varying ordering practices between services. Solutions may include education or a secondary MBT protocol for lowusage areas.

AP112

Reducing Unnecessary Sample Collection in a Busy Transfusion Service

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Background/Case Studies: In response to AABB standards, the Transfusion Laboratory began, in October of 2010, to perform testing of ABO/RH types on two separate samples on patients who had no historical typing in the medical information system. Although there were processes, change communications, and training provided to phlebotomists, there continued to be unnecessary samples collected. This was an unexpected outcome that affected the quality of our service to our patients. Event reports were shared with the leadership from all sample collection areas. Training materials and reminders were distributed periodically. Despite small improvements made following these actions, the issues remained. **Study Design/Methods**: The DMAIC model (Define, Measure, Analyze, Improve, and Control) was used to complete this project. Define phase: We first identified process changes that were made since early 2011 and identified the project scope and stakeholders. Measure phase: Data collection was done using sample status crystal reports from the Laboratory Information System (LIS). Monthly sample disposition summary reports were used to monitor the number of unnecessary collections. Analyze phase: Data results were shared with leadership from transfusion services and all sample collection areas in March of 2015. Discussions with the phlebotomy team revealed occasional times when the patient's historical blood type was not looked up due to time constraints imposed by multiple steps required to navigate through 2 computer applications with occasional inaccuracies. Improve phase: It was decided an Information Technology (IT) solution would be more effective than the periodical reminder. With this information and support from the leadership and IT, we were able to create a crystal report that pulls historical blood type information directly from our blood banking system. We further improved the process by creating a shortcut link directly to the data entry screen of the crystal report making it user friendly. **Results/Findings**: The average unnecessary sample collections per month were 96 in 2013, 85 in 2014. Since the implementation of the crystal report in June of 2015, the number of average unnecessary samples collections dropped to a current average of 42 samples per month in 2016. **Conclusion**: The issue of unnecessary sample collections was greatly improved because a reliable, easy to use and accurate tool was developed according to user feedback and the leadership support. Our Control phase is to maintain the gains made and continue to monitor the number of unnecessary collections.

AP113

Safety Events as the Framework for a Redesign of Electronic Blood Product Ordering

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Background/Case Studies: According to the Food and Drug Administration, the blood supply is "safer today than at any time in history." However, fatalities still occur due to transfusion related adverse events (TRAEs) (56 in FY2014). A study in New York State revealed the greatest threats occur outside the blood bank and most are human error. Due to significant safety events at a pediatric hospital, the blood product ordering process was

TABLE. Review of MBTs in 2015 (n=137)

	Uncrossmatchedat Issue	Avg timeto issue	Survival rate (0-24 hrs)	Service*	Avg RBCstransfused (0-24 hrs)	Avg RBCsnot transfused (0-24 hrs)	Used ≥ 1 round RBCs**
All	46%	4 min	89.6%		8	52.6%	47%
Medical				53%	9	52.8%	54%
Trauma				47%	6	52.3%	40%

* Trauma: emergency department and operating rooms; Medical: all other areas
** 1 round = 6 RBCs
Avg = average.

evaluated and a redesign was deemed necessary. **Study Design/Methods**: A newly created role of a Transfusion Safety Officer (TSO) was pivotal to awareness and creation of a multi-disciplinary team. Safety events reported in 2015 were categorized and significant events that impacted patients were evaluated, providers (including pediatric residents) and nurses were interviewed and process mapping was performed. Other institutions (3) electronic ordering practices were inquired about. **Results/Findings**: The multidisciplinary team encouraged conversation between nurses, providers, blood bank personnel and clinical informatics staff to discuss available options and determine key components of a new electronic order. In 2015, a total of 74 safety events related to blood products were reported. Patients were directly impacted in 20 events with 1 patient requiring higher level of care. Examples included: excessive volume transfused (3), incorrect rate of transfusion (2), insufficient order (4), transfusion practices not reflective of nursing policy (6), name change during admission (2) and lack of informed consent (3). Interviews with the providers and nurses revealed a need for more clinical decision making tools including clinical practice recommendations on volume dosing, transfusion rate and product special requirement needs. Furthermore, feedback led to an update of the Blood Component Therapy Recommendations by Transfusion Medicine and embedding the recommendations in the new electronic order. Process mapping led to the creation of a white paper outlining the roles, rules and responsibilities of involved health care providers. Information from other institutions assisted with understanding available electronic capabilities. Finally, a "test drive" of the new electronic order was done in order to obtain feedback from providers. **Conclusion**: In order to decrease transfusion error, the TSO is in a prime position to spearhead a multidisciplinary team and liaise with chief quality and safety officers, chief residents, Transfusion Medicine and hospital executives to ensure safety initiatives are met. Safety events, interviews and survey results indicated a need for a drastic change in blood product ordering and provided a framework for a redesign.

AP114

Quality Management of Platelet-rich Plasma Systems in an Outpatient Practice

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Background/Case Studies: Prior to 2014, the Autotransfusion (AT) team at the hospital provided platelet-rich plasma (PRP) services to outpatient areas. AT received notice the day prior to the procedure and staffed accordingly. In October 2013, the Sports Medicine Center (SMC) planned to accommodate same-day procedures and move the practice to a new building located two blocks away with a goal start date of May 2014. Due to limited staff and location, AT would not be immediately available for the PRP services at SMC. It was important to develop a process for SMC and other outpatient areas that would mirror the methods that the AT team followed in order to meet regulatory requirements and AABB standards. **Study Design/Methods**: In order to ensure compliance with AABB standards, an implementation plan was developed for these separate PRP practices. Since January 2014, the AT management has performed: device validation, standard operating procedure/training module development, quality control logistics and staff training. Upon practice initiation, the AT team implemented quality control (QC) review, equipment/QC troubleshooting, documentation review/updates and periodic competency assessments. **Results/Findings**: From January 2014 until May 2014, two identical PRP devices were validated for patient use. Four staff members were trained on the devices and all staff were deemed proficient after successfully performing three separate PRP procedures on patients with an AT management member. QC (pre/post platelet count) was performed on all PRP procedures, and results were sent to the AT management team and the ordering physicians. Review of these results determined if the PRP device met the validation requirements as well as the QC acceptance criteria set by the AT medical directors and ordering physicians. Each month, all PRP QC results were sent to the AT associate medical director for review. In early 2015, this practice expanded to the Physical Medicine and Rehabilitation (PMR) location in a different building. From May 2014 to February 2016, 214 PRP procedures were performed in these two outpatient areas. Prior to the implementation of these PRP practices, an average of only 20 PRP procedures had been performed annually. **Conclusion**: At this institution, implementation of the PRP practices in the SMC and PMR has enabled timely delivery of same-day procedures for a greater number of patients while simultaneously meeting regulatory/AABB requirements. Training the respective areas to properly use the devices and providing quality oversight has resolved the geographic obstacles. Objectively, this expanded program has resulted in a 10-fold increase in PRP procedures.

AP115

The Individualized Quality Control Plan (IQCP) Tool Implemented for Performing Quality Control Tests on Cellular Products

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Background/Case Studies: The Centers for Medicare & Medicaid Services (CMS) rolled out a plan for implementing IQCP (Individualized Quality Control Plan) as a new quality control option based on a risk management plan for CLIA laboratories performing non-waived testing. This plan was meant for CLIA approved tests, but actually serves as a good tool for labs performing non-traditional tests and traditional tests on non-traditional samples Clinical laboratories can either follow traditional clinical CLIA QC requirements according to the regulations or Implement IQCP. While we perfrom traditional QC assessments on all the tests we perfrom on our cellular products, we did decide to follow the risk assessment process to help reduce risk in our testing process **Study Design/Methods**: We followed the IQCP process for some of our QC tests used to assess the safety, purity and potency of our cellular products. We chose to apply this tool to our QC sterility testing method and found the tool very useful in improving the overall process. We considered our sterility testing process at risk as it is technically considered "Off Label" use of the BacT/ALERT System, even though it has been fully validated for each cellular product and media tested. The IQCP tool builds on the validations and good laboratory practice. The tool provided by CMS walks you through the three steps: 1) Risk Assessment, 2) Quality Control Plan and 3) Quality Assessment Process for the pre-analytical, analytical and post analytical phases of testing. The Risk Assessment includes evaluation of five components: specimen requirements, test system, reagents, environment and testing personnel. The Quality Control Plan includes the number, type and frequency of testing as well as acceptable performance review. The Quality Assessment step includes the monitoring and assessments performed as well as follow-up on any corrective actions. The process also evaluates is all six CLIA competency methods are used in assessing laboratory testing personnel **Results/Findings**: This assessment helped us identify gaps and more importantly areas that needed to be clarified. One example included the need to clarified steps in the SOP and in staff training focusing on the examination of the culture media for suitability prior to use. Another step focused on the upstream (preanalytic) cleansing of the bottle septum **Conclusion**: We were able to revise our procedures, reeducate those involved in the process and hopefully prevent future errors or deviations. Ultimately looking at what could go wrong, coming up with preventable solutions and reassessing through auditing can improve any process which leads to a better work environment for our staff and will help us to have better test processes in place for our product assessments.

AP116

Viewing the Blood Transfusion Incident of a Patient with ABO-incompatible Living-Donor Organ Transplantation through Root Cause Analysis to Build Proactive Security Measures

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Background/Case Studies: Patients who receive ABO-incompatible living-donor organ transplants require special blood transfusion strategy. Fresh-frozen plasma (FFP) which is compatible with recipient's and donor's blood type should be selected for desensitization plasmapheresis and transfusion. In June 2015, an incident of failure to order/issue the appropriate blood group of plasma was identified and considered a sentinel event, prompting root cause analysis (RCA) **Study Design/Methods**: RCA analysis was used to investigate systemic problems of this incident. Why-tree analysis was used to identify the proximal and distal causes. Barrier analysis was employed to design barriers to prevent reoccurrence. **Results/Findings**: RCA identified the following root causes: no alerting system to prompt a special need of designated blood group, the medical ordering system and blood issuing system not adequately designed to handle such special need (the blood bank system automatically self-check patient's original blood type but not the designated blood type) and imperfect communication between the ward and dialysis unit during transfer. The preventive programs were divided into two stages. The first stage mainly employed manual safeguard procedures including: 1) to increase font-size of key medical advice to alert laboratory scientists 2) to keep a patient list for special need of blood type in the laboratory 3) to design a note card for patients undergoing ABO- incompatible organ transplant and insert on the hard shell cover of the medical record

4) to make a special shift checking list conducive to the communication between wards and dialysis units when transferring the patients. At the second stage, a proactive information mechanism, which had been used for ABO-incompatible stem cell transplantation with excellent results, was built into the transfusion service information system which files the blood type of donor- recipient pairs at time of decision to undergo ABO-incompatible organ transplantation. The system automatically decides and checks the blood type designated for FFP transfusion. **Conclusion**: Through RCA and barrier analysis, we have established a safety system to ensure the special transfusion safety of patients receiving ABO-incompatible organ transplants.

AP117

Automation of a Serology Department using the Blood Management System: The Egyptian Experience

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Background/Case Studies: The Egyptian National Blood Transfusion Services (ENBTS) is in the process of applying an automated Blood Management System (BMS) to 17 of its sites including the headquarters, the National Blood Transfusion Center (NBTC). The software will allow the Serology department to do its daily work through the BMS according to its business rules and to save the data to a secure database. All suitable medical equipment will be connected to the software through suitable communication protocols. The serology department is equipped with fully automated medical equipment, but they are acting separately. All the work is done through medical equipment, and then the results of all tested samples are printed as reactive and nonreactive. The results of each sample will be gathered manually in a release sheet from users at each lab: Virology, Grouping, and NAT. **Study Design/Methods**: The laboratory validation rules, SOPs and work instructions were explained thoroughly and documented in Laboratory Software Requirement Specification (SRS) after a series of meetings held between the BMS software house. There were also meetings to decide on the devices that will be connected to the BMS, and how they will be connected. After connecting each device a document will be sent by the software house explaining how the users can interact with the BMS through the installed interfaces. Using the SRS documents and the medical equipment document it was possible to extract test cases to validate that the laboratory module meets all the user requirements. **Results/Findings**: Validation rules were applied to the laboratory module, therefore once the primary results for all samples are completed, the results will be saved. Then the user will be able to verify the results. The software will automatically decide what are the samples to be released, and others that will be pending as they need to be retested or additional reflex tests will be needed. The report will be printed automatically for the accepted, rejected and verification pending samples each separately. Two test cycles were executed to determince how accurate the BMS applies the validation rules. The first cycle gave a failure of 25% and the second cycle gave failures of 21%. This was due to some misunderstandings in the validation rules and the sequence of applying them. At the same time ENBTS made modifications to their validation rules. **Conclusion**: The implementation of the BMS is a positive step for the ENBTS, as it has great advantages in terms of accountability. The users won't have to do anything manually, all results will be sent by the medical equipment to the BMS, except in certain cases where errors appear or having to do certain retests. The application of the BMS will apply the validation rules automatically, and provide the users with the sample final status.

AP118

Effect of Automation on the Key Performance Indicators of the Issuing Department of the Egyptian National Blood Transfusion Services

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Background/Case Studies: Egyptian National Blood Transfusion Services are going through an automation process, aiming to connect 15 regional blood transfusion centers to the Headquarter in Giza. The governmental hospitals' blood banks will be simultaneously connected. Indicators will be set to quantitatively assess how the automation will positively affect the performance. **Study Design/Methods**: The main key indicators are now being calculated manually. The main focuses of the study are the time and effort that will be saved and how some defects can be avoided upon the implementation of E-Delphin Blood Management System.
Some of the indicators that will be studied are listed here.
Indicators that Are Manually Calculated
Ratio between Incompatible Units and Total Units Matched
This indicator will help in determining the following:

- Causes of technical errors (human errors or pipetting errors)
- The kits' quality
- Whether a patient has developed antibodies

The Actual Monthly Stock Issued to Contracted Hospitals is currently calculated for financial departments, but it is not easily accessible by technical lab staff to assess the blood stock needed by each hospital. The Percentage of Remaining Units of Each Blood Component/Total Units Received by Issuing Department: Aiming to have a random figure about the relation between the stock available and actual need
Indicators That Can't Be Calculated Now, but Automation Will Make Them Possible:

- Rate of Positive Antibody Screening Cases among Total Number of Samples Tested: Patients with previous positive screening tests will be identified by the system and will be automatically directed for antibody identification. This is expected to increase cost-effectiveness.
- Ratio between Units in Unfulfilled Requests (due to the lack of inventory stock) and Total Requested Units: the relation between the stock available and the actual need will be more accurately calculated.
- Percentage of Each Blood Group of Units Issued will be a good indicator of the blood groups distribution among the Egyptian population and can be considered in the donor recruitment system.

Results/Findings: An example of key indicators manually calculated in the period from Jan-Dec 2015 follows:

- Incompatible units/Total units matched (Compatible units)
- Remaining units of blood component/Total Units Delivered.

Other indicators discussed in this study are set to be calculated with the first implementation of the E-Delphin Blood Management System. **Conclusion**: Automation of Egyptian blood banks is expected to result in more accurately calculated key performance indicators, in an easier and less tedious method, which will eventually lead to more productivity and improvement in performance.
A comparative study will be done to investigate the differences between key performance indicators before and after implementation of the E-Delphin Blood Management System.

AP119

Process Improvement: Patient-Centered Information Management after a 4-day Laboratory Information System Downtime

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Background/Case Studies: AABB TS standard 3.9.2 requires facilities to maintain alternative systems if their laboratory information system (LIS) is unavailable. Often referred to as "Downtime and Recovery Plans," these are part of a facility's emergency management preparedness. Our facility's LIS was designed and validated to prevent a downtime exceeding 6-8 hours. However, in March 2015, our LIS experienced a downtime that lasted almost 4 days – far exceeding 8 hours. This experience highlighted the reality that the Downtime and Recovery Plan was insufficient to support the complex needs of our patients. Downtime work and records were designed and organized "by task" (i.e., testing forms, dispense logs, etc.) as opposed to "by patient," which is how the LIS functions. Such "task-focused" organization over the course of days made it difficult to locate and manage a patient's needs to prepare products efficiently. As a result, a process improvement initiative commenced to better prepare our blood bank to meet the intent of the Standards and assure patient safety as well as BB operational efficiency. **Study Design/Methods**: Immediately after the downtime, all BB staff completed a survey to identify areas for improvement. Survey results were mapped to Quality System Essentials (QSE) and the results showed two areas for improvement (see Table). To address the QSE PC, Process Mapping was used to first depict downtime processes focused on patient information management. To address the QSE DR, forms were then designed to map to each process (for user ease) and also mapped to the LIS recovery steps (needed when the LIS became functional again). Finally, an overall document map was developed to show where forms and records were stored during the downtime and their order of priority for LIS recovery. **Results/Findings**: The team designed 10 process maps, 5 new procedures and 12 forms. Final implementation occurred February 2016. Initial feedback from staff, through focus groups, reveals the increased number of forms/records/SOP have increased the staff's confidence in the process. The Downtime and Recovery process will now be an annual competency for all BB staff. **Conclusion**:

TABLE. Survey Results Mapped to QSE

Quality System Essential (QSE)	% of Responses
Process Control (PC)	61%
Documents and Records (DR)	33%
Organization/Leadership	6%

Downtime is more than just the unavailability of LIS to document work performed. Staff surveys and Process Mapping helped our facility focus on process control and effective document management to assure patient safety. Our new processes will ensure our continued compliance with AABB Standards for emergency preparedness, as well as ensure our lab maintains a ready-state of patient-centered preparedness for LIS downtimes.

AP120

Management of Anti-CD38 Interference at a Large Academic Medical Center

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Background/Case Studies: Because of our large population of myeloma patients, it was essential to identify efficient clinical and laboratory workflows to manage patients receiving anti-CD38 therapy, and better characterize patterns of expected reactivity. **Study Design/Methods**: A nursing liaison in our myeloma clinics partnered with transfusion medicine. Joint conferences and outreach with clinics and nursing staff were performed. Mitigation of interference was performed according to published protocols utilizing dithiothreitol (DTT). Strategies included facilitation of notification of anti-CD38 therapy, performance of screening prior to infusion, communication of upcoming infusion schedules, collection of additional tubes when appropriate, and special designation within the LIS. Requisitions accompanying samples have a large, bright-pink sticker indicating daratumumab/anti-CD38 therapy. Molecular phenotyping is reserved for select cases. When screens are positive, screening is performed on DTT treated red cells. When appropriate, samples are typed for the K-antigen. If anti-K cannot be excluded by testing with a K positive cord cell, the patient will receive K negative red cells for all future transfusions. A new antibody, deemed as clinically insignificant, was built into our LIS as "anti-CD38" (to be applicable to daratumumab and other similar antibodies). When the antibody is no longer demonstrating, electronic crossmatching of K-negative red cells is used. For incompatible crossmatches, patients are issued least incompatible units after rule-out of common, clinically significant alloantibodies. Outpatient clinics and inpatient units were educated on the significance of the incompatibility. **Results/Findings**: 73 patients were treated with daratumumab. 136 units of incompatible red cells were transfused with no reports of transfusion reactions related to this incompatibility. Coordination with nursing staff resulted in timely delivery of care. Outreach to our myeloma clinics and inpatient floors established an effective partnership. Reactivity ranged greatly in strength among patients (from 0 to 4+). Strongest reactivity was generally observed in gel-phase testing, and weaker in solid-phase testing. ~10% of patients have antibody screening that remains negative during therapy. Prior to described protocol, the most common misidentification was a "High titer low avidity (HTLA)"-type antibody. Of positive screens, ~40% show positive auto-controls, and 10% with positive direct antiglobulin tests. Positive eluates were observed in select cases. **Conclusion**: As a result of multidisplinary coordination, we have nearly eliminated unnecessary testing and wait times for patients on anti-CD38 therapy. We have maximized timely delivery of transfusions, and have not observed adverse transfusion-related events due to the incomaptibility associated with anti-CD38 therapy.

AP121

Using Transfusion Service Automated Analyzers in the Laboratory to Perform Routine Testing on Cord Blood Samples

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Background/Case Studies: Georgetown University Hospital is a 609-licensed bed hospital. In July 2000, Georgetown University Hospital became part of the MedStar Health family. Annually MedStar Georgetown receives 19,000 T/S, transfuses 21,500 blood components, and tests 460 cord blood samples. With 14 FTEs in the Transfusion Service, automation is a necessary tool for the facility to maximize efficiency and patient care. **Study Design/Methods**: MedStar Georgetown receives cord blood samples for testing under the following conditions: Group O Mothers, Rh Negative Mothers, Mothers with clinically significant alloantibody(ies). The Transfusion Service has been automating cord blood samples on two TANGO optimos since implementation in 2012. The samples are collected in EDTA-pink top tubes to prevent clotting, to allow automated testing. To prepare the cord bloods for testing, the technologists swirl a clot stick in the tube to remove any small clots, spins the samples, and performs an ABO/Rh (front type only) and DAT on the TANGO optimo. If the Rh test result is negative, a weak D test is performed. The results are validated by the technologist and sent via interface to the Cerner/PathNet LIS. If the DAT is positive, the test is repeated manually by tube for confirmation. If confirmed, either a glycine acid eluate is performed in the case of suspected allo-antibodies, and/or a Lui Freeze-Thaw is performed in the case of mother-baby ABO incompatibility. Turnaround times vary between 32-38 minutes depending on sample number. Operator hands-on time is two minutes per test run. These testing assays were validated upon instrument validation in 2012. MedStar Georgetown is currently in the process of upgrading to the TANGO infinity that is validated for cord blood testing. **Results/Findings**: When cords are run on the TANGO optimo, this frees up significant technologist hands-on time to be utilized on more pertinent situations such as antibody Identification determinations, eluates,emergencies, etc. **Conclusion**: Automating cord blood testing reduces the opportunity for errors, staff bio-hazard exposure, and allows technologists to focus their expertise and technical training on more complex serologic and clinical problems.

AP122

Direct Hemovigilance Feedback to Hospitals: An Information Technology Approach to Transfusion Safety

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Background/Case Studies: Hemovigilance in the United States (US) was established in 2010 as a voluntary reporting system for hospital transfusion services through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) Hemovigilance Module. To provide support and feedback to hospitals, a Patient Safety Organization (PSO) was established in which hospitals reporting to NHSN are encouraged to participate and receive input on their hemovigilance and patient safety reports. The PSO is required by statute to comply with the US Patient Safety Rule and regulations of the US Agency for Healthcare Research and Quality. These include requirements to provide direct feedback and assistance to healthcare providers to minimize patient risk and to promote a culture of safety, thereby allowing the CPS to incentivize hospital participation in the voluntary US hemovigilance program. **Study Design/Methods**: The PSO developed an IT solution that provides its member hospitals the ability to access, submit, interact with and consume confidential and protected hemovigilance data and reports. **Results/Findings**: The secure and interactive web portal was launched in 2015 to interface the PSO with more than 85 member hospitals. The cloud-based portal has multiple interactive capabilities, including collection of supplemental information linked to transfusion reaction reports, delivery of confidential and protected comparative benchmarks using data from the CDC NHSN addressing adverse transfusion reactions and patient safety events within a secure HIPAA compliant environment, member communication, notification of upcoming events, and provision of targeted educational material. **Conclusion**: A national hemovigilance system that relies on voluntary reporting may be challenged for consistent hospital participation. The interactive web portal allows delivery of valuable metrics and resources to PSO hospital membership, thereby providing the enhanced and timely feedback needed to encourage consistent participation and accurate reporting.

AP123

Adverse Outcomes of Blood Donation and Transfusion in International Library of Medical Products of Human Origin

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Background/Case Studies: A joint global initiative established a pubic library about adverse outcomes associated with Medical Products of Human Origin (MPHO), including blood, organs, tissues and cells, to support sharing of published vigilance information for the purpose of education and transparency. Since 2014, adverse events associated with blood collection and transfusion are entered into the library. Only peer-review published material, legal documents, and reports from well-established hemovigilance systems have been included. **Study Design/ Methods**: A taxonomy for transfusion and donation adverse reactions was adopted to allow the incorporation of hemovigilance records into the database. During 2015 experts developed a more accurate mapping of transfusion and blood donation complications, while instructions for entering new cases have been circulated. The reports added to the library were categorized by adverse occurrence type, MPHO type, latency, alerting signals, frequency, demonstration of imputability and relevant references. **Results/Findings**: The library contains 2,245 references linked to 1,524 didactic cases, 318 of which are related to blood/blood products. During 2015, a group of international experts have reviewed 194 blood cases. A proposal for the establishment of a functional blood adverse occurrence review structure to decrease the burden to the expert participants has been implemented, including recognition for individual participation and involvement of early career clinicians. **Conclusion**: Lessons provided through review of the rich hemovigilance literature associated with blood collection and transfusion may be transferable to other MPHOs of more recent clinical use and serve as a didactic tool for trainees. In order to achieve the library's aim to be a comprehensive reference tool including all MPHO, a comprehensive, mutually supported approach for incorporating the hemovigilance literature must be agreed upon for further progress. A gap analysis is now needed to determine missing cases related to blood.