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Multicenter, multidisciplinary user-centered design of a clinical decision-support and simulation system for massive transfusion

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Acknowledgements
We acknowledge the contributions of our participants and thank them for sharing their clinical experience and time to contribute to this work.

BS is supported by an ANZCA project grant (#20/014) and National Blood Authority scholarship (#ID410)

EMW is supported by an NHMRC Investigator Grant (#1177784) and an NHMRC Synergy Grant (#1189490)

Conflict of interest statement
The authors have no conflicts of interest to disclose

Word Count
Abstract 246 words
Main text 2698 words
Figures 4
Tables 3
References 32

Running Headline
Clinical decision support for massive transfusion

Abstract

Background

Managing critical bleeding with massive transfusion (MT) requires a multidisciplinary team, often physically separated, to perform several simultaneous tasks at short notice. This places a significant cognitive load on team members who must maintain situational awareness in rapidly changing scenarios. Similar resuscitation scenarios have benefited from use of clinical decision support (CDS) tools.

Study design and methods

A multicenter, multidisciplinary user-centered design (UCD) study was conducted to design a computerized CDS for MT. This study included analysis of the problem context with cognitive walkthrough, development of a user requirement statement and co-design with users of prototypes for testing. The final prototype was evaluated using qualitative assessment and System Usability Scale (SUS).

Results

18 participants were recruited across four institutions. The first UCD cycle resulted in the development of four prototype interfaces that addressed the user requirements and context of implementation. Of these, the preferred interface was further developed in the second UCD cycle to create a high-fidelity web-based CDS for MT. This prototype was evaluated by 15 participants using a simulated bleeding scenario and demonstrated an average SUS of 69.3 (above average, SD 16) and a clear interface with easy-to-follow blood product tracking.

Discussion

We used a UCD process to explore a highly complex clinical scenario and develop a prototype CDS for MT which incorporates distributive situational awareness, supports multiple user

roles and allows simulated MT training. Evaluation of the impact of this prototype on the efficacy and efficiency of managing MT is currently underway.

Key Words

Blood Management, Transfusion Practices (Adult)

Introduction

Major hemorrhage requiring massive transfusion (MT) is commonly managed with the implementation of a locally-adapted massive transfusion/hemorrhage protocol (MTP/MHP) that outlines the allocation of tasks, pre-configuration of blood product packs to be transfused, transfusion goals and management guidelines specific to bleeding etiologies.[1]

Management of these patients is extremely challenging, due to the often unpredictable occurrence of major hemorrhage, requirement for multiple tasks to be completed simultaneously by a multidisciplinary team, who are often physically separated, and where the risk of morbidity and mortality increases with every passing minute should delays occur.[2,3] The physical separation and reliance on telephone communication adds an extra layer of difficulty for each team member to maintain current knowledge of the scenario, known as distributed situational awareness.[4]

MT research efforts to date have largely focused on transfusion strategy such as optimal blood product ratios, however there are many other process- or human-related factors that may influence both patient outcomes and blood product utilisation. Human factors (HF), a discipline that examines factors affecting work processes with the goal of improving both human performance and process outcomes, has been used to provide insight into many emergency resuscitation scenarios, including those with similarities to major hemorrhage.[5,6]

One approach to address these issues that has already shown benefit in resuscitation scenarios similar to MT is the use of computerized clinical decision-support systems (CDS).[7] CDS are paper-based or electronic algorithms designed to assist decision-making by

comparing patient information against a knowledge base to generate patient-specific assessments or recommendations.[8] CDS have been implemented in a range of areas, including transfusion decision-making, where they have shown in the non-MT context to improve patient outcomes and reduce wastage.[9] CDS can also be applied to group or team-based decision-making such as oncology care with multiparticipant/group decision support systems that provide a structured approach to group decision processes by removing communication barriers, enhancing participation and facilitating prioritisation.[10-12] We have previously surveyed anesthetists across Australia and New Zealand on their attitudes towards MT and views on CDS for MT which demonstrated potential design features and barriers to implementation that we have incorporated in the design of this study.[13] Patients receiving MT are prominently represented in both blood product utilisation and wastage, with one study finding that 1.3% of patients were issued 10% of blood products, so the potential of CDS applied to MT is substantial.[14]

This study presents the design approach of an electronic CDS specifically for MT. Successful implementation of these health IT solutions depends on several sociotechnical factors and overcoming many real-world implementation issues. Failure to address these can contribute to physician burnout and patient harm, particularly where usability and clinician engagement is not a priority during development and implementation.[15,16] Therefore, we wanted to develop a CDS for MT using user-centered design (UCD), a software development approach based on a four-step cycle of problem analysis, solution design, prototyping and evaluation that focuses on the end-user in each step, and has been used to develop many previous health IT solutions.[17] We also chose to focus on the clinical implementation barriers and establish

the potential clinical benefit prior to exploring production level implementation issues such as interfacing with existing information systems.

We hypothesized that a prototype computerized CDS for MT developed using UCD would maximize its utility and usability when used to support decision-making in MT. Here we describe the process of co-designing such a prototype system, and testing the prototypes using simulation in collaboration with staff who manage MT.

Materials and methods

Design approach

Our design approach included an analysis of the problem context, development of a user requirement statement, and development and revision of prototypes in conjunction with users relevant to MT across multiple sites.

After receiving institutional review board approval (Westmead Hospital, Sydney, New South Wales, Australia) we recruited participants via purposeful sampling across four Australian institutions to reduce recruitment bias due to geographical location, clinical practice, and available hospital services, and improve the external validity of the resulting experimental system. The sites included two level one trauma centers, Westmead hospital (975 beds, Westmead, NSW) and Royal North Shore hospital, (713 beds, St Leonards, New South Wales) one level two trauma center, Monash Medical Centre (640 beds, Clayton, Victoria) and a level three trauma center, Coffs Harbour Health Campus (292 beds, Coffs Harbour, NSW). In Australia and New Zealand, blood products are prepared and supplied by a blood bank

scientist, and the MT process is primarily supervised by a laboratory trained hematopathologist as the transfusion medicine specialist, who commonly dual train as a clinical hematologist. At each site we aimed to recruit five staff members most relevant to MT for the following roles: hematopathologist, anesthetist, trauma surgeon/emergency physician, blood bank scientist and critical care nurse for a total of 20 participants. For the medical roles we included at least one specialist in training (resident, registrar or fellow) and one specialist, to reduce bias due to level of experience or training. Eligible participants were invited based on our research teams' work networks.

Analysis of MT context

Each participant participated in a semi-structured interview to discuss their perceptions, role and experiences of MT tasks, and issues pertaining to the conduct of MT (See appendix A for interview questions), along with a cognitive walkthrough of MT tasks using the "think aloud" approach.[18] Based on these sessions we completed a qualitative analysis, developed a user requirement statement, and modelled the process of conducting a MT using a data flow diagram. We analyzed the goals, barriers, artefacts (design term for man-made object), and tasks for each role during a MT. Thematic analysis was based on an open coding approach[19] that was calibrated by two authors (BS and AK) based on analysis of two participant interviews. Inter-rater agreement was assessed using the kappa co-efficient.

Prototype development

Following the thematic analysis, we completed two UCD cycles as shown in Figure 1. During the first cycle, four different prototype web-based interfaces were developed as storyboards using *Sketch 53.2* (Sketch B.V, Netherlands) to test different potential decision-support

functions that might address the user requirements identified. All designs also incorporated existing evidence-based Australian and New Zealand guidelines and MT protocols.[20-22] Each storyboard was demonstrated to each participant with verbal description of intended function, and feedback was sought on utility and interface preference.

During the second design cycle, participant feedback from the first cycle was reviewed and addressed during the development of a high-fidelity web-based final prototype. This final prototype was developed using technologies including React (Meta Platforms Inc, USA), ClojureScript (Rich Hickey, USA) and DataScript (Nikita Prokopov, Germany). Final prototype evaluation was based on a simulated trauma MT scenario with simulated patient data that was presented at six times real time, such that a two-hour scenario could be completed remotely in 20 minutes. Participants were expected to activate an MTP, document tasks and respond to scripted events and suggested tasks based on the simulated scenario. The final prototype allowed full interaction with all interface elements but was not connected to a real clinical environment nor capable of supporting real-world use. Participants were requested to complete an online questionnaire that included a usability assessment and request for specific prototype feedback (shown in Appendix B). Usability was assessed using the System Usability Scale (SUS), a 10-question Likert scale usability assessment used extensively in user experience design.[23,24]

Results

Context of use and user requirements

18 staff across four sites were recruited and completed the structured interview and workplace observation. This comprised the following roles: blood bank scientists (n=4),

anesthesia (n=4), nursing (n=3), hematopathology (n=3), surgery (n=2) and emergency medicine (n=2). The medical roles overall included five specialists in training. Interview transcripts were analyzed with an open coding approach (kappa co-efficient of 0.76) and results are shown in Table 1. The process of conducting an MT was also modelled with a data flow diagram and each role was analyzed based on relevant tasks, artefacts required, and issues, shown in figure 2 and table 2.

Based on this analysis and existing evidence-based guidelines for MT, a user requirement statement and system specification document were created (shown in Appendix C). There were also three unanswered design questions: (1) how should this information be presented (graphical/text)? (2) in what timeframe (latest vs trend)? And (3) how accessible should this information be (flat, where all information is available on main screen, or hierarchical, where some information is only available on sub screens/menus)?

UCD cycle 1: Evaluating four prototypes

Based on the user requirement statement and system specifications, our team (including a user experience expert, AK) developed four different CDS prototypes which were then presented as storyboards of a web-based application (shown in Appendix D). The different prototypes aimed to address all the required tasks/functions whilst exploring solutions to the unresolved design questions above. Each of these four CDS prototypes were evaluated by 15 participants (one participant withdrew and two participants were unable to complete final step) via video conferenced interviews. Participants were guided through each prototype where individual features were discussed, and feedback invited. Thematic analysis of the evaluation feedback is summarized in table 2.

UCD cycle 2: Final prototype

The second UCD cycle involved analysis of the feedback from the previous cycle and design modifications made to prototype four (shown in figure 3) being preferred by 11 (73%) participants to develop the final prototype (shown in figure 4). Significant design modifications included blood product tracking by type of product and displaying treatment suggestions as a dynamic prioritized checklist, which also integrated general protocol measures such as patient assessment and integrated antithrombotic reversal guidance. This checklist of suggestions was based on real time, rules-based comparison of patient results to protocol target endpoints.

Fifteen participants were invited to complete the second cycle evaluation via email and use the final prototype to complete a simulated bleeding scenario, provide feedback and complete the SUS assessment. Fourteen participants completed the final evaluation (1 participant was unavailable) where an average SUS was found to be 69.3 (above average, SD 16). Overall features liked by participants included a clean and clear interface that displayed color-coded patient results, easy-to-follow blood product tracking in real time, and closed loop text communication. Disliked features included that treatment suggestions were too crowded, and some initial difficulty in using the interface that improved with ongoing use. Suggestions for improvement included integration of a help screen or guide, adaptation for viewing on mobile device and integration of other vital signs, such as heart rate.

Discussion

This study revealed a highly complex problem space with many design challenges and options for solutions, and the value of user feedback based on real-world experience of MT to design and refine the CDS prototype. To our knowledge, although there have been several studies on paper-based CDS for MT and computerized CDS for the non-MT bleeding, this is the first description of the design of a computerized CDS specifically for MT.[25-27] Structured interview and cognitive walkthrough with MT users demonstrated the importance of maintaining distributed situational awareness through information sharing and support of multiple user roles. Following two UCD cycles with MT users, we designed a high-fidelity prototype CDS for MT with above average usability and a clear interface with easy-to-follow blood product tracking.

No two MTs are the same

The challenge in evaluating a CDS for MT is that no two MT scenarios are the same, with multiple interacting issues that can impact on team performance. Recruitment of participants across multiple clinical roles and institutions allowed us to appreciate both shared commonality and unique institution-specific issues that need to be considered. During the first UCD round, the four interface storyboards experimented with different display techniques which helped to explore and refine the presentation of a complex process to multiple users working in different clinical contexts. The final evaluation was presented as an interactive prototype using simulated patient data to replicate its real-world use within the limitations of our study. This evaluation was completed without prior instruction to assess usability in circumstances where potential future users may not have received recent instruction yet still require urgent MTP activation. Achievement of an above average usability

assessment in the final evaluation suggests the interface is intuitive without extensive instruction.

CDS for MT must simultaneously support multiple clinical roles

Design of this CDS for MT did not identify a particular specialty or role as the primary user of the software. This likely reflects the fact that MT episodes commonly involve multiple specialties and roles with changes to the team leader role where a patient may transition from emergency department to operating theater to intensive care. Therefore, continuity of care during these transitions became a key design feature, such that the MT episode was independent of any one user and multiple users could interact simultaneously with the software. We aimed to apply human-centered design best practice to our CDS design by ensuring each user group was represented in the design process and specifically supported.[28] Beyond decision support, this design process identified two key areas relevant to MT: distributive situational awareness and support for team-based activities.

MT requires distributed situational awareness

Distributed situational awareness, defined as "situational awareness in teams in which members are separated by distance, time and/or obstacles"[29], was identified as a need by multiple participants. Clinical teams, blood bank scientists and hematopathologists work across physically separated sites to facilitate transfusion support where decision-making, and tasks are based on shared information. This process is repeated multiple times during a MT with changes to decision variables, namely the patient's current condition and location, and laboratory results that determine required blood products. To address this design requirement the CDS presented the same information to all user roles and provided blood

product tracking from request to transfusion. Sharing real time information during these scenarios with all MT users will likely extend the benefit of a CDS beyond individual clinical decisions where delays in information sharing can significantly impact on decision outcomes.

CDS for MT and non-MT

Mileo and colleagues co-designed a hemostasis 'traffic light' cognitive tool to guide the initial assessment and management of critical bleeding based on severity of bleeding; however the authors did not elaborate on the particulars of the co-design process.[30] A subsequent randomized simulation trial of this tool demonstrated that for the management of simulated bleeding scenarios, the Haemostasis Traffic Light tool, when compared to text-based guidance, allowed anesthesia providers to solve text-based scenarios more successfully and efficiently.[25] This study however did not have participants use both interventions and did not attempt to simulate environmental stressors, which may have significantly affected (or influenced) the outcome. For the non-MT context, the majority of CDS studies have focused on reducing blood product requests via changes to the computerized physician order entry requests and have demonstrated more appropriate usage.[26,31,32]

Strengths and limitations

Limitations of this study included development of this CDS based on expert opinion and clinical experience rather than observation of real-world MT episodes. This was chosen as the model because real-time observation of decisions during real MT episodes would not allow us to explore the rationale and underlying issues without delaying patient care. Secondly, we recruited participants via purposeful sampling based on our professional networks, which might have introduced recruitment bias, and had a dropout rate of just over twenty percent.

The dropouts were not skewed towards any role and there was saturation in most areas of participant contributions. Thirdly, we chose to focus on clinical barriers to implementation rather than expected from a production system, such as staff education and training, interfacing with existing systems and downtime procedures. Strengths included the participation of a multidisciplinary group of staff with different levels of experience from a variety of centers. Our final prototype simulation also demonstrates the potential for this system to be utilised for simulation-based education and training compared to existing paper-based protocols.

In summary, decision support for complex, high-risk, distributed team activities such as MT has the potential to significantly improve patient safety and outcomes and blood utilisation. This multidisciplinary, multicenter UCD study demonstrates the importance, process and complexity of developing a CDS for MT using a UCD approach. Its impact on the efficacy and efficiency of clinical decision processes of MT must now be examined in a simulated or controlled clinical environment, and this is presently underway.

Acknowledgements

We acknowledge the contributions of our participants and thank them for sharing their clinical experience and time to contribute to this work.

BS is supported by an ANZCA project grant (#20/014) and National Blood Authority scholarship (#ID410)

EMW is supported by an NHMRC Investigator Grant (#1177784) and an NHMRC Synergy Grant (#1189490)

EC is supported by an NHMRC Investigator Grant (#2008645) and an NHMRC Centre for Research Excellence in Digital Health

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Tables

Table 1 – MTP CDS design requirements and context of implementation

Design requirement and implementation context	% of participants (No Mentions)
Process-related and system specifications	
- Blood product tracking and reporting	89% (59)
- CDS to support autonomy within limitations and escalation as required	56% (23)
- Enhancement of distributed situational awareness	61% (32)
- Integrated user education and prioritized system usability	28% (6)
- MTP process support and auditing	33% (15)
Decision Support	
- Anticoagulant/antiplatelet reversal guidance	28% (9)
- Patient/etiology specific MT decision support	72% (30)
- Target endpoints relative to laboratory results with treatment recommendations	61% (39)
- Time/criteria-based prompts for MTP guidance	61% (30)
Information needs	
- Expert and team member opinions	78% (37)
- Patient details, previous management and progress	78% (41)
- Patient laboratory results	44% (27)
- Protocol guidance	50% (17)
- Resource availability	11% (3)
Barriers to CDS implementation	
- Applicability and capacity to utilise	22% (6)
- Endorsement, evidence and medicolegal support for recommendations	17% (4)
- IT system trust and accuracy	39% (10)
- Previous EMR implementation experience	50% (10)
Barriers to conduct of MTP	
- Inefficient communication	50% (24)
- Limited distributed situational awareness	22% (8)
- Limited staff and resources	56% (20)
- Process delays or perceived delays	72% (28)
- Team composition and leadership	17% (3)
MTP workflow	
- Communication and transport between teams	78% (40)
- Documentation and investigations	39% (10)
- Efficient and effective transfusion support	78% (45)

Table 2 - Massive Transfusion – Staff, Tasks, Artefacts and Issues

	Patient and Clinical team	**Hematopathology (onsite/remote)**	**Laboratory/Blood Bank**	**Electronic medical record**
Staff	- Doctors and nursing staff (Anesthesia, Emergency Medicine, Operating Suite, Surgery, Trauma, Radiology, etc)	- Hematopathologist - Hematopathology trainee	- Blood Bank Scientist - Laboratory scientist	
Tasks	- MTP activation and deactivation including specifying scenario details - Review laboratory results - Respond to suggesting etiology specific bleeding treatments - Request blood products and modify blood packs - Document receipt, transfusion or return of blood products - Document administration of hemostatic adjuncts - Text communication with blood bank scientist and hematopathologist - Review antithrombotic reversal guidance - Update clinicians contact and patient location	- MTP activation and deactivation including specifying scenario details - Liaise with blood bank and clinical team - Advise on transfusion strategy based on patient details, laboratory results, blood bank stock levels and bleeding etiology - Provide antithrombotic reversal guidance	- MTP activation and deactivation including specifying scenario details - Review of laboratory results - Request blood products and modify MTP packs - Text communication with clinician and hematopathologist - Update clinicians contact and patient location - Receive and process laboratory specimens - Report result of laboratory test via EMR - Advise clinical team/blood bank of critical results	- Receive results of laboratory systems
Artefacts	- Blood products and hemostatic adjuncts - Telephone (land line or mobile) - Computer for EMR access	- Computer for EMR access - Telephone (landline or mobile)	- Laboratory specimens - Laboratory testing equipment - Computer for EMR and blood inventory access/cross match of blood products	- Computer to access
Issues	- Delays or perceived delays for blood products and laboratory results - Limited staffing, particularly afterhours	- Intermittent communication with clinicians and blood bank that determines situational awareness	- Difficulty predicting blood product requirements - Poor communication and inaccurate patient location - Limited blood product inventory and wastage concerns - Lack of closed loop result notification - Difficulty accessing live point-of-care results	- Lack of user notification for critical results - Laboratory results not presented in MT context - Delayed availability of point of care results forces user to access paper result

Table 3 – Comparison of UCD cycle 1 prototypes and feedback

	Prototype 1 (3 preferred)	Prototype 2 (1 preferred)	Prototype 3 (0 preferred)	Prototype 4 (11 preferred)
Main Features	- Static list of patient results and corresponding MTP target - Grouped blood product requests, documentation, and administration with text updates	- Prominent color-coded display of patient results in context of protocol targets - Treatment suggestions available via pop-up	- Display of patient results and interventions on a timeline - Blood product requests grouped by type of product and stage of preparation	- Display of patient results in context of protocol targets with repeat times - Sub-screen timeline display of results and interventions. - Blood product requests grouped by product type and stage of preparation
Liked features	- 'Pushed' patient results in the context of target endpoints - Intuitive interface - Color coding - Blood product tracking - Treatment suggestions based on patient results	- Prominent patient results Report of blood products transfused	- Blood product tracking with individual products - Timeline of patient results and interventions - Adjustment of blood product tracking	- Repeat investigation prompts - Text-based chat - Return blood products to reduce waste - Patient result trend in sub screen - Ability to review previous MTPs
Disliked features	- Concern about duplication documentation with a team-based interface - Clinician suggestions on blood bank view - Blood bank inventory	- Lack of treatment suggestions on main interface - Interface doesn't help non-experts - Two column display of patient results - Excessive focus on results - Excessive color scheme without clear focus	- No suggested treatments on main screen - Result abbreviations not specific - Difficult to document in real time - Concern about return time limit accuracy - Timeline doesn't add much value - Interface sections not differentiated	- Blood product tracking difficult to interpret - No notification of changed information

Figures

Fig. 1. Overview of user-centered design (UCD) process where two cycles were completed by participants to develop prototype

Fig. 2. Data flow diagram of massive transfusion that maps the flow of information and physical artefacts

Fig. 3. Clinician role view of interface design resulting from user-centered design cycle 1 prototype 4

Fig. 4. Clinician role view of interface design resulting from user-centered design cycle 2 prototype 5

Appendix A
Structured interview questions

Standard introductory statement
Thank you for agreeing to participate in this study. Our aim is to develop an experimental clinical decision support system to improve clinical decision-making processes in massive transfusion. A computerized clinical decision support system (CDS) is software designed to support clinicians to make decisions by comparing patient information to a knowledge base (for example, antibiotic guidance).

During the following interview, we will ask you questions about your role and experience during massive transfusion, your current work processes and how a clinical decision support system could support these processes. This interview will be audio recorded for anonymous transcription and notes will be taken. Please refrain from providing identifying information.

1. What is your role during MT and how long have you worked in this role?

2. In the last 12 months, how many MTs have you been involved in?

3. What is the process, step by step, of getting blood urgently from blood bank to the patient in your hospital and what is the main limitation?

4. Have you used a CDS before and if so, what was your experience?

5. Thinking about the last MT you were involved in; can you please talk through what happened from recognition to resolution of bleeding and focus on what worked and didn't work well in relation to the MT?

<u>Prompts for the participant when answering question 5 depending on relevance to role</u>

   a. How long was the bleeding episode and what was the etiology?
   b. How did you manage the overall scenario, including the MT protocol and processes?
   c. How did you decide which blood product to give and when?
   d. How did you ensure hemostatic adjuncts were given?
   e. Were there any issues with teamwork, role allocation and task prioritisation?
   f. How and when did you document patient management?
   g. Were there any issues communicating with team members including blood bank and hematopathologist
   h. Were there any issues performing laboratory investigations and interpreting results

6. What information sources do you predominantly use to support your decision-making during MT?

7. What electronic medical record and/or laboratory result software do you use and how do you use it during a MT?

8. If we developed a CDS for MT, what would you want it to do?

9. Are there any other issues or concerns relevant to decision-support for MT that we haven't covered?

10. Do you have any other comments/suggestions?

Appendix B
Final prototype evaluation questionnaire

Post evaluation survey
Participants will be asked to complete an evaluation survey after the scenario based on the following questions:

Thank you for evaluating *MTP Assistant*. Please complete the following survey to provide feedback and a usability assessment.

1. What features did you like about *MTP Assistant*?
2. What features did you not like about *MTP Assistant*?
3. Can you suggest any improvements? (Please describe problem along with improvement)

The following questions relate to a usability assessment called the System Usability Scale (SUS) – 5-point Likert Strongly Agree to Strongly Disagree

4. I think that I would like to use this system frequently.
5. I found the system unnecessarily complex.
6. I thought the system was easy to use.
7. I think that I would need the support of a technical person to be able to use this system.
8. I found the various functions in this system were well integrated.
9. I thought there was too much inconsistency in this system.
10. I would imagine that most people would learn to use this system very quickly.
11. I found the system very cumbersome to use.
12. I felt very confident using the system.
13. I needed to learn a lot of things before I could get going with this system.

Appendix C
User requirement statement and system specifications
MTP Assistant - Design Specifications.pdf

Appendix D
Prototype systems developed during first user-centered design phase
Prototype Systems Cycle 1.pdf