Process-of-care in the ICU:

A multi-method exploration of an electronic checklist to support medical morning rounds

Karena Conroy

A thesis submitted in accordance with the total requirements for admission to the degree of

Doctor of Philosophy

Faculty of Health
University of Technology, Sydney

November 2014

Certificate of Authorship/Originality

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

_____

Signature of candidate

Acknowledgements

The two people that I would like to acknowledge and thank first and foremost, are my supervisors Doug and Tony for offering me the opportunity to contribute to an area of work and study they are both very passionate about. Both have contributed greatly to my skills development which has helped me become a more well-rounded health researcher. They have guided and mentored me in the field of intensive care medicine, and widely promoted my work. Doug and Tony have always been very supportive and I cannot thank them enough for all that they have done for me – without them my doctoral studies would not be possible and my future career as a health researcher would be uncertain.

I am thankful that my employers, the NSW Intensive Care Coordination & Monitoring Unit (ICCMU), afforded me the opportunity to combine my studies with my work and provided both cash (i.e. for hardware, software development, data collection during the intervention phase, publishing results in open access journals and presenting results at conferences) and in-kind (Director, Research, Data and Administrative Officer's time) support for this work. Without this support, this research would not have been possible. I would like to acknowledge and thank my work colleagues Ms Diane Kowal and Ms Kaye Rolls for their advice and support, and Mr Yi Zeng and Mr Allan Zhang for developing the e-checklist software, networked server and web portal. Allan (ICCMU's Data Manager at the time) deserves special mention for all his hard work in ensuring the IT solution for the e-checklist was the best it could be, for his assistance with data management, for offering support when needed and for making me laugh, especially when times were tough. I don't know how this project would have worked or how I would have coped without Allan sitting literally by my side – I thank him for being both a great colleague and friend.

I would also like to acknowledge and thank the UTS Faculty of Health for the support they have provided me through their post-graduate program, including education and training opportunities and Student Research Forums where I was able to obtain constructive feedback on my work from both academic staff and fellow students in a friendly and supportive environment. The Faculty also provided funding for statistical advice offered by Dr Georgina Luscombe during the planning stages of the intervention study. Statistical advice was sought again during the data analysis phase of the intervention study and at that time was offered by

Professor David Sibbritt (Faculty of Health, UTS). I thank both Georgina and David for their sharing their knowledge and expertise with me.

I would like to thank Professor Anthony McLean, ICU Director and Ms Veronica McCarten, Nurse Unit Manager, for giving me permission to conduct research at Nepean ICU and for providing in-kind support (staff time) for the project. My thanks goes to Dr Ian Seppelt and Dr Stuart Lane for their valuable input into the practicalities of the research, for being clinical champions, demonstrating leadership throughout the project and for supporting my work. Thanks also to a host of other ICU staff who assisted with the intervention study – Ms Leonie Weisbrodt for her valuable input during study preparation, and for helping guide and participating in data collection for the intervention study; Ms Phoebe Palejs for doing the bulk of audit data collection and to all other staff who assisted with this task; to Ms Danielle Phillips who assisted by extracting and providing the required ICU data; and to the ward clerks who updated the patient list in the e-checklist server every morning during the intervention study period.

A big thank you goes to all the busy ICU clinicians and administrators who either participated or contributed in some way to this research project – your interest and passion for improving patient care is inspiring and I am grateful for the amount of support I received for this work.

I acknowledge and thank the ANZICS Clinical Trials Group for endorsing the point prevalence study and the Intensive Care Foundation for providing partial funding for this study with a one-year $15,000 grant (2009). Thank you to the research coordinators who collected the data at each of the participating sites, and to the George Institute for collating the data and providing project management for the overarching Point Prevalence Program – without this infrastructure in place the process-of-care point prevalence study would not have been possible. Dr Ian Seppelt again deserves special mention for his vision and hard work in getting this Program up and running, including obtaining competitive funding from the Intensive Care Foundation.

Thank you to my family and friends who have offered moral support and understood why I was an absentee from their lives at times. I would especially like to thank my devoted husband Matthew for his support throughout this process – the amount of patience and

tolerance he displayed was quite remarkable. I am fortunate to have him as my partner and I hope I have made him proud.

In order to alleviate any possible confusion, I would like to point out that I had a few name changes throughout the course of my PhD candidature. After getting married I transitioned from my maiden surname (Hewson) to my married name (Conroy) by hyphenating the two together (Hewson-Conroy) for a period of time to ensure there was an apparent link between my published work. This will be evidenced in my list of publications and presentations located in the Introduction chapter of this thesis.

Finally, I would like to express how thankful I am that I was given the opportunity to reach this milestone. I do not come from what western society considers a 'privileged' background, but I had all I needed to grow, learn and make informed choices about my future. There are many people in the world who are not afforded such opportunities, therefore I consider myself privileged and fortunate to be in this position. I am sure I will put the knowledge and skills acquired throughout my PhD candidature to good use.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

ACSQHC	Australian Commission for Safety and Quality in Health Care
AE	Adverse Event
AERA	American Educational Research Association
AHRQ	Agency for Healthcare Research and Quality
ANZ	Australia and New Zealand
ANZICS	Australian and New Zealand Intensive Care Society
APA	American Psychological Association
APACHE	Acute Physiological, Age and Chronic Health Evaluation
API	Application Programming Interface
apps	Software applications
BI	Bias Index
BSL	Blood Sugar Level
CDSS	Clinical Decision Support System
CEC	Clinical Excellence Commission
CI	Confidence Interval
CIS	Clinical Information System
CL	Central Line
CLAB	Central Line Associated Bacteraemia
CLABSI	Central Line Associated Bloodstream Infection
COW	Computer-On-Wheels
CR-BSI	Catheter Related-Blood Stream Infection
CRF	Case Report Form
CTG	ANZICS Clinical Trials Group
CUSP	Comprehensive Unit-based Safety Program
CVC	Central Venous Catheter
CVI	Content Validity Index
DVT	Deep Venous Thromboembolism
EBM	Evidence-Based Medicine
e-checklist	Electronic checklist

FASTHUG	Feeding, Analgesia, Sedation, Thrombo-prophylaxis, Head-of-bed elevation, stress Ulcer prevention, Glucose control
GEE	Generalized Estimating Equations
GI	Gastro-Intestinal
HDU	High Dependency Unit
HOB	Head-of-Bed
HREC	Human Research Ethics Committee
ICCMU	Intensive Care Coordination and Monitoring Unit
ICU	Intensive Care Unit
IHI	Institute of Healthcare Improvement
IoM	Institute of Medicine
IQR	Inter-Quartile Range
IV	Intra-Venous
JVM	Java Virtual Machine
LOS	Length of stay
M&M	Morbidity & Mortality
MAC	Macintosh computer
MET	Medical Emergency Team
MRN	Medical Record Number
NA	Not Applicable
NCME	National Council on Measurement in Education
NHMRC	National Health and Medical Research Council
NICE SUGAR	Normoglycaemia in Intensive Care Evaluation (NICE) and Survival Using Glucose Algorithm Regulation (SUGAR)
NICS	National Institute of Clinical Studies
NICU	Neonatal Intensive Care Unit
NSW	New South Wales
NUM	Nurse Unit Manager
OR	Odds Ratio
PC	Personal Computer
PDA	Personal Digital Assistant
PDSA	Plan-Do-Study-Act
PI	Prevalence Index

PICU	Paediatric Intensive Care Unit
PIMS	Performance Indicators and Medication Safety
Pneg	Proportion of negative agreement
Ppos	Proportion of positive agreement
Pt	Patient
QI	Quality Improvement
QUM	Quality Use of Medicines
RCT	Randomised Controlled Trials
SAQ	Safety Attitudes Questionnaire
SD	Standard Deviation
SPC	Statistical Process Control
SPSS	Statistical Package for the Social Sciences
SUP	Stress Ulcer Prophylaxis
TPN	Total Parenteral Nutrition
US	United States of America
UK	United Kingdom
VAP	Ventilator-Associated Pneumonia
VTE	Venous Thrombo-Embolism
WHO	World Health Organization

Glossary of Terms

APACHE	Predicted risk of death score calculated using the worst physiological values in the first 24 hours and other patient and admission data
FASTHUG	Mnemonic for use by ICU clinicians at bedside e.g. during patient rounds
MRN	Medical record numbers are unique patient identifiers, specific to each individual hospital.
PDA	An electronic handheld computer
PDSA	Model for implementing and evaluating quality improvement strategies
Process-of-care	Practices involved in the delivery of care
SPC	Statistical process control is a method of analysing data that utilises control charts to display variation in process data over time.

Abstract

The need for comprehensive and effective methods to ensure the delivery of required processes of care to intensive care unit (ICU) patients is acknowledged globally. In response various tools have been implemented, although many have not yet been empirically tested or rigourously evaluated in ICUs. Early evidence suggests that using a checklist is one way of ensuring evidence-based or accepted processes of care are performed routinely and systematically.

The aim of this program of study was to identify areas of need, then develop, validate, test and evaluate an electronic process-of-care checklist (e-checklist) for use by intensive care physicians during morning ward rounds in a tertiary-level adult ICU. Need for improvements in the delivery of ICU processes of care were identified via a comprehensive literature search, a point prevalence study of 50 Australian and New Zealand ICUs, and baseline data collected at the local ICU level.

Evidence on checklist validity was obtained via multiple methods at different research stages: comparison of checklist responses and documentation of care recorded in patients' medical records demonstrated high correlations for each care component, providing support for its concurrent validity; local clinician interviews and a modified-Delphi technique using an expert clinician panel confirmed the relevance and adequacy of content and produced a list of clear, concise and descriptive checklist statements; high levels of concordance between clinician and auditor responses during the intervention phase contributed evidence to the e-checklist's construct validity based on response processes; and user feedback obtained before and after the intervention demonstrated the e-checklist had face validity with ICU physicians. Importantly, the prospective before-after intervention study demonstrated improved compliance with processes of care over time (odds ratios ranged from 1.9 for mechanical ventilation weaning to 22.9 for pain management) and user-satisfaction was achieved.

Implications for practice include implementing this versatile tool at the point-of-care to collect real-time, process-of-care data that can be completed by clinicians delivering and auditing care. Recommendations for further research include: testing for reliability; investigating the reasons for practice variability and impact on outcomes; conducting observations of e-checklist utility in clinical practice and in larger multi-centre studies

adequately powered to detect significant differences in patient outcomes over time; and comparing the e-checklist with other clinical support tools or across different delivery platforms such as tablet PCs.

Overall, this research demonstrated the utility of an e-checklist in measuring and improving the delivery of ICU processes of care and provided a substantial amount of evidence in support of its' construct validity.

Chapter 1.
Introduction

Background to the problem

The ongoing need for health care improvement is evident from the plethora of literature demonstrating deficiencies in health care delivery. As an example, serious adverse events occurred at a rate of 39 events per 100 patient days in intensive care units (ICUs) from 29 countries (Valentin et al. 2006). Adverse events are of particular concern in critical care as they can lead to costly additional treatments and prolonged hospital stays amongst other implications for patients, families and health care providers (Moyen, Camire & Stelfox 2008).

The ICU is clearly a high-risk clinical environment where attention to detail is essential to achieving optimal patient care. When faced with the challenge of providing appropriate care to a number of critically ill patients with complex health problems and the need to develop comprehensive patient management plans that require the interpretation of many clinical variables, task saturation (i.e. when the number or complexity of tasks exceeds the capability to execute them well) can ensue (Davis et al. 2014). Task saturation (or overload) has been associated with poor performance of nontechnical skills such as communication and teamwork and can lead to poorer outcomes for patients, particularly after a decline in patient condition (Davis et al. 2014).

Given the limited power of the human brain to process information (Miller 1956) and the potential for mis-communication in the average ICU ward round (Pronovost et al. 2003a), there are times when routine care particularly in large busy units, is overlooked. Human error is unavoidable and can be exacerbated in stressful situations (Sexton, Thomas & Helmreich 2000) and as levels of stress and fatigue increase, cognitive function starts to decline (Bourne & Yaroush 2003). Critical care clinicians work in complex, high-intensity situations which can lead to not only stress and fatigue, but also to increased errors in judgment, decreased compliance with standard procedures, and

decreased proficiency (Hales & Pronovost 2006). This creates a human factors situation where the quality of care delivered to ICU patients can be unintentionally compromised.

The quality of care delivered to patients can be assessed in numerous ways, including risk-adjusted outcomes, incident monitoring, structural and process indicators. Risk-adjusted outcomes receive significant attention in intensive care research; with low mortality rates the main objective. There are many issues and arguments however for why this may not necessarily be the ideal goal (Lilford et al. 2004; Rubin, Pronovost & Diette 2001); one such argument is that when emphasis is placed largely on measuring outcomes, omissions in important processes of care will not be apparent. Also, risk-adjusted outcomes cannot be used as a daily performance management tool at the local level – they are used to compare and benchmark against other similar units. Clinical process measures however, directly measure performance by assessing adherence to established clinical standards (Lilford et al. 2004). As a result, a substantial amount of work has occurred in development of process indicators as a part of the ICU quality agenda e.g. (Berenholtz et al. 2002).

Specific process-of-care measures that have been identified in the literature as being important to routine intensive care practice and are broadly applicable to the general adult ICU patient population include: appropriate provision of nutrition, deep vein thrombosis (DVT) and stress ulcer prophylaxis, pain assessment and effective management, appropriate management of sedation, semi-recumbent body positioning, glucose control, assessment of readiness to extubate, pressure ulcer prevention, reviewing medications e.g. (Pronovost et al. 2001; Vincent 2005).

The importance of translating evidence pertaining to clinical process into practice has led to the development of a great number of clinical practice guidelines, unit protocols and procedures. Although there have been some attempts to ensure their adherence – such as the development of standardised order sets and clinical pathways, there are few clinical practice tools that cover a number of care processes and can be applied routinely and systematically to the general ICU patient population (Pronovost et al. 2003a; Vincent 2004). Ward round templates, bundles of care and checklists have been introduced to some ICUs in the United States (US), United Kingdom (UK), and Canada

however there are considerable limitations to the reported studies (Hewson-Conroy, Elliott & Burrell 2010). Despite recent reports of the benefits of using checklists in acute care, relevant Australian studies have only been reported for two critical care settings – one in an Anaesthetic department (used during simulation of preparation for a procedure) and the other in a tertiary ICU (pilot study of a paper-based process-of-care checklist conducted by myself and Dr Tony Burrell, pre-candidature, (Hewson & Burrell 2006)).

With an ever-increasing emphasis on quality improvement in health systems nationally and internationally, numerous models and strategies for achieving higher levels of performance continue to be developed and evaluated. This has created an opportunity for health care providers and researchers to learn about what works and what does not. There are however, gaps in the evidence-base that require further attention including a paucity of research in Australia (e.g. rates of adherence to routine processes of care in ICUs are unknown), and a lack of detailed and rigourous intervention studies evaluating the impact of checklists on practice adherence and their validity in ICUs. This research attempts to address some of the gaps.

Research objectives

This programme of research involved a staged and step-wise approach to the exploration of process-of-care in the ICU. The focus was on assessing the utility of an e-(lectronic) process-of-care checklist designed and implemented to support the medical morning rounds in an ICU. Multiple methods were used to examine the research questions posed at each stage of the research. An iterative approach was also undertaken, where findings and knowledge from one study were used to inform subsequent stages. Key aspects of this research involved:

- a comprehensive literature review;
- measuring process-of-care in Australian and New Zealand ICUs;
- tests for checklist validity;
- development of an e(lectronic)-checklist;
- prospective evaluation of the e-checklist in an adult ICU; and
- obtaining information on usability and staff satisfaction with the e-checklist.

The first step was to determine which patient care processes are most important to intensive care practice and could be considered for inclusion in a ward round checklist as well as how consistently those cares were delivered in published studies. It was also important to consider various approaches and strategies for improving care delivery so that relevant aspects were incorporated into the research design and methodology for the thesis, the appropriate measurement methods for use in quality improvement (QI) research, and any technological advancements in healthcare that might assist in the delivery of clinical support tools.

To establish the current levels of compliance with routine processes of care in Australian and New Zealand ICUs, a study that measured actual delivery of care was required. This would help inform the consistency with which care is delivered within a geographic region that shares similar governance structures and provide direction for future studies both within and outside of this research.

Formal validation of new clinical tools is important as health providers need to be assured that using the tool is beneficial to both their practice and the patients they care for. The objectives for this aspect of the research were to: develop relevant checklist content that adequately covers the daily processes of care expected in the ICU; determine whether completion of the checklist reflects actual delivery of care (its intended purpose); and evaluate whether the checklist is perceived as useful to clinical practice.

In light of both the reported and perceived benefits of integrating clinical support tools with information and communication technology e.g. (Kawamoto et al. 2005; Sucher 2008), appropriate hardware was sought and software custom-built to meet the requirements for use of the checklist in practice. Detailed specifications were developed to ensure the e-checklist functioned as intended and was fit-for-purpose.

Prospective evaluation in an ICU was then required to test whether an e-checklist intervention is clinically useful as a safety prompt, ensuring that all patients receive appropriate therapies and treatments, and prevents or minimises any omissions in care that could lead to adverse or less than optimal patient outcomes. The first step for this

stage was to collect baseline data using the developed e-checklist as an audit tool, then after a wash-out period, implement the e-checklist as a tool for intensive care physicians to use during their morning medical rounds. This intervention study utilised aspects of QI strategies and approaches identified in the literature review, to incorporate the best available evidence for effective implementation of a new clinical support tool. The main objectives of this intervention study was to test whether e-checklist use improved compliance with cares delivered over time and reflected actual delivery of care. A secondary objective was to gauge whether there was any difference in adverse patient events following implementation of the e-checklist.

In evaluating the utility of the e-checklist, the key objectives were to gather information pertaining to the usability of, and staff satisfaction with the e-checklist; key to determining the tool's face validity. It was also important to evaluate the QI methodology used to enable identification of aspects that did or did not work, as well as the barriers and enablers to e-checklist implementation. Evaluating the impact of the intervention on staff member perceptions of safety in the ICU was another way of determining its effectiveness.

As a result of this research, there are several key implications for practice that can be utilised by clinicians and health administrators. These will be discussed as issues are presented throughout the course of the research programme and the related thesis chapters. There is much work to be done in this area of study, and this research reflects a specific focus, therefore recommendations for further research are also made throughout and at the conclusion of the thesis. Notably, some recommendations are addressed in later stages of the research, while others did not fall within the scope of this doctoral study.

Thesis overview

Following this first chapter, a detailed background describing the area for study is presented (Chapter 2). This background is informed by a comprehensive review of the quality and safety in health care literature with a focus on intensive care practice. The major topics covered include quality and safety agencies and projects, evidence-based processes of care, translating evidence into practice, quality improvement strategies including care bundles and checklists, use of technology, and measuring process-of-care.

Chapter Three presents the findings of a bi-national national study examining the prevalence of established care processes in Australian and New Zealand ICUs; it provides a unique snapshot of process-of-care delivery in a large number of units in this geographic region.

Chapter Four introduces the concept of construct validity in relation to development of the checklist items – how it is conceptualised and how it will be addressed in this research, particularly for the two sections (Chapters 4.1 and 4.2). The first section (Chapter 4.1) pertains to a test of the criterion-related concurrent validity of the process-of-care checklist which involved evaluating whether checklist completion corresponds with an independent measure of care delivery i.e. care documented in the patients' medical records. The second section (Chapter 4.2) contributes further evidence of the e-checklist's content validity – particularly in terms of sufficiency, relevance, and clarity (Goodwin 2002).

The work completed for development of the e-checklist's software is outlined in Chapter Five. This includes the user requirements and detail around the development process such as the hardware and software components, programming and connectivity. As there were refinements at key stages of the research, description of the changes and the resulting product at pre- and post-audit and pre-implementation (i.e. the final product) is also provided.

The e-checklist intervention study is detailed in Chapter Six. The work presented in this chapter reports the culmination of work completed previously, to determine the utility of the e-checklist intervention in clinical practice. The methods are sufficiently detailed to enable replication and results follow logically from the methods in addressing each of this study's research questions.

Chapter Seven presents findings of the user/staff evaluation component of the intervention study, including before and after survey measures (user feedback and safety climate) and interviews with ICU staff specialists.

The final chapter (Chapter 8) is a summative and synthesis discussion that collates all major findings into a cohesive overview. Key implications for practice and recommendations for further research are also discussed prior to the final conclusion to this programme of research and doctoral thesis.

Contribution to the thesis

The work for this thesis was completed by myself with the support, guidance, input and advice from my PhD supervisors – Professor Doug Elliott and Adjunct Professor Anthony Burrell. In addition, the following contributions are noted for various elements of this work.

Mr Allan Zhang, Data Manager, NSW Intensive Care Coordination & Monitoring Unit assisted with data management during the point prevalence and e-checklist intervention studies, and development of the business requirements document for the PDA and server applications for the e-checklist tool, sequence diagrams, the e-checklist software, server application, web-based reporting function, and wireless connectivity.

Point prevalence study (Chapter 2)

The co-investigators (other than myself - KC) for this study were Adjunct Professor Anthony Burrell (AB), Professor Doug Elliott (DE), Dr Ian Seppelt (IS), Dr Steve Webb (SW). Two other people also contributed work related to this study and were co-

authors on the publication of study findings (Hewson-Conroy et al. 2011) – Ms Parisa Glass (PG) and Mr Colman Taylor (CT). Details of contributorship are as follows:

IS conceived the overall Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group (CTG) Point Prevalence Program, and coordinated submission of the study for ethical review; AB, KC, DE conceived the 'process-of-care' study; IS, KC, DE, AB participated in the design of the study; IS, PG, KC participated in study coordination; KC, DE, AB, IS, SW developed the CRF and data dictionary; CT contributed to data management; KC conducted data analysis and drafted the manuscript; DE, AB, IS, SW, provided critical review of results; KC, AB, DE participated in interpretation of data; all authors contributed to revising the manuscript and all read and approved the final manuscript. This study was endorsed by the ANZICS CTG as a part of the ANZICS CTG Point Prevalence Program. The ANZICS CTG reviewed and endorsed the manuscript prior to submission. The George Institute for Global Health administered research funds and provided support for management of the CTG Point Prevalence Program.

Contribution to data acquisition for this study was by site-based contributors, listed as follows (in alphabetical order, with all in Australia unless specified as New Zealand [NZ]): *Alfred Hospital, Melbourne*: V. Bennett, J. Board, A. Davies, S. Vallance; *Auckland City Hospital Cardiovascular Intensive Care Unit, Auckland, NZ*: V. Cocharne, S. McGuiness, R. Parke; *Auckland City Hospital Department of Critical Care Medicine, Auckland, NZ*:,C. McArthur, L. Newby, C. Simmonds; *Austin Health, Melbourne*: R. Bellomo, G. Eastwood, L. Peck; *Bendigo Hospital*, Bendigo: J. Fletcher, J. Smith; *Blacktown Hospital, Sydney*: G. Reece, T.Sara; *Box Hill Hospital, Melbourne*: S. Eliott, D. Ernest, J. Sidhu; *Cabrini Hospital, Melbourne*: F. Hawker; *Calvary Mater Newcastle Hospital, Newcastle*: K. Ellem, S. Meakes; *Canberra Hospital, Canberra*: R. Ashley, I. Mitchell, E. Taylor; *Christchurch Hospital, Christchurch*: S. Henderson, J. Mehrtens; *Concord Hospital, Sydney*: D. Milliss, H. Wong; *Epworth Eastern Hospital, Melbourne*: C. Giannellis, S.Ho; *Flinders Medical Centre, Adelaide*: E. Matheson, S. Verghese; *Frankston Hospital, Melbourne*: J. Botha, D. Lewis, J. Vuat; *Fremantle Hospital, Fremantle*: D. Blythe, A. Palermo; *Geelong Hospital, Geelong*: C. Cattington, T. Elderkin, M. Fraser; *Gold Coast Hospital, Southport*: B. Richards, M. Tallott, R. Whitebread; *Gosford Hospital, Gosford*: R. Cameron, S. Hatter; *Hawke's Bay Hospital,*

Hastings, NZ: L. Chadwick, R. Freebairn; *John Hunter Hospital, Newcastle*: M. Hardie, P. Harrigan, D. Whitaker; *Liverpool Hospital, Liverpool*: S. Micallef, M. Parr; *Lyell McEwin Hospital, Elisabeth Vale*: R. Ramadoss, J. Wood; *Mater Adult Hospital, Brisbane*: K. Gregory, J. Morgan, J. Presneill, J. Sutton; *Middlemore Hospital, Auckland, NZ*: J. Tai, A. Tilsley, T. Williams; *Monash Medical Centre, Melbourne*: P. Galt, C. Walker; *Nepean Hospital*: I. Seppelt, L. Weisbrodt; *North Shore Private Hospital, North Sydney*: S. Ash, A. Delaney, D. Hogben; *The Northern Hospital, Melbourne*: G. Duke, M. Park; *Prince of Wales Hospital, Randwick*: F. Bass, M. Campell, Y. Shehabi, V. Stockdale; *Princess Alexandra Hospital, Brisbane*: M. Howard, C. Joyce; *Queen Elizabeth Hospital, Adelaide*: S. Peake, T. Williams; *Royal Brisbane Hospital, Brisbane*: R. Boots, P. Jarrett; *Royal Darwin Hospital, Darwin*: D. Stephens, J. Thomas; *Royal Hobart Hospital, Hobart*: D. Cooper, R. McAllister, A. Turner; *Royal Melbourne Hospital, Melbourne*: D. Barge, C. MacIsaac; *Royal North Shore Hospital, North Sydney*: S. Ankers, S. Bird, A. O'Conner, R. Rai; *Royal Perth Hospital, Perth*: J. Chamberlaine, G. McEntaggart, S. Webb; *Royal Prince Alfred Hospital, Sydney*: D. Gattas, D. Rajbhandari; *Sir Charles Gardiner Hospital, Nedlands*: S. Baker, B. Roberts; *St George Hospital, Sydney*: V. Dhiacou, J. Myburgh; *St John of God Health Care, Subiaco*: S. Webb; *St Vincents Hospital, Melbourne*: J. Santamaria, R. Smith; *St Vincents Hospital, Sydney*: J. Holmes, P. Nair, R. Smith; *Toowoomba Hospital, Toowoomba*: B. Cheung; *Townsville Hospital, Townsville*: G. Gordon, L. Jones; *Wellington Regional Hospital, Wellington, NZ*: L. Andrews, D. Dinsdale, D. Mackle; *Western Hospital, Melbourne*: C. French, H. Raunow; *Westmead Hospital, Sydney*: A. Bannerjee, C. Skelly; *Wollongong Hospital, Wollongong*: B. Johnson, M. Sterba, R. Xu.

E-checklist intervention study (Chapter 6):

Dr Ian Seppelt and Dr Stuart Lane were clinical champions for this study at the study site and provided local input into the proposed checklist content prior to formal content development and data definitions, facilitated clinician engagement and scheduled times at unit meetings for discussion and education pertaining to study implementation.

Contribution to audit data acquisition for this study was by the local ICU research staff, particularly Phoebe Palejs, Leonie Weisbrodt, Larissa Hoyling, and other casual research staff where required.

Patient-level data was matched and extracted by the ICU Data Manager Danielle Phillips at the study site. The IT solution for the e-checklist intervention (i.e. PDA-based software, networked server and web portal) was developed by Yi Zeng and Allan Zhang.

Dr Georgina Luscombe and Professor David Sibritt provided statistical advice for analyses of e-checklist data.

Publications and presentations resulting from this work

Publications

Hewson-Conroy, K.M., Elliott, D., Burrell, A.R. 2010, 'Quality and safety in intensive care – A means to an end is critical', *Australian Critical Care*, vol. 23, no. 3, pp. 109-29.

- Paper based on content of the literature review (Chapter 2)

Hewson-Conroy, K.M., Burrell, A.R., Elliott, D., Webb, S.A.R., Seppelt, I.M., Taylor, C.B., Glass. P. 2011, 'Compliance with processes of care in Intensive Care Units in Australia and New Zealand – a point prevalence study', *Anaesthesia & Intensive Care*, vol. 39, no. 5, pp. 926-35.

- Reports findings of the Australian & New Zealand point prevalence study (Chapter 3)

Conroy, K.M., Elliott, D., Burrell, A.R. 2013, 'Validating a process-of-care checklist for intensive care units', *Anaesthesia & Intensive Care*, vol. 41, no. 3, pp. 342-48.

- Reports findings of the first formal study evaluating construct validity of the process-of-care checklist (Chapter 4.1)

Conroy, K.M., Elliott, D., Burrell, A.R. 2013, 'Developing content for a process-of-care checklist for use in intensive care units: a dual-method approach to establishing construct validity', *BMC Health Services Research*, vol. 13, no. 380.

- Describes the process for developing content for the e-checklist and reports the resulting checklist statements for use in the intervention study (Chapter 4.2)

Conroy, K.M., Elliott, D., Burrell, A.R. 'Testing the implementation of an electronic process-of-care checklist in a tertiary intensive care unit: a prospective before-after study'. Currently under review.

- Reports findings from the intervention study evaluating the impact of implementing an e-checklist.

Presentations

Burrell, A.R., **Hewson, K**. 2008, 'Compliance with the process-of-care in the ICU', paper presented to the *ANZICS Clinical Trials Group 10th Anniversary Meeting on Clinical Trials in Intensive Care*, Noosa, QLD.

Hewson-Conroy, K. 2008, 'CTG point prevalence study: process-of-care in the ICU', paper presented to the *2nd International Conference on Safety, Quality, Audit & Outcomes Research in Intensive Care*, Christchurch, New Zealand.

Hewson-Conroy, K. 2009, 'Developing and validating an electronic process-of-care checklist for intensive care units', paper presented to the *3rd International Conference on Safety, Quality, Audit & Outcomes Research in Intensive Care*, Queenstown, New Zealand.

Hewson-Conroy, K. Burrell, A.R., Elliott, D.E., Seppelt, I., Webb, S. 2009, 'Compliance with processes of care in the intensive care unit', paper presented to *the 3rd International Conference on Safety, Quality, Audit & Outcomes Research in Intensive Care Conference*, Queenstown, New Zealand.

Hewson-Conroy, K.M., Elliott, D., Burrell, A.R. 2009, 'Validating a process-of-care checklist for intensive care units', paper presented to the *7th Australasian Conference on Safety and Quality in Health Care Conference*, Sydney, NSW.

Burrell, A.R., **Hewson-Conroy, K.M.**, Elliott, D.E., Seppelt, I., Webb, S. 2009, 'CTG Point Prevalence Study: Compliance with process-of-care in the ICU', paper presented to the *34th Australian and New Zealand Annual Scientific Meeting on Intensive Care Conference*, Perth, WA.

Hewson, K. 2010, 'Electronic checklist as a strategy for improving processes of care', paper presented to the *4th International Conference on Safety, Quality, Audit & Outcomes Research in Intensive Care Conference*, Creswick, VIC.

Hewson, K. Elliott, D., Burrell, T. 2010, **'**Electronic checklist improves care delivery in tertiary intensive care unit', paper presented to the *35th Australian and New Zealand Annual Scientific Meeting on Intensive Care Conference*, Melbourne, VIC.

Conroy, K. Elliott, D., Burrell, T. 2013, 'Evaluating an electronic checklist as a strategy for improving processes of care', paper presented to the *7th International Conference on Safety, Quality, Audit & Outcomes Research in Intensive Care*, Sydney, NSW.

Chapter 2.

Background

This chapter summarises the background context for the thesis. A comprehensive literature review was initially conducted for the period January 1996 to October 2009 (detailed search strategy published in Hewson-Conroy, Elliott & Burrell 2010). Information was then updated as new, relevant literature was published during the course of the doctoral studies. The literature is discussed below using the following themes: setting the scene; quality and safety agencies and projects; evidence-based processes of care; translating evidence into practice; quality improvement strategies (including care bundles and checklists); use of technology (particularly clinical decision support systems and handheld devices); and measuring process-of-care.

Setting the scene

Improving quality and safety in healthcare is an important issue for health systems worldwide. Two landmark reports from the United States' Institute of Medicine (IoM) in 1999 and 2001 highlighted deficiencies in quality of care and patient safety (Kohn, Corrigan & Donaldson 1999) and outlined strategies for system and practice redesign (Institute of Medicine Committee on Quality of Health Care in America. 2001) respectively. A number of agencies and projects across the globe have since been established, further exploring issues designed to improve the quality and efficiency of health services. The discipline of 'safety science' has also evolved, with specific application to health care delivery (Ilan & Fowler 2005) including critical care medicine (Pronovost et al. 2009), particularly since the Declaration of Vienna (Moreno, Rhodes & Donchin 2009).

In any discussion on healthcare quality, it is important to define the term 'quality of care'. From a contemporary perspective, the IoM considered health care quality as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge' (Lohr & Schroeder 1990, p. 707). 'Quality and safety' in healthcare is commonly

described in terms of Donabedian's approach (Donabedian 1966), originally with three major domains, and more recently with an added fourth domain:

1. Patient outcomes - the results of care in terms of recovery, restoration of function and / or survival;
2. Process - the practices involved in the delivery of care;
3. Structure - the way the healthcare setting and / or system is organised to deliver care;
4. Culture – to evaluate the context in which care is delivered (suggested specifically for patient safety models) (Pronovost et al. 2009).

The contemporary model for healthcare improvement therefore recognises that the resources (structure) and activities carried out (processes) must be addressed within a given context (culture) to improve the quality of care (outcome). Quality Improvement (QI) activities identify and address specific gaps between knowledge and practice (Garland 2005a). Importantly, these activities are dynamic as they reflect the most recent and robust clinical evidence to improve patient care and reduce harm (Garland 2005b).

Of note, the complexity of patient care creates a human factors environment where errors are potentially common and safety systems are required to minimise adverse events for patients (Lohr & Schroeder 1990). To quantify deficiencies in healthcare delivery one exemplar US study assessed compliance with specific recommended processes of medical care for a wide range of conditions (McGlynn et al. 2003). Overall, participants received recommended care only 55% of the time across preventive, acute, and chronic care settings.

Importantly in Australia, national reporting of omissions in care or adverse events is in its infancy. The first, and so far only national report for Australia focused on sentinel events (i.e. a specific set of adverse events considered to be serious) in public hospitals, served to pilot a national reporting framework resulting in recommendations for improving data collection and reporting methods (Australian Institute of Health and Welfare & The Australian Commission on Safety and Quality in Health Care 2007). Earlier work conducted in 28 hospitals across two States (New South Wales and South

Australia) also clearly demonstrated the need for improved care – 17% of admissions were associated with an adverse event, with 51% of adverse events considered preventable and over half (52%) deemed errors of omission (Wilson et al. 1995). This study also demonstrated the impact of adverse events on patient outcome, with 18.5% of events resulting in permanent disability or death. A more recent study conducted specifically in a tertiary-level ICU over a 2-month period found 84% of 211 incidents were preventable, with 53% occurring during ongoing care (Beckmann et al. 2003).

A number of national and international studies further examined types of errors made in clinical (particularly critical care) settings as well as the contributing factors. Findings revealed that highly prevalent errors related to:

- patient management and treatment including errors of diagnosis and failure to apply basic cares (Beckmann et al. 2003; Sutcliffe, Lewton & Rosenthal 2004);
- staff related issues such as communication, inattention or absent mindedness, and non-adherence to policies/ procedures/ guidelines (Beckmann et al. 2003);
- delays, omissions or commissions in care delivery including that of prescribed non-medication treatments, diagnostic tests, and necessary or planned procedures (Osmon et al. 2004; Rothschild et al. 2005; Sutcliffe, Lewton & Rosenthal 2004).

Collectively these studies reflected the need for improvement in the delivery of routine patient care in adult ICUs and provided insight into the causes of error. Following the identification of this need, increased international attention was paid to the quality and safety of intensive care practice with a range of initiatives targeting improvement in a number of identified areas. These are described in the following section.

Quality and safety agencies and projects

Internationally, agencies promoting healthcare quality and safety are gaining the support of governments and funding bodies and obtaining media attention. Although there is still much to achieve, these agencies are committed to implementing changes to healthcare systems to improve the quality of care and safety of patients. To promote patient safety issues across the globe, the World Health Organization (WHO) launched

the World Alliance for Patient Safety in 2007 to 'initiate and coordinate the work of developing and disseminating solutions for patient safety' (WHO Collaborating Centre for Patient Safety Solutions 2007, p.1). An international collaborative project was then established to achieve significant reductions in five highly prevalent patient safety problems: 1) patient care hand-over errors; 2) wrong site / wrong procedure / wrong person surgical errors; 3) medication errors; 4) high concentration drug errors; and 5) hand hygiene practices. The World Alliance has since developed a classification system for patient safety (Runciman et al. 2009), including identification of 48 major concepts and definition of key terms. Other groups are also conducting similar concept mapping work e.g. (de Vos et al. 2007; Minkman et al. 2009). With a focus on intensive care medicine, the 'Declaration of Vienna' developed a directive for change noting the importance of patient and clinical team safety, and translation of knowledge to improve quality of care (Moreno, Rhodes & Donchin 2009). Following the Declaration, a task force initiated by the European Society of Intensive Care Medicine identified a set of indicators to be used to measure and improve the quality and safety of care in ICUs (Rhodes et al. 2012).

A similar initiative, the '100,000 Lives Campaign' (McCannon et al. 2006) was widely implemented throughout the US by the Institute of Healthcare Improvement (IHI) using six evidence-based interventions demonstrated to improve patient outcomes:

1. deploy rapid response teams to patients at risk of cardiac or respiratory arrest
2. deliver reliable, evidence based care for acute myocardial infarction
3. prevent adverse drug events through reliable documentation of changes in medication orders
4. prevent central line infections
5. prevent surgical site infections
6. prevent ventilator-associated pneumonia.

The majority of these interventions relate to critical care practice. While the claim of reportedly saving 122,000 unnecessary deaths over an 18-month period (Tanne 2006) was criticised for being unverifiable due to a lack of supporting hospital data (Ross 2009), the campaign was successful in promoting actions that had the potential to save patient lives and eliciting widespread stakeholder engagement (Berwick et al. 2006).

In Australia, a number of national and state-based agencies are now focused on healthcare improvement in a range of areas. The Australian Commission for Safety and Quality in Health Care (ACSQHC) facilitates national collaboration on quality and safety improvement, including the development of a national strategic framework and associated work program to guide efforts in improving quality and safety across the health care system (Australian Commission on Safety & Quality in Healthcare 2006). Recent initiatives include a Clinical Handover project as part of Australia's participation in the WHO Patient Safety Alliance's 'High Fives' initiative. Further plans include translation of Australian research into practical tools that can be implemented in various settings of care (Australian Commission on Safety & Quality in Healthcare 2007).

Another Australian agency, the National Institute of Clinical Studies (NICS), aims to improve health care by closing important gaps between best available evidence and current clinical practice by working in partnership with consumers, healthcare professionals, researchers and relevant peak organizations (Silagy 2001). The Commonwealth Government has developed a national strategy for 'Quality Use of Medicines' (QUM) and a related action plan to promote safe medication practices to improve health outcomes. The plan assists a range of stakeholders - healthcare consumers, practitioners, educators, facilities, funders and purchasers, pharmaceutical companies, the media, and governments to: become more aware of policy; enable them to integrate their own activities with the national strategy; and to gain and improve commitment to working in partnership to achieve QUM (Commonwealth of Australia 2002).

Other State-based organisations have also implemented a range of quality and safety projects (see Table 2.1). For example, in NSW the Department of Health established the Clinical Excellence Commission (CEC) to implement projects that promote improved patient safety and excellence in clinical care (The Clinical Excellence Commission 2007). Some CEC projects with particular relevance to ICUs include Performance Indicators and Medication Safety (PIMS) Project (in conjunction with NSW Therapeutic Advisory Group), Venous Thromboembolism Prevention Program (in conjunction with NICS), Safer Systems-Saving Lives, and Central Line Associated Bloodstream Infections (CLABSI) in ICUs. The CLAB ICU project is a 'top-down,

bottom-up' collaboration in NSW ICUs. Primarily aimed at promoting aseptic insertion of central lines, a similar reduction in CLABSI rates to those reported in other studies (Pronovost et al. 2006c) has been achieved (Burrell et al. 2011).

The translation of clinical evidence into practice is therefore a key underlying principle to achieving improvements in healthcare delivery and outcomes (Pronovost, Berenholtz & Needham 2008; Woolf 2008), with numerous models, methods and strategies proposed (Grol 1997; Rubenfeld 2004a).

Table 2.1. Examples of State-based organisations that have implemented quality and safety projects

Organisation	Project	Year	Description
NSW Clinical Excellence Commission (CEC)	Safer Systems-Saving Lives (SSSL)	2006-2007	Based on the IHI's 100K Lives Campaign, six interventions (prevention of adverse drug events, ventilator-associated complication, central venous catheter-related blood stream infections, surgical site infections, and implementing a rapid response system) were implemented at 48 regional and metropolitan sites across Australia (7 states and territories).
CEC	CLABSI in ICUs	2007-present	Involves a modified collaborative methodology to implement a consensus guideline to reduce CLABSI in Intensive Care, building on the work commenced through the SSSL project.
CEC & National Institute of Clinical Studies	Venous Thromboembolism Prevention Program	2005-2009	Developed to improve the assessment of all patients at risk, improve the use of preventive measures and integrate effective thromboprophylaxis systems into Australian hospitals.
CEC & NSW Therapeutic Advisory Group	PIMS Project	2004	Focused on improving medication safety systems and monitoring performance in QUM in Australian hospitals by: 1) adapting US developed risk assessment tools specifically for hospitals to take a proactive and system-based approach to medication safety; and 2) producing a revised manual of 'Indicators for Quality Use of Medicines in Australian Hospitals' (NSW Therapeutic Advisory Group 2007) to enable hospital managers and clinicians to guide improvements in medication management.

Organisation	Project	Year	Description
Victorian Quality Council	Pressure Ulcer Point Prevalence Surveys (PUPPS) project	2003, 2004 & 2006	Conducted three state-wide surveys on the prevalence of pressure ulcers within acute and subacute health services. The level of improvement in pressure ulcer prevalence, prevention and management was tracked over time. In 2006, mean prevalence was 17.6% (a 33% reduction since 2003), there was a 25% increase in the use of a risk assessment tool, and 22% increase in the proportion of patients with a pressure reducing/relieving device in situ (Victorian Quality Council 2006).
Victorian Quality Council	Pressure Ulcer Basics (PUBS) education program	2004	In responding to recommendation from the PUPPS project, developed two online education programs aimed at providing basic information on pressure ulcer development, assessment, management and prevention, for all clinical staff (Victorian Quality Council. 2005).

Evidence-based processes of care

One of the three domains of quality proposed by Donabedian (Donabedian 1966), and arguably one that has been unjustly overshadowed by outcomes (Lilford et al. 2004), is the measurement of clinical process. Process measures assess the extent to which health care providers perform certain activities that lead to desirable patient outcomes (Rubin, Pronovost & Diette 2001). These measures offer important insights into quality by providing a direct measure of care. To be valid, process measures need to: be supported by good clinical evidence, logic or experience; based on either established clinical standards or agreed criteria; and include identifiable actions (Lilford et al. 2004). Table 2.2 describes studies that examined process-of-care delivery in intensive care.

Contemporary process measures of health care quality exhibit both advantages and disadvantages. Advantages include: data collection can be embedded into the daily practice routine; relates directly to clinical practice; are easy to benchmark; and when compared with risk-adjusted outcomes – have lower costs, take less time to collect, and require a smaller sample size (as all eligible patients experience the process). Importantly, these types of measures facilitate acceptance from clinicians because of the direct relationship with care activities, and offer clear and interpretable feedback for

quality improvement (Rubin, Pronovost & Diette 2001). Disadvantages include having to: specify eligible populations for a process given there can be exclusions and contraindications and many are specific to a single disease; create valid summary measures given they are rarely comprehensive; and regularly update and maintain the relevance and appropriateness of measures (Rubin, Pronovost & Diette 2001). Although these limitations pose challenges to the implementation of process measures, they can be addressed by proper design, planning and close monitoring during implementation.

The role of evidence in improving the quality of healthcare is crucial. Evidence-based medicine (EBM) integrates individual clinical expertise with the best available external clinical evidence from systematic research (Sackett et al. 1996). Good quality clinical care is achieved by implementing practices that work according to the current knowledge base, and avoiding those that do not. Over the past decade, increasing attention has been directed towards the development, implementation and evaluation of evidence-based process-of-care measures. For example, a review prepared for the US Agency for Healthcare Research and Quality (AHRQ) (Shojania et al. 2001) identified 79 evidence-based practices most likely to improve patient safety. Eleven received the highest rating, with three of these related to ICU process measures: appropriate deep venous thromboembolism (DVT) prophylaxis; appropriate provision of nutrition; and pressure ulcer prevention. 'Prevention of ventilator-associated pneumonia (VAP) via semi-recumbent positioning' was also rated highly on strength of evidence, while stress ulcer prevention and inadequate pain relief were rated with a 'medium' strength of evidence category.

To specifically develop ICU process measures, Berenholtz and colleagues (Berenholtz et al. 2002) conducted a systematic review and an extensive evaluation of several potential measures including appropriate sedation, prevention of VAP via semi-recumbent positioning, appropriate stress ulcer prophylaxis, appropriate DVT prophylaxis and effective assessment of pain. Most measures were rated highly on strength of evidence and recommendation for use, while pain was the only measure to be selected on face validity alone. These indicators were later used to measure quality of care in 13 ICUs (see Pronovost et al. 2003 in Table 2.2) (Pronovost et al. 2003b).

Table 2.2 Studies describing process-of-care delivery in intensive care units

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Scales et al, 2011. (Canada)	Cluster-randomised trial	15 community hosp, medical-surgical ICUs (ranging from 4-19 beds)	9269 admissions during trial, 7141 admissions during "decay-monitoring" period; 32 interviews with ICU clinicians (3 physicians, 27 nurses, 1 respiratory therapist, 1 dietitian)	• During each 4-month trial phase, each grp of ICUs received intervention targeting pairs of related care practices whilst acting as control grp for other ICUs targeting different care practices; all ICUs eventually received all interventions • Pairs of process measures were: 1) HOB positioning & DVT prophylaxis; 2) sterile precautions for CVC insertion & daily SBT; 3) early enteral nutrition & daily risk assessment of developing pressure ulcers • Multi-faceted QI strategy used for each targeted practice included educational outreach, audit & feedback, reminders, summarised guidelines, local champions provided educational rounds/activities. • *Subject to bias- practices requiring direct observation (e.g. HOB angle) & cares measured using data from medical records (e.g. DVT prophylaxis)* • *Baseline compliance with POC already high for some practices making further improvements difficult to achieve* • *Pt outcomes not measured*	• Adoption of targeted practices overall greater in intervention than control ICUs (summary OR=2.8; 95% CI=1-7.7); improvements sustained over time despite shifts in focus to new process measures • Improvements in delivery of care greatest for HOB positioning (90% vs 50%; OR=6.4; 95% CI=2-22) and precautions to prevent CR-BSI (70% vs 11%; OR=30; 95% CI=11-82); practices with high adherence at baseline changed little • Interviews with clinicians revealed: feedback of comparative results key to driving improvements; participation increased within-ICU communication; focus on POC measures appreciated due to heterogeneity of pts; local improvement strategies prior to study leads to higher baseline measures; most important components of QI intervention were audit & feedback of process measures, EB summaries & availability of central coordinating office
Berenholtz et al, 2011. (USA)	Multi-centre cohort before-after study	112 ICUs from 72 hospitals	550,800 vent-days	• Multi-faceted interventions to reduce incidence of VAP • Cross-sectional sampling to collect vent bundle compliance • Process measures (HOB positioning, DVT & stress ulcer prophylaxis, sedation mx, assessing readiness to extubate) collected daily during 1st quarter, then approx 1-2 days per week (min. 15 vent pts per month) thereafter if continuous not feasible • *No concurrent control grp to compare with*	• Overall median VAP rate decreased from 5.5 cases (mean = 6.9 cases) per 1,000 vent-days at baseline to 0 cases (mean = 3.4 cases) at 16-18 mths post-intervention (p<.001) & 0 cases (mean = 2.4 cases) at 28-30 mths post-intervention (p<.001) • After adjusting for confounders and clustering in data, there was a sig decrease in VAP rates over time with incidence rate ratios (95% CI) of .5 (.4-.6) at 16-18 mths and .3 (.2-.3) at 28-30 mths; results similar for ICUs reporting continuous data

				• *Uniform surveillance definition of VAP not enforced* • *Reliability of diagnosing VAP uncertain* • *Importance of all bundle components not evaluated* • *Contribution of each strategy used in intervention not evaluated*	• Composite compliance with process measures increased from 32% of vent-days to 75% at 16-18 mths (p<.001) & 84% at 28-30 mths (p<.001) post-intervention
Study	**Design**	**Sample**		**Method / *Critique***	**Findings**
		Setting	**n / cohort**		
Morris et al, 2011. (Scotland)	Before-after study	18-bed medical-surgical ICU	Pre-intervention = 1460 pts, post-intervention = 501 pts	• Tested the effect of implementing VAP prevention bundle (daily sedation hold & trial of ventilator weaning i.e. "wake & wean", HOB positioning, chlorhexidine mouth care) • Multiple QI strategies used: asking nurses to complete "wake & wean" checklist, clinical champions, teaching materials, education sessions, bedside cues, feedback on compliance • Bundle compliance audited weekly at variable times, obtaining data from previous day's charts • Outcome measures = clinically diagnosed & microbiologically confirmed VAP, antibiotic use & MRSA acquisition • Secondary measures = mech vent duration, ICU LOS & mortality • *Unequal sample sizes* • *Possible confounders not factored in to analysis* • *Audit of documentation may not reflect actual practice* • *Impact of variable bundle compliance not measured* • *Primary outcome measures used surveillance data and secondary outcomes not measured prospectively* • *Contribution of each strategy used in intervention not evaluated*	• Post-intervention compliance with oral chlorhexidine & HOB positioning consistently >95% , "wake & wean" less consistent with 70% compliance on average; full compliance with all elements of VAP bundle during post-intervention 70% • Sig reduction in VAP (32 cases per 1,000 vent-days to 12 cases per 1,000; p<.001) • SPC charts showed decrease was most marked after bundle implementation • Pts with ≥6 & ≥14 days had greater reduction in VAP acquisition & also had reduced antibiotic use (reduced by 1 & 3 days; p = .008/.007 respectively) • MRSA rates decreased from 10% to 3.6% (p<.001) • No change to mech vent duration & ICU LOS • Crude ICU mortality reduced from 25% to 20% (p = .03), reduction more pronounced in pts staying ≥6 & <14 days; SMR for entire ICU population trended down over the study period from .88 to .68.

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Papadimos et al, 2008. (USA)	Before/after study using historical control in a single-centre	10-bed surgical ICU	1315 (over 2 yrs Pre-intervention); 1653 (over 3 yrs post-intervention)	• Historical control (1 year pre-intervention) and year 1 combined were compared to extended post-FASTHUG period • Year 1 - procedural interventions included oral care, early extubation, mx of respiratory equipment, hand-washing & maximal sterile precautions • Year 2- FASTHUG used on twice daily pt rounds • *Compliance with care processes not measured* • *No randomisation, no causal links between process and outcomes*	• No difference in VAP rate b/w historical control yr (19.3/1000 vent days) and Intervention yr 1 (16.6/1000 vent days), p=0.62. • Sig reduction after Intervention yr 2 (7.3/1000 vent days), p<.01 • Median VAP rate sig lower during Year 2 compared with control yr (z=2.2, p=.03) and yr 1 (z= 2, p=.03). • Reduction in VAP rates (p=0.0004) using time series analysis • Pt severity of illness sig higher in post-FASTHUG group compared to pre-FASTHUG group (p=0.001) • No difference in other pt characteristics
Ilan et al, 2007. (Canada)	Retrospective observational study reviewing both print and electronic medical records	20-bed tertiary academic medical-surgical-trauma ICU	100 randomly selected pts admitted over 1yr	• Multiple regression analysis tested the association between compliance (%) and severity of illness and adjusted for age, gender, source of admission (surgery & trauma vs. medical). • *Audit of prescription of best practice, not actual delivery* • *Directional relationships cannot be implied among associations found*	• Variability in eligibility for (median 37%, range 10-100%) & actual prescription (57%, range 8-95%) of best practices • Percentage of eligible pts receiving practice: VTE prophylaxis 95%; SUP 90%; enteral nutrition 72%; insulin infusion 59%; specialty mattress for prevention/mx of pressure ulcer 18%; interruption of sedation 8% • Greater prescription of practices when standard admission orders existed i.e. nutrition, VTE & stress ulcer prophylaxis vs. all others (p = .05) • Inverse relationship between prescription of best practices and severity of illness (β= -.93, p = .001)

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Keroack et al, 2006. (USA)	Point prevalence; Retrospective chart review	38 academic medical centers - 114 ICUs of 15 types (65% medical, surgical, cardiac, cardiothoracic)	1463 cases, mech.vent >96 hrs	• Data extracted from clinical database & supplemented by chart review • Correlations between pairs of interventions and logistic regression model for mortality included each intervention as an independent variable (also incorporated severity of illness, age, gender, race & 21 specific comorbidities) • *Audit sampled a single day as a proxy for practice throughout the ICU stay* • *Some outcomes e.g. VAP, not measured* • *Confounding factors not accounted for in the regression model*	• Median (range) of adherence: sedation mx 59% (31-100%); SUP 89% (60-100%); DVT prophylaxis 88% (53-100%); HOB positioning 52% (0-100%); spontaneous breathing trials 53% (0-100%); glycaemic control 42% (30-87%). • In evaluating the 'ventilator bundle', 31% of eligible pts received all 4 measures • No correlation between pairs of interventions • Progressive decrease in observed mortality as the no. of interventions increased • Strong association with survival for 2 interventions- sedation management and glycaemic control (odds ratios for death = .30 and .46 respectively, $p < .01$)
Hatler et al, 2006. (USA)	Prospective, before-after	8-bed medical ICU over 12 months	Not stated	• Multi-faceted intervention included clinician engagement, daily rounds & pt goals forms, data feedback, range of communication strategies & rewards using rapid-cycle approach • 'HOTSPUD' mnemonic reminder: HOB>30°, oral care, turning pt, sedation vacation, peptic ulcer and DVT prophylaxis • *Impact of individual components of multi-faceted intervention not reported* • *Compliance with individual care components not detailed* • *Tools not formally evaluated* • *Uncontrolled study design* • *Statistical analysis not detailed*	• Adherence to ventilator bundle increased from 73% to 99%; DVT prophylaxis greatest variability in implementation • VAP rate reduced 54% from 11.4/1000 ventilator days to 5.3/1000 resulting in 23 fewer VAP occurrences • Rate of CR-BSIs reduced 78% from 12.8 to 2.9 • Mean LOS reduced 18% from 3.6 to 4.4 days • Annual cost savings = $97,700 - $267,700 for reduction in VAP; $220,000 - $1,309,000 for reduction in CR-BSIs; $726,600 for reduced mean length of stay

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Resar et al, 2005. (USA)	Before-after	35 ICUs	Not stated	• Implemented vent bundle, multidisciplinary rounds and daily pt goals • Outcome measures- weighted averages of 6-mthly VAP rates (1st 6 months= "before", 2nd 6 months = "after") • *No baseline data collected prior to intervention* • *Voluntary data submission = incomplete & inconsistent* • *Reporting bias - outcomes assessment not standardised or blinded* • *Other relevant outcomes not measured e.g. VTE, GI bleed*	• 57% of teams reported data required for analysis • Units with the highest compliance rates with bundle had highest rates of VAP reduction • In 21 units with ≥95% compliance, VAP rates decreased 59% from 6.6 to 2.7 per 1,000 vent days (p<.001) • VAP rate decreased 45% in all units that provided required data and a minimum 20% improvement in adherence to vent bundle
Wall et al, 2005. (USA)	Before-after using real time process measurement	14-bed adult medical ICU	Not stated	• CQI methodology including provider education, continuous audit, performance feedback & checklist developed as a measurement tool/ reminder • SPC charts used- measured process of CVC care in real time • Baseline: approx. 2 yrs, 9 months; Intervention: approx. 2 yrs (630 CVCs inserted) • *Extraneous variables that may have impacted on CR-BSI rate not controlled for e.g. case-mix, catheter duration* • *Contribution of strategies used in intervention not evaluated*	• CR-BSI rate reduced from 7/1000 catheter days to 3.8/1000. • No. days between infections increased post- intervention (depicted graphically using process control chart).
Crunden et al, 2005. (UK)	Retrospective	6-bed general ICU/HDU	Baseline audit n=21 (pt obs.); Post- intervention n=24 Pt outcomes & unit activity: Pre-test: 286; Post-test: 372	• Evaluated impact of a vent care bundle (DVT & stress ulcer prophylaxis, sedation stop, HOB>30°) on outcomes • Audit data by chart review; compliance (pre- and post-implementation of care bundle, 7 months apart) • Measure outcomes over 2 yr study period • *Methods not detailed* • *Only limited improvement in compliance, other factors could have influenced changes in outcomes*	• Compliance with care bundle: DVT prophylaxis decreased (81 to 71%), HOB>30° increased (71 to 83%) & sedation stop increased (29 to 63%). Stress ulcer prophylaxis 100% at both • Mean ICU LOS reduced from 13.8 days to 8.4 days (p<.05) • Mean vent days reduced from 10.8 days to 6.1 days • Unit pt throughput increased 30% & no. of mech vent pts increased 40%

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Pronovost et al, 2003. (USA)	Prospective, cross-sectional, observational	13 adult medical & surgical ICUs	Not stated	• Compliance with process measures • *No outcome measures* • *'Appropriateness' of SUP and DVT prophylaxis not clearly defined or explicitly evaluated* • *Reported results of pilot data collection only*	• Performance varied widely among & within 13 ICUs. • Median (ranges): effective assessment of pain 84% (30-98%); appropriate sedation 64% (2-100%); head-of-bed elevation 67% (42-99%); appropriate SUP 89% (71-98%); appropriate DVT prophylaxis 87% (48-98%)
Clemmer et al, 1999. (USA)	Before / after quasi-experimental with historical controls	12-bed tertiary shock/trauma/ respiratory ICU	2,764 (range: 512-602 per yr) over 5 yrs	• Formal staff training, create & implement computerised standard practice protocols • *Impact of individual components of multi-faceted intervention not reported* • *No randomisation* • *Methods of process measurement and analysis not described* • *Despite certain controls and risk adjustment, causal links between improvement projects and costs of care cannot be directly inferred*	• Sig improvement in glucose control (mean of all glucose measurement reduced from 9.9 ± 4.4 to 8.2 ± 2.7 mmol/L), use of enteral feeding (reduction of pts on TPN from 15% to 8%, reduction in days starting enteral feeding from 3 to 1.6 days), and appropriate use of sedation (95% reduction in sedation costs), among others. • A severity adjusted total hosp cost reduction of $2,580,981 with 87% of the reduction in cost centers directly influenced by the intervention

^ Results from critical care units reported in this table.

Abbreviations: b/w = between; CQI = continuous quality improvement; CR-BSI = catheter-related bloodstream infection; CVC = Central Venous Catheter; DVT = deep vein thrombosis; GI = gastro-intestinal; HOB ≥30° = head-of-bed elevated to greater than or equal to 30 degrees; grp = group; HDU = high dependency unit; hosp=hospital; ICU = intensive care unit; LOS = length of stay; mech vent = mechanical ventilation; mx = management; no. = number; pts = patients; yr = year; QI = quality improvement; sig = significant; SPC = statistical process control; SUP = stress ulcer prophylaxis; TPN = total parenteral nutrition; VAP = ventilator associated pneumonia; vent = ventilator; VTE = venous thromboembolism.

Importantly, these type of process measures of care have been linked with better health outcomes. For example, in an international randomised control trial (RCT) consisting of a large sample of Australian and New Zealand intensive care patients, conventional glucose control (i.e. maintenance of glucose concentrations below 10.0mmol/L) was associated with lower mortality and a lower rate of hypoglycaemia when compared with tight glycaemic control (4.5 – 6.0mmol/L) (Finfer et al. 2009). When compared to usual care, protocolised sedation has been associated with decreased mortality and both ICU and hospital length of stay in mechanically ventilated patients (Minhas et al. 2013), and use of standardised weaning protocols associated with reductions in duration of ICU stay, mechanical ventilation and weaning (Blackwood et al. 2011). In a systematic review of RCTs, early enteral nutrition was associated with a reduced hospital length of stay and lower incidence of infections (Marik & Zaloga 2001) and a cluster-RCT revealed that evidence-based algorithms were associated with shorter hospital stay and improved nutritional support in ICU patients (Martin et al. 2004).

Some processes have also been shown in to improve surrogate end-points; e.g. semi-recumbent body position has been associated with lower nosocomial pneumonia rates (Drakulovic et al. 1999); heparin thromboprophylaxis was associated with decreased rates of DVT and pulmonary embolism (PE), and low-molecular-weight heparin associated with decreased PE and symptomatic PE (Alhazzani et al. 2013).

Arguably, intensive care practice has a substantial body of good clinical evidence that should be integrated into everyday practice, and there appears to be an increasing number of broad-scale QI projects to achieve that aim. There has also been a range of recent clinical trials examining elements of practice (e.g. glucose control, nutrition, sedation, deep venous thrombosis prophylaxis), and subsequent work evaluating implementation of best practice and QI initiatives at local ICU levels.

Translating evidence into practice

The widespread translation of evidence into practice is the necessary next step following identification of best practice. Despite gaining national and international attention, achieving practice change at a local level has however proved challenging (Weinert & Mann, 2008), leading to an area of research dedicated to developing, implementing and evaluating strategies for the translation of evidence into practice (Woolf, 2008).

A contemporary model for translating evidence into practice has been successfully trialled in 100 intensive care units in the US (Pronovost, Berenholtz & Needham 2008). Findings demonstrated that implementing a series of targeted interventions can improve healthcare processes and unit safety culture and reduce adverse events (Pronovost et al. 2006a). Although the model was tested in this large scale collaborative project, it can be equally applied to smaller projects. The framework involves four key steps: 1) summarise the evidence; 2) identify local barriers to implementation; 3) measure performance; 4) implement the intervention using the "four Es" i.e. *Engage* local teams, *Educate* staff, *Execute* the intervention, and *Evaluate* the intervention (Pronovost, Berenholtz & Needham 2008).

To identify more specific strategies that are effective in clinical settings, further exploration of the literature revealed that much of the existing knowledge around translating clinical evidence into practice has focused on guideline implementation. For clinical practice guidelines to be successfully implemented, clinicians must believe they are beneficial to clinical practice by reducing practice variation, assist the implementation of research findings at the bedside and result in a more rapid implementation of best practice (Sinuff et al. 2007). There is evidence to suggest that evidence-based guidelines, recommendations and practices are followed more than those that are not supported by scientific evidence (Grol, Dalhuijsen & Thomas 1998; Leape et al. 2003). Other enabling factors include aspects related to a constructive ICU culture such as effective leadership and positive inter-professional team dynamics (Sinuff et al. 2007). With regard to changing provider behaviour, dissemination and implementation strategies that are more likely to be effective take active rather than

passive approaches and involve multifaceted rather than single interventions (Grimshaw et al. 2001). In terms of delivery, guideline formats need to be simple (e.g. pre-printed orders, checklists) and electronic media may assist with implementation (Shiffman et al. 1999; Sinuff et al. 2007).

Potential barriers to successful implementation of clinical practice guidelines have also been identified. Barriers to guideline adherence by physicians included a lack of awareness, familiarity, agreement, self-efficacy, outcome expectancy as well as inertia of previous practice (Cabana et al. 1999). External barriers identified included those related to the guidelines (e.g. inconvenient, difficult to use), patients (e.g. inability to reconcile patient preferences with guideline recommendations) and the environment (e.g. lack of time/ resources/ reminder systems, increased costs and liability) (Cabana et al. 1999). Physicians are also more likely to deviate from following practice guideline recommendations in practice guidelines in situations where its value is debatable or it might be more risky (Leape et al. 2003).

A number of strategies have been proposed to overcome the potential barriers to translating evidence into practice. These strategies are derived from identifying and addressing both the enablers and barriers to the implementation process. Strategies could include implementing multifaceted interventions that have demonstrated some degree of effectiveness such as reminder techniques, audit and feedback, the use of local opinion leaders, electronic media and communication technology, educational materials, in-services and continuing education (Berenholtz & Pronovost 2003; Grimshaw et al. 2001; Oxman et al. 1995; Sinuff et al. 2007). Interventions also need to target specific areas for improvement and utilise multi-faceted strategies where appropriate for the greatest impact (Oxman et al. 1995; Shojania & Grimshaw 2005).

Quality improvement strategies

The need for targeted, complementary QI strategies in ICU settings was highlighted as part of a comprehensive plan to improving delivery of care in the ICU (Garland 2005a, 2005b). It was proposed that instead of expecting individual physicians to remember all of their patient's details, 100% of the time, it is necessary to create structures and

processes in the ICU that ensure all patients receive every applicable evidence-based best practice. Strategies to increase or improve the use of specific practices included education, audit with feedback, clinical practice guidelines, reminders, order sets, computerisation, and combinations of these (Garland 2005a, 2005b). For example, in a systematic review of 30 studies that used various strategies to improve venous thromboembolism (VTE) in hospitals, the most effective strategies incorporated using a reminder system (electronic or paper based) to assess for VTE risk and used both audit and feedback to assist with refining the intervention (Tooher et al. 2005).

In an important viewpoint paper discussing evidence-based practices in the ICU, Vincent proposed that to achieve effective bedside rounds, a series of evidence based statements needs to be raised systematically and considered for each patient (Vincent 2004). With further reference to relevant clinical literature, he later introduced the 'FASTHUG' mnemonic (Feeding, Analgesia, Sedation, Thromboembolism prophylaxis, Head-of-bed elevation, stress Ulcer prevention, and Glucose control) (Vincent 2005). Although 'FASTHUG' does not cover all aspects of every patient's care and will not apply to all patients at all times, it does highlight seven key areas to be considered daily by the entire clinical team for each patient during their ICU stay (Vincent 2005).

An IHI collaborative project developed a set of quality indicators for the evaluation of care, resulting in a comprehensive guide to measuring performance in ICUs that included evidence-based measures, strategies for change, and a range of implementation tools (Pronovost & Berenholtz 2002). A number of other initiatives have since been implemented to improve care delivered both within and outside ICUs, including the implementation of process tools such as daily goals (Pronovost et al. 2003a), morning briefings (Thompson et al. 2005), and safety scorecards (Berenholtz & Pronovost 2007), as well as a unit-based safety program (Pronovost et al. 2005; Pronovost et al. 2004b).

The daily goals form was devised to improve communication between ICU clinicians and to assist in developing explicit patient-centred goals. The form contained standard processes of care including semi-recumbent patient positioning, sedation cessation, peptic ulcer prophylaxis and DVT prophylaxis, and was to be completed during patient

ward rounds. Clinical staff reviewed the goals throughout the day and updated them if a change occurred. Form use increased the proportion of resident doctors and nurses who understood what the patient daily goals and tasks to be completed were, from less than 10% to over 95% over an 8-week period (Pronovost et al. 2003a). Similarly, the morning briefing tool was introduced to direct attention to safety issues during clinical handover. Briefings covered: an update of issues that occurred overnight (e.g. adverse events, near misses, admissions, discharges); prioritised the order in which patients were seen; and identified current problems or defects (e.g. equipment availability, staffing, patient scheduling & testing) (Thompson et al. 2005).

The comprehensive unit based safety program (CUSP) identified deficits in care using a structured 8-step approach designed to: encourage staff to identify and eliminate potential errors in patient care settings; engage senior hospital executives to work with staff on identifying patient safety issues; and empower unit staff to address identified issues. The program required six months for implementation and consisted of the following steps: 1) conduct a culture survey with staff; 2) educate staff on patient safety; 3) identify specific safety concerns through a separate staff survey; 4) implement the 'Senior Executive Adopt-a-Work Unit Program which involved assigning an executive to a unit who worked collaboratively with staff to identify potential areas for improvement and develop strategies to address them; 5) implement improvements using a plan-do-study-act (PDSA) cycle; 6) document the results and share stories on project successes and failures; 7) disseminate results within the organisation; and 8) repeat the cultural survey with staff after six months to compare with baseline data (Pronovost et al. 2008). While the CUSP intervention improved median 'teamwork climate' from 47% to 51% (in the 72 ICUS with before-after Safety Attitudes Questionnaire data), adherence to evidence-based practices ranged from 25-89%, and the before-after design limited any causal inference (Pronovost et al. 2008).

As noted earlier, other clinical tools that are typically used for quality and particularly process improvement include clinical practice guidelines, standardised order sets and pre-printed protocols or clinical pathways (Hales et al. 2008). As also discussed previously, clinical practice guidelines have numerous potential limitations and are often static documents that are not actively implemented, evaluated or easily

interpretable. Order sets are instructional tools that contain a thorough list of all the possible orders to be considered for a certain group of patients (e.g. those requiring anticoagulation therapy) which means not everything needs to be addressed (Winters et al. 2009). Protocols and pathways contain steps to follow for a single aspect of care and although they have their place in the clinical management of certain patient conditions, they are purposely directive and cannot be used broadly across the ICU patient population. Common and relevant approaches for practice improvement, particularly in relation to ICU practice, such as care bundles and checklists, are described in more detail below.

Care bundles

Leading from the development of the above process initiatives, evidence-based 'bundles of care' were developed by the IHI (Berwick et al. 2006). The previous Table (2.2) also outlines studies examining process-of-care delivery in critical care units, including those where care bundles were implemented and evaluated. One bundle directed towards reducing the incidence of ventilator-associated pneumonia (VAP) in critically ill patients included the following elements:

- elevating the head of the patient's bed to 30-45 degrees;
- daily 'sedation vacations' or gradually lightening sedative use each day;
- daily assessment of the patient's readiness to extubate or wean from the ventilator;
- delivering both DVT and stress ulcer prophylaxis.

While other evidence-based strategies for VAP prevention are noted (Muscedere et al. 2008), and some care components in the IHI bundle (particularly DVT and stress ulcer prophylaxis) have not been directly associated with a reduction in VAP (Ruffell & Adamcova 2008), when these components were delivered as a part of a bundle of care, patient outcomes improved. For example, increased bundle compliance was associated with decreased ICU length of stay (LOS), reduced ventilator days and increased ICU patient throughput (Crunden et al. 2005), and decreased rates of ventilator-associated pneumonia (Berenholtz et al. 2011; Morris et al. 2011; Resar et al. 2005).

Other quality improvement studies targeted similar processes of care without using a bundled approach (Table 2.2). A range of measures demonstrated improved outcomes:

- decreased VAP (Hatler et al. 2006; Papadimos et al. 2008), catheter-related bloodstream infection (CR-BSI) rates and LOS (Hatler et al. 2006);
- increased days between CR-BSIs (Wall et al. 2005);
- decreased hospital mortality as the number of process interventions increased (Keroack et al. 2006); and
- reduction in severity-adjusted total hospital costs related to improvements in process measures of care, including glucose control, use of enteral feeding and appropriate sedation (Clemmer et al. 1999).

Although studies revealed improvements in both processes and outcomes, variation in levels of compliance with process measures were also reported. Importantly, substantial variations in practice were identified, including the prescription and delivery of stress ulcer and DVT prophylaxis, enteral nutrition, glycaemic control, prevention and management of pressure ulcers, sedation management practices, semi-recumbent positioning, spontaneous breathing trials, and pain assessment (see Table 2.2 for detail). Three studies reported variation in compliance of processes between units (Keroack et al. 2006; Pronovost et al. 2003b; Resar et al. 2005). Interestingly, one study (Ilan et al. 2007) reported an inverse relationship between the prescription of best practices and severity of illness (coefficient β= -.93, p=.001). That is, the sicker the patient was, the less likely they were to have received practices they were eligible for.

These studies were not without their limitations in both design and measurement. Measurement poses the greatest challenge for examining the effect of implementing interventions to improve processes of care. Common limitations included practicalities of data collection (Ilan et al. 2007; Resar et al. 2005; Ross 2009), establishing consistent definitions e.g. not all units use the Centers for Disease Control and Prevention criteria for VAP (Berenholtz et al. 2011; Resar et al. 2005), using appropriate process (Papadimos et al. 2008) and/or outcome measures (Keroack et al. 2006; Resar et al. 2005; Ross 2009), not controlling for extraneous variables that could impact on outcomes (Crunden et al. 2005; Morris et al. 2011; Papadimos et al. 2008; Resar et al. 2005; Wall et al. 2005), and lack of baseline data for comparisons (Resar et al. 2005). Low inference study designs were common; e.g. uncontrolled (Berenholtz et al. 2011; Crunden et al. 2005; Hatler et al. 2006; Ilan et al. 2007; Papadimos et al. 2008; Resar et

al. 2005), and retrospective (Crunden et al. 2005; Ilan et al. 2007; Papadimos et al. 2008). Other methodological limitations included: small, unknown or unequal sample sizes (Crunden et al. 2005; Hatler et al. 2006; Morris et al. 2011; Resar et al. 2005); limited representation of ICU population due to single centre studies (Clemmer et al. 1999; Crunden et al. 2005; Hatler et al. 2006; Ilan et al. 2007; Morris et al. 2011; Papadimos et al. 2008; Wall et al. 2005); failure to evaluate tools developed and used as part of the intervention (Hatler et al. 2006); and not evaluating the impact of individual components of multi-faceted interventions on outcomes (Berenholtz et al. 2011; Clemmer et al. 1999; Hatler et al. 2006; Morris et al. 2011; Wall et al. 2005).
As evident from the above summary, there are various methodological approaches to improving processes of care, particularly those pertaining to care of the ventilated patient (Ruffell & Adamcova 2008), and clinician opposition to the concept of care bundles has been noted (Camporota & Brett 2011). Professional opinion on what the components of a 'ventilator bundle' should be also varies greatly (Heyland, Cook & Dodek 2002; Tolentino-DelosReyes, Ruppert & Shiao 2007), and processes of care that require attention may vary from one ICU to another (Fulbrook & Mooney 2003; Westwell 2008).

Checklists

Checklists can be separated from other cognitive aids, reminders and protocols, as they are more formal and more structured than simple mnemonics, but less formal than protocols that require completion of mandatory items in order to reach a pre-determined outcome. A checklist typically contains a list of action items or criteria arranged in a systematic way, allowing the user to record the presence or absence of individual items to ascertain that all are considered or completed (Hales & Pronovost 2006).

Checklists have multiple uses, including standardisation and regulation of processes or methods, providing a framework for evaluations and assessments, aiding memory recall, and providing a diagnostic tool (Scriven 2007). Regardless of how they are used, their main purpose is commonly to ensure adherence to best practice or error reduction (Hales & Pronovost 2006).

In recognising the likelihood of human error and the potential for risks to safety, the use of checklists is highly regulated in aviation and aeronautics and for the most part, is

considered a mandatory part of practice. There are numerous checks performed before, during and after flights e.g. pre-flight checks, cockpit checks, starting engine checks, and takeoff and landing checks (Degani & Wiener 1990). Checklists have since been adopted for use in a number of different industries including product manufacturing, mechanics, software engineering, and are key to workplace safety assessments.

The use of checklists in healthcare, particularly surgical, anaesthetic, and intensive care settings has increased markedly in recent years. The most prominent study to date developed as part of the World Health Organization's 'Safe Surgery Saves Lives' program – a multi-centre study (8 hospitals in 8 cities across the globe) evaluating the impact of a 19-item surgical safety checklist on patient outcomes (Haynes et al. 2009). Results demonstrated improvement in all 6 process measures (from 34% to 57%, $p<0.001$) and a reduction in both the rate of death (from 1.5% to 0.8%, $p=0.003$) and complications (from 11% to 7%, $p<0.001$). Since this study, numerous others have since utilised or adapted the World Health Organization's checklist for use in operating theatres to reduce patient mortality, complications from surgery and adverse events (Askarian, Kouchak & Palenik 2011; Bliss et al. 2012; Van Klei et al. 2012; Weiser et al. 2010). Other reported benefits included increased compliance with VTE guidelines (Truran, Critchley & Gilliam 2011), improved safety attitudes of staff (Haynes et al. 2011), improved communication, familiarity with other team members and teamwork (Böhmer et al. 2012; Kearns et al. 2011; Takala et al. 2011).

In intensive care settings, checklists have been used to detect errors, improve handover of patient care, check compliance with safety standards and evidence-based processes of care (such as those outlined previously), increase knowledge of patient-centred goals and prompt clinicians to review certain practices on morning rounds in the ICU. Findings from studies (see Table 2.3) noted that checklists:

- reduced loss of critical information during patient handover (Stahl et al. 2009);
- assisted in improving the understanding of patient therapy and care goals (Agarwal et al. 2008; Dobkin 2003; Narasimhan et al. 2006), communication amongst ICU clinicians (Narasimhan et al. 2006; Phipps & Thomas 2007) and compliance with safety standards (Piotrowski & Hinshaw 2002);

- detected patient safety errors (Ursprung et al. 2005) and omissions in care (Hewson & Burrell 2006; Pronovost et al. 2003b);
- improved compliance with evidence-based care (Byrnes et al. 2009; DuBose et al. 2008; Piotrowski & Hinshaw 2002; Wall et al. 2005);
- were not time consuming (Hewson & Burrell 2006; Pronovost et al. 2003b) or labour intensive (Pronovost et al. 2003b);
- when developed in conjunction with clinicians produce a valid and reliable tool that is consistently used (Pronovost et al. 2003b);
- enabled collection of real-time process measures to assist in the immediate identification of anomalies (Wall et al. 2005); and
- may be most beneficial when combined with additional prompting (Weiss et al. 2011).

Some of the studies suggested that checklists also contributed to improved outcomes: 1) reduced LOS (Narasimhan et al. 2006), ventilator days and unit mortality (Dobkin 2003); 2) catheter-related bloodstream infections (Wall et al. 2005); and 3) reduced mean monthly rates of VAP (DuBose et al. 2008). However, the current evidence base is scant and lacking in methodological rigour. Limitations of all the studies evaluating checklists included:

- study designs that lack comparison with other methods (Byrnes et al. 2009) and/ or control of extraneous variables (Dobkin 2003; DuBose et al. 2008; Wall et al. 2005), preventing inference of causal links between checklist use and improved outcomes;
- outcomes closely related to practices in the checklists not measured (Dobkin 2003; Hewson & Burrell 2006; Pronovost et al. 2003b);
- impact on care not evaluated (Agarwal et al. 2008; Byrnes et al. 2009; Narasimhan et al. 2006; Phipps & Thomas 2007; Piotrowski & Hinshaw 2002; Pronovost et al. 2003b; Ursprung et al. 2005);
- utility of a checklist in detecting and correcting omissions or errors not evaluated (Hewson & Burrell 2006; Ursprung et al. 2005);
- not determining the contribution of multifaceted interventions to reported improvements; (DuBose et al. 2008; Wall et al. 2005)

- lack of baseline data or statistical process control limited inferences of measured improvements (Byrnes et al. 2009; Hewson & Burrell 2006; Pronovost et al. 2003b; Ursprung et al. 2005);
- lack of formal validity and reliability testing (Byrnes et al. 2009; DuBose et al. 2008; Hewson & Burrell 2006; Narasimhan et al. 2006; Piotrowski & Hinshaw 2002; Ursprung et al. 2005; Wall et al. 2005);
- extensive lists imposed additional burden on busy clinical staff (Ursprung et al. 2005); and
- sustainability issues, particularly where data collection was resource intensive (Pronovost et al. 2003b).

Additional studies that address these methodological limitations are therefore required to demonstrate the benefits of checklists in different healthcare settings, including intensive care. Improving rigour and quality of study methods can be improved with attention at the design and data collection, management and analysis phases; including standardised data collection forms, training, auditing for data quality, and management of missing data (Needham et al. 2009).

In response to early promising results however, and their proven ability to reduce error in industries such as aviation (Boorman 2001), checklists are being promoted widely (BBC News 2009; Gawande 2007) and an increasing number of healthcare settings are integrating them into clinical practice.

Theoretically, some of these limitations could also be addressed by integrating checklists into existing technology, such as computer information systems. The electronic collection, analysis and presentation of data have the potential to deliver outcomes in a timely, consistent and reliable manner that is sustainable over time. The use of technology in this context is considered in the next section, below Table 2.3.

Table 2.3. Studies evaluating the implementation of checklists in ICUs

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Weiss et al, 2011. (USA)	Prospective concurrently controlled cohort study and retrospective analysis	Medical ICU	Prospective: 140 pts in intervention, 125 control Retrospective: 1,283 pts in pre-intervention grp	• Verbal prompting for 6 POC (mech vent weaning, empirical antibiotics, CVCs, Foley urinary catheters, DVT and stress ulcer prophylaxis) during daily ward rounds, if overlooked • Compared POC delivered to pts admitted to 'prompted' team vs pts admitted to 'unprompted' team, both with access to checklist • Pre-intervention group obtained via retrospective analysis of admission data spanning almost 1 yr prior to intervention • Secondary outcomes were ICU & hosp mortality, ICU LOS • *Pts in intervention arm included even if prompter not present during their ICU stay; no subgrp analysis of prompted grp* • *Unclear how separation b/w grps studied concurrently was achieved* • *Different sample sizes between pre- & post-intervention* • *No difference b/w grps in median LOS which is appropriate measure for skewed data* • *Use of and compliance with checklist not measured*	• Prompter present on 68% of prompted grp daily rounds & prompting was required on 65% of pt days • Compared with control, prompted grp had increased median (IQR) vent-free days (22 [14-26] vs 16 [0-22], p = .03) decreased empirical antibiotic (2 [1-3] vs 3 [2-7], p = .01) and CVC (3 [2-5] vs 5 [2-8], p = .007) days, increased mean (SD) rates of drug DVT (0.9 [0.2] vs 0.7 [0.3], p <.001) and stress ulcer prophylaxis (0.9 [0.2] vs 0.8 [0.3], p <.001) • Compared with control, prompted grp had lower risk-adjusted ICU (OR = .36, 95% CI = .1 – .9, p = .04) & hosp mortality (10 vs. 21%, p = .014) also sig after risk adjustment (OR = .34, 95% CI = .15–.76, p = .008) & lower mean (SD) LOS (3.5 [4.3] vs 4.9 [7], p = .07 • Prompted grp had lower hosp mortality than pre-checklist grp and remainder of pre-intervention grp. No such difference b/w control & pre-intervention grps
Stahl et al, 2009. (USA)	Prospective cohort study	Trauma/ surgical ICU	332 pt days observed (119 control, 213 intervention). 689 care items tracked (303 control, 386 intervention)	• Implemented/evaluated an ICU handover checklist • 2 weeks control (observers collected data using checklist) and 2 weeks intervention (medical staff & observers used checklist) • Measured amount of critical information lost during handover • *Response rates unknown* • *Impact of lost data not studied* • *Adverse outcomes to patients not measured* • *Direct observation subject to Hawthorne Effect*	• Loss of critical information including information on laboratory or test results, antibiotics/cultures/medicines, nutrition/ventilation, tubes/CVP/intravenous orders, reduced from 20% to 3.6% (p<.0001) with use of checklist.

Study	Design	Sample		Method / *Critique*	Findings
		Setting	**n / cohort**		
Byrnes et al, 2009. (USA)	Before-after observational (prospective and retrospective)	24-bed surgical/ burn/ trauma ICU	114 pts (prospective), 1285 pts (retrospective)	• Prospective component – before-after real-time bedside audits on morning rounds. Pre-intervention = checklist available, not mandated. Intervention = verbal review of all checklist items mandated. • Retrospective component – evaluable domains in database compared 4 mths baseline (prior to checklist development) with 4 mths post-intervention • *No true baseline of all checklist domains, prospective audits commenced once checklist was available* • *Actual delivery of care not quantified – the endpoint of audit was discussion of domains on multidisciplinary morning rounds* • *Only 4 of 14 domains were evaluable via database analysis* • *No reliability or validity tests on checklist*	• Consideration of checklist domains improved from 91% (530/583 assessments) at pre-intervention to 99.7% (669/671) post-intervention (p<.0001) • Variation between checklist domains (range = 77-100%) decreased post-intervention (range = 98-100%) • Sig improvement in SUP (89 vs 100, p=.007), DVT prophylaxis (92 vs 100, p=.03), electrolyte repletion (89 vs 100, p=.007), oral care for ventilated pts (85 vs 98, p=.008), physical therapy use (81 vs 98, p=.02) & documentation of restraint orders (77 vs 100, p<.0001) • Evaluation of related data elements demonstrated sig improvement in no. of pts transferred on telemetry (16 vs 35, p<.0001) & physical therapy use (27 vs 42, p<.0001) • Trends towards more rapid initiation of pharmacologic DVT prophylaxis (1.8 vs 1.4, p=.08) & CVC duration (6.1 vs 5.4, p=.11) weren't statistically significant
Du Bose et al, 2008. (USA)	Prospective, before-after	Level 1 trauma ICU	810 pt days (244 pre-implementation, 185 month 1, 188 month 2, 193 month 3)	• Quality Rounds Checklist (QRC) tool developed & used to measure compliance with 16 prevention measures e.g. VAP, CL infection • QRC used to collect baseline data for 1 month (clinical staff blinded) • Implementation included monthly process improvement activities i.e. reminders, prompts, education, revising protocol • *Contribution of each component of multifaceted intervention to improvements not determined* • *No formal reliability or validity tests on checklist*	• Compliance with following cares increased significantly (p<0.05): HOB elevation (35.2% to 84.5%); sedation holiday (78% to 86%); stress ulcer prophylaxis (76.2% to 92.3%) • Decrease in CL duration >72 hrs (62% vs 53%) and ventilator duration >72 hrs (74% vs 62%) • Decrease in mean monthly rates per 1,000 device days of VAP (16.3 vs 8.9), CL infection (11.3 vs 5.8) & self-extubation (7.8 vs 2.2)

				• *Not controlled for extraneous variables that may have impacted on outcome measures* • *Relevance of all outcome measures to process measures reported unclear* • *Relationship between process measures and outcomes not tested* • *Statistical analyses conducted not detailed* • *Before/after analysis included 3 months of intervention as 'after' measure*	
Study	**Design**	**Sample**		**Method / *Critique***	**Findings**
		Setting	**n / cohort**		
Argarwal et al, 2008. (USA)	Prospective, pre- and post-intervention study	12-bed medical-surgical PICU	Staff members – 419 pre-intervention, 387 post-intervention	• Daily goals sheet implemented during morning ward rounds, completed by medical staff, able to be modified by all members of interdisciplinary team • Measured understanding of daily patient care goals (via questionnaire) and LOS (using midnight census 4 months pre- and 4 months post-implementation) • *Census methods for calculating LOS known to be inaccurate and confounders impacting on LOS not factored in e.g. severity of illness* • *Non-independence of data due to duplication of respondents* • *Possibility of responder bias to unvalidated questionnaires* • *Completion rates of goal sheets and individual items unknown* • *Primary outcome measure relied on self-report data* • *No process or patient outcome data*	• Understanding of pt care goals improved for nurses – mean scores increased from 4.2 (SD=0.8) to 4.5 (SD=0.6), p<.001; and for physicians from 4.0 (SD=0.6) to 4.7 (SD=0.5), p<.001 • Nurses knowledge of: who attending physician responsible for pt was increased from 75% (SD=0.4), to 92% (SD=0.3), p<.001; who fellow responsible for pt was increased from 79% (SD=0.4) to 93% (SD=0.3), p<.001 • 76% respondents found goal sheets helpful • No change in LOS

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Phipps et al, 2007. (USA)	Prospective, pre- and post-intervention study	12-bed medical-surgical PICU	Nurses – 26 pre-intervention, 22 post-intervention	• Daily goals sheet implemented • Measured nurses perception of communication via questionnaire prior to intervention and 12months post-intervention • *Different samples before and after and response rate lower post-intervention; nurse turnover unknown* • *Possibility of responder bias to unvalidated questionnaires* • *Completion rates of goal sheets and individual items unknown* • *Primary outcome measure relied on self-report data* • *Views of medical staff unknown* • *No process or patient outcome data*	• Reported improvement: communication between physicians and nurses = 85% and communication amongst nurses = 73%.
Narasimhan et al, 2006. (USA)	Longitudinal study	16-bed ICU	Not described	• Daily goals sheet implemented • Measured level of understanding around goals of care and perceived communication (5-point scale) via questionnaire, patient LOS (first 9 months post-intervention compared to same 9-month period in preceding year) • *Unknown sample size and response rates* • *LOS data assumed normally distributed (known to be skewed)* • *Possibility of responder bias due to unvalidated questionnaires* • *Completion rates of goal sheets and individual items unknown* • *Primary outcome measure relied on self-report data* • *No process or patient outcome data*	• Understanding daily goals scores increased from 3.9 (SD=1) to 4.8 (SD=0.4) for nurses (p=.001) and from 4.6 (SD=0.7) to 4.9 (SD=0.3) for physicians (p=.03) • Communication scores increased from 3.6 (SD=.9) to 4.3 (SD=.9) for nurses (p=.03) and from 3.4 (SD=0.9) to 4.7 (SD=0.5) for physicians (p=.01) • Mean LOS decreased from 6.4 to 4.3 days (p=.02)

Study	Design	Sample		Method / *Critique*	Findings
		Setting	**n / cohort**		
Hewson & Burrell, 2006. (Australia)	Prospective, observational	16-bed tertiary adult ICU	426 checklists (114 pts) Evaluation: 10 medical staff at baseline, 15 post-implementation	• Develop, implement & review a 16-item EB process-of-care checklist • Checklists completed daily as a direct 'challenge and answer' on morning ward rounds by medical staff for 1 month. Checklists served as data collection tool. • Baseline and evaluation surveys conducted with ICU staff • *Correction of omissions not measured* • *Manual collection of data was burdensome* • *No baseline data = no quantification of improvement* • *Psychometric properties of checklist not evaluated*	• 81% compliance in completing the checklist • Certain cares not delivered when appropriate (e.g. 21% of pts were in pain, 31% of invasively ventilated pts could not respond appropriately) • Majority of medical staff believed care improved with use of checklist & all thought it assisted in ensuring good quality care was delivered • It took an average of 2.5 mins to complete checklist
Wall et al, 2005. (USA)	Before-after using real time process measurement	14-bed adult medical ICU	Not stated	• Baseline: approx. 2 yrs, 9 months; Intervention: approx. 2 yrs (630 CVCs inserted) • Multi-faceted intervention included implementation of a nursing checklist for CVC insertion developed as a measurement tool/reminder** • SPC charts used- measured process of CVC care in real time • *No validity or reliability tests on checklist* • *Extraneous variables that may have impacted on CR-BSI rate not controlled for e.g. case-mix, catheter duration* • *Contribution of each component of multifaceted intervention to improvements not determined or evaluated*	• CR-BSI rate reduced from 7/1000 catheter days to 3.8/1000. • No. days between infections increased post-intervention (depicted graphically using process control chart).

Study	Design	Sample		Method / *Critique*	Findings
		Setting	**n / cohort**		
Ursprung et al, 2005. (USA)	Prospective, observational	20-bed tertiary care medical-surgical neonatal ICU	Average daily census of 19.5 pts	• 36-item pt safety checklist developed via modified Delphi technique. • Safety process audits performed using checklist during and after morning ward rounds 2-3 days per week for 5 weeks (13 days) • Errors reported to appropriate staff upon detection • *Auditing process was time consuming and occasionally disrupted the flow of rounds* • *Reliability of checklist not tested* • *Impact of detecting errors on quality of care not measured*	Utility: • 338 errors detected representing a range of systems problems • Errors detected on all days of auditing- 35 errors detected during multidisciplinary rounds, 303 via observation at pts bedside including medical record review Feasibility: • Auditing was completed all 13 days attempted • Clinical staff disclosed errors on all days of auditing • Errors not evaluated by the checklist were reported on more than 17 occasions Content validity: • 9 items detected no errors & additional errors were reported
Pronovost et al, 2003. (USA)	Prospective, cross-sectional, observational	13 adult medical & surgical ICUs in urban teaching & community hospitals	Not stated	• A scannable Daily Rounding form was completed on morning ward rounds & collected data on process measures** • Tests for reliability (inter-rater) and validity (construct and content) • *Sustainability of data collection for the measures tenuous without additional resources due to data processing external to the unit* • *Impact of data collection form on care delivered not measured* • *No baseline data = no quantification of improvement*	• Performance varied widely among & within 13 ICUs • Interviews: the form was easy to understand and could be completed in < 2 mins per pt • Focus group: low burden of data collection, collecting process measures much less onerous than outcome data • Validity: ICU physicians and quality experts agreed process measures addressed important aspects of ICU quality & all were supported by clinical evidence • Reliability: high reliability for each of the process measures (K = 0.9 for appropriate sedation and 1.0 for the 5 other measures)

Study	Design	Sample		Method / *Critique*	Findings
		Setting	n / cohort		
Dobkin, 2003. (USA)	Observational	Surgical ICU	Not stated	• Implement & evaluate a pt daily goals check-off form • The form comprised pt safety goals & EB process measures & used twice daily by multidisciplinary team on ward rounds • Measured accuracy of nurse's knowledge of pt goals • *Medical staff knowledge of daily goals not measured* • *Extraneous variables that may have impacted on outcome measures not controlled for* • *Outcomes some practices were designed to prevent not measured*	• Improvement in nurse's understanding of the goals of therapy (from approx. 50% of the goals planned to 98-100%) • Reduction in LOS by an average of 1.5 days • Reduction of ventilators days by an average of 1 day • Decreased overall unit mortality from 11.5% to 8.3%
Piotrowski & Hinshaw, 2002. (USA)	Prospective, observational	Medical, surgical and thoracic ICUs at one medical centre	Not stated	• Pt safety checklists to be completed by nurses, respiratory therapists and maintenance staff. • Nurses incorporated checklist (includes rotating and intermittent standards) into change of shift report • Compliance data presented in graphs and tables provided to staff as feedback on performance • *No baseline data* • *No formal reliability or validity tests on checklist* • *Time burdens on staff to complete an extensive list of safety checks* • *Data not subject to statistical control* • *Difficult to quantify the effect of checklist given its configuration altered several times*	Improvements made over 2 yr period included: • 60% increase in physician restraint assessments completed • 50% increase in completion of restraint safety flow sheets • 42% increase in delivery of mouth care every 4 hrs • 31% increase in documentation of sedation scale

Abbreviations used in table: approx = approximately; CI = confidence interval; CL = central line; CVC = Central Venous Catheter; CR-BSI = catheter-related bloodstream infection; DVT = deep vein thrombosis; EB= evidence based; grp = group; HOB = head-of-bed; hosp=hospital; ICU = intensive care unit; LOS = length of stay; mins = minutes; no. = number; OR = odds ratio; POC = process-of-care; pts = patients; SBT = spontaneous breathing trial; sig = significant; SPC = statistical process control; SUP = stress ulcer prophylaxis; USA = United States of America; VAP = ventilator-associated pneumonia; WHO = World Health Organisation; yr = year.

** The checklist was not the sole intervention in this study. Only information relevant to the checklist component is reported in this table.

Use of technology

The use of technology to improve care delivered in intensive care settings is on the increase (Rubenfeld 2004b). Bedside clinical information systems and related clinical decision support systems, order-entry strategies and handheld technologies are being used and combined in various ways for a range of purposes (Levy 2004; Seiver 2000). Importantly, the impact of these systems on quality of care are being evaluated, resulting in a growing evidence base demonstrating the successful attributes of technologies implemented in clinical settings (Mills et al. 2013). This is particularly relevant to intensive care settings where a multitude of information is used to inform important clinical decisions (Bosman 2009). This section describes implementation and evaluations of clinical decision support systems and use of handheld devices in clinical practice.

Clinical Decision Support Systems

Clinical decision support systems (CDSSs) can be defined as "information systems that aid providers in various aspects of clinical decision making" (Mack, Wheeler & Embi 2009, p.24). These systems provide patient-specific decision support at the point of care by interfacing with hospital databases to retrieve patient specific and other relevant clinical data and to generate recommended actions (Sim et al. 2001). Importantly, clinical decision making at the bedside can be enhanced by providing clinicians with a readily available tool that incorporates relevant clinical information and evidence-based medicine (Sucher 2008). In an early systematic review of computer-based CDSSs on physician performance and patient outcomes, 43/65 studies (66%) reported improved physician performance and 6/14 (43%) studies reported better patient outcomes (Hunt et al. 1998). Nineteen studies evaluated the effect of CDSSs providing preventive care reminders on clinician performance and 14 (74%) found benefit for at least one of the measured processes of care e.g. vaccination, cancer screening. Examining a different range of implementation systems, a systematic review of the functionality and effectiveness of computer-based guideline systems identified a total of 25 papers that described 20 discrete systems (Shiffman et al. 1999). Improvement was evident in 14/18 studies that evaluated provider adherence to guidelines resulting from electronic recommendations, advice, and reminders. Three studies demonstrated improved patient outcomes e.g. a system designed to help prevent pressure ulcers was associated with a

decreased incidence of decubiti (Wilson, Ashton & Wingate 1995). A rigourous more recent systematic review of RCTs evaluating the ability of CDSSs to improve clinical practice identified four independent predictors of effective decision support: 1) automatic provision of a CDSS as part of clinician workflow; 2) provision of recommendations rather than just assessments; 3) provision of a CDSS at the time and location of decision making; and 4) computer-based generation of decision support (Kawamoto et al. 2005). Other potentially beneficial features included: integration with charting or order entry system rather than stand alone systems; providing periodic performance feedback to clinicians about their compliance; sharing recommendations with patients; and requesting documentation of reasons for not following recommendations (Kawamoto et al. 2005).

Implementation of a CDSS designed to provide immediate information pertaining to venous thromboembolism prevention among surgical patients resulted in changed physician behaviour (i.e. improved appropriateness of prescription), improved compliance with guidelines (from 83% to 95% overall) and decreased error rates (from 17% to 5% overall) (Durieux et al. 2000). CDSSs have also been associated with improvements in intensive care delivery including adherence to guidelines on head-of-bed positioning for patients receiving mechanical ventilation (Lyerla et al. 2010), adherence to a lower tidal volume mechanical ventilation strategy (Eslami et al. 2009), reduction in red blood cell transfusions (Fernandez Perez, Winters & Gajic 2007), antibiotic utilisation i.e. reductions in total and broad-spectrum antibiotic use and increased de-escalation to narrower spectrum antibiotics (Thursky et al. 2006), reductions in the use of antibiotics and patient length of stay (Sintchenko et al. 2005), improved mechanical ventilatory support of patients with ARDS (McKinley et al. 2001), and increased standardisation of intracranial pressure management after traumatic brain injury (McKinley, Parmley & Tonneson 1999).

A number of recommendations to consider when implementing CDSSs have been made. Similar to other clinical tools, decision support needs to: incorporate the highest level of evidence available; be “evidence-adaptive”, reflecting the most recent developments and customised to the local environment; and be integrated with existing computerised systems so all the relevant information can be drawn upon (Sim et al.

2001). Pre-implementation education needs to be comprehensive and purposeful (need to know why the system is being implemented as well as how to use it), practical (multi-modal, includes training at the bedside), and involve all relevant staff (Sucher 2008; Weber et al. 2009). In terms of practical application of CDSSs, it is important for clinicians to decide that the intervention is appropriate for the individual patient in the current clinical context before delivering interventions recommended by the CDSS (Sucher 2008).

With the success of CDSS being very much reliant on integration with information technology and existing clinical information systems, there is an obvious gap to be filled for units that do not have such systems in place and are not resourced to have them developed and implemented.

Handheld devices

The combination of wireless applications and portable electronic devices enable mobility within clinical settings, facilitating access to clinical information at the point of care. Handheld computers or personal digital assistants (PDAs) have been reported as a popular tool among medical trainees and physicians (Kho et al. 2006) and usage amongst clinicians continues to grow (Payne, Wharrad & Watts 2012). Clinical uses for these devices are also evolving at a rapid pace (Mitchell 2012).

Systematic reviews have explored both perceptions of handheld technology and its' effectiveness in healthcare settings. The results of one review suggested handheld devices enabled more accurate, complete and efficient documentation, provided easy and timely access to information and enhanced clinical work flow allowing increased efficiency to work practices (Mickan et al. 2013). With regards to workflow, physicians required less time per patient encounter when using PDAs in comparison to paper (Prgomet, Georgiou & Westbrook 2009); and PDA use by physicians reportedly led to improved efficiency of daily ward rounds and more time for direct patient care as a result of spending less time accessing, retrieving and recording data (Lu et al. 2005).

In critical care, handheld computers were a feasible and useful tool for implementing an internet-linked procedure logging system (Martinez-Motta et al. 2004), and a reliable method of collecting observational data relating to clinical work tasks and

communication (Ballermann et al. 2011). They have also been used to deliver point of care decision support to improve antibiotic prescribing (Sintchenko et al. 2005), increase resident physician knowledge and accuracy in antibiotic selection (Bochicchio et al. 2006), and deliver an interactive weaning protocol that assisted respiratory care practitioners wean patients from mechanical ventilation more efficiently when compared with the use of a paper-based weaning protocol (Iregui et al. 2002).

Despite all the positive attributes of handheld devices, limitations have also been reported including a lack of user-friendly interfaces, data crashing, hardware breakage, encryption of patient data, small screen sizes, difficulty in entering data and viewing all relevant information (Mickan et al. 2013; Prgomet, Georgiou & Westbrook 2009).

Measuring process-of-care

One of the most prominent methods for measuring process quality, particularly in the field of healthcare improvement, is statistical process control (SPC). This method utilises control charts to display variation in process data over time; observations are plotted as they would on a run chart, along with a centre-line representing the average of the observed data, and both upper and lower confidence limits set at plus and minus three standard deviations from the average (Pronovost et al. 2004a). SPC comprises 'statistically derived decision rules' that assist in determining whether performance of a process is stable and predictable (common cause variation) or whether there is variation in performance that makes it unstable and unpredictable (special cause variation) (Thor et al. 2007). When observed data fall within the confidence intervals and there are no rule violations, the process is deemed to be stable. Conversely, when data points fall outside the confidence intervals or rule violations are present, further investigation is required to explain the unpredictable pattern of variation in the data and eradicating it (e.g. by informing staff about new unit policies that may differ substantially from current practice).

SPC reporting has the advantages of: allowing continual assessment of performance which can be measured in real-time; presenting data in such a way that it is easy to understand and interpret in the clinical setting; avoiding false alarms (due to

conservative critical limits) that can arise from small sample sizes and non-normal data; distributions identifying early important changes to care processes that may signal potential harm and providing the opportunity to prevent or mitigate that harm (Pronovost et al. 2004a). Importantly, SPC has been used to identify areas for improvement, contribute to actual improvement of healthcare processes, assess the impact of changes to the process (Thor et al. 2007) and measure, monitor and evaluate safety and quality improvement initiatives in ICUs e.g. (Krimsky et al. 2009; Wall et al. 2007).

There are however, limitations to SPC to consider when evaluating improvement efforts, including: improvement does not occur automatically after performance data is shared via control charts; process control or stability does not necessarily equate to clinical control nor desired performance; SPC cannot establish cause and effect relationships and cannot adjust for confounding variables such as patient severity of illness; correct application and interpretation of SPC requires sufficient knowledge in both QI and SPC; other limitations regarding data for use in control charts such as autocorrelation (Thor et al. 2007). Measurement of care processes may therefore require other complementary approaches that deal with the limitations that are likely to apply to the data being collected.

Accurate measurement of care processes within the context of a QI project also requires application of data quality control methods to all project phases (Needham et al. 2009); these key principles are outlined in Table 2.4.

Measuring patient-level adverse events may be another useful way of monitoring and evaluating the effectiveness of strategies to improve processes of care (Frutiger 1997). The challenges associated with this include separating preventable from inevitable harm and linking failure to deliver a process-of-care with a related adverse event (Pronovost et al. 2009).

Table 2.4 Data quality control methods for QI projects

Project phase	Key principles
Design	Clearly stated project aims Valid definitions and measurement system for the required data Focus on data quality
Data collection	Standardised data collection forms and data definitions Written instructions for collecting data Train staff to collect data Review data for quality assurance Utilise electronic database for data management Put data controls in place to identify errors Back-up plan for electronic database
Data management	Evaluate data using basic statistics Strategies for minimising missing data Review data for missing values
Data analysis	Report missing data, account for it using appropriate methods Identify and evaluate potential outliers Use appropriate measurement methods to provide a summary of project results Present measures of precision with results Use appropriate methods to evaluate the impact of factors that may confound the results

Note: table content adapted from Needham et al. (2009).

Summary

The need for healthcare organisations to constantly strive for improvements in the delivery of care has been demonstrated. The complexity of care delivered in an ICU makes this particularly challenging as there are many structures and processes to consider. Importantly, any improvement initiative must ultimately impact positively on patient care.

A number of evidence-based processes of care identified in the literature can be measured to help drive improvements in intensive care. They include appropriate provision of nutrition, assessment and management of pain and sedation, appropriate DVT and stress ulcer prophylaxis, semi-recumbent positioning, blood sugar management, pressure ulcer prevention and management, prevention of central line-associated bloodstream infection, and aspects of ventilator care such as assessing the patient's readiness to be weaned from the ventilator.

Translating this evidence into clinical practice is key to making improvements to the delivery of care. A model tested by Pronovost, Berenholtz & Needham (2008) provided a clear and logical framework for this study and literature evaluating the implementation of clinical practice guidelines provided advice on strategies most likely to make an impact such as multi-faceted rather than single interventions and active rather than passive approaches to implementation. Other suggested strategies included clinician engagement and leadership, education and training, audit and feedback, and using information technology where appropriate.

The development, implementation and evaluation of QI strategies to improve care delivery in ICUs is still in its' infancy. Bundles of care that aim to improve cares delivered to certain patient groups (e.g. ventilated patients) showed promise, but have received clinician opposition due to inflexibility of content and limited applicability across the broader ICU patient population. The literature reveals some momentum behind the use of checklists in clinical settings however, more rigourous studies are required to confirm the proposed benefits (such as improved practice adherence) in intensive care settings.

The reported utility of technology in clinical settings is of particular interest to this area of study, particularly with claims of improved clinical processes and patient outcomes resulting from the provision of patient-specific decision support at the point of care. The latest technology can incorporate many useful features such as providing timely evidence-based recommendations and reminders, recording important aspects of patient care, and issuing periodic feedback on performance. These functions can be built into portable, handheld devices for use by clinicians at the bedside.

Given the reported benefits of integrating technology into healthcare, along with the reported benefits of using checklists in clinical settings, it seems both reasonable and necessary to combine the two concepts in devising a tool that has the potential to improve patient care. Such a tool could serve to reduce errors by reminding clinicians to deliver essential care that is based on the best available evidence.

The following chapter provides baseline data on evidence-based processes of care of ICU patients, within the Australian context. Following chapters then describe the processes involved that culminate in development and testing of an electronic checklist of processes of care, using a handheld device during morning clinical rounds.

Chapter 3.

Prevalence of care processes in Australian and New Zealand ICUs

Introduction

As demonstrated in Chapter 2, a set of common evidence-based practices for ICU patients, along with related process measures, have been identified, reviewed, and recommended based on established level of evidence gradings (Berenholtz et al. 2002; Berwick et al. 2006; Pronovost et al. 2003b; Shojania et al. 2001). The 'FASTHUG' mnemonic (Feeding, Analgesia, Sedation, Thromboembolism prophylaxis, Head-of-bed elevation, stress Ulcer prevention, and Glucose control) has also been widely promoted for use at the bedside (Vincent 2005). Bowel management and pressure area risk assessment were also identified as cares that require increased clinical attention (Hewson-Conroy, Elliott & Burrell 2010; Hewson & Burrell 2006). Many of these practices have been incorporated into contemporary clinical practice guidelines that are relevant to the treatment of critically ill patients (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2010; Australian Wound Management Association 2001; Critical Care Clinical Practice Guidelines Committee 2009; Dellinger et al. 2008; Heyland et al. 2003; Jacobi et al. 2002; Muscedere et al. 2008; National Health and Medical Research Council 2009), and into bundles of care (Berwick et al. 2006).

Although a number of recent studies have reported different levels of compliance with these processes of care in ICUs, indicating that omissions in care may be common (Crunden et al. 2005; DuBose et al. 2008; Hewson & Burrell 2006; Ilan et al. 2007; Keroack et al. 2006; Pronovost et al. 2003b), it was not known whether this is the case in Australian and New Zealand practice. The aim of this study was to therefore measure the prevalence of routine care processes actually being delivered in a large sample of Australian and New Zealand ICUs.

Methods

Design

A cross-sectional analytic design was employed for a one-day point prevalence study, as part of the annual Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group (CTG) Point Prevalence Program (The George Institute for Global Health 2014).

Settings and patients

The study was conducted in a sample of 50 ICUs treating adult patients in Australia and New Zealand on one of three designated days in May/June 2009. A total of 182 adult ICUs (35 tertiary, 39 metropolitan, 49 rural/regional, 59 private) were eligible in both countries (Drennan, Hart & Hicks 2010) at the time of recruitment. To obtain a large sample of ICUs, an invitation to participate was issued via mailing lists to all ANZICS members, including member units of the ANZICS CTG. All patients admitted to the participating ICUs at 10am on the study day were included.

Data collection

Statements exploring process-of -care activities were developed by the research team after completing a comprehensive literature search and considering relevant recommendations by professional bodies e.g. NHMRC (National Health and Medical Research Council 2009), Institute of Healthcare Improvement (Institute for Healthcare Improvement. 2010)), then reviewing and modifying them for clinical appropriateness within the context of Australian and New Zealand intensive care practice. This informed development of a study specific Case Report Form (CRF) and data dictionary (key definitions provided in Table 3.1) that were piloted by three ICUs and subsequently refined based on feedback from research staff at the pilot sites. On the study day, data were collected by research staff using the refined CRF and data dictionary, on multiple processes of care including nutrition, presence and management of pain, sedation, prophylaxis for venous thromboembolism, ventilation, elevation of the head-of-bed, stress ulcer prophylaxis, management of constipation, and pressure areas. Items required a ‘yes’, ‘no’ or ‘not applicable’ answer; ‘not applicable’ was defined as not clinically indicated according to the data dictionary. The definitions provided were used in conjunction with local clinical policies.

Table 3.1 Data Definitions for point prevalence study

Item	Description	Reason 'not applicable'
Nutrition	Any form of caloric intake i.e. enteral, parenteral, oral. Includes patients who have had feeds suspended temporarily but will be fed for more than half of the study day (or is expected to receive an adequate caloric intake if on intermittent feeds or an oral diet)	1. Low acuity – patient expected to recover quickly 2. 'Nil by mouth' for gastrointestinal reasons 3. Fasting for surgery 4. Palliative or terminal care 5. Other (please document)
Nutrition within 24 hours	Refers to whether nutrition was commenced within 24 hours of admission to the ICU	Unknown e.g. Patient has been in the ICU for < 24hrs
Formal assessment of nutritional goals	The prescription of a nutritional goal based on a combination of weight, demographics and biochemistry	Patient receiving a normal ward diet
Nutritional goals	Achieved when at least 80% of the calculated requirement had been delivered, averaged over the preceding 24 hours	Patient in ICU < 24 hours
Pain assessment	Refers to whether the medical team has assessed the patient's pain on the study day. The medical team needed to have asked the patient or bedside nurse about pain.	Medical team had not seen the patient at time of audit or patient has not been in ICU long enough to assess.
Patient pain	Refers to whether the patient was experiencing significant pain at the time of audit. 'Significant' pain might be worse than 3/10 on a visual analogue score, or pain that is clearly distressing to the patient or the nurse.	

Item	Description	Reason 'not applicable'
Pain management plan	Documented by ICU staff, anaesthetist or acute pain service. Standing orders for pain management count as a plan provided they are clearly being applied to the patient.	
Need for sedation	Includes those patients with an artificial airway (endotracheal tube or tracheostomy only) and requires sedation for facilitation of ventilation. Excludes patients on non-invasive ventilation, and those who do not require sedation for facilitation of ventilation.	
Sedation medications	Includes any drugs given for the purpose of sedation, delivered via infusion or bolus in the last 24 hours. This includes benzodiazepines (midazolam, diazepam etc), propofol, opioids if used with sedative intent (morphine, fentanyl), dexmedetomidine, antipsychotic drugs used with sedative intent (haloperidol, olanzepine, quetiapine) and other drugs such as chloral hydrate	
Sedation titration	Includes patients being titrated to the sedation score or level as prescribed by medical staff. Can include extremely deep sedation targeted to an intracranial pressure (ICP)	
Pharmacological Deep Vein Thrombosis (DVT) prophylaxis	Includes unfractionated heparin (sodium heparin, calcium heparin), low molecular weight heparin (enoxaparin, dalteparin)	1. Systemic anticoagulation (heparin / warfarin / heparinoids / pentasaccharide) or inferior vena cava (IVC) filter 2. Coagulopathy / bleeding risk 3. Repeat surgery 4. Not indicated due to unit policy 5. Other contraindication

Item	Description	Reason 'not applicable'
Mechanical prophylaxis	Includes the use of Sequential Compression Devices, NOT anti-embolic stockings.	Unit policy
DVT prophylaxis (drug and/or mechanical)	Calculated variable using 'Pharmacological DVT prophylaxis' and 'Mechanical prophylaxis' variables. Patient receiving either drug prophylaxis or mechanical prophylaxis or both.	
Ventilation	Invasive ventilation is defined as ventilation via an endotracheal tube or tracheostomy, includes CPAP. Patients who are totally unsupported (just receiving supplemental oxygen via an artificial airway) are not considered 'ventilated'.	
Ventilation orders	Refers to a written protocol allowing nurse titration of ventilation that is being followed. Ventilation orders were to be reviewed within the previous 24 hours.	Patient in ICU < 24 hours
Readiness to wean from the ventilator	The use of formal techniques including spontaneous breathing trials (SBT), negative inspiratory pressure (NIP), or rapid shallow breathing index (RSB).	
Head-of-bed elevation	Objective assessment using a protractor when the head-of-bed was visibly elevated (to the nearest 5 degrees, categories provided on the CRF).	1. Haemodynamically unstable 2. Unstable spine 3. Other defined reason (please indicate)
Stress Ulcer prophylaxis	The prescription of proton pump inhibitors (omeprazole, esomeprazole, pantoprazole etc) or H2 antagonists (ranitidine, famotidine etc) or sulcralfate.	Unit policy

Item	Description	Reason 'not applicable'
Blood Sugar Level (BSL) treatment	Includes patients currently needing treatment for either high or low BSL such as insulin, oral hypoglycaemics for high BSL, oral glucose, food or intravenous glucose for low BSL	
Pressure area risk assessment tool	Includes Waterlow Scale, Braden scale and others.	Patient in ICU < 24 hours
Pressure area	Includes anything from stage 1 "Intact skin with non-blanchable redness of a localized area usually over a bony prominence" to stage 4 "Full thickness tissue loss with exposed bone, tendon or muscle".	
Pressure area interventions	Pressure-relieving devices, positioning the patient off the area, topical or systemic antibiotics, protecting the area from moisture, debridement, cleansing, applying clean dressings, implementing patient (re-) positioning, transferring and turning techniques.	
Bowel management (treatment for constipation)	Patient's bowels not opening normally within the past three days. 'Normal' bowel function excluded patients with diarrhoea.	Patient has experienced significant diarrhoea

Data relating to care delivered were collected using patient observation charts and medical records, and by questioning the relevant bedside nurse and treating medical staff. Head-of-bed elevation was measured using an inclinometer (Lev-o-gage®, Sun Company, Inc., Arvada) calibrated in 5-degree increments. Clinical and demographic information was collected as part of the overall Point Prevalence Program.

Data Analysis

Descriptive statistics were used for all clinical and demographic data. Prevalence was the number of cares delivered (or clinical condition present e.g. patient in pain) divided by the total number of patients. Compliance was calculated as the number of patients who received a process-of-care, divided by the total number of 'applicable' patient cares. Patient cares deemed 'not applicable (NA)' to the patient at the time of audit were excluded (except where indicated in the Results). Variability in compliance with processes of care between participating units was examined using medians, ranges and inter-quartile ranges. No assumptions were made for missing data. Proportions were compared by Chi-square analyses where appropriate, using SPSS version 17 (IBM SPSS Statistics, Chicago, Illinois, USA).

Post-hoc analysis was also conducted to evaluate compliance with the IHI's VAP bundle (Berwick et al. 2006) i.e. DVT prophylaxis, stress ulcer prophylaxis, cessation of sedation (due to preparation for extubation and daily cessation per protocol), readiness to wean from mechanical ventilation, and elevated head-of-bed (> 25 degrees). The IHI's method of calculating compliance for the care bundle (Institute for Healthcare Improvement 2006) was utilised i.e. the number of 'yes' or 'NA' (i.e. contraindication) responses to all care components in the bundle divided by the total number of mechanically ventilated patients. This method was used so that compliance with the care bundle can still be credited despite contraindications to the care components.

Ethical considerations

The study was approved by the Human Research Ethics Committees at each of the participating institutions and the need for individual patient consent was waived at all sites (note: this was submitted by the George Institute for Global Health who took on administration for the Point Prevalence Program).

Results

Fifty ICUs treating adult patients participated (31 tertiary, 12 metropolitan, 3 rural/regional, 4 private). This represented 27% of all adult ICUs in Australia and New Zealand (89% of all tertiary units, 31% of metropolitan units, 6% of rural/regional, and 7% of private ICUs). A total of 662 patients were studied – patient demographics are summarised in Table 3.2.

Table 3.2 Patient demographics (n = 662): point prevalence study

Age (years)*	65 [50-73]
Gender (male)	403 (61)
Severity of illness (APACHE II score)*	18 [13-24]
Days in ICU (up to and including study day)*	4 [2-9]
Readmissions to ICU	53 (8)
Source of admission to ICU:	
Operating Theatre	263 (40)
Accident & Emergency	150 (23)
Hospital floor	143 (22)
Another ICU / Hospital	104 (16)
Most common major diagnostic categories (post-operative):	
Cardiovascular	92 (33)
Gastrointestinal	64 (23)
Neurological	35 (13)
Trauma	35 (13)
Most common major diagnostic categories (non-operative):	
Respiratory	101 (27)
Sepsis	63 (17)
Cardiovascular	45 (12)
Trauma	44 (12)

* Median and [interquartile range]. All other values are n (%).

Overall compliance with processes of care is outlined in Table 3.3. Considerable variability in compliance with care activities between ICUs was identified (see Fig. 3.1). Descriptive and prevalence data for each care component (nutrition, pain, sedation,

ventilation, head-of-bed elevation, DVT and stress ulcer prophylaxis, glucose and bowel management, pressure areas) are detailed below.

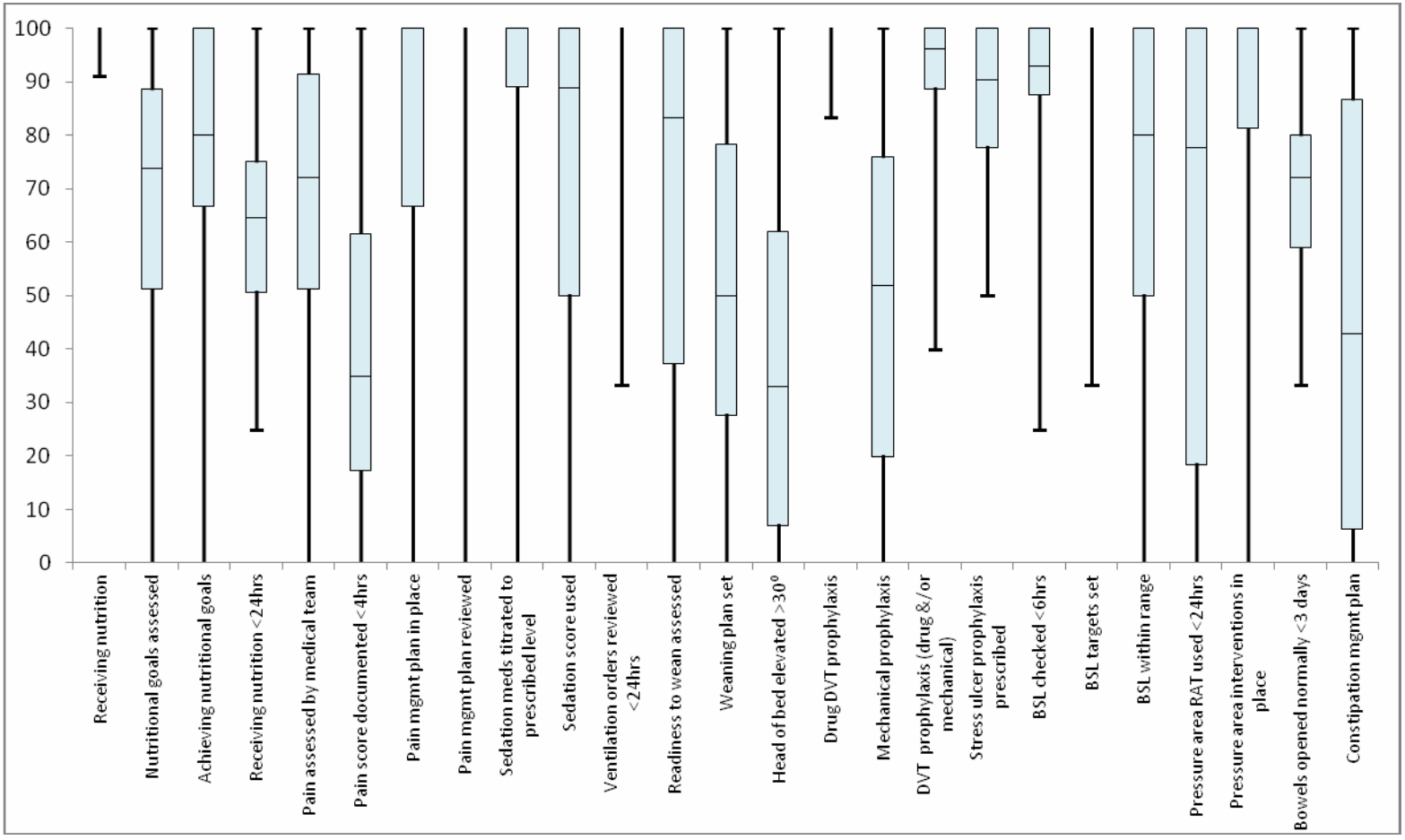
Table 3.3 Compliance with processes of care: point prevalence

Care item	Yes	No	NA	*Total*	Compliance *%*
Patient receiving nutrition today	524	10	120	*654*	98*
Nutritional goals formally assessed	324	213	112	*649*	67*
Nutritional goals being achieved	237	63	21	*321*	79
Patient receiving nutrition <24hrs	368	222	59	*649*	62
Patient pain assessed by medical team today	426	174	53	*653*	71
Pain score documented <4hrs	279	380	-	*659*	42
Pain management plan in place	92	23	-	*115*	80
Progress of pain mx plan reviewed	69	8	12	*89*	90
Sedation medication titrated to sedation score or prescribed level	200	29	-	*229*	87
Sedation score used to assess patient	170	59	-	*229*	74
Ventilation orders reviewed <24hrs	262	22	-	*284*	92
Readiness to wean formally assessed	179	120	-	*299*	60
Weaning plan set	155	144	-	*299*	52
Head-of-bed elevated > 30 degrees	114	170	-	*284*	40
Drug DVT prophylaxis (where appropriate)	518	14	127	*659*	97*
Mechanical prophylaxis	312	323	21	*656*	51*
DVT prophylaxis (drug and/or mechanical)†	601	53	-	*654*	92
Stress ulcer prophylaxis prescribed	544	91	26	*661*	86*
BSL checked in past 6hrs	599	60	2	*661*	91
BSL targets set	192	12	-	*204*	94
BSL within range	135	52	-	*187*	72
Pressure area risk assessment tool used <24hrs	408	186	61	*655*	69
Targeted interventions implemented for patients with pressure areas	82	25	-	*107*	77
Bowels opened normally <3 days	345	209	101	*655*	68*
Constipation management plan	96	109	-	*205*	47

***** Numerator = 'Yes' + 'Not Applicable' responses; Denominator = total responses (including NAs).

† Calculated variable where any form of DVT prophylaxis and valid contraindications to both = 'Yes'

Figure 3.1 Variation in compliance with care components amongst participating ICUs



Box and whisker plots illustrate medians (horizontal lines), inter-quartile ranges (shaded box), and range (minimum & maximum) amongst ICUs. Medians and inter-quartile ranges are not evident when these measures are at 100%.

Nutrition

Some form of nutrition (enteral, parenteral, oral) was delivered to 80% of patients and not applicable for 18% (6% of patients were nil by mouth for gastro-intestinal reasons, 3% were low acuity and expected to recover quickly, 2% were fasting for surgery, 1% were receiving palliative/terminal care, and 6% were for other unspecified reasons), leaving 2% patients who received no form of nutrition without identified clinical reasons. Nutritional goals were assessed in 67% of applicable patients and of these, goals were achieved in 79%, but not in 21%. In the first 24 hours following admission, 38% of applicable patients had not received any nutrition.

Pain

Of all applicable patients, pain had been assessed by the treating medical team for 71%, and 42% had a documented pain score in the preceding 4 hours. Patients who had their pain levels formally assessed by the medical team were more likely to have a documented pain score (46% vs 32%, $\chi^2 = 9.45$, $p = .002$). Patients who had surgery up to four days prior to the study day were also likely than non-surgical patients to have their pain assessed by the medical team (79% vs 67%, $\chi^2 = 9.85$, $p = .002$) and have a pain score documented in the previous four hours (51% vs 37%, $\chi^2 = 12.53$, $p < .0001$). According to bedside nurses, 17% of patients (n = 115) were experiencing significant pain; 42% of these did not have a pain score recorded in the preceding four hours. Of the 115 patients assessed as in pain, 80% had a pain management plan in place. Of applicable patients, 90% had their plan reviewed in the preceding 24 hours.

Sedation and ventilation

There were 301 invasively ventilated patients with 229 patients receiving sedatives to facilitate ventilation. Sedation medication was titrated to a prescribed level for 87% of patients. A formal sedation score was used to assess 74% of sedated patients. The most frequently used tools were the Riker Sedation-Agitation Scale (32%) and the Richmond Agitation and Sedation Scale (25%). Complete cessation of sedation was evident in 28% of patients on the study day. The main reason for cessation (determined by clinical observation) was preparation for extubation (13%), 2% were receiving routine daily interruption of sedation, 1% were over-sedated, and 12% patients had an unspecified reason.

Ventilation orders had been reviewed in 92% of participants within the previous 24 hours. Formal assessment of readiness to wean from mechanical ventilation was conducted in 60% of patients and a weaning plan was set for 52% of patients. The head-of-bed was visibly elevated for 95% of ventilated patients; the angle was between 5 and 30 degrees for 60%, 31 to 45 degrees for 30%, and greater than 45 degrees for 10%.

DVT prophylaxis

Pharmacological (drug) DVT prophylaxis was prescribed in 79% (n = 518) of patients; of those, 45% also received mechanical prophylaxis, 51% received no mechanical prophylaxis, and mechanical prophylaxis was not applicable for 4%. Drug prophylaxis was not applicable for 19% of patients (n = 127) and in this group 58% received mechanical prophylaxis, 41% received no mechanical prophylaxis (majority of these patients were not applicable to drug prophylaxis due to coagulopathy/bleeding risk), and mechanical prophylaxis was not applicable for 2%. Of the remaining 2% (n = 14) of patients who were eligible to receive drug prophylaxis and did not, 9 were receiving mechanical prophylaxis, leaving only 5 patients that did not receive any form of DVT prophylaxis without clinical reasons.

Stress ulcer prophylaxis

Stress ulcer prophylaxis was prescribed for 86% of the patients where applicable. Of the 340 patients possibly at higher risk of stress ulceration (i.e. patients ventilated and/or with a coagulopathy), 12% were not receiving stress ulcer prophylaxis.

Blood Sugar Level

Overall, 91% of patients had their blood sugar levels (BSL) checked in the previous 6 hours. Of the 204 patients receiving treatment for high or low BSL, targets were set for 94%. Of the 192 patients with targets set, 27% were not within the desired range. For these 52 patients, all had their BSL checked in the previous 6 hours, 79% were receiving nutrition, while 19% were not receiving nutrition because of a deliberate clinical decision (2% missing). Patients receiving treatment for high or low BSL appeared more likely to have their BSL checked than patients not receiving glycaemia treatment (99% vs 87%, $\chi^2 = 22.17$, $p < .0001$).

Pressure area

A pressure area risk assessment tool (e.g. Waterlow, Braden) had been used in the previous 24 hours in 69% of applicable patients. Of the 110 patients who had one or more identified pressure areas, a risk assessment tool was not used for 35%, and no targeted interventions had been implemented for 23%.

Bowel management (constipation)

Just over half of the patients audited (53%) had 'normal' bowel function, 32% of patients had not had a normal bowel action in the previous 3 days, while 15% had experienced diarrhoea with or without aperients. Of the 209 patients who had not had a normal bowel action, 53% did not have a constipation management plan in place.

Ventilator care bundle

Using the original IHI calculation method, compliance for this bundle of care activities was 11% (see table 3.4). When factoring in all patients who where applicable for sedation cessation regardless of reason, compliance was 15%; 13 patients were being prepared for extubation, only one received a 'daily wake-up'. When replaced with 'appropriate sedation management' (i.e. titrated to and at a predefined level at time of assessment), bundle compliance was 43%.

Table 3.4 Comparison of compliance with different versions of the ventilator Bundle: point prevalence

Version of Ventilator Bundle	Yes	NA	No	Total	% Compliance (Yes+NA/Total)
Original IHI (incl. daily wakeup)	1	30	261	292	10.62
IHI variation 1 (sedation cessation)	14	30	248	292	15.07
IHI variation 2 (sedation titration)	31	96	165	292	43.49

Notes. Ventilator bundle = DVT & stress ulcer prophylaxis, Sedation, Readiness to wean, HOB elevation; Yes = Yes to ALL components of the bundle; NA = not applicable to ANY bundle component (including where other responses = Yes); No = No to ANY bundle component (i.e. only requires one 'No' response to any of the five bundle elements).

Discussion

Major findings

Our findings demonstrated variability in the delivery of routine interventions in ICUs in Australia and New Zealand. Care components delivered consistently included nutrition delivery, DVT and stress ulcer prophylaxis, and blood sugar management. These findings are consistent with previous international studies (Crunden et al. 2005; Ilan et al. 2007; Keroack et al. 2006; Pronovost et al. 2003b) and are not surprising given these aspects of intensive care practice are reasonably well-established (Critical Care Clinical Practice Guidelines Committee 2009; Dellinger et al. 2008; Institute for Healthcare Improvement. 2010; National Health and Medical Research Council 2009). Conversely, wide variations in compliance were evident in several aspects of care: assessment of nutritional goals, pain, and sedation; care of ventilated patients (particularly head-of-bed elevation and weaning practices); pressure area and bowel management practices. This is also consistent with previously reported findings from the US (Keroack et al. 2006; Pronovost et al. 2003b), UK (Crunden et al. 2005) and Canada (Ilan et al. 2007).

While it was beyond the scope of this point prevalence study to determine the reasons for omissions of care, there is evidence to suggest many may be due to preventable slips and lapses that can lead to adverse patient events (Beckmann et al. 2003). Human error has been identified as a factor in 55% of largely preventable ICU incidents. Violations of standard practice were a cause in 28%, distractions were a cause in 22%, and slips occurred in 18% (Buckley et al. 1997). Evidence of omissions in care highlights the need for clinician support tools such as checklists, daily goals forms, and regular audits to enhance work practices and the delivery of routine care (Bion, Abrusci & Hibbert 2010; Hewson-Conroy, Elliott & Burrell 2010; Pronovost et al. 2006b). It was unknown how many of the participating ICUs used any support tools at the time of the study, although this should be a topic for further study.

The lack of convincing clinical evidence and/or agreement around some of the indicators is another factor that may have influenced some of our results. For example, inconclusive evidence on the benefit of early enteral nutrition (Doig et al. 2009; Marik & Zaloga 2001; Peter, Moran & Phillips-Hughes 2005) makes it unclear whether the

38% of patients not receiving nutrition in the first 24 hours represents deficient practice or is a result of the lack of agreement on this practice. Clinical practice guidelines (Heyland et al. 2003) recommend that enteral feeding be commenced within the first 24-48 hours following admission, however due to the practicalities of this one-day point prevalence study, only the previous 24 hours was reviewed. Another recommended practice that displayed considerable variability and may be viewed as a deficiency was the formal assessment of nutritional goals. Although this is considered best practice, it is currently based on low-level evidence and may not be feasible or necessary for all patients. Further studies are therefore needed to help inform practice guidelines for these aspects of care.

Although clinical evidence is far from definitive, best practice recommendations for analgesia and sedation management in mechanically ventilated adults have been developed (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2010; Jacobi et al. 2002), and include regular assessment of pain and sedation with validated scales, setting goal scores, and regularly reviewing response to treatments (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2010; Jacobi et al. 2002). Regardless of whether we examined mechanically ventilated patients or all ICU patients, our findings on pain management were similar; over one-quarter did not have their pain assessed by the medical team, and over one-half did not have a recent pain score documented, including those in pain according to the bedside nurse. The finding that postoperative patients seemed more likely to have their pain assessed and documented may suggest a focus on those patients where pain is anticipated, however the observational research design precludes establishing any cause-and-effect relationships.

For sedation, a quarter of mechanically ventilated patients receiving sedatives were not assessed with a formal sedation scale, potentially leading to prolonged duration of mechanical ventilation and length of stay (Brook et al. 1999). Our findings also demonstrated that a daily ‘sedation hold’ (Kress et al. 2000) has not been widely adopted in Australian and New Zealand practice, with only 2% of patients receiving routine daily interruption of sedation. This is consistent with an earlier study (Shehabi et al. 2008), and reflects a practice preference to titrate the sedative dose to a defined

endpoint while remaining consistent with practice guidelines for mechanically ventilated patients (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2010; Jacobi et al. 2002).

Other deficiencies in practice for mechanically ventilated patients were also apparent. Almost two-thirds of patients were positioned lower than the recommended 30-45 degrees head-of-bed elevation (Dellinger et al. 2008; Institute for Healthcare Improvement. 2010), which exposes patients to an increased risk of aspiration of gastric contents (Torres et al. 1992) and nosocomial pneumonia (Drakulovic et al. 1999). Despite some evidence suggesting that daily weaning assessments reduce the duration of mechanical ventilation, e.g. (Ely et al. 1996) compliance with weaning practices (i.e. assessing readiness to wean and setting weaning plans) was only moderate, with significant variability noted between ICUs.

Evidence for delivery of stress ulcer prophylaxis can be interpreted in two ways; either delivered routinely in the ICU (Institute for Healthcare Improvement. 2010) or for high-risk patients only (Robertson, Wilson & Cade 2008). While overall compliance in this and earlier point prevalence studies (Keroack et al. 2006; Robertson, Wilson & Cade 2008) was relatively high, the wide range in compliance across ICUs (50 to 100%) may reflect disparate views held by treating clinicians. A small proportion of patients (12%) possibly at high risk of bleeding were also not receiving stress ulcer prophylaxis; this may indicate omissions in care rather than a deliberate clinical decision. Conversely, there appears to be general agreement about delivering DVT prophylaxis to ICU patients (National Health and Medical Research Council 2009); almost all eligible patients in this study received pharmacological or mechanical DVT prophylaxis (97%), confirming previous work demonstrating wide implementation in Australian and New Zealand ICUs (Robertson et al. 2010).

Management of blood glucose levels is also important in clinical management of ICU patients. A large majority (91%) of patients in this study had their BSL checked within the previous 6 hours. Although over one-quarter of patients with targets set were not within the prescribed target range, all had blood sugar estimations in the previous 6 hours, as did those patients receiving treatment for high or low BSLs. These findings

could reflect the difficulty in maintaining BSLs, rather than inadequate management (Kanji et al. 2004).

Our findings regarding prevalence of pressure areas, the use of risk assessment tools and targeted interventions are similar to a previous Australian study (Victorian Quality Council 2006). Although assessment tools for pressure areas were not used in almost one-third of patients, the efficacy of these instruments have been questioned (Saleh, Anthony & Parboteeah 2009). That aside, 23% of patients with pressure areas were not receiving relevant care (Australian Wound Management Association 2001).

Constipation is considered common in critically ill patients. In this study one-third of patients had not had a bowel action in the previous three days and of these, over one-half did not have a constipation management plan. The evidence for deleterious effects of constipation is however contradictory (Mostafa et al. 2003; Nassar, da Silva & de Cleva 2009), and there are also issues with definition, with claims that the common state of non-defecation in critically ill patients is often (and perhaps inappropriately) treated the same as constipation which could be quite rare (Bishop et al. 2010).

Compliance with a ventilator bundle as defined by the IHI was very low i.e. 10%. When taking local practice into consideration (i.e. using sedation titrated to and at a predefined level at time of assessment in addition to daily cessation of sedation), compliance was still less than 50%. This is of concern given previous studies have reported an association between compliance for grouped cares and improved outcomes for mechanically ventilated patients e.g. (Crunden et al. 2005; Resar et al. 2005). There were however some definition differences between the IHI bundle and the data collected for this study, preventing meaningful comparisons between Australia and New Zealand and other international literature. The IHI uses ‘readiness to extubate’ as opposed to ‘readiness to wean’, and elevation of the head-of-bed is recommended to be between 30-45 degrees whereas due to the measurement device used in this study, greater than 25 degrees was considered compliant. Despite these differences, the need for improvement in delivery of care to ventilated patients is evident.

Study Strengths and Limitations

This study required research nurses to ask treating clinicians about and document *actual* care delivery. This approach enabled determination of compliance with *care*, rather than compliance with *documentation* of care; this was more credible than surveys capturing individual's perceptions of adherence which may elicit results that differ from actual practice (Brunkhorst et al. 2008). This study also examined a number of areas of care at one point in time, which provided a unique snapshot of care that has not been attempted previously. As this study included almost 90% of all tertiary ICUs in Australia and New Zealand, we have a clear indication that omissions in care do occur – even in ICUs within teaching hospitals.

One limitation of this and similar work is that there continues to be no general consensus about the evidence for some elements of care, which means that some results need to be interpreted with caution. There were also methodological limitations to this bi-national point prevalence study. Sampling from self-selected ICUs, most of which were involved in CTG studies, may not be representative of overall Australian and New Zealand practice. Although there was good representation of tertiary ICUs in the sample, ICUs from metropolitan, rural/regional, and private hospitals were under- represented. A study of over 3000 US hospitals found that hospitals with smaller case volumes were significantly less likely to apply evidence-based processes of care than hospitals with larger caseloads (Williams et al. 2008). Arguably participating units from teaching hospitals have the capacity to understand and implement the evidence base for current practice and this may potentially underestimate the overall rate of omissions in care.

Findings derived from a single time-point, cross-sectional analysis may not reflect usual practice, although this method has been used in previous international studies e.g. (Robertson et al. 2010; Robertson, Wilson & Cade 2008; Rose et al. 2009). This study design does not provide insight into why there are variations in practice both within and between Australian and New Zealand ICUs. Despite the development work for the CRF and data dictionary, there were still some ambiguities around definitions. For example, it is unlikely that questions relating to weaning were answered consistently across sites

since the definition of ‘weaning’ is generally unclear and both the practice of assessing weaning readiness and methods of weaning can vary greatly (Rose et al. 2009).

The way forward involves further research in a number of areas including: 1) large pragmatic clinical trials focussing on processes of care where there is currently equivocal evidence; 2) examining the reasons for variability in practice, including the impact of ICU culture and the lack of consensus about clinical evidence; 3) quality improvement studies evaluating the impact of clinician support tools on practice adherence; 4) the impact of variability in practice on patient outcomes; and 5) prospective evaluation of ventilator care bundles in Australian and New Zealand ICUs.

Conclusion

There appears to be some lack of uniformity in the delivery of ‘routine’ cares in Australian and New Zealand ICUs. It may be important to implement mechanisms that ensure patients receive every applicable care consistent with current best practice. However, there is lack of consensus around what is best practice in ICU, which requires increased attention given these findings. The results of this study highlight the need for further process-of-care research in Australian and New Zealand ICUs.

Chapter 4.

Construct validity of checklist

Introduction

This chapter addresses relevant components of construct validity in relation to development of the process-of-care items and checklist. First, the theoretical and conceptual aspects will be discussed. This is followed by two sub-sections that present the results of two studies completed to test the validity of the checklist as a measurement tool.

Current standards for Educational and Psychological Testing (American Educational Research Association et al. 1999) reflect contemporary views of measurement validity, how it is conceptualised and recommendations for its estimation. In the 1999 Standards, validity was defined as "the degree to which evidence and theory support the interpretations of test scores entailed by proposed uses of tests" (American Educational Research Association et al. 1999) (American Educational Research Association et al, 1999, p.9). The process of validation was described as the most fundamental concern in the development and evaluation of measures and requires the gathering of evidence to provide a sound scientific basis for proposed interpretations of scores.

Measurement validity is currently considered a unitary concept, (Geisinger 1992; Goodwin 2002) with 'construct validity' considered the "whole" of validity theory (Shepard 1993). Five distinct types of validity evidence have been identified:

- Evidence based on test content
- Evidence based on response processes
- Evidence based on internal structure
- Evidence based on relations to other variables
- Evidence based on the consequences of testing

The five types of validity evidence do not represent distinct types of validity – rather, they offer different aspects of validity that should be accumulated and integrated to provide a comprehensive view of validity evidence for a given test or measure

(Goodwin 2002). This includes evidence gathered from both new and previously reported research. The resulting validity 'argument' may: indicate the definition of the construct needs further refinement; suggest revisions in the measurement tool or other aspects of the measurement process; and indicate areas requiring further study (American Educational Research Association et al. 1999).

Preliminary content work for the process-of-care checklist had been completed in a pre-candidature study (Hewson & Burrell 2006) and in the comprehensive literature review conducted for the Background section (i.e. Chapter 2) of this thesis. This early work helped inform the content areas for inclusion in the checklist, contributing evidence in support of the relevance and adequacy of the measure's components to intensive care practice. It also enabled identification of the need for further validation studies.

The following two sections in this chapter address these two aspects of validity that were identified as important to the development of the electronic process-of-care checklist, and conducted as part of an iterative process where results of one study informed the next.

4.1 Checklist validation

Introduction

With an increased use of checklists in clinical settings (Hewson-Conroy, Elliott & Burrell 2010), the need for rigourous validation processes has been emphasised (Hales et al. 2008; Winters et al. 2009). Appropriate methods for evaluating the validity of checklists have not however been described in these or subsequent publications.

To date, few studies have reported formal validity testing of checklists in clinical settings e.g. (Hart & Owen 2005; Norgaard, Ringsted & Dolmans 2004; Pronovost et al. 2003b; Ursprung et al. 2005). Three studies conducted real-time audits; a neonatal ICU using randomly selected checklists during and after morning work rounds (Ursprung et al. 2005); a simulated environment using an electronic checklist for both audit and clinician use during preparations for non-emergency Cesarean delivery under general

anesthesia (Hart & Owen 2005); and internal medicine ward rounds using a checklist to assess trainee competence (Norgaard, Ringsted & Dolmans 2004). A fourth study piloted implementation of a daily rounding form in 13 adult ICUs (Pronovost et al. 2003b). Three of these studies focused on validity of content development for the checklist tool, obtaining 'face' validity (evidence of the checklist content) with clinicians used as experts (Hart & Owen 2005; Pronovost et al. 2003b; Ursprung et al. 2005).

Only one study (Norgaard, Ringsted & Dolmans 2004) reported validity evidence based on relationships between variables comparing: checklist item scores between groups of physicians; checklist item scores with overall performance scores; observer and bedside nurse performance scores. There is currently little evidence however, to suggest that a process-of-care checklist leads to the actual delivery of care (its intended purpose). No studies described the characteristics of their sample, therefore generalisability of these results to other in-patient settings is also unknown.

Concurrent validity can be defined as the extent to which scores obtained with a measure correlate with scores from another measure of the same construct (Goodwin 2002; Soeken 2010). Testing the criterion-related concurrent validity of the process-of-care checklist would involve evaluating whether checklist completion corresponded with an independent measure of care delivery. In line with contemporary measurement theory in health research (DeVon et al. 2007; Soeken 2010), significant associations between two measures that were collected during the same time period would provide some evidence supporting the notion that use of the checklist corresponded with delivery of care and is therefore fit for its intended purpose.

After demonstrating both the utility of a paper-based process-of-care checklist in an ICU pre-candidature pilot study (Hewson & Burrell 2006), and a need for improvement in delivering identified processes of care (Hewson-Conroy et al. 2011), the next logical step in this programme of research was to conduct a preliminary examination of criterion-related concurrent validity of the paper-based checklist prior to developing, implementing and evaluating an electronic process-of-care checklist for use on morning ward rounds in an ICU. While the pilot study served as initial proof-of-concept for the

checklist as both a measurement tool and a reminder to consider certain cares during the morning ward rounds, whether use of the checklist corresponded with actual care delivered in the ICU during the same time period required further evaluation. As data were available on the processes of care identified from the literature, the next step was to obtain retrospective data that reflected care delivered during the checklist pilot study.

The aim of this study was therefore to test whether a 'process-of-care' checklist was a valid tool for the purpose of measuring and ensuring daily care delivery in an ICU. The specific research questions were:

1) What is the association between checklist responses and actual delivery of care?
2) What is the association between checklist responses that highlight abnormal findings and subsequent delivery of appropriate care?

Method

Design

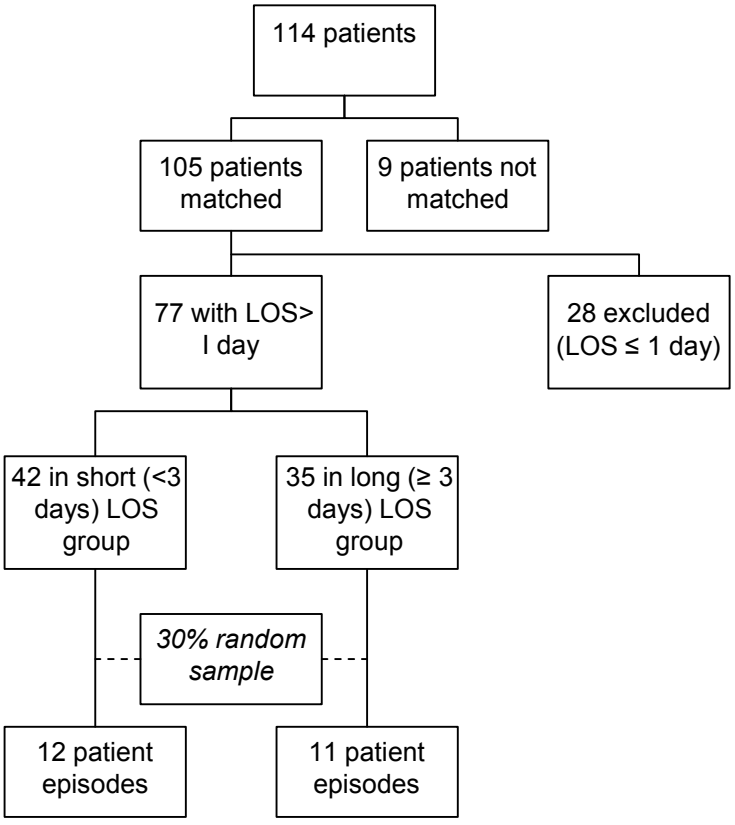
As the paper-based checklist data had already been collected in a tertiary ICU, a retrospective audit was designed to examine the concurrent validity of the checklist, with responses to checklist statements compared with data extracted from patient medical records (legal documentation of patient care). Checklist statements were designed to reflect routine daily checks expected to be performed daily by the medical team during the morning ward rounds. Documentation in a patient's medical record was used as a proxy measure for actual completion of care.

Sample

Following ethics approval by Sydney West Area Health Service (Nepean) Human Research Ethics Committee (approval number 06/046; see Appendix A), a stratified random sample of records were selected from the 114 patients who received care during the 2004 pilot of the process-of-care checklist (Hewson & Burrell 2006), using the procedure outlined in Figure 4.1. To ensure the sample was representative and typical of a general medical/surgical ICU, cases were drawn from two groups of patients – those with both short and long ICU LOS. As the median LOS for all patients admitted to the ICU was 3 days, the sample was stratified by a short LOS groups of less than 3 days

(LOS range = 1.0 - 2.8 days) and a long LOS group of three or more days (LOS range = 3.9 - 75.0 days). A random sample of 30% for each group was generated using the 'select cases' method in SPSS (version 17, IBM SPSS Statistics, Chicago, Illinois, USA), totaling 23 ICU patient episodes (12 with a short LOS and 11 with a long LOS) selected for inclusion in the medical record audit. This sample size for a comprehensive medical record audit was deemed achievable given constraints on time and available resources. If initial analyses revealed the sample was not representative of the study population, further patient records would be randomly selected to improve generalisability.

Figure 4.1 Procedure for stratifying and generating a sample of patients for the medical record audit



Data collection instrument

To examine the level of agreement with the checklist, an audit tool was developed to extract information on the processes of care documented by the medical team for patients admitted during the previous pilot study period. Data fields reflected the checklist items reviewed daily by medical staff upon completion of each individual patient assessment during the morning ward rounds (see Table 4.1). Each data field recorded the number of days each care was: 1) ticked on the checklist; 2) delivered according to the medical record; and 3) clinically applicable at the time of the checklist completion (contraindications to cares were classified 'not applicable'). Dates for inclusion in the medical record audit corresponded to the checklist dates indicated for each patient.

Only items that were collected systematically and were required documentation by medical staff were included in the audit. Some checklist items could not therefore be consistently or reliably identified during retrospective review of medical records, particularly those related to checks by physicians that may not require action or documentation of action, such as head-of-bed elevation, responsiveness of sedated patients, review of antibiotics and microbiology reports), and were therefore excluded from analysis.

The checklist was used as a 'challenge and answer' tool on the morning ICU ward rounds, so the medical record audit examined the previous 24 hours for documentation of care (from 8am – the commencement time of ward rounds). To address the second research question, the audit expanded on two aspects of care (blood sugar levels [BSL] and bowel management) to determine whether appropriate care was delivered to patients who were detected as being outside pre-defined limits (i.e. BSL was 10mmol/L or above, non-defecation in last 24 hours) according to the checklist. These items (see Table 4.1), which were aligned with unit policies at the time of the study, were compared with documentation in the medical record from 12pm (after ward rounds) until 6pm (when intensivists leave for the day).

Table 4.1 Checklist and medical record audit data fields

Care component	Checklist item	Medical record audit
Nutrition	Is the patient being fed (enteral, parenteral, oral)?	Nutrition delivered
Weaning	Is the patient being weaned?	Weaning plan, ventilation orders
Pain addressed [a]	If there is pain, has it been addressed?	Pain medications delivered to patient
BSL recorded	Was the BSL recorded in the last 12 hours?	Documentation of BSL in previous 12 hours
BSL above upper limit [b]	If the BSL was recorded in the last 12 hours, was the last recorded BSL 10mmol/L or above?	Number of days BSL was 10mmol/L or above
BSL management	Number of days where the last recorded BSL was 10mmol/L or above	Number of days treatment was delivered when BSL was above limit
Sit out of bed	If not ventilated, is the patient sitting out of bed?	For non-ventilated patients, was sitting out of bed documented on flow sheet or in notes?
Bowels opened	Have the patient's bowels opened in the last 24 hours?	Was there bowel output documented on flow sheet or in notes?
Bowel management [b]	Number of days where bowels not opened in last 24 hours	Number of days there is evidence of constipation management via treatment
Stress ulcer prophylaxis	Is the patient receiving stress ulcer prophylaxis?	Was stress ulcer prophylaxis documented on drug sheet?
DVT prophylaxis	Is the patient receiving thromboprophylaxis?	Was pharmacological thromboprophylaxis documented on drug sheet?

Notes [a] Follow-on question from 'is the patient in pain' [b] Inversely scored for detection of care delivered when outside of limits

Data management and analysis

Data from the audit tool data were matched to information obtained from the ICU database using medical record numbers and date of birth as patient identifiers. Demographic (gender, date of birth for calculation of age at checklist completion), clinical data (major diagnosis according to APACHE III diagnostic code, total number of hours on mechanical ventilation), and other information on ICU and hospital stay (admission and discharge dates and times, ICU and hospital lengths of stay, type of admission, vital status on discharge from ICU) were entered into an SPSS (version 17; IBM SPSS Statistics, Chicago, Illinois, USA) database for analysis. Data quality checks including frequency distribution analysis to test for outliers and ensuring data ranges were within defined limits were conducted prior to analysis.

Descriptive statistics were used for patient demographic data and the number of days each care was delivered (on the checklist and in the medical record). Tests for normality were conducted for continuous data. Non-normally distributed data were described using medians and interquartile ranges; normally distributed data were summarised using means and standard deviations.

For the purposes of comparison, the number of 'applicable days' for each aspect of care was calculated (i.e. the total number of days the checklist was delivered minus the number of days the care was indicated as not applicable (NA) by medical staff completing the checklist). It was not possible to determine whether cares were applicable from the medical record, therefore NA's were excluded from further analysis. To examine the relationship between checklist and medical record audit data, correlation analyses were performed, using Spearman's rho correlation co-efficient, because of the small number of patient records reviewed.

Results

All patient demographic data with the exception of age were not normally distributed; this was similar to the overall study population. All checklist and medical record audit data also displayed non-normal distributions. Patient demographics for the sample and the study population (i.e. matched patients who had an ICU LOS of greater than one

day) are outlined in Table 4.2. The two groups were comparable, except for the proportions of mechanically ventilated patients and ICU deaths. This suggests the random sample generated was reasonably representative of the study population, and therefore further sampling was not required to enable assumptions of generalisability. The sample demonstrated a moderate severity of illness range (APACHE III: 41-80 points). The majority of patients (61%) were non-operative, with a wide spread of diagnoses (4 cardiovascular, 3 neurological, 2 respiratory, 2 gastrointestinal, 2 metabolic, 1 sepsis). There was also a wide range of diagnoses for the post-operative patients – 3 gastrointestinal, 2 trauma, 1 cardiovascular, 1 respiratory, 1 genitourinary, 1 musculoskeletal/skin. These diagnoses were representative of the overall sample.

Table 4.2 Patient demographics: checklist validity study

	Sample (n = 23)	**Study population (n = 77)**
Gender (male)	13 (57)	40 (52) Age
at ICU admission date (years) [a]	58 (16)	57 (1.8)
Severity of illness (APACHE III score) [b]	42 [25 - 70]	45 [31 - 63]
Non-operative diagnosis	14 (61)	46 (60)
ICU length of stay [b]	3 [2 - 10]	2.6 [1 - 5]
Hospital length of stay [b]	14 [9 - 28]	12 [8 - 25]
Number of checklist days (per patient) [b]	3 [2 - 10]	2 [1 - 5]
Number of patients mechanically ventilated	14 (61)	15 (20)
Mechanical ventilation hours [b]	106 [26 - 278]	176 [98 - 335]
Readmission to ICU this hospital stay	2 (9)	9 (12)
Discharged alive from ICU	19 (83)	72 (94)
Type of ICU admission:		
Emergency ICU	11 (48)	32 (42)
Elective ICU	5 (22)	15 (20)
Emergency HDU[c]	5 (22)	14 (18)
Elective HDU	2 (9)	15 (20)

Notes [a] Mean and (Standard Deviation); [b] Median and [interquartile range]. All other values are n (%).[c] High dependency unit.

The median and inter-quartile ranges for the number of days each care item was delivered according to both the checklist and the medical record are shown in Table 4.3, with number of applicable days noted. In relation to the first research question, there were significant strong positive correlations for all care processes between responses on the checklist and medical record documentation, except for 'pain addressed'

Table 4.3 Care components delivered (median [inter-quartile range] in days): checklist and medical record audit

Care Component	Applicable days	Checklist	Medical Record	Spearman's rho
Nutrition	2 [2-9]	2 [1-9]	2 [2-9]	0.950**
Weaning	1 [1-7]	1 [1-4]	1 [0.75-4.25]	0.932**
Pain addressed	0 [0-2]	0 [0-2]	2 [2-9]	0.296
BSL recorded	3 [2-10]	3 [2-9]	3 [2-9]	0.964**
BSL above upper limit	0 [0-2]	0 [0-1]	0 [0-2]	0.877**
Sit out of bed	2 [1-3]	1 [0-1]	1 [0-2]	0.746**
Bowels opened	3 [2-10]	1 [0-3]	1 [0-2]	0.952**
Stress ulcer prophylaxis	3 [1-7]	2 [1-6]	3 [0-6]	0.882**
DVT prophylaxis	3 [2-10]	3 [2-6]	3 [2-6]	0.972**

**p=0.01

For the second research question, two measures (BSL, bowel management) were used to determine whether appropriate cares were delivered to patients for patients with abnormal findings (i.e. BSL was 10mmol/L or above, non-defecation in last 24 hours) according to the checklist. There was a strong correlation between the number of days the last recorded BSL was above 10mmol/L with the checklist, and the days of treatment in the medical record (Spearman's Rho = 0.865, p=0.01). There was a moderate correlation between the number of days where bowels were not opened in the last 24 hours on the checklist and the number of days there was evidence of constipation management (Spearman's Rho = 0.654, p=0.01). There was therefore a significant

association between checklist responses that highlighted abnormal findings and consequent delivery of care for these two measures.

Discussion

Major Findings

The checklist data demonstrated significant strong correlations with the medical records for eight of the nine checklist items. The checklist (completed by medical staff as a 'challenge and answer' after individual patient assessments) therefore reflected actual practice delivery, as documented in the medical record (prior to checklist completion). This initial evidence provides some support for the concurrent, criterion-related evidence of the process-of-care checklist as a valid measure. Care processes with the highest correlations (>0.80); nutrition, weaning off ventilation, DVT prophylaxis, stress ulcer prophylaxis, BSL recording and management, and bowel activity, may also have good 'face validity' with experts (i.e. ICU clinicians) with these cares generally well-accepted in ICU practice (Hewson-Conroy, Elliott & Burrell 2010). These practices have also received high profile attention (Vincent 2004, 2005), and some are linked to well-established local clinical policies (Wentworth Area Health Service. 2003, 2004, 2005).

Pain management is also an important care process emphasised in both the literature and local policies. The low correlation between the number of days pain was addressed with the checklist and days of pain medication delivered was the only exception for the otherwise high correlations demonstrated in this study. It was clear from the lack of overlap in the median and inter-quartile ranges (see Table 4.3) that pain medications were delivered more often than what was being indicated on the checklist. Similar findings were reported from a 12-month prospective observational study conducted in 43 ICUs in Europe (predominantly France), where pain assessment rates were shown to be significantly lower than that of drug treatment for pain (Payen et al. 2007). There are a number of possible reasons for this finding. First, as there were likely to be fluctuations in patient pain throughout the course of the day e.g. pain associated with routine ICU procedures (Puntillo et al. 2001; Puntillo et al. 2002), it is possible that

patients did not require treatment for pain upon assessment during the morning ward rounds, but did require active pain management later in the day.

Second, there may have been issues related to the interpretation of the checklist item and relating that to care documented in the medical record. The checklist item stated, 'if the patient was in pain, has it been addressed?' During the earlier pilot study data collection, there was no clear definition pertaining to what it meant for a patient to have their pain 'addressed'. It was assumed this would entail either the initiation of administration, continued administration, or change to the administration of analgesic medications. However, it is unknown whether this was the way clinicians interpreted this item. Given these results, it is possible that clinicians interpreted "addressing" pain to mean only one of these things i.e. an alteration in existing pain treatment, which may be somewhat less frequent (Puntillo et al. 2002). Finally, this was also dependent on the accuracy of the assessment process, which is often less than adequate in studies evaluating pain in critically ill patients (Chanques et al. 2006; Erdek & Pronovost 2004).

The findings also suggested that use of the checklist may lead to appropriate delivery of care. Significant positive correlations were evident for the two care items (BSL and bowel management) when outside pre-defined limits according to the checklist. This supports the view that when detected via the checklist, missing or omitted cares are subsequently delivered; an indication of an important safety measure. It is worth noting that it may not be necessarily appropriate to treat ICU patients who have not had a bowel movement within 24 hours for constipation (Bishop et al. 2010), and this may have contributed to the slightly lower correlation for this care component.

Study strengths and limitations

This study addressed some methodological limitations of previous studies and gaps in the validation of clinical checklists. First, sample characteristics were compared with the patient population, with the sample demonstrating good representation of the overall patient population initially studied. This provided support to the generalisability of the results from this sample to other patients in this particular ICU, and potentially others with similar patient and unit characteristics. Second, the positive and significant relationships between the checklist and the medical record data provided evidence in

support of the checklist's concurrent, criterion-related validity. It therefore appeared that what was indicated on the checklist reflected actual care delivery; the measure therefore fulfils its intended purpose. Third, this study also evaluated the relationship between checklist care items that required attention and the consequent delivery of appropriate care, revealing a significant positive relationship between the two. This suggests that when omissions are detected, they are consequently attended to – another intended purpose of the checklist.

There were methodological limitations related to the retrospective study design. Comparisons were made between data from two different sources with two different purposes, albeit with the same time periods on the same sample of patients. The checklist used by medical staff during the morning ICU ward rounds had two main functions; to: 1) serve as a prompt/reminder to regularly assess, and where required, deliver certain aspects of care; and 2) collect data about whether certain aspects of care were delivered upon assessment. Medical records in contrast provide a documented record of a patient's hospital care, and are usually completed by a diverse range of healthcare professionals.

The retrospective design also meant that exact reasons for any differences detected between the two data sources could not be determined. Since the medical record is a legal document that must be kept to a certain standard, (NSW Department of Health 2005; NSW Department of Health. 2005a, 2005b) it was deemed a reasonable proxy measure as to whether care was actually delivered in this retrospective study design. Given the strong positive correlations between checklist responses and care documented in the medical record, it appears this proxy measure was appropriate for use in determining whether what staff said they did on the checklist was actually performed for several aspects of care.

Limitations related to measurement are also noted. Some of the differences detected may be attributed to the imprecise unit of measurement used (i.e. the number of days cares were delivered). This measurement was used as: 1) the checklist was completed as a challenge and answer on the morning ward rounds, after patient assessment; and 2) the exact timing of patient assessment and checklist use could not be determined during

the retrospective review. Due to the nature of the data collected it is likely that repeated measurements for the same patient over time had some impact on the correlation coefficients, but this was not controlled statistically in this study. This does not however invalidate the findings – the checklist was used daily to ensure cares were delivered each day, and if the checklist was being used as it was intended, a high correlation between checklist responses and care documented in the medical records would be expected (though unknown unless measured). Further, due to resource constraints the sample size was small and it is not known whether the sample was truly representative of the study population. Finally, not all the cares covered by the checklist were assessable in the medical record audit, highlighting the need for prospective research in this area.

Recommendations for research

Several issues were identified for consideration when designing future checklists for use in clinical settings. As some items cannot be verified from the medical records, content of a checklist needs to be measurable by some other means, with data collected concurrently. Greater rigour in content development is also required – checklist statements need to be clear and concise statements, used in conjunction with explicit definitions that are readily understood, unambiguous and interpreted consistently by ICU clinicians. Future studies also require detailed consideration of the local context, particularly with regards to work processes and procedures. Developing measurable checklist content will require the involvement of local ICU clinicians and/or other experts.

To build further evidence on the psychometric properties of a checklist, reliability and validity testing should be incorporated into a prospective research design that evaluates checklist use with a concurrent audit of practice. Incorporating greater rigour into measurement design, such as real-time data collection, more specific response options, and the ability to control for repeated measures on individual patients would enable greater accuracy and the ability to detect actual changes in clinical practice over time.

Conclusion

This study revealed a strong and positive association between checklist responses provided by clinicians on the morning ward rounds, and care delivered according to the medical record, and an association between checklist care items requiring attention and subsequent delivery of care. These findings provide support for the concurrent validity of a process-of-care checklist, particularly its use as a tool for measuring and ensuring the delivery of daily cares in an ICU. Further work is required to establish a body of evidence that supports the use of these checklists in ICUs – particularly checklist content development, and further evaluations of checklist validity and reliability in producing meaningful clinical outcome improvements.

4.2 Electronic checklist content development

Introduction

Following completion of the first validation study (Chapter 4.1), a subsequent step in this programme of research was to extend the existing checklist content development work. In line with general recommendations for the development of checklists, a comprehensive review of the literature in Chapter 2 identified a number of processes of care suitable for the general ICU population. The above validation study demonstrated the concurrent validity for eight specific processes of care (nutrition, weaning, BSL management, sit out of bed, bowel management, stress ulcer & DVT prevention). This work also identified some issues requiring further examination. First, some items on the earlier version of the checklist (i.e. those related to checks by physicians that may not require action such as head-of-bed elevation) (Hewson & Burrell 2006) could not be assessed for their clinical utility due to lack of documentation during review of the medical records. Further evaluation was therefore needed to determine the continued inclusion of these items in the checklist. Second, increased rigour in content development was highlighted. Checklist statements needed to be clear and concise enabling both comprehension and consistent interpretation (Hales et al. 2008). Third, consideration of the local ICU context was identified as important to successful implementation and evaluation of the checklist. Local policies and guidelines,

concurrent projects and research studies, as well as work processes and procedures needed to be addressed for both checklist development and study design.

The unitary concept of 'construct validity' (American Educational Research Association et al. 1999) i.e. the degree to which an instrument measures the construct it is intended to measure (DeVon et al. 2007), informed development and testing of the checklist. Establishing evidence about the content of a measure examines the representativeness and relevance of the content of an instrument, as well as to the content domain the instrument purports to measure (Goodwin 2002; Pittman & Bakas 2010). This type of validity evidence can be obtained via logical analyses and experts' evaluations of the measure's components – particularly its' sufficiency, relevance, and clarity (Goodwin 2002). It was critical to know that the checklist's content was sufficient for the intended purpose and relevant to: the clinical setting; the clinicians who were using it; and the patient population it was being used for. This was partially addressed in our preliminary work previously mentioned, particularly regarding the general ICU setting, clinicians and patient populations on a broad scale. Further work was however required for practice relevance at the local ICU level. Clarity was another component not yet formally evaluated in this development process.

The Delphi technique is a valid method to verify the content and face validity of a measure (Hasson & Keeney 2011), important when gathering evidence in support of a measure's overall construct validity (Goodwin 2002). The approach involves collecting and organising informed opinions from a panel of experts with specialised knowledge in the area being studied, who are purposely chosen to develop and refine the content of a specific measure or tool during a series of consensus rounds (Huang, Lin & Lin 2008). Where appropriate, findings from a comprehensive literature review can be used for initial content development for the first round of questionnaires (Minkman et al. 2009). Delphi techniques have been used to develop content for a variety of checklists for use in community nursing (Huang, Lin & Lin 2008); palliative care tools (Biondo et al. 2008); and a quality management model for integrated care (Minkman et al. 2009).

As noted in Section 4.1, few studies reported any formal validity testing of checklists for use in clinical settings (Hart & Owen 2005; Norgaard, Ringsted & Dolmans 2004;

Pronovost et al. 2003b; Ursprung et al. 2005). Three studies that utilised the Delphi technique focused on content development obtained via face validity with expert clinicians, but did not report a number of key methodological issues (see Table 4.4). More recently however, two non-ICU studies (also outlined in Table 4.4) comprehensively detailed the process of using Delphi techniques to develop content for a fall-risk checklist (Huang, Lin & Lin 2008) and a simulation performance checklist to evaluate the performance of practising anaesthesiologists (Morgan et al. 2007). While these two studies provided a model of how the Delphi technique can be used effectively in the development of checklist content, they did not relate specifically to the development of a tool for measuring and ensuring the delivery of daily cares in an ICU.

Limitations evident in the critical care literature on checklist content development, highlight a gap in knowledge that needs to be addressed. The aim of this study was therefore to develop the most relevant process-of-care checklist items that were clear, concise, and descriptive statements for daily use during ward rounds in an ICU. The statements were to be developed using rigourously applied and reported methods, and be valid for use in a planned checklist intervention study. The specific research questions were:

1) What is the relevance and adequacy of the process-of-care measures identified from a literature review to the local ICU?
2) What are the most clear, concise and descriptive statements to use for the checklist items?

Methods

Design

A dual-method approach was used for developing the final content for the process-of-care checklist – local clinician interviews; and a modified Delphi technique using an expert clinician panel. Local clinician input to checklist content was obtained via semi-structured one-on-one interviews with a purposive sample of clinical staff members at a tertiary level adult ICU of a university hospital.

A modified Delphi technique involving a wider purposive sample of experts was then constituted for refinement of existing checklist items. This process enabled expert clinicians to develop consensus on clear and concise checklist statements. Given the previous development work (i.e. comprehensive literature review, point prevalence study, and checklist validation via medical records review), 2-3 Delphi rounds were anticipated to reach consensus.

Table 4.4 Studies utilising the Delphi technique to develop content for checklists to be used in clinical settings

Study	Sample		Purpose / Method	Findings[a] / *Critique*
	Setting	**n / cohort**		
Huang, Lin & Lin, 2008. (Taiwan)	College of Nursing	14 / 20 invited panel members accepted; 10 scholars in relevant fields of expertise, 4 clinical nurses.	• To develop content for a fall-risk checklist • Framework presented to panel who were asked to review a 4-point Likert scale checklist (from strong agreement to strong disagreement), submit comments & provide revision suggestions • Likert scale used to calculate content validity index (CVI) score for each item, rated along 3 dimensions i.e. content importance, appropriateness and discreteness • Scoring calculation method detailed	• 70% of potential panel members accepted, 3 rounds required, completed over 4-month period • Response rates: round 1, 78.5% (3 withdrew); 2, 91% (1 withdrew); 3, 100% • Results of each round reported in summarised format • Key suggestions & resulting refinements for each round provided • Changes to domains and checklist processes documented • CVI scores for each domain along the 3 dimensions and total score (range 0.84 – 1.00) in last review round provided • *Information not provided: complete checklist, criteria for deleting items,* v*ariation in responses & scores to individual items (results summarised by domain)*

Study	Sample		Purpose / Method	Findings[a] / *Critique*
	Setting	n / cohort		
Morgan et al, 2007. (Canada)	2 independent academic centres	5 anesthesiologists	• To develop a simulation performance checklist to evaluate performance of practicing anaesthesiologists, using a computer-based Delphi technique • Checklist items generated by participants after reading 2 pre-prepared scenarios, error weighting assigned to each item based on risk level • Responses collated anonymously & emailed back to participants asking them to check off items to retain or delete & to (re)assign weightings • Process repeated until no further items added, deleted or changes to weightings • *A-priori* decision to delete responses endorsed by ≤ 20% respondents	• 100% response rate • Required four rounds to reach consensus • Participants generated 104 items for scenario 1 & 99 items for scenario 2 • Final percentage weightings for checklist items provided • *Small sample size* • *Information not provided: variation in error weighting to individual items,* k*ey study timeframes e.g. time from survey distribution to response*

Study	Sample		Purpose / Method	Findings[a] / *Critique*
	Setting	**n / cohort**		
Hart & Owen, 2005. (Australia)	Anaesthesia Department at a tertiary hospital	Not reported - consultants with special interest in obstetric anaesthesia	• To generate checklist items for use prior to commencing non-emergency Cesarean delivery under general anesthesia • Participants contacted via email and remained anonymous to other participants • Two questionnaires were circulated	• Results of 2 questionnaires informed construction of checklist items • Items were later divided into four sub-categories • *Key information not reported: sample size; contents of questionnaires; response rates; how responses were used to inform 2nd round questionnaire & construct final checklist items e.g. not known whether pre-defined consensus methods were used, how checklist items were grouped & ordered*
Ursprung et al, 2005. (USA)	20-bed tertiary care medical-surgical neonatal ICU	Not reported - experts in neonatology, pediatrics, health services research, systems engineering, infection control, advanced practice nursing	• To develop a patient safety audit checklist for PICUs • Questions formatted into a checklist and refined iteratively by consensus • Participants responses based on potential clinical impact of mistakes, system failures, perceived frequency • Checklist reviewed and refined by physicians and nursing staff from study NICU to ensure relevance locally	• 36 audit questions representing a broad range of errors associated with NICU patient care generated • Questions later divided into 2 categories • *Information not reported: sample size and participant designations; contents of questionnaire; number of rounds required; method of obtaining consensus; how checklist items were further reviewed and refined for relevance by local PICU staff after consensus was reached; method of categorisation*

Study	Sample		Purpose / Method	Findings[a] / *Critique*
	Setting	**n / cohort**		
Pronovost et al, 2003. (USA)	13 adult medical & surgical ICUs in urban teaching & community hospitals	Interviews: 8 nurses & 5 ICU physicians Focus group: not reported	• Development and pilot testing of daily goals form • Validity of measures: obtaining agreement from ICU physicians and quality experts who developed the measures; semi-structured interviews with nurses & physicians who piloted the measures • Face validity: focus group of physicians and nurses from 13 participating ICUs	• Validity of measures: ICU physicians and quality experts unanimously agreed process measures addressed important aspects of ICU quality • Focus group: participants believed measures 'evaluated the domain of quality they intended to measure and identified important opportunities to improve quality'[b] • *Information not provided: sample sizes for development of measures and focus group; content for focus group discussion & semi-structured interviews; how qualitative data analysed and interpreted*

[a] Only findings that related to the Delphi technique used to generate checklist items are reported here

[b] Pronovost et al., 2003; p.154

Participants

The participants in each component of the study were ICU clinicians; seven were invited to participate in the semi-structured interviews, and 18 were included in the Delphi survey.

Interviews were arranged with five intensivists (intensive care physicians), one clinical nurse consultant, and one research nurse at the local ICU prior to commencing the Delphi study. Participants were selected based on their designation and role and had expressed an interest in quality and safety as well as improving care processes in their ICU. Each person was contacted individually either in person or via telephone, a brief outline of the proposed discussion was provided, and following consent, a time to meet was arranged.

To adequately represent the area under study and maximise content validity, the expert panel invited to participate in the Delphi study comprised two sub-groups. First, members of the NSW Intensive Care Coordination & Monitoring Unit's (ICCMU) Quality Group (a state-wide intensive care quality & safety committee) were invited: 1 NSW Health representative, 3 intensive care staff specialists (intensivists) and 4 senior intensive care nurses. All group members had extensive clinical experience in the specialty of intensive care, with an interest in quality and safety. Membership and participation in Quality Group activities were voluntary. Second, 10 intensivists from the pilot site were also invited to participate. The study was discussed at a Quality Group and ICU management meeting respectively, to engage potential participants.

Background information pertaining to the Delphi component was presented at staff meetings attended by potential participants. Information included study context, purpose and methods, the role of the participant, and the process of the modified-Delphi technique. The importance of obtaining unbiased expert opinion that was to remain anonymous to other participants was highlighted. The information sheet, instructions and Delphi questionnaire were then circulated to potential participants by hardcopy (if in attendance at the meetings) or email. All participants were given a two week deadline to respond; on day 12 non-responders were sent personalised reminder emails in an attempt to gain maximum responses.

Data collection instrument

In addition to exploring the relevance and adequacy of the process measures, the semi-structured interviews also sought identification of current issues and work practices that could impact on checklist content. The semi-structured approach to discussions with individuals enabled flexibility to obtain relevant information from the most appropriate person. All discussions commenced with the researcher providing general information pertaining to the proposed checklist intervention study and how this pre-intervention study would help inform it. The remainder of the content differed depending on designation of the person and the following discussion points were covered:

- Intensivists (n=5) – relevance and adequacy of proposed checklist items; opinions on inclusion or exclusion of checklist items for evaluation on the morning ward rounds, particularly those that were not explored in the medical records review (head-of-bed elevation for ventilated patients, pressure ulcer prevention, assessing responsiveness of sedated patients, checking the length of time since insertion for intravascular lines, review of antibiotic use and microbiology reports); current work practices and procedures that should be factored into checklist development and study design; and local policies and guidelines pertaining to potential checklist items.
- Clinical nurse consultant – current and planned unit initiatives as well as work practices associated with the planned checklist study and the proposed checklist items.
- Research nurse – current and planned research studies that may impact on the use and evaluation of the proposed processes of care.

The modified Delphi Technique involved sufficient rounds in order to achieve consensus. For the initial round, participants were asked to rate a list of existing checklist statements generated from previous work, according to their clarity, conciseness and instructional value, on a 5-point likert scale (from strongly disagree to strongly agree). This modification to the traditional Delphi technique has been described as a 'reactive Delphi' as participants respond to previously prepared information, rather than generating items from scratch (McKenna 1994b). Participants were informed of checklist response options which included 'clinical contraindication'. Additional space was provided for participants to make suggestions for improving each

statement (see Appendix B for tool). Similar approaches have been used previously (Huang, Lin & Lin 2008) with the qualitative comments section described as being a valuable addition to the questionnaire (Roberts-Davis & Read 2001).

Statements that did not reach consensus were modified according to suggestions made by respondents. In the next round, two alternate statements for each component were devised – this served two purposes: 1) participant feedback on grouped responses; and 2) an opportunity to choose their preferred statement based on the refinements made after round one. Participants were asked to select which of the two statements they believed better described the process-of-care in terms of clarity, conciseness and instructional value. Additional space was provided for participants to make comments about the statements if required (see Appendix C for tool).

Data management and analysis

Notes taken during the discussions with clinicians were reviewed and important points that required consideration were listed. Key points were then discussed with the research team and were integrated into the first round of the Delphi questionnaire where appropriate.

A-priori decisions were made regarding the minimum standard for consensus agreement. Statements that obtained a median score of greater than or equal to 4.0 (representing 'agree' on the 5-point rating scale), had no 'strongly disagree' responses and no suggested changes, were accepted as having reached consensus. A similar scoring approach previously used a 4-point Likert scale (Duffield 1993), however in this instance it was decided that a neutral response option was required for respondents who had suggestions for improving the statements and neither agreed nor disagreed with a statement in its current form.

When devising the second round questionnaire, a decision was made to accept one of the two statements provided on the questionnaire that gained at least 51% of the respondents' preference – an approach used previously (Biondo et al. 2008; Loughlin & Moore 1979; McKenna 1994a). Although this cut-off point has been questioned (Crisp et al. 1997), there remains no scientific rationale or recognised guidelines for deciding appropriate consensus levels (Keeney, Hasson & McKenna 2006). In addition to the

majority vote, for a statement to have reached consensus there could not be a significant number of suggested changes.

After data collection was completed for each stage, data were de-identified prior to entry into a spreadsheet with identification numbers assigned to respondents. The participant log was kept separate from the data to be analysed and password protected. To ensure valid interpretations, qualitative data were analysed initially by the first author and then verified by the other authors. Conclusions based on qualitative data were discussed and agreed upon prior to further iterations of the Delphi questionnaire being developed and the reporting of results.

Ethical considerations

Human Research Ethics Committee approval for this sub-study as part of a larger study program was obtained from both university and Area Health Service Committees. Participants provided informed consent prior to involvement in this study.

Results

Following interviews with all seven ICU clinicians who agreed to participate, a number of important issues were integrated into the Delphi questionnaire (see Table 4.5). Other than broadening one of the checklist items i.e. from reviewing antibiotics to reviewing all medications, no further additions to the checklist items were suggested. Importantly, other than the issues identified in Table 4.5, participants believed the proposed checklist items adequately covered important elements of care to be checked for each patient on the morning ward rounds, and were applicable to standard or expected clinical practice in the ICU. Three of the intensivists mentioned some of the checklist items were supported by local policies and guidelines i.e. nutrition (Wentworth Area Health Service. 2004), DVT prophylaxis (Wentworth Area Health Service. 2003), and stress ulcer prophylaxis (Wentworth Area Health Service. 2005).

Table 4.5 Issues identified by clinicians and how integrated into Delphi questionnaire

Issue identified	Action
Sit out of bed managed by nursing staff and physiotherapists	Sit out of bed checklist item removed
Checking the length of time since insertion of intravascular lines redundant due to unit policy (i.e. catheters left in place as long as clinically indicated), nursing prompt card (age of lines, dressings & site), and concurrent quality improvement project targeting improved insertion and care of central lines (Burrell et al. 2011)	Checking the length of time since insertion of intravascular lines removed from checklist
All medications should be reviewed on the morning round, not just antibiotics	Changed 'review of antibiotics' to 'review of all medications'
Checking microbiology reports done in conjunction with the review of medications, so doesn't need to be a separate item on the checklist	Checking microbiology reports removed from checklist
Head-of-bed elevation for ventilated patients important to review by both medical and nursing – retain on checklist	Head-of-bed elevation retained on checklist
Assessing responsiveness of sedated patients an important aspect of medical rounds and needs to be retained	Assessing responsiveness of sedated patients retained on checklist
Pressure ulcer prevention managed by nursing staff, an item on the nursing prompt card	Pressure ulcer prevention not included in checklist
Bowel management practices were covered by nursing staff, an item on the nursing prompt card	Bowel management practices not included in checklist

In Round 1 of the Delphi survey, 9 responses were received (56%); 6 intensivists (60%) from the local ICU, and 3 from the Quality Group (50%). All statements achieved a median ≥ 4.0; equivalent to 'agree' and 'strongly agree' and there were no 'strongly disagree' responses (see Table 4.6). Suggestions were provided for changing the wording for all statements (refer to Appendix D), except for stress ulcer prevention. All comments were considered and where appropriate, were integrated into two alternate statements for each remaining care component for the expert panel's consideration in the second round of the Delphi process. As an example, although 89% either agreed or strongly agreed with the statement for pain, 11% neither agreed nor disagreed and a more detailed statement was suggested. For the next Delphi round, the original

statement was provided along with a more detailed version to gauge the majority preference.

Table 4.6 Descriptive statistics for Delphi survey responses by care component

Care component	Median [IQR]	Min - Max	Mode	% agree & strongly agree
Stress ulcer prevention	5 [4-5]	4 – 5	5	100
Pain	5 [4-5]	3 – 5	5	89
Head-of-bed elevation	4 [4-5]	3 – 5	4,5	89
Medications	5 [3.5-5]	3 – 5	5	78
Sedation	5 [3.5-5]	2 – 5	5	78
Glucose management	5 [3.5-5]	2 – 5	5	78
Nutrition	5 [3-5]	2 – 5	5	78
Readiness to wean from mech vent	5 [3-5]	2 – 5	5	78
Thrombo-prophylaxis	4 [3.5-5]	2 – 5	4	78

IQR = inter-quartile range; Min = minimum; Max = maximum; Mech vent = mechanical ventilation. Responses were scored 1 = strongly disagree; 2 = disagree; 3 = neither agree or disagree; 4 = agree; 5 = strongly agree.

In Round 2, a total of 8 responses were received (50%); 5 (50%) intensivists from the local ICU and 3 (50%) from the Quality Group. For each item, statements with the majority (>50%) of preferences was either accepted or slightly amended in response to suggestions for further changes to the statement. Three statements were accepted without the need for further changes – feeding (57%), extubation (71%), medications (71%). The remaining five statements required only minor adjustments to wording to

be clearer, more concise, and to improve instructional value. The few comments made by the experts in this round (see Appendix E) improved the statements without changing the context or the key message e.g. abbreviating 'An appropriate means of delivering DVT prophylaxis has been chosen and is being delivered' to 'Mechanical and/or drug DVT prophylaxis is being delivered'.

Following this round, it was evident that no further rounds were required as there was sufficient coherence in participants' responses. Following recommendations for checklist composition (Hales et al. 2008), minor editorial changes ensured that terminology and phrasing was consistent across all nine checklist statements, which were purposely ordered to align with the FASTHUG mnemonic (Vincent 2005). The resulting final checklist statements were:

- Nutrition goals have been set and progress reviewed
- Pain has been assessed, a management plan set and progress reviewed
- Sedation target set, sedation level assessed and managed
- Mechanical and/or drug DVT prophylaxis is being delivered
- Patient is positioned with the head of the bed raised >30 degrees
- Stress ulcer prophylaxis is being delivered
- Blood sugar level (BSL) limits have been set and are being managed to achieve those limits
- Patient's readiness to be weaned from mechanical ventilation has been assessed
- All medications have been checked and reviewed

Discussion

Key Findings

The key study outcomes were development and validation of a suite of clear and concise statements on nine essential processes of care, to be used as a checklist for supporting practice during daily rounds in an ICU. Study findings added evidence in support of the content validity of the checklist items - particularly the relevance, adequacy, and clarity (Goodwin 2002) of checklist statements.

Interviews with local ICU clinicians confirmed the adequacy of content covered by the process-of-care checklist as well as providing initial information pertaining to the practice relevance of each individual statement. These informants also offered important information on the local context, which supported the refinement of checklist statements for inclusion in the first round of the Delphi survey. These initial revisions provided additional credibility to the Delphi process by ensuring the preliminary statements were relevant to the local ICU.

Only two rounds were required to reach consensus. When viewed collectively, findings from both Delphi rounds demonstrated the "stability" of responses, suggesting a reasonable indicator of consensus (Crisp et al. 1997; Hasson, Keeney & McKenna 2000). Despite almost gaining consensus after the first round, several suggestions were made to improve the clarity for all but one of the statements. After second round responses were collated, all statements had either been accepted without further changes, or suggestions for changes had been integrated into the final statements. This is evidence of: 1) previous work on developing checklist content was a sufficient starting point for this modified-Delphi study; 2) only refinements to the existing statements were required to generate the most clear, concise and instructive statements. It is likely that the preliminary work also ensured quick replies from panel respondents and a shorter time to reach consensus. Other studies, particularly those that generated content from scratch reported much longer study periods (Huang, Lin & Lin 2008; Keeney, Hasson & McKenna 2006).

Although there is contention pertaining to acceptable consensus levels, recent recommendations suggested that levels be: established prior to data collection; based on the importance of the research topic; and supported by rational justification (Keeney, Hasson & McKenna 2006). The decision to accept second-round statements with at least 51% agreement was based on the following: 1) majority agreement was more practicable than 100% consensus given there could be countless minor variations of the same statement that met the criteria of being clear, concise and instructive statements; 2) there was near consensus after the first survey round; and 3) to minimise respondent burden and exhaustion from busy ICU clinicians, and managers, which has also been reported (McKenna 1994b).

Study strengths and limitations

The modified Delphi technique used was developed in line with contemporary research guidelines (Hasson & Keeney 2011; Hasson, Keeney & McKenna 2000) to address the limitations of other research in this field and enhance rigour in this type of study. This was exemplified by the methods used (i.e. the incorporation of information obtained from a literature review (Hewson-Conroy, Elliott & Burrell 2010), a point-prevalence study (Hewson-Conroy et al. 2011), and a criterion-related validation study (Conroy, Elliott & Burrell 2013b)), prior to and during the pre-Delphi interviews, that consequently informed revision of the checklist items. This preliminary information was then incorporated into the first Delphi round, as this approach may be more reliable than an open-first round Delphi survey (Hasson & Keeney 2011).

Purposive sampling for this Delphi study allowed selection of experts best able to provide advice on statement development. Similar to a previous study (Biondo et al. 2008), the use of two expert panels strengthened the validation process. The participation of Quality Group members lent support to the external validity of the checklist statements i.e. they can be used in all general ICUs as a starting point from which local clinician input can be obtained. The panel of intensivists provided the desired local ICU input, ensuring that terminology was applicable for use in that ICU. Their involvement also enabled an opportunity for input into tool development that would ultimately be used by themselves or their colleagues, in routine practice, and also facilitate engagement in planned future studies.

The Delphi panel size of at least 8 respondents was in line with recommendations that the membership number be relevant to the purpose of the study, the selected design, and data collection time frame (Hasson & Keeney 2011; Huang, Lin & Lin 2008). The panel size was also large enough to obtain a substantial amount of useful feedback, and proved adequate for reaching consensus on the wording of checklist statements. A larger sample size may have generated more variations that still met the criteria of being clear, concise and instructive, but this may have prolonged the process unnecessarily, and may have diminished applicability of the statements to the local setting. Similar to other studies using the Delphi technique, treatment of data obtained from panel members was de-identified (i.e. individual responses were not made available to other

participants), removing any risk of influence on group conformity, power, and the effect of others on responses (Morgan et al. 2007).

Unlike previous studies (Hart & Owen 2005; Pronovost et al. 2003b; Ursprung et al. 2005), results of the Delphi technique were reported for each round, with key suggestions for improvements to the statements reflected in the second round Delphi questionnaire and the final checklist statements. The importance of describing the sampling process in detail has also been emphasised in the literature (Hasson, Keeney & McKenna 2000), and as such, detailed information pertaining to the selection processes and characteristics of the panel members has been reported. This level of data collection and reporting allows for increased transparency for the purposes of study replication and provides evidence of sufficient methodological rigour in developing the checklist statements.

There were limitations to this study. First, the response rate to the Delphi survey was moderate (56% and 50% in the two rounds, respectively). A previous paper (Biondo et al. 2008) reported a range of response rates from two Delphi studies – the highest response rate was 73% for a second-round Delphi survey of 22 international panelists; the lowest was 39% for a second-round survey of 18 regional panelists. They partly attributed the higher response to pre-selecting panelists that indicated their willingness to participate (which was not the case with other panels they used), resulting in a motivated, committed panel of experts. Response rates to our study were similar to a first-round survey of one of these previous studies (i.e. 56% of 16 national panelists), supporting the notion of pre-selecting willing participants as a possible solution to improve response rates. Where possible, other suggestions made in the literature for obtaining an optimal response rate were followed, including: making personal contact and building rapport by informing participants to enhance personal ownership of the project (Keeney, Hasson & McKenna 2006); and planned follow-up (Boberg & Morris-Khoo 1992) in the form of a reminder email.

Second, non-responders were not followed-up further and therefore their reasons for non-participation were unknown. Similar to earlier studies (Biondo et al. 2008), we opted not to pursue non-responders further as we did not wish to pressure already busy

clinicians who we needed to be supportive of any future studies that required their contribution. It was possible however, that non-responders were not interested in checklist development, did not have anything to add to the process, or were not able to make study participation a priority given their primary role was in clinical and teaching responsibilities.

Participants within each of the panels were known to each other and all participants were known to the researcher. The risk of potential bias was minimised by allowing respondents to complete the questionnaires in their own time, ensuring responses remained strictly anonymous within the Delphi process, and providing synthesised feedback during the second round survey. It has been suggested that this kind of 'quasi-anonymity' could actually motivate panelists to participate, discourage ill-considered hasty judgements, and ensure some level of accountability for the responses given (McKenna 1994b).

Due to practical constraints of creating a parallel-form measure we did not test reliability by comparing the final checklist statements generated using the Delphi technique with statements generated by another method of developing the tool – for example via a focus group or consensus meeting with experts, or alternative forms of the questionnaire (Hasson & Keeney 2011). Coordinating a single meeting time to suit all experts would have been difficult, particularly since the majority had clinical duties. Even if one had been arranged, it is questionable whether a group meeting can produce reliable results given the risk of bias with group conformity (Morgan et al. 2007). Devising an alternative Delphi survey was not appropriate given the need for a final set of standard statements.

Recommendations for research

There are a few key areas that require evaluation in future studies. First, it is important to verify these findings with further research conducted in clinical settings. The checklist items generated should be evaluated for their practical use, interpretation and clinical utility. Second, testing the reliability of items should be undertaken in order to establish whether the items produce consistent results. Third, the methods used for checklist development and validation also have applicability beyond the ICU and can be tested as a model for improvement in other clinical areas.

Conclusion

The use of both interviews and a modified Delphi technique with ICU clinicians produced a series of checklist items that represented relevant content for essential practices in the process-of-care for ICU patients, and were deemed clear, concise, and instructive statements for use by intensivists during the morning clinical rounds. The use of rigourous methods lends support to the content validity of the process-of-care checklist. Transparent reporting of both methods and results allow for study replication and further testing for the purposes of determining reliability and clinical utility.

Chapter 5.

Electronic checklist software development

After identifying essential processes of care items to be checked routinely on the morning ward rounds in an ICU, confirming the checklist's concurrent validity and finalising the checklist content including clear, concise and instructive checklist statements, the next step in this programme of research was to integrate the statements developed into an electronic format. This chapter details the user requirements for the electronic checklist, the development process (including hardware and software components), method of connectivity, the pre- versus post-audit product, as well as the final product prior to implementation.

User requirements

The essential e-checklist user requirements were devised by myself in conjunction with my PhD supervisors and the ICCMU Data Manager in 2008. As the checklist required completion by clinicians at the bedside for every patient in the ICU, the device needed to be portable. At that time, assessment of available handheld devices was carried out, particularly for their functionality, programmability and utility. The Palm TX™ handheld was deemed the most suitable portable device for software programming and utility by clinicians at the bedside (Craig 2007). Notably, this work commenced just prior to the initial release and subsequent widespread availability of smartphones and tablet devices, and the related development of software applications ('apps') for those devices.

At the outset two separate key functions for the e-checklist were identified: 1) a checklist tool to be completed by clinicians at the bedside on morning ICU ward rounds; and 2) an audit tool for use by research nurses after ward rounds were completed, for the purpose of validity testing. While these two checklist functions needed to be identical in terms of content, their functionality differed slightly. The general, personal digital assistant (PDA)-specific and server-specific features, and data fields are listed in Tables 5.1-5.4.

Table 5.1 E-checklist user requirements – General features

Components	Design specifications
Automatic save	• Data entry saved in real time • Data stored on the server, not the PDAs
Date and time stamp	• Each checklist entry assigned a date and time stamp upon creation • Edited entries have a separate date and time stamp added upon modification
Edit option	• Individual checklist entries can be edited, with date and time stamp attached • User number recorded for edits to existing checklist item responses
Auto-fill	• Enable auto-completion of items to eliminate unnecessary data entry i.e. NA responses to certain items for patients not ventilated (auditor and clinician checklist); checklist status changed to completed if patient not in ICU during audit (response = 'patient not in unit' to explain why patient not audited) • Database to record auto-filled responses to pre-determined value
Help function	• Help icon on both patient list and patient checklist screens containing instructions for use • Help icon on Summary screen of terminal application opens instruction booklet in PDF format in separate window
Data transfer	• Data fields from checklists transferable into a spreadsheet for later analysis • Simple and standardised coding for responses
Device management	• PDA is traceable via recording of login information including date & time, username, latest action, and MRN • Device activity can be viewed via the terminal application

Table 5.2 E-checklist user requirements – PDA-specific features

Components	Design specifications
Start screen	• Contains Checklist and Notepad applications only • Click on checklist icon to go to e-checklist
Log-in screen	• Display date • User number field
Patient selection	• List of patient MRNs, their corresponding bed numbers and checklist status • Select patient via tapping on-screen
Tasks screen	• Staff number and patient MRN appear above checklist • List of checklist items (i.e. tasks) with corresponding boxes for either a 'Yes' or 'No' response
Checklist items	• Brief descriptor on screen with pop-up window containing detailed statement when task descriptor selected (click-on function) • Items remain the same and in same order for each checklist • 'Tick' symbol for item completed in 'YES' column; Red 'Cross' symbol for item completed in 'NO' column (without valid reason); Green 'Cross' symbol for item completed in 'NO' column where reason was 'Not applicable' • Change or reset responses in event of data input error
Reason for 'No'	• For items not completed, a 'Reason' field containing pre-defined list enacted i.e. 'NO' box selected > enter reason why item not done • Items are static (i.e. not user defined) on PDA, but could be modified via server if required
Checklist completion	• 'Finish' button to close one checklist (per patient) before moving to the next
Checklist status	• After login the main screen displays a list of patient MRNs in order of allocated bed number, with checklist status displayed (i.e. not started, completed, incomplete) • After each checklist completion, a window containing a list of remaining patients a checklist needs to be completed for is displayed

Table 5.3 E-checklist user requirements – Server-specific features

Components	Design specifications
Start screen	• Login required via username and password
Summary screen	• Date display • Checklist completion rate (overall % of patient checklists completed for current day) • Summary information of patient checklists i.e. patient MRN, checklist status (not started, completed, incomplete), Staff ID (for device management), and device number (i.e. PDA1 or PDA2) • Display menu items (patient summary, reporting, user admin, device settings) • Help/information button (refer to general features) • Log-off function button
Patient level functions	• Add new patient – manually enter patient details i.e. MRN, name, gender, bed number, and open text field for comments to assist staff to identify patients in the ICU (e.g. diagnoses) • Edit patient – ability to select a patient, edit details or remove from patient list (i.e. when discharged) • View tasks – select a patient for detailed list of tasks and responses collected for the day • View event – view all adverse events entered for the patient during their ICU stay • Add event – ability to add adverse events via server. Select event from drop-down list including an 'other' category that can be specified by an open text field • Edit event – ability to edit patient level events via server regardless of data source i.e. PDA or server. Include ability to attach related notes • Remove event – ability to remove events from the patient record
Reporting (clinician only)	• Standardised reports generated via the server in real time to provide immediate feedback to clinicians on performance • Reports to indicate the no. and percent of daily cares delivered/omitted per checklist item and overall for the current day, week, and 'to-date' • Use of real-time compliance charts for summary of trends over time • Reports to be printable

Table 5.4 E-checklist user requirements – Data fields

Components	Design specifications
User number	• Unique user numbers (user's staff identification number) • Option to change user number i.e. logout and login a new user • Login determines use of either auditor or clinician checklist • Validation process - restrict number of digits
MRN	• MRNs entered, changed, removed prior to checklist completion e.g. entered by ward clerks prior to clinical staff commencing ward rounds (currently not feasible to link server to hospital patient databases) • MRN selected from a list table • Maximum of one clinician and auditor checklist per MRN each day the patient is in the ICU
Adverse Events	• Recorded at the patient level via the PDA and the terminal application

The key technical differences between the two functions were:

- Data collected by clinicians needed to be distinguishable from data collected on audit.
- Slight variations in response options (see Table 5.5).
- Reporting function only applicable to clinician data.

The reporting tool was only applicable to the data collected by clinicians as the purpose was to provide feedback on checklist compliance. The calculation of compliance was as follows:

- Numerator for item compliance = cares delivered to patients i.e. a tally of 'yes's for each checklist item.
- Denominator for item compliance = total number of patients in sample minus those that were not applicable for the care.
- Numerator for composite compliance = the number of patients, per day, that received all cares.
- Denominator for composite compliance = the total number of patients, per day, where all cares were applicable.

For sustainability, the whole software package needed to be transferrable onto different hardware such as portable PC devices. This would assist with roll-out of the tool if it was shown to be an effective and clinically useful tool.

Table 5.5 E-checklist response options by item

Checklist Item	Auditor Response Options	Clinician Response Options
Is the patient invasively ventilated?	Yes	Yes
	No	No
Patient is positioned with the head of the bed raised >30 degrees	Yes	Yes
	No:	No:
	Omission- now corrected	Omission- now corrected
	Omission- not yet corrected	Omission- not yet corrected
	NA – unit policy	NA – unit policy
Patient's readiness to be weaned from mechanical ventilation has been assessed	Yes	Yes
	No:	No:
	Omission- now corrected	Omission- now corrected
	Omission- not yet corrected	Omission- not yet corrected
Sedation target set, sedation level assessed and managed	Yes	Yes
	No:	No:
	Omission- now corrected	Omission- now corrected
	Omission- not yet corrected	Omission- not yet corrected
	NA - Patient has not required sedation in past 24 hours	NA - Patient has not required sedation in past 24 hours
Pain has been assessed, a management plan set and progress reviewed	Yes	Yes
	No:	No:
	Omission- now corrected	Omission- now corrected
	Omission- not yet corrected	Omission- not yet corrected
	NA – pain assessment cannot be determined	**NA – patient pain cannot be assessed**
Mechanical and/or drug DVT prophylaxis is being administered or applied.	Yes	Yes
	No:	No:
	Omission- now corrected	Omission- now corrected
	Omission- not yet corrected	Omission- not yet corrected
	Clinical contraindication	Clinical contraindication
Stress ulcer prophylaxis is being administered.	Yes	Yes
	No:	No:
	Omission- now corrected	Omission- now corrected
	Omission- not yet corrected	Omission- not yet corrected
	Clinical contraindication	Clinical contraindication
	NA –unit policy	NA –unit policy

Checklist Item	Auditor Response Options	Clinician Response Options
Nutrition goals have been formally assessed and progress reviewed	Yes No: Omission- now corrected Omission- not yet corrected NA- nutrition goals do not need to be assessed or reviewed	Yes No: Omission- now corrected Omission- not yet corrected NA- nutrition goals do not need to be assessed or reviewed
Blood sugar levels (BSL) have been assessed, limits have been set and are being managed to achieve those limits	Yes No: Omission- now corrected Omission- not yet corrected NA – deliberate clinical decision	Yes No: Omission- now corrected Omission- not yet corrected NA – deliberate clinical decision
All medications have been checked and reviewed	Yes No: Omission- now corrected Omission- not yet corrected **NA – Unable to determine**	Yes No: Omission- now corrected Omission- not yet corrected

Development process

Following completion of the user requirements, functional and technical requirements were developed and documented in a business requirement document (see Appendix F). The development process followed this document, with input and feedback obtained from the research team along the way. The hardware and software components are listed below:

Hardware components

- Server: 1x laptop Dell D800, 2Ghz, 1G ram.
- PDAs: 2x Palm Pilot TX
- Wall mounting brackets.
- Wi-Fi Routers (audit Stage): 2x Netgear WNR834B v2
- Wi-Fi Routers: Hospital ICU Wi-Fi network (Cisco equipment)

Software components

Development Tools:

- Microsoft Office incl. Visio was used to document and provide paper trail on development snapshots.
- Netbeans IDE. This was used to develop the Java server and the JavaME application on the PDA.
- MYSQL GUI workbench. This was primarily used to develop the database schema required to power the application.
- Microsoft Windows XP SP2. This was the operating system used in the development environment.

Server Side:

- Apache Tomcat 6.0.18 Java application server. This is the software that powered the website component in the server.
- Struts software application framework. The Java framework used in the development of the application. Primarily used to ensure a Model View Controller (MVC) model was maintained in the application development to

separate the solution into 3 parts i.e. the data component (the model), the user interface (the view) and the business logic and rules (the controller).

- MySQL 5.1.30GA. The database engine powering the application.
- Jquery JavaScript framework. This allows for Web 2.0 functionality on the server application. Provided a smoother and more interactive user interface (i.e. website graphics)
- Microsoft windows XP SP2 the installed operating system from Dell.

PDA:

- JavaME was the main environment installed on the PDA to run the java application. The Java Virtual Machine installed was the IBM Java VirtualMachine (Java VM) ver. J9 2.2 ARM (20040706_1505_IHsCmV))
- Netbeans MIDP (mobile information device profile) components. This component allows the programmed code to communicate and control the device according to the device specification.

Programming

The main approach was a feature driven Agile development method. An overall model was discussed at inception and it was agreed that because no existing or similar products were available at the time, the approach had to be incremental. A prototyping approach to each feature milestone was therefore undertaken, with one feature developed at a time.

The first stage required a decision on what software platform to use. At the time the variables to consider were availability (was it free to use), universality (i.e. can it work on other devices) and maturity (was there an established user base – i.e. widely used), both in terms of solution distribution (i.e. how to package and install it on the PDA) and the development tools and testing.

The use of JavaME ensured that the solution (pertaining to the entire software package) would be developed once and would not have to be translated to any other platform e.g. PC, MAC, mobile or other handheld devices if the device were to change. JavaME

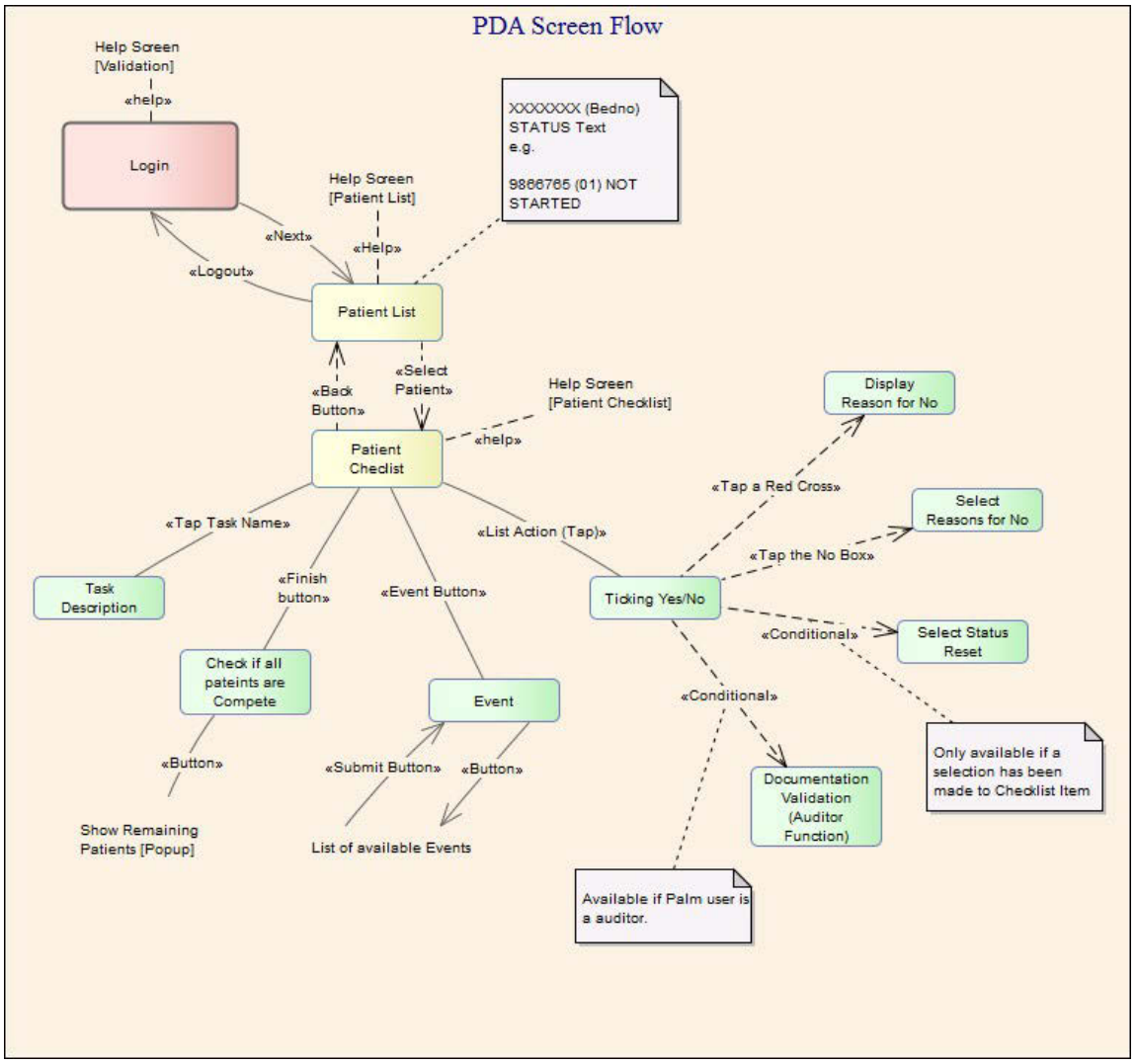
allowed the solution to be deployed to various devices as long as the device supported Java VM. At the time of development, Java technology was proven and supported by Sun Microsystems (now owned by Oracle, California, USA.), with a well-documented support and resource system to allow any Java developer to start building an application.

Once the platform was decided, software architecture was examined. With the higher level requirements specified, it was apparent that the PDA would only need to act as a 'thin client', with single function operations, solely for the purpose of the e-checklist application and it's intended operations. The PDA was therefore not required to perform any high level operation, but would only be used as a tool to communicate information to the server. The server would store and process all data. Two components to this solution therefore required development - a mobile application (the thin client) and the server application.

The database to house the transactional data (i.e. data collected and updated via the PDA) was designed first. The design schema (available upon request) was mapped against the data requirements identified in the user and functional requirement documents. Tables and views were created followed by internal processes necessary to facilitate the processing of new records or changes to records to enforce referential integrity between related tables (ensuring relationships between data tables remained consistent).

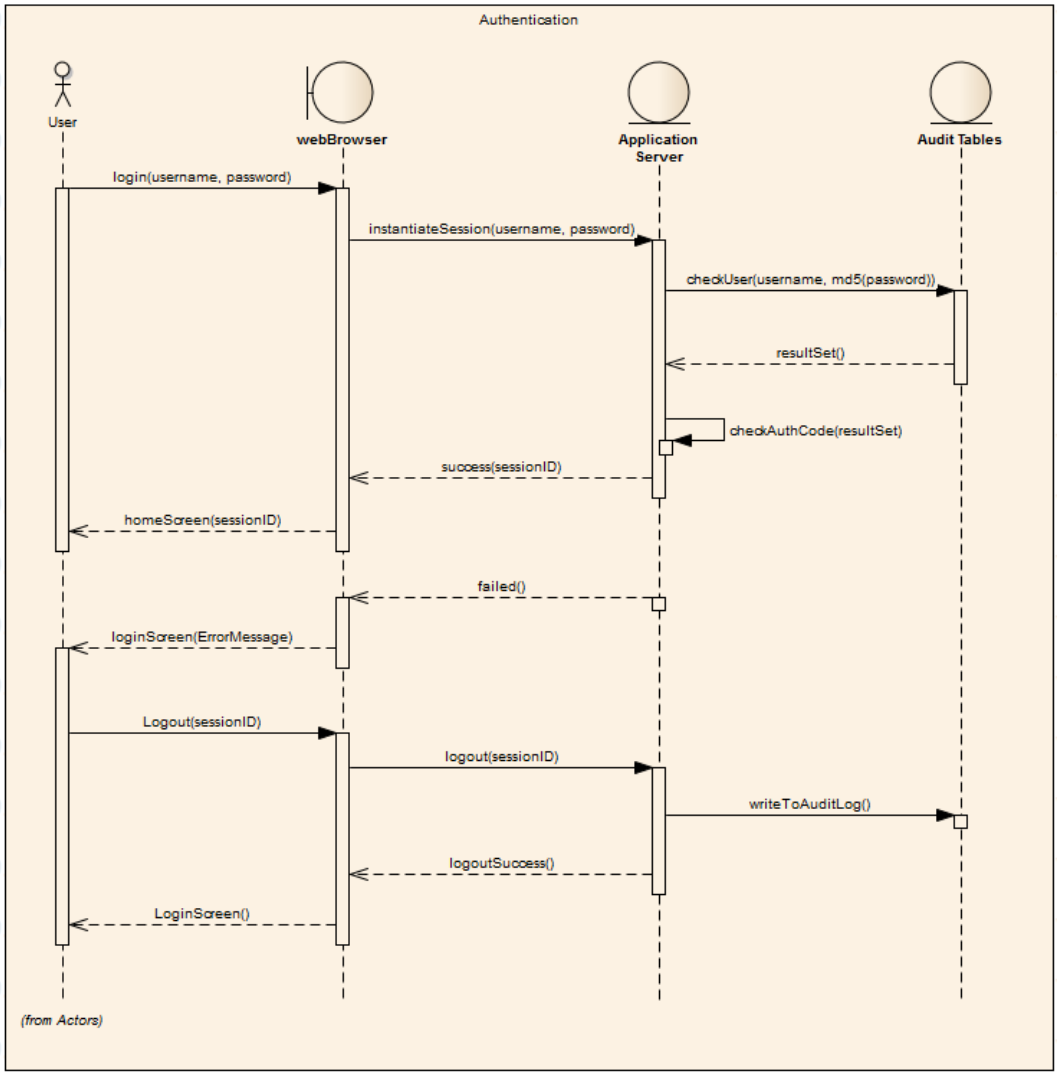
The next task was to work with the PDA, designing the screen flow (see Figure 5.1) and allocating data checkpoints where the e-checklist application required a read or write function from the database. This was developed so that an action on-screen could instigate a process where that action was checked against the database (read) and recorded (write). Application Programming Interface (API) 'hooks' were coded on the server side, mapping a one to one relationship to the data checkpoints on the PDA. These API hooks allowed the PDA to communicate with the database via the application server (the laptop).

Figure 5.1 PDA screen flow: e-checklist



An example of this is the authentication process (see Figure 5.2) – PDA user logs in by typing in their username and password, then clicks the 'login' button. 'Login' is a predefined action which sends login details to the server. The server passes this information to the database, the database then runs a procedure to check whether the login details are registered. It returns a true or false value to the PDA via the application server. The PDA then knows to progress to the next screen i.e. home screen if successful, login screen with error message if login failed.

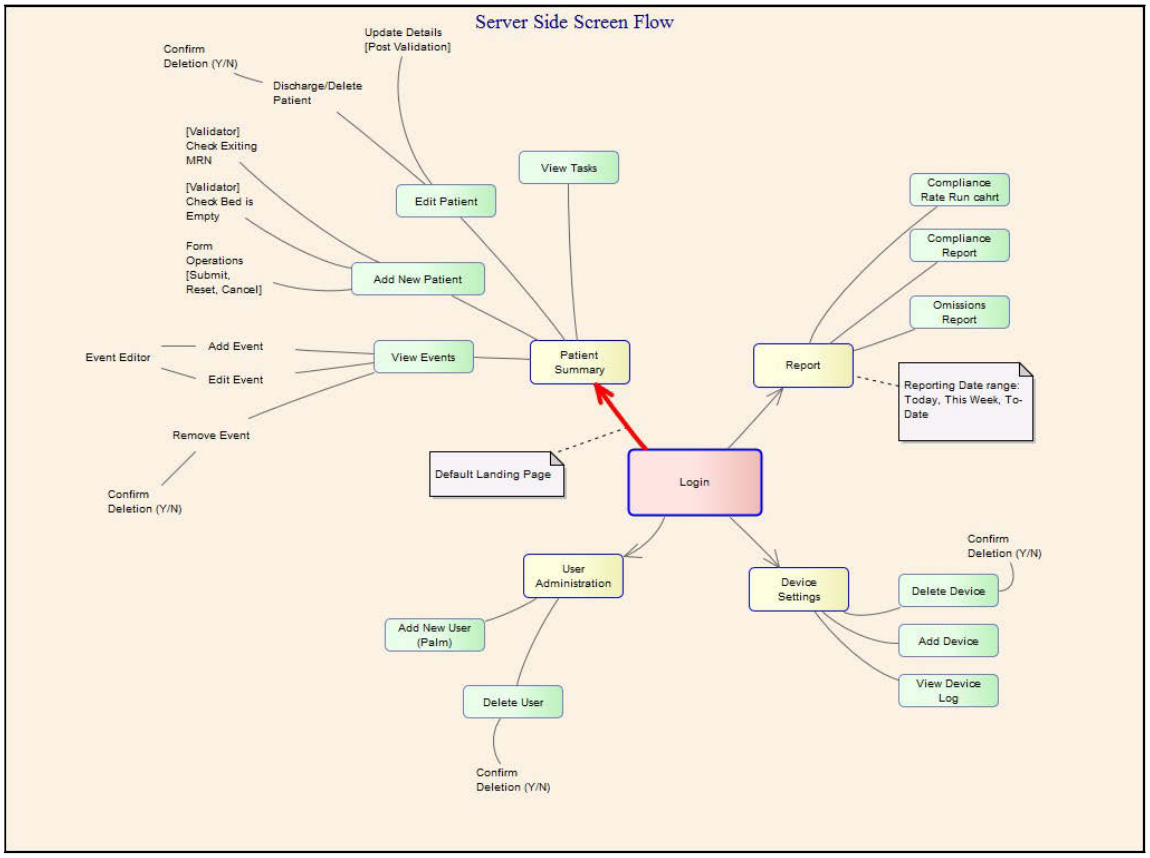
Figure 5.2 Authentication sequence: e-checklist



Work on the PDA application commenced by designing and coding one screen at a time, using a top-down approach as each screen to be developed was the child of the parent screen just developed. Each screen was tested to ensure the data flow and the actions initiated were reflected in the database.

The server application was also developed in a top-down approach, with the page flow structure first identified and then a stub (i.e. file structure) for each page was coded (see Figure 5.3). The look and feel of each page was then implemented onto the stubs to ensure that once there was content, there would not be significant change in the look and feel between pages.

Figure 5.3 Server screen flow: e-checklist



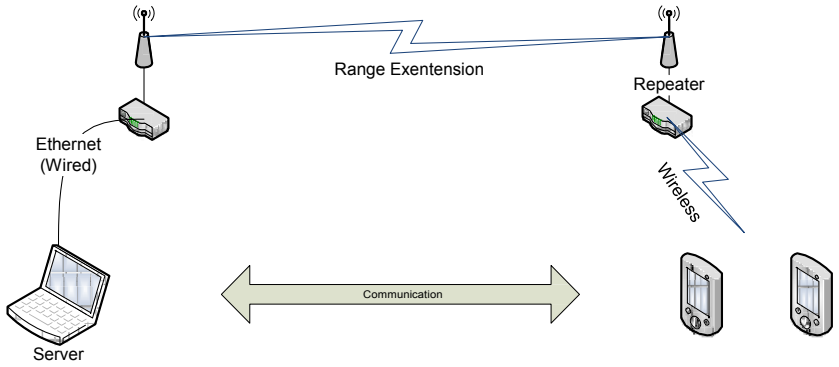
Once this structural architecture was developed, content was then added to each page, and each page element (e.g. table, chart, click actions) was developed and tested in parallel with what the PDA would display, e.g. if a patient is discharged at the server computer, then patient would no longer appear on the PDA patients list.

As each of the features (outlined in Appendix F) was implemented feedback from the research team was sought and any changes or alterations were implemented along the way.

Connectivity

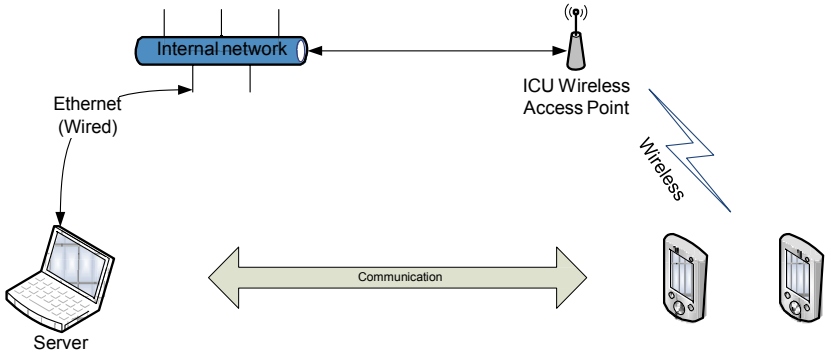
For the baseline audit period, two-way connectivity of the PDAs to the server was established using two wireless routers on a repeated network that extended the range of a single router to twice its normal range (see Figure 5.4). This ensured coverage of the entire ICU physical space was around 80-90%.

Figure 5.4 Diagram depicting e-checklist connectivity during baseline audit



For actual implementation of the clinician checklist for the study, connection to a wireless network became possible (see Figure 5.5), with the routers replaced by an enterprise grade wireless network that covered 100% of the ICU physical space.

Figure 5.5 Diagram depicting e-checklist connectivity during implementation period



Pre- and post-audit product

The software package for the baseline audit data collection period was implemented as outlined in the user and functional specifications. Pre-audit testing was then conducted by the research student, in conjunction with the software developer, data manager and auditor to ensure the package was operational and fully-functioning.

After the baseline audit data collection was completed, feedback was obtained from the auditors using the package. The issues highlighted by the auditors and the consequent remedial actions are outlined in Table 5.6.

Table 5.6 Feedback from auditors on software package and remedial actions implemented

Issues identified	Actions taken	Result
Network problems i.e. drop-outs and freezing	Connection to ICU's wireless connection	Connectivity significantly improved with very few drop-outs and freezing from PDAs
'Patient not in ICU' auto-fill function prevented user from coming back to complete patient checklist if patient returned to ICU during data collection period, as the patient status was changed to 'completed' and nothing further could be added to that record	Removed 'Patient not in ICU' auto-fill function	Missing data pertaining to checklists not completed were designated specific codes on server and excluded from compliance reports
Too much repetition and wasted time due to having to manually enter 'NA' to three checklist items (sedation, head-of-bed elevation and extubation)	Added 'pt not ventilated' function to auto-complete these items as 'NA – not ventilated. Checklist items were re-ordered so that these items were at the top of the list following the patient ventilated question	A saving of time for both clinicians and auditors
Too many steps when editing a response to a checklist item	Reduced number of steps to change a response	A saving of time for both clinicians and auditors

Pre-implementation (final) product

Further testing prior to implementation was conducted to ensure connection to the wireless network was reliable, and that the modifications made were functioning correctly and in line with modified user requirements. Testing revealed faster response times, with no disconnection between the server and the PDAs. The response time (ping) and transfer rate was improved, and this ensured minimal (near zero) dropout rates in checklist completion. All functional changes were also working prior to the e-checklist study start date.

Chapter 6.

Electronic checklist intervention study

Introduction

As outlined in Chapter 2, contemporary evidence suggests that quality improvement initiatives to ensure the delivery of specific evidence-based processes of care in the ICU e.g. (Vincent 2005) can lead to better health outcomes for patients e.g. (Finfer et al. 2009). The need for improvement in the delivery of important processes of care in Australian and New Zealand ICUs was demonstrated in Chapter 3, highlighting a gap between evidence and practice on a wide scale. Evidence of omissions in care highlights the need for clinical support tools to enhance work practices and the delivery of routine care (Bion, Abrusci & Hibbert 2010; Pronovost et al. 2006b). The use of "best practice" checklists during patient care rounds in the ICU has been identified in a recent systematic review as one of several factors that could improve the quality of service delivery (Lane et al. 2013). The contribution that checklists make to improvements in patient care is unclear due to the limitations of published studies (Hewson-Conroy, Elliott & Burrell 2010; Ko, Turner & Finnigan 2011), however the benefits are now well-documented e.g. (Centofanti et al. 2014; Lane et al. 2013).

In Chapter 4, two validation studies were undertaken to ensure that checklist: 1) use corresponded with delivery of care; and 2) content was relevant, with clear, concise, and instructive statements for use by intensivists during the morning ward rounds. Together these studies provided evidence in support of the checklist's construct validity. The integration of clinical support tools such as checklists into computerised technology was also highlighted in Chapter 2 as being important to current and evolving future practice. After obtaining evidence of the checklist's construct validity, the electronic component was designed and developed with purpose-built software as described in Chapter 5. After completion of this preliminary work, the need to test implementation of the e(lectronic)-checklist in an ICU was required.

As identified during the first validity study (Chapter 4.1), a clear and comprehensive understanding of the local clinical environment and context was necessary prior to any

interventional study. Careful and detailed observation of the morning ward rounds, noting key work process, procedures and flow would assist in identifying how the electronic checklist could be integrated into clinical practice. At the conclusion of the content validity study (Chapter 4.2), the need for checklist items to be tested and validated in the clinical setting was also identified. Measurement of care delivered before and after checklist implementation was required to determine whether checklist use improved actual delivery of care. An audit component enabled evaluation of whether the checklist was being used as intended; contributing important information related to response processes – a key source of evidence required to establish construct validity (Goodwin 2002).

As also noted in Chapter 2, QI interventions can improve patient safety in ICU. Measurement of patient-level adverse events is a relevant and important indicator of patient safety as incidents may impact negatively on patient outcome (Wilson et al. 1995). With many adverse events in the ICU shown to be preventable (Beckmann et al. 2003), it is important to know whether an intervention that aims to improve delivery of certain cares can also reduce potentially relatable adverse incidents.

Importantly, prospectively evaluating the impact of an electronic checklist on patient care measures would address identified limitations and gaps in the current literature: lack of baseline data for comparisons, retrospective study designs, and most notably, the use of appropriate outcome measures, particularly those the checklist was designed to prevent e.g. ventilator-associated pneumonia (VAP), unplanned extubation, hyperglycaemia, deep vein thrombosis (DVT), gastrointestinal (GI) bleed, medication error.

Study Aim and Research Questions

The overall study aim was to test the implementation of an e(lectronic)-checklist designed to facilitate patient safety and quality of care during medical ward rounds in an ICU. The primary outcome of interest was compliance with processes of care identified by the checklist. The secondary outcomes were adverse events and concordance between checklist completion and delivery of cares.
The specific study questions were:

1. Is there a significant difference in the delivery of processes of care following implementation of an e-checklist?
2. What is the level of concordance between checklist item completion by physicians on the ICU ward rounds and actual delivery of care?
3. Is there a difference in adverse patient events i.e. incidence of VAP, gastro-intestinal bleeding, medication errors, unplanned or accidental extubation, hyper/hypo-glycaemia, DVT, venous thromboembolism (VTE), pulmonary embolism (PE), following implementation of an e-checklist?

The study intention was to test whether an e-checklist intervention was clinically useful as a safety prompt to ensure that all patients receive appropriate therapies and treatments, and therefore prevent or minimise any omissions in care that could lead to adverse or less than optimal patient outcomes.

Methods

Design

A prospective, mixed-methods design with a nested before-after intervention component was used to address the research questions. This approach combined QI principles, (Speroff & O'Connor 2004) methods of knowledge translation (Pronovost, Berenholtz & Needham 2008) and point-of-care technology (Taylor 2005) to implement and evaluate the electronic process-of-care checklist. Process data that directly informed the quality of patient care was collected daily to evaluate the utility of the e-checklist as a tool for use during the morning ward rounds in an ICU.

Setting

The study site was a 19-bed general adult ICU/HDU within a tertiary university hospital located in Metropolitan Sydney, NSW, Australia. The unit operated under a closed medical model with patients admitted under the care of specialist intensive care physicians (intensivists). Patients were nursed at a 1:1 nurse-to-patient ratio and 1:2 for HDU patients. At the time of the study, the ICU was funded for 13 ICU beds and 5 HDU beds, though in practice patient-mix was flexible. There was an annual throughput

of 1,318 patient admissions for the 2007/2008 financial year, with 931 patient episodes having a length of stay greater than 24 hours.

The unit was separated into two physical pods both with central nursing stations. During morning ward rounds, the medical staff divided into two groups, each commencing in a different pod. During the study period each ward round team usually consisted of one consultant and/or senior registrar, a registrar and one or two junior medical officers

Participants

Each participant with direct involvement in completion of the e-checklist was a senior medical officer (intensivist, senior registrar or registrar). During baseline data collection (6 week period from April to June, 2009) there were 19 senior medical staff – seven intensivists (four first on-call, three second on-call), four senior registrars, and eight registrars who were on day rosters. For the intervention period (6 weeks from July to August, 2009) there were also 19 senior medical staff –seven intensivists, three senior registrars and nine registrars. Changes in staffing and rostering meant that four new registrars and three of the four senior registrars were rostered during the intervention period. There were no changes to intensivist staffing between the two time periods.

Recipients of the checklist were all applicable adult ICU patients (aged 16 years and over) admitted to the ICU during the study periods. A checklist was completed for each patient once a day during the morning round. Patients not present in the unit at the time of morning rounds (e.g. for procedure) were excluded for that day.

Recruitment frame & sample size calculations

The primary outcome of interest was compliance with the process-of-care checklist. To examine the significance of change in rates over time, *a priori* power calculations were computed for overall compliance with checklist statements. A previous multi-site study (Haynes et al. 2009) found compliance rates prior to intervention of 34.2% and post intervention 56.7% in a total sample of 7,688, equating to an odds ratio (OR) of 2.52 (95% CI 2.30 - 2.76). That is, the chance of compliance increased 2.5 times post intervention. Using this figure, sample size calculations for analysis comparing two proportions were conducted using Power Analysis & Sample Size (PASS) software

(version 12.0.2; NCSS Statistical Software, LLC. Kaysville, Utah, USA. www.ncss.com). With checklist item compliance as the outcome variable and time (baseline or follow-up) as the predictor variable, 206 participants were required to detect an odds ratio of 2.5 with a power of 0.90 and alpha set at 0.05. Based on the throughput of the study ICU for patients with a length of stay >24 hours (taking into consideration the possibility of patients being admitted after or discharged before morning ward rounds), it was estimated that 6 weeks each of baseline and post-intervention measurement would result in 214 patients; sufficient to detect clinically significant differences in compliance with process-of-care components.

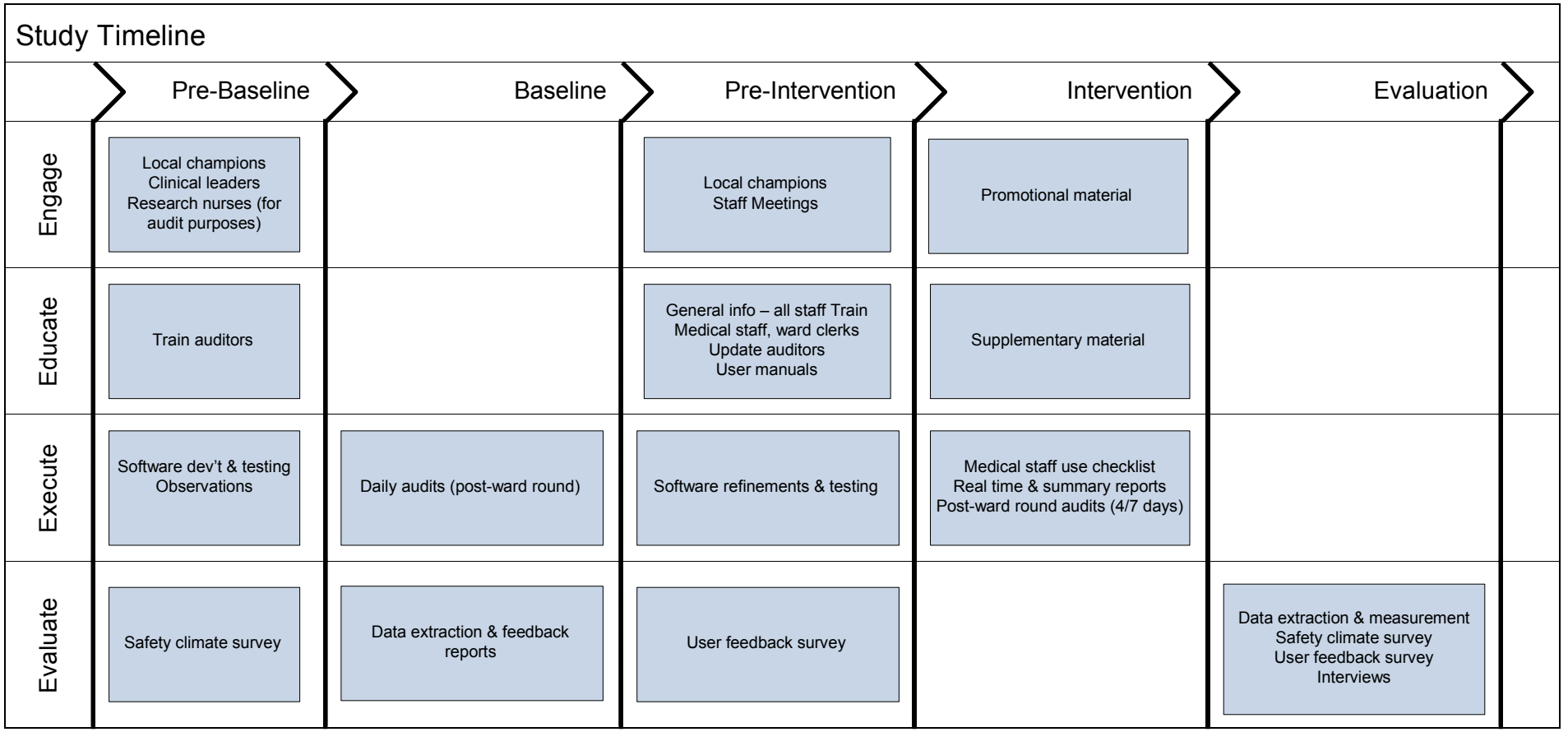
Intervention

The 'e-checklist' was designed as a practice delivery tool that provided a series of prompts during the clinical round. As described earlier (see Chapter 4), the checklist contained nine core 'process-of-care' statements, phrased as care considerations for the medical team to explore for each individual patient (i.e. the checklist was not designed to replace clinical decision-making). The e-checklist was available to medical staff on morning ward rounds to: 1) document either the delivery or clinical reasons for non-delivery of processes of care at the time of the round; 2) document any adverse events occurring to the patient during their ICU stay; and 3) generate real-time process data that informed clinicians about their practices.

Study Procedure

In line with a strategy proposed by Pronovost, Berenholtz and Needham (2008) for translating evidence into practice, the project incorporated four phases: Engage, Educate, Execute and Evaluate. The procedure was further informed by the QI methods identified in the literature (Chapter 2) as beneficial and effective. The study timeline indicating when key study features were completed within each of the four phases is presented in Figure 6.1, with each of the phases described below. The evaluation component of this study not directly related to the primary or secondary outcomes are described later in Chapter 7.

Figure 6.1 Overview of e-checklist study procedure within phases over time



Pre-baseline

Engage:

Two senior intensivists from the study site were invited and consulted to serve as local clinical champions (i.e. drivers of change), with involvement in unit-level planning, development and implementation of the study. The champions then engaged other medical staff, particularly the Senior Registrars who were present in the ICU the majority of the time. These clinicians provided input into the pragmatics of the project at the local ICU, proactively supported the implementation of the checklist procedure, encouraged staff participation in project-related activities (e.g. education sessions), and evaluation (e.g. completion of surveys). Unit-based research nurses were also engaged from the beginning, providing input into audit procedures, the audit tool, and further development of instruction booklets.

Educate:

An initial information session was scheduled with ICU research staff assisting with audit data collection. Information covered an overview of the research completed, an outline of the intervention study plan and timeline, and their roles during study implementation. Staff members were provided an opportunity for input and feedback on this process to ensure their buy-in and ease of data collection. This session was then followed by scheduled one-on-one training for each of the data collectors on use of the e-checklist audit tool (including live demonstration and practice runs) and the checklist server.

Execute:

Current clinical practices that may impact on the delivery of care to ICU patients during ward rounds were investigated to identify any considerations that needed to be factored into the study intervention.

Using a semi-structured observation tool (described in 'Measuring instruments' below), a systematic description of ICU structure, resources, and processes was conducted. Part 1 involved a pre-observation interview with the ICU Nurse Unit Manager to provide preliminary information pertaining to structure and resources. Observations then occurred over a 5-week period to account for different shift rotations for medical staff.

This process involved shadowing the ICU team as a non-participant on the morning ward rounds and documenting field notes on ward round processes as they happened. Questions of clarification were asked of clinicians only where necessary to accurately describe the process being observed. The clinical teams were advised that observations were being used to describe the process of ward rounds. Note-taking did not involve the identification of individuals – codes were assigned to staff designation only. In addition to obtaining approval from the Director and the Nurse Unit Manager (NUM) to conduct the observations, informed consent was obtained from each intensivist leading the ward rounds prior to each observation.

Observations commenced at 8am when the morning handover began and lasted for as long as necessary to gain understanding on ward round practices for any given clinical team – the minimum time was until X-ray rounds at 11am, but often went longer (maximum was 4 hours i.e. until 1pm) when the ICU was busy, or when the round was suspended for attendance at medical emergency calls elsewhere in the hospital. Findings from these observations were used to refine subsequent steps in preparation for checklist implementation.

Software development and testing was also conducted during this stage (as described in Chapter 5).

Baseline

Execute:

Prior to e-checklist implementation, process-of-care data were collected during the baseline period by a team of five research nurses (who had no responsibility for direct patient care on a daily basis) as an audit of the morning ward rounds. The audit was used to identify actual practice during ward rounds. One research nurse collected data the majority of the time, with other research team members filling in on days off and on weekends. Audit data were collected using the e-checklist seven days a week during the baseline data collection period, to ensure that the audit encompassed all rotations and medical teams. Each audit was conducted independently after completion of the medical

ward rounds, with the auditors checking each included patient's medical records (for the current chart day) and conferring with the bedside nurse as required.

Evaluate:

After completion of baseline audit data collection, data were extracted from the database and compliance with cares was summarised using statistical process control charts, to enable feedback to clinicians during the next stage of the project.

Pre-Intervention

The four-week period between baseline data collection and intervention was used to prepare the ICU for the intervention. This included providing participant education, training and general information; preparing relevant documentation such as detailed instruction booklets for all relevant staff involved in the project; refining the e-checklist software and conducting further testing of the e-checklist.

Engage & Educate:

After baseline data collection and with the assistance of local champions, a presentation to ICU medical staff was scheduled during a routine ICU meeting attended by medical staff. Prior to the meeting, medical staff were sent an email containing introductory information, including a concise project summary and two key articles of interest that provided relevant context to the project (Haynes et al. 2009; Hewson & Burrell 2006). This information along with the oral presentation formed the first educational component to the intervention phase. The presentation covered the following information:

- Broad study aims and significance of the research
- Background on evidence based processes of care, implementation methods and potential for improvement, including the results of the Australian and New Zealand point prevalence study (Hewson-Conroy et al. 2011)
- Feedback of results from earlier studies including the first checklist pilot study (Hewson & Burrell 2006), validity studies (Conroy, Elliott & Burrell 2013b; Lane et al. 2013), key observations made during the ward rounds, baseline audit data and patient level adverse events

- Project information- what is involved, what is expected of participants, project protocols, procedures and timeline
- Introduction to checklist use and feedback mechanisms

To minimise any Hawthorne effect, clinical staff were informed that the project was testing the utility of the e-checklist in delivering care, and was not an audit of individual practice. Senior medical staff not present at the meeting were sent an email containing the project information. After receiving the project information, participants also received consent forms to complete prior to study commencement.

After the presentation, time was arranged with each of the senior medical staff members participating in the research for detailed one-on-one instruction on use of the e-checklist and the reporting tool via the web portal. This type and level of training was essential due to medical staff schedules and it also allowed for individualised content that was beneficial to participants due to the different levels of knowledge and experience with PDAs and wireless technology. Checklist statements and data definitions were also discussed with each participant.

Following the presentation to medical staff, an information session was provided to all other ICU staff (nursing and allied health), presenting the project in general terms so that they were aware of the changes to the ward rounds – particularly the use of PDAs and the checking mechanism to be introduced at the end of each patient assessment.

As ward clerks were required to update the patient list in the e-checklist server after the ICU patient list was updated prior to the morning medical handover and ward rounds, they also received one-on-one training on use of the e-checklist server. In addition to managing the patient list they were also asked to ensure the PDAs were returned and charged at the end of each day.

Intensivists, research nurses, and ward clerks were issued with detailed instruction booklets that covered content specific to each of their roles in the project. The booklets created for research and medical staff included the checklist statements, response options and data definitions, and detailed instruction (including screen shots) on e-

checklist use. Medical staff also received information about accessing data summaries (e.g. charts, tables) via the web portal. All three versions of the booklets were available in both hard and electronic copies to enable ready access to information when required. Medical staff could access the booklet via the web portal (see Appendix G for e-checklist manual for medical staff).

The data definitions used were informed by: 1) previous work as outlined in Chapters 3-4; 2) consultation with the ICU's Research Manager prior to study commencement to ensure accuracy and precision of data collected via the audit tool, then with all research staff after the baseline data collection period; and 3) consultation with both site-based clinical champions to ensure accuracy and precision for the purpose of using the checklist during clinical rounds.

Execute:
Software refinements were conducted prior to the intervention period (as detailed in Chapter 5). Final testing of the e-checklist software, web portal, and wireless connection in the ICU was then completed prior to commencement of the intervention period to ensure all components were functional.

Intervention
Engage:
Information about the study was posted in patient waiting rooms (see flyer, Appendix H) and staff areas accessed by medical staff (see flyer, Appendix I).

Educate:
Supplementary material including tips on PDA use (e.g. what to do in the event of losing wireless connection with the server), and other aspects of the project (e.g. accessing data reports, location of instruction booklets and definitions, device management) were circulated to e-checklist users on a needs basis during the intervention period.

Execute:

The e-checklist was completed by senior medical staff (intensivist, senior registrar or registrar) during the morning ward round for all patients in the ICU, at the end of each patient assessment as a 'challenge-and-answer' tool. The e-checklist software enabled generation of real-time summary reports that provided clinicians with ready access to compliance data displayed using tables, charts and a progress bar via the web portal (see e-checklist manual in Appendix G). These reports summarised compliance overall and for each process-of-care over time. Additional feedback reports were generated on a fortnightly basis and circulated via email to medical staff and displayed on notice boards in staff common areas (see Appendix J for a sample report). This feedback to clinicians was designed to:

- quantify the delivery of cares on the ICU clinical rounds;
- generate process data in a format that was easily interpretable, informing clinicians about their practice;
- enable ICU clinicians to identify areas for improvement.

During implementation, post-clinical round audits were completed by a research nurse four days a week (usually Monday, Wednesday, Friday and one day of the weekend) for verification of physician responses. As with the baseline audit, data were collected independently after daily ward rounds were completed.

Evaluation

Evaluation of primary and secondary outcomes involved the following:

- Process data measurement to determine whether there were any significant improvements in compliance over time.
- Physician responses were compared with corresponding audit responses to evaluate checklist validity.
- Occurrence of patient-level adverse events (e.g. VAP) that this intervention was designed to prevent were described at baseline and post-implementation.

Measuring instruments

The measuring instruments used for the evaluation of primary and secondary outcomes included an observation tool and the e-checklist itself.

Observation tool

A semi-structured observation tool was devised to: 1) describe the study's clinical setting; 2) inform the checklist implementation strategy; and 3) describe clinical practices prior to checklist implementation. The tool (see Appendix K), enabled systematic description of the ICU setting (including type of unit, layout, bed numbers) structure (including staffing/ rostering), resources (particularly the use of technology) and processes (including how care was delivered, how ward rounds were organised, intensivist-led differences, communication between ICU staff).

E-checklist

The e-checklist also functioned as a measuring instrument, with the PDA collecting real time data after patient assessment on ward rounds and enabling an independent audit of whether identified processes of care during the round were implemented. The checklist also enabled collection of data on any patient adverse events that occurred during the study period. The specific events of interest were: VAP, CLABSI, unplanned extubation, re-intubation related to unplanned extubation, hyperglycaemia, hypoglycaemia, DVT, pulmonary embolism, GI bleed, medication error. There was also a free-text 'other' field where e-checklist users (both clinician and auditor) could record other events they felt relevant to document (i.e. related to cares covered by the checklist).

Data management and analysis

Pre-implementation measures

Observations

Handwritten notes taken during observations were transcribed, then organised into relevant themes. All relevant content information including consistencies and differences in ward round practices were extracted and synthesised for the purpose of describing the study environment and informing the e-checklist implementation model.

Post-intervention measures

All e-checklist data were automatically sent to and stored in a specifically designed networked database via a secure dedicated server where it was accessed for data management and analysis. Patient demographic and clinical data were obtained from a separate ICU database, with data linkage enabled via unique patient identifiers (i.e. medical record number), other patient level information (e.g. date of birth) as well as dates of ICU admission, discharge and checklist completion. Checklist level data were then combined with patient level data (age, gender, severity of illness, diagnosis, ventilator hours, hospital and ICU length of stay, vital status, and other admission details such as ICU or HDU, emergency or elective, non- or post-operative, readmission). Data were then de-identified and entered into SPSS (version 17; IBM SPSS Statistics, Chicago, Illinois, USA) for analyses.

Patient level data

A subset of the total checklist dataset was created containing only one record per patient to enable accurate description of the patient sample. Descriptive statistics were employed; means and standard deviations for normally distributed data, medians and inter-quartile ranges for non-normally distributed data, and percentages for categorical data. Sample characteristics for baseline and intervention patient groups were compared using: 1) independent t-test for normally distributed interval data; 2) Mann-Whitney U test for non-normally distributed data; and 3) Pearson's chi-square for categorical data. No assumptions were made for missing data.

Data on patient level adverse events (e.g. VAP, DVT, GI bleed) documented in the e-checklist were obtained before and after e-checklist implementation. Duplicated records of adverse events were removed where appropriate (i.e. events that only required documentation once per ICU stay such as VAP, DVT, and PE).

During the intervention period, adverse events were recorded by both physicians and auditors. Multiple incidents for the same patient on the same day were therefore also removed from the dataset prior to analysis. Descriptive statistics were then used to describe the incidence of events before and after the intervention at both the patient and event level.

Compliance data

To evaluate each process-of-care individually, Generalised Estimating Equations (GEE) analyses were conducted using SPSS to examine the significance of any change in compliance rates over time. GEE enabled the time component of this before/after study to be factored in, and to account for any correlated (non-independent) data (Garson 2013) such as the repeated measurement of compliance with cares delivered to individual patients during the study period. GEE also had the advantage of including confounding variables that could impact on the primary outcome (compliance at intervention). Potential confounders were identified from the literature and included patient age, gender, severity of illness score (APACHE III), ICU length of stay, vital status upon discharge from ICU, readmission to ICU (per separation for current hospital stay only), and type of admission (i.e. emergency or elective, post-operative or non-operative, and admitted as an ICU or HDU patient).

Physician responses 'omission – now corrected' and 'omission – not yet corrected' were concatenated into a single 'non-compliant' response. All 'not applicable' checklist responses were excluded from analyses as they all pertained to valid reasons as to why a care was not delivered e.g. patients were 'not applicable' to sedation assessment if they did not require sedation in the past 24 hours (see Appendix G for further detail pertaining to all of the possible 'not applicable' responses).

To illustrate process measurement at the unit level over time, daily compliance data obtained from the e-checklist database were extracted and entered into an SPSS spreadsheet, and Statistical Process Control (SPC) charts were produced using the P-chart (proportion nonconforming) function. SPC charts are one method of displaying and presenting process-of-care compliance data, demonstrating whether performance of a process was stable and predictable (common cause variation) or whether there was variation in performance that made it unstable and unpredictable (special cause variation) (Thor et al. 2007). Special causes are flagged in SPC charts using the following rule violations (Benneyan, Lloyd & Plsek 2003):

- A single point falls outside the upper or lower control limits
- At least two out of three successive values are more than two standard deviations (SD) from the mean on the same side of the centre line

- At least four out of five successive values are more than one SD from the mean on the same side of the centre line
- At least eight successive values fall on the same side of the centre line
- Six consecutive points trending up or down
- 14 consecutive points alternating.

The numerator for the calculation of daily compliance was the sum of all 'Yes- care delivered' responses; the denominator was the sum of all applicable responses (excludes 'not applicable' and 'not ventilated' responses).

Post-hoc analyses were also conducted to evaluate compliance with the IHI's VAP bundle (Berwick et al. 2006) i.e. DVT prophylaxis, stress ulcer prophylaxis, sedation management, readiness to wean from mechanical ventilation, and elevated head-of-bed (> 30 degrees). The IHI's method of calculating compliance for the care bundle (Institute for Healthcare Improvement 2006) was utilised i.e. the number of 'yes' or 'NA' (i.e. contraindication) responses to all care components in the bundle divided by the total number of mechanically ventilated patients. This method was used so that compliance with the care bundle can still be credited despite contraindications to the care components. Cases with missing data were excluded from this analysis.

Concordance data

To evaluate the validity of the e-checklist, established measures of concordance (the degree of agreement between two sets of observations) were used to compare physician responses with responses from the corresponding audit by ICU research nurses. Analyses were conducted on a defined subset of the checklist data where audit had been completed and patients who were not applicable for a care (during ward round or audit) were excluded. To enable accurate comparisons between the two response sets, physician responses 'omission – now corrected' were re-coded into a 'yes' response as the audit was conducted upon completion of the morning ward rounds.

Several measures pertaining to concordance were required – proportion of observed agreement, Byrt's (Byrt, Bishop & Carlin 1993) kappa, prevalence and bias indexes (Byrt, Bishop & Carlin 1993), and the proportions of both positive and negative

agreement (Cicchetti & Feinstein 1990). Byrt's method of calculating kappa was used as: 1) Cohen's kappa is subject to biases in some instances and only suitable for fully-crossed designs with exactly two coders (Hallgren 2012; Kraemer, Periyakoil & Noda 2002); and 2) the potential for checklist data to have a prevalence bias with a larger proportion of observed ratings falling under one category was identified – this type of bias would cause Cohen kappa estimates to be unrepresentatively low (Byrt, Bishop & Carlin 1993; Hallgren 2012).

Byrt's kappa (Byrt, Bishop & Carlin 1993) corrects for bias in marginal distributions, and is presented with the Bias Index (BI) – a measure of bias between 'observers' (intensivist-entered data and audit data) present when the marginal distributions for the raters are unequal (BI = 0 when marginal proportions are equal); and Prevalence Index (PI) – a measure of the differences between the overall proportion of 'yes' and 'no' assessments (PI = 0 when both responses are equally probable) (Byrt, Bishop & Carlin 1993).

These measures along with both positive and negative agreement ('Ppos' / 'Pneg') enable clear demonstration of the nature of any relationship between respondent groups (physician versus auditor) for each checklist item. Byrt's kappa statistics were calculated using a 2x2 contingency table (i.e. 'yes care delivered or considered' and 'no- care not delivered') using the concord package (version 1.4-9) in RStudio (version 0.97.168; RStudio Inc. Boston, Massachusetts, USA); PI, BI, Ppos and Pneg were calculated in Excel using published formulas (Byrt, Bishop & Carlin 1993; Cicchetti & Feinstein 1990).

Ethical considerations

Human Research Ethics Committee approval was obtained from both university and Area Health Service Committees (see ethics approval letters in Appendix L & M). Participants (i.e. ICU staff) provided informed consent prior to study involvement (see Appendices N and O for participant information sheet and consent form). Individual patient consent was not required as the study was considered a quality assurance project. Any patient-level data was de-identified prior to analysis.

Results

Study findings presented below include results of the pre-study observations, description and comparison of patient demographics, comparison of checklist compliance over time, concordance between checklist completion and actual delivery of care, and description of patient-level outcomes including adverse events.

Pre-study observations

Detailed information pertaining to the structure and resources of the ICU are outlined in Appendix P (i.e. responses to pre-observation interview with NUM. Note: some findings were integrated into appropriate sections in the Method section above). Observations were taken from the commencement of the morning clinical handover to the end of ward rounds in the ICU noting the purpose, function and process of each.

The morning ICU clinical handover involved a large group of clinicians i.e. at least 18 people, moving from bed to bed with the aim of exchanging important information on each patient that was essential for the transfer of patient care. The group was multidisciplinary in that it included medical and nursing staff; the focus however, was on the exchange of information between the medical team on night shift (communicated by the most senior medical staff member – usually a registrar) to the medical team taking over responsibility of patient care for the day (information was always directed at the consultant and sometimes to the senior registrar or registrar depending on the information being relayed).

The night registrars provided information on patient details and history, admission information and any planned discharges, diagnoses, treatments, tests completed or planned, updates on patient condition, any issues that arose overnight, and any plans for the day. After each patient presentation they waited to obtain confirmation that the information was received and responded to any questions that the day staff had.

It was common for most medical staff (particularly senior medical staff) to be either directly involved in the information exchange at handover, or to at least be close to people who were engaged in the communication process. Occasionally the junior medical staff would have separate discussions at the back of the group. Nurses were

often on the periphery of the large group however some of the more senior nursing staff would involve themselves where required for example, the liaison nurse would ask questions pertaining to the plan for the day for particular patients. The consultant would also ensure the nursing team leader was aware of any patients that were cleared for transfer out of the ICU to another ward in the hospital.

At the end of the handover the Consultant would summarise the actions required as a matter of priority, thank and dismiss the night staff, allocate tasks to the day staff particularly the junior medical officers (e.g. arranging allied health consults, scheduling tests and investigations) and split the medical team into two smaller groups for commencement of ward rounds (one per pod). Each team had a combination of senior and junior medical staff.

Each medical team was led by the most senior physician i.e. the consultant or the senior registrar. They were responsible for setting priorities, directing, instructing, teaching, and informing patients, families and staff. There was variation in how the clinical lead conducted the morning ward rounds. Some would order the rounds by bed number, others prioritised the order in which patients were seen based on severity of illness i.e. the more critically ill were seen first, followed by new admissions, then long stay patients (who had established treatment plans in place). The roles of the medical team also varied depending on the preference of the consultant. Some consultants preferred to take responsibility for reviewing and writing in the patient's medical record whilst providing guidance from the end of the bed, whereas others preferred to be more 'hands-on' with the patient i.e. doing the patient assessment themselves and communicating the findings to a junior medical officer who wrote in the notes, reviewed previous documentation, and completed order forms for tests. This meant there was some variation in the roles and responsibilities of the medical team that was dependent on both the clinical lead and the composition of the ward round team.

Regardless of the individual roles performed during the ward round it was generally structured as follows:

- Clinical lead introduces self to patient and/or family (if present) and informs them of the purpose of the visit;

- Conduct physical patient examination which was either a head-to-toe or systems-based assessment of the patient's clinical condition, or focused on the most pressing problem for the patient at that time;
- Senior medical staff discuss solutions to problems, possible treatments, important issues to consider, evidence-based care;
- Refer to patient notes, document current clinical status and findings of patient assessment concurrently with patient examination;
- Review recent test results and scans, ventilator settings, medications;
- Order further tests, schedule scans, procedures and consultations, and prescribe medications;
- Conduct procedures that were required immediately e.g. insert central line, intubate patient, perform log roll;
- Often a summary of the visit was provided and a plan for the day was detailed;
- Medical team shares the plan for the day with the bedside nurse including ongoing care, treatment, and goals and nursing staff were sometimes provided with the opportunity to ask questions of the medical team.

The level of detail covered in patient assessments appeared to depend on the length of ICU stay and level of familiarity the medical team had with the patient. New and more complex patients required more time, as more thorough assessments and considered decisions pertaining to care plans were necessary. Visits to medically stable patients with a long ICU stay and no pressing issues on the other hand, were brief and checks were minimal, if done at all. It seemed that for these long-term patients there was an assumption that all appropriate cares were being attended to, without actively checking.

It was apparent that multi-tasking was a routine part of the morning ward rounds. In addition to the usual routine, consultants and senior registrars would also integrate bedside teaching. There were also times when external consultants e.g. surgical team would need to discuss a patient with the ICU team despite them being at a different patient's bedside, which took them away from their current task.

Disruptions to the ward round were commonplace. Consultants would often need to take phone calls made to the unit e.g. requests for ICU bed, answer their mobile phones and

pagers, and answer questions and queries made by other ICU staff. There were internal ICU alarms that required medical attention such as when a patient required resuscitation, there were also medical emergency team calls from elsewhere in the hospital that allocated medical staff were required to attend. In the majority of cases where disruptions occurred, the remaining medical staff continued with the ward rounds, rotating roles and responsibilities to fill the gap of whoever was missing at the time. This meant that a range of medical staff i.e. from resident to consultant had the role of documenting and referring to previous documentation in patient medical records.

Although all processes of care covered by the e-checklist were attended to during ward rounds across the total observation period, checking mechanisms for essential daily cares at the patient level were often cursory and incomplete. The reason for this was often not apparent to this student observer, though they may have only been verbalising things they had not already covered or considered in some way, perhaps covertly. There were two specialists that attempted to do routine checks from memory at the end of some patient visits during the observation period. Their checks were often incomplete and this was sometimes due to being interrupted e.g. at the end of two separate patient visits one consultant was interrupted by a registrar on the same ward round team. Once the registrar asked about the dosing amounts, frequency and supporting evidence for delivery of heparin (it was uncertain whether this was prompted by the consultant's check re: DVT prophylaxis), and on the second occasion it appeared the registrar was trying to complete the required documentation and needed to check certain things with the consultant. This resulted in the consultant re-starting the checking mechanism (i.e. FASTHUG) at least twice due to losing his place, and omitting some checks.

During the ward rounds the bedside nurses and the junior medical officers appeared the most mobile. Nurses went between the bedside and the nursing station, the stores room and other locations throughout the unit for equipment and supplies. The junior medical staff also accessed the nursing station to obtain forms, make calls, retrieve test results and scans. They also accessed other areas of the unit to retrieve equipment, prepare drugs, injections, and IV fluids. This appeared to be reflective of the hierarchy within the ICU, with the most senior medical staff remaining at the bedside as much as possible (perhaps to ensure thorough assessment and review and appropriate delivery of

care), and the junior medical and nursing staff responding to requests made by the senior medical staff.

Technology present in the unit reportedly consisted of four computers-on-wheels (COWs) although only two were ever seen being used at one time. The COWs had a wireless connection to the hospital's IT network, allowing access to Cerner Millenium Powerchart (Cerner Corporation PTY Limited, North Sydney, Australia) which provided laboratory/ pathology reports, medical imaging, and emergency department notes. The COWs were also used to access the internet allowing retrieval of medical literature, clinical practice guidelines and drug information. They were often wheeled around from bed to bed during the morning ward rounds so that information could be readily accessed where required however because they were not necessary to all patient assessments, they were not always used.

There were three stationary computers with wall-mounted screens (two in ICU 1, one in ICU2) that also provided access to medical imaging and test results. These were generally not used during ward rounds unless viewing high quality imaging was required as the screens provided more precision and clarity than the COWs or the PCs at the nursing stations (two in ICU1 and one in ICU 2). Screensavers on all unit PC screens displayed alerts and reminders such as the existence of new clinical guidelines, hand hygiene prompts and clinical process mnemonics such as FASTHUG.

Notably, none of the technology was used to record any other patient or clinical data – all documentation including flow charts, medication and treatment sheets, and all other patient notes were paper-based. A ward round tool that was printed from an electronic template onto labels and stuck into the medical record outlined some of the prompts included on the e-checklist, but was only used once out of the five days of observations (one day it was requested by the clinical lead but it was not working). On the one day it was used it appeared that it was being completed differently by various medical staff which may have been due to the lack of clear, definitive statements (presented as brief prompts, most of which consisted of 1-2 words).
The only other electronic device seen being used on the ward rounds was a smartphone – a consultant used the electronic notepad to insert handwritten notes (using a stylus on

the phone's screen) that were used as reminders such as current patient issues, tests ordered, and tasks to complete.

Information obtained from the observations was used to finalise the implementation method prior to the commencement of the intervention study period (outlined in Table 6.1).

Table 6.1 Outline of how key observations were integrated into the intervention study method

Key observations	**How integrated into study method**
Role of handover versus role of ward round	Use of e-checklist during morning ward rounds confirmed as the most suitable time
After handover medical staff split evenly (in terms of numbers and roles) into two groups – 1 team per pod	Two devices were required to be used concurrently, the e-checklist server was required for collection of data from both devices, and technical specifications were devised to ensure one source of truth for the collated data
Ward rounds lead by most senior physician	Emphasis placed on engaging senior physicians in the project, training them on e-checklist use, and requesting they lead and/or encourage its use
Roles of the medical team during ward rounds differed depending on clinical lead	All senior medical staff (registrars, senior registrars, consultants) were provided with individual logins for the e-checklist
Ward round flow and content covered	In order to accurately reflect care delivered during ward rounds and to be a useful checking mechanism, use of the e-checklist at the end of the patient visit was deemed most appropriate

Key observations	How integrated into study method
Regular disruptions to the ward round	Provided a supporting argument to the need for improvement and possible utility of e-checklist – examples were fed back to clinicians during information sessions
Processes of care covered by the e-checklist seemingly not addressed for all patients during ward rounds (despite some apparent attempts to do checks from memory alone)	As above
All processes of care were attended to during ward rounds across total observation period	Confirmed content validity work in the clinical setting
Senior medical staff tended to remain at the bedside more often than other staff during ward rounds	Provided additional confirmation that senior medical staff should lead the use of e-checklist
Existing technology in the unit not used routinely e.g. COWs were not necessary to patient assessments, nor as conveniently portable as a handheld device	Provided confirmation there was no existing IT infrastructure suitable for the delivery of the e-checklist
Inconsistent and irregular use of the printed ward round tool	Provided further supporting argument to the need for improvement and possible utility of e-checklist – this was fed back to clinicians during information sessions
No other electronic device was used as a checklist of routine cares to be delivered during ward rounds	Provided confirmation of the suitability of delivering the e-checklist via a PDA

Patient demographics

During the entire 12 week study period (6 weeks each of pre- and post-intervention data collection) there were 293 patients admitted to the ICU – 141 at baseline and 152 at intervention. Patient demographics outlined in Table 6.2 revealed that the two groups were comparable with no statistically significant differences identified. Although slight differences in proportions for diagnoses were apparent between groups, these were not statistically significant different for any of the major diagnostic categories. For example, there were 10% more patients diagnosed with respiratory related diagnoses during the intervention period ($p=0.08$), which coincided with the peak winter season and a H1N1 (swine flu) outbreak (Webb et al. 2009) (see 'Discussion' section for the influence of this and other related issues on the study).

Checklist compliance

From these 293 patients, 1,212 valid checklist records were generated; 635 during baseline (generated from 43 consecutive audit days) and 577 during intervention (generated by physicians across 41 consecutive days with 333 corresponding audit responses collected on 23 non-consecutive days). Summaries of responses to checklist items are outlined in the Appendices (Appendix Q to S: baseline audit; physician response during intervention; and audit responses during intervention). In addition to the 577 valid checklist records during the intervention period, there were 110 checklists generated by the e-checklist server that were not completed by physicians (due to records generated for patients who were discharged, ready for discharge, or not in the ICU during morning ward rounds) and 15 checklists (1.1% of raw checklist dataset) that could not be matched with the ICU patient dataset (patient identifiers were incongruent). These records were excluded from analyses.

Table 6.2 Patient demographics:[a] e-checklist study

Variable	Baseline (n=141)	Intervention (n=152)	P-value
Gender (male)	57%	55%	0.73
Age[b]	57 (21)	57 (18)	0.79
APACHE III score	56 [37 – 76]	57 [37 – 79]	0.67
ICU LOS (days)	3 [2 – 6]	2 [1 – 6]	0.08
Hospital LOS (days)	10 [5 – 75]	11 [6 – 23]	0.90
Checklist days (per patient)	2 [1 – 5]	3 [2 – 5]	0.53
Mechanical ventilation hours	72 [14 – 165]	77 [20 – 194]	0.49
% Mechanically ventilated	50%	48%	0.82
Crude[c] ICU mortality	7.8%	7.9%	1.00
Crude[c] hospital mortality	11.4%	9.2%	0.57
ICU re-admissions	4.3%	6%	0.60
ICU : HDU admissions (%)	63 : 37	63 : 37	1.00
Emergency : Elective (%)	77 : 23	80 : 20	0.48
Non-Operative : Post-Operative	64 : 36	72 : 28	0.13
Diagnosis on admission (%):			
Respiratory	27.7	37.5	0.08
Gastrointestinal	13.5	11.2	0.60
Neurological	13.5	9.9	0.37
Sepsis	7.8	13.8	0.13
Cardiovascular	8.5	9.2	1.00
Metabolic	9.9	7.2	0.53
Trauma	10.6	3.3	0.19
Genitourinary	3.5	5.9	0.42
Gynaecological	2.8	2.0	0.71
Musculo-skeletal / skin	1.4	0	0.23
Haematological	0.7	0	0.48

Notes [a] All patient demographic data obtained from the ICU database.

[b] Descriptive data for age are mean and standard deviation (normal distribution), other (no-normal distribution) interval data use median and inter-quartile range.

[c] Percentage of ICU admissions who died in ICU or in hospital.

When comparing compliance with each individual care component over time all nine cares improved significantly (see Table 6.3). The largest increase was for pain management where the odds of receiving this care during the intervention period were 23 times greater than for baseline. Glucose management and head-of-bed elevation also demonstrated much higher compliance rates during the intervention period, with Odds Ratios (ORs) greater than 10. Medication review displayed significant improvement with an OR of just under 10, however the confidence intervals were wide (1.3 to 74) and the percentage of absolute change was only 1.4% (see Table 6.3). This finding was probably due to the very low number of omissions (8 during baseline, 1 during intervention) and a large sample size as all patients were applicable for this care component.

Nutrition assessment, sedation management, stress ulcer prophylaxis displayed moderate improvement over time with ORs between 3 and 5. DVT prophylaxis and mechanical ventilation weaning demonstrated the least amount of improvement, although compliance rates at baseline were already very high (95 and 91% respectively).

Table 6.3 Compliance with care processes over time (baseline versus intervention)

	% Absolute Change	Pre- (%)	Post- (%)	Adjusted[a] Odds ratio (95% CI)	P-value
Pain management	42.2	53.4	95.6	22.85 (13.69-38.16)	<.001
Glucose management	22	75.7	97.7	13.82 (7.01-27.27)	<.001
Head-of-bed elevation	19	78.3	97.1	10.98 (5.39-22.35)	<.001
Sedation management	7.5	89.7	97.2	3.89 (1.80-8.42)	.001
Nutrition assessment	7.4	89	96.4	4.36 (2.4-7.92)	<.001
Mechanical ventilation weaning	3.6	90.9	94.5	1.92 (1.03-3.59)	.041
Stress ulcer prophylaxis	3.2	94.4	97.6	3.73 (1.68-8.28)	.001
DVT prophylaxis	1.7	94.8	96.5	2.24 (1.06-4.70)	.034
Medication review	1.4	98.4	99.8	9.86 (1.31-74.33)	.026

Notes

'Not applicable' and 'not ventilated' responses were excluded.

[a] GEE adjusted for patient age, gender, APACHE III severity of illness score, ICU length of stay, vital status upon discharge from ICU, readmission to ICU, type of admission (emergency or elective, post-operative or non-operative, ICU or HDU).

At the patient level, omissions were evaluated further to gauge whether omissions detected by the physicians led to care delivery the following day. There were a total of 81 omissions that were 'not yet corrected' during the morning ward round; of these, 64 (79%) were corrected the next day, 13 (16%) cases related to either patients who were only in the unit for one day or on their last day in ICU before discharge, and four (5%) were also omissions the following day. Of these four omissions, two were for the checklist item 'readiness to wean' and two for 'nutrition', and all were corrected the following day.

There were a total of 45 omissions corrected during the morning ward round; of these, 32 (71%) were recorded as being delivered the next day (i.e. a 'yes – care delivered' response), 10 cases (22%) related to either patients who were only in the unit for one day or on their last day in ICU before discharge, and three (7%) were also omissions the following day. These three omissions were for 'pain', 'DVT prophylaxis', and 'readiness to wean'. The omission (not yet corrected) for pain was recorded on the last day the patient was in the ICU; the other two cases (readiness to wean was 'not yet corrected' and DVT prophylaxis was 'now corrected') were both corrected the following day.

For the IHI ventilator bundle of care activities for mechanically ventilated patients, baseline compliance was 65%, and intervention period compliance was 88% - a 23% improvement (see Table 6.4).

Table 6.4 Comparison of compliance with the ventilator bundle over time: e-checklist study

Time	Yes/NA	No	Total	% Compliance (Yes+NA/Total)
Baseline	170	90	260	65.38
Intervention	301	42	343	87.76

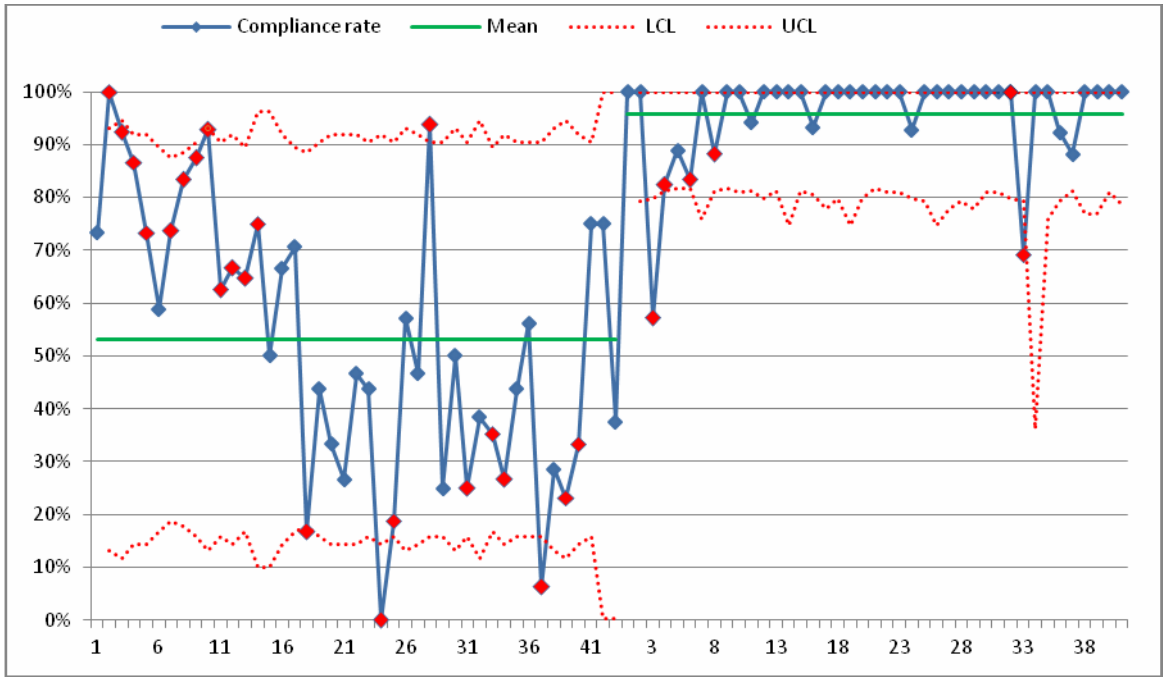
Notes. Ventilator bundle = DVT & stress ulcer prophylaxis, Sedation, Readiness to wean, HOB elevation; Yes/NA = Yes or NA to ALL components of the bundle; No = No to ANY bundle component (i.e. only requires one 'No' response to any of the four bundle elements).

When examining process improvement, the SPC charts generated for each care component (see Figures 6.2 – 6.10) illustrated that the majority displayed reduced variability in compliance over time. The only exceptions were DVT prophylaxis and medications management, which as noted above, displayed high levels of compliance that were relatively stable over time. Some care components (i.e. pain and sedation management, and weaning off the ventilator) displayed variability during the first week of the intervention, but then evidence of improvement that was largely sustained for the remainder of the intervention period. Despite improvements in compliance, there was some continued variability for two of the cares (nutrition and stress ulcer prophylaxis); both had two days where compliance fell below the lower control limit, with each instance followed by improved compliance within control limits the following day.

For the intervention period, the reduction in variability appeared to coincide with an increase in the number of SPC violations for some aspects of care – particularly runs of 8 consecutive data points above the centre (mean) line (i.e. DVT prophylaxis, medications, sedation management, mechanical ventilation weaning). Given the aim of the checklist was to reach 100% compliance on a daily basis these violations were not considered 'special cause' variation for the purposes of this study.

Narrative interpretation is provided below each of the SPC charts that follow (Figures 6.2 – 6.10). Each graph depicts daily unit compliance (blue line) over time – the first 42 days represents the baseline data collection period and the second run of 42 days represents the intervention period. The green lines show the average compliance for each of the two time periods. The red dotted lines show the upper and lower confidence (or sigma) limits i.e. 3 standard deviations either side of the mean. The red diamonds highlight SPC rule violations and are detailed in the box to the right of each graph.

Figure 6.2 *Compliance with pain management over time*

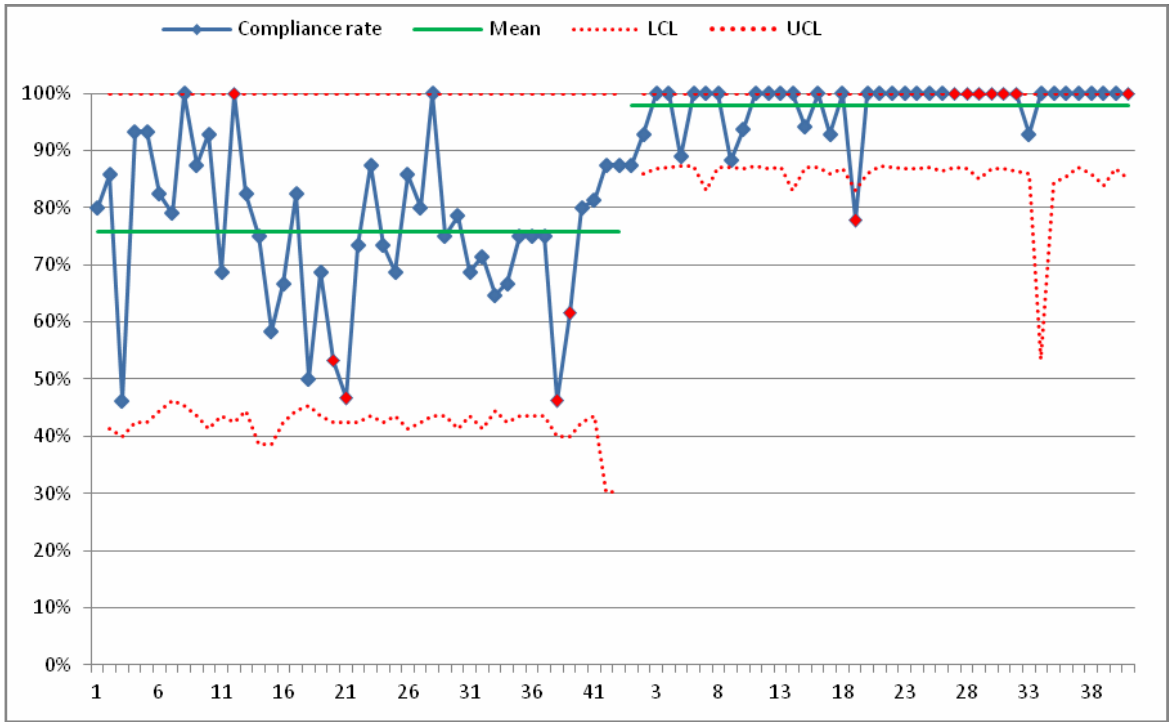


Rule violations

Study period	Day no.	Violations for points
Baseline	2, 28	> +3 sigma
	3-4, 9-10	2pts of last 3 above +2 sigma
	4-5,7-8, 9-10,12	4pts of last 5 above +1 sigma
	8-14,25	8 consecutive pts ^ centre line
	18, 24, 37	< -3 sigma
	25, 31, 39	2pts of last 3 below -2 sigma
	33-34, 40	4pts of last 5 below -1 sigma
Intervention	3, 33	< -3 sigma
	4, 6	2pts of last 3 below -2 sigma
	6, 8	4pts of last 5 below -1 sigma
	32	8 consecutive pts ^ centre line

Interpretation: Daily compliance during baseline measurement was highly variable with average compliance just over 50%. During the intervention period average compliance increased and variability reduced dramatically with few process violations when compared with baseline, and a 69% increase in the number of fully compliant days.

Figure 6.3 Compliance with glucose management over time

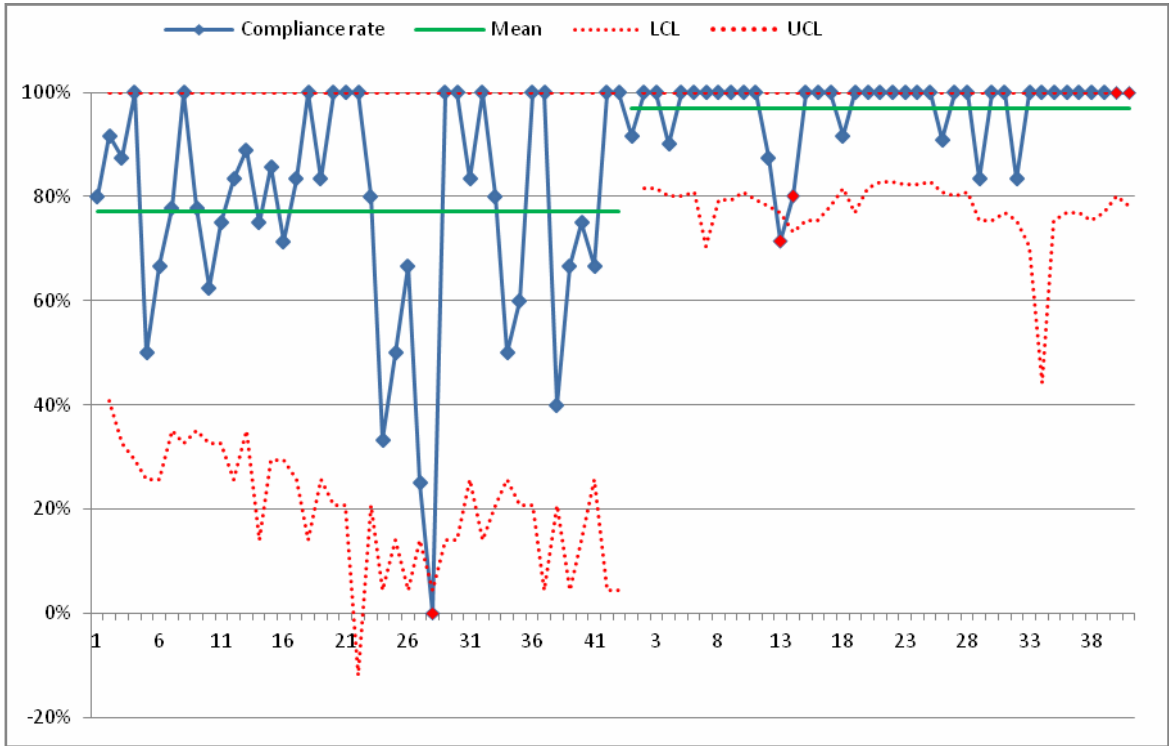


Rule violations

Study period	**Day no.**	**Violations for points**
Baseline	12	4pts of last 5 above +1 sigma
	20-21	2pts of last 3 below -2 sigma
	38-39	8 consecutive pts below centre line
Intervention	19	< -3 sigma
	27-32, 41	8 consecutive pts ^ centre line

Interpretation: Dramatic reduction in variability during intervention period with the majority of days achieving 100% compliance representing a 69% increase in fully-compliant days.

Figure 6.4 ***Compliance with head-of-bed elevation over time***

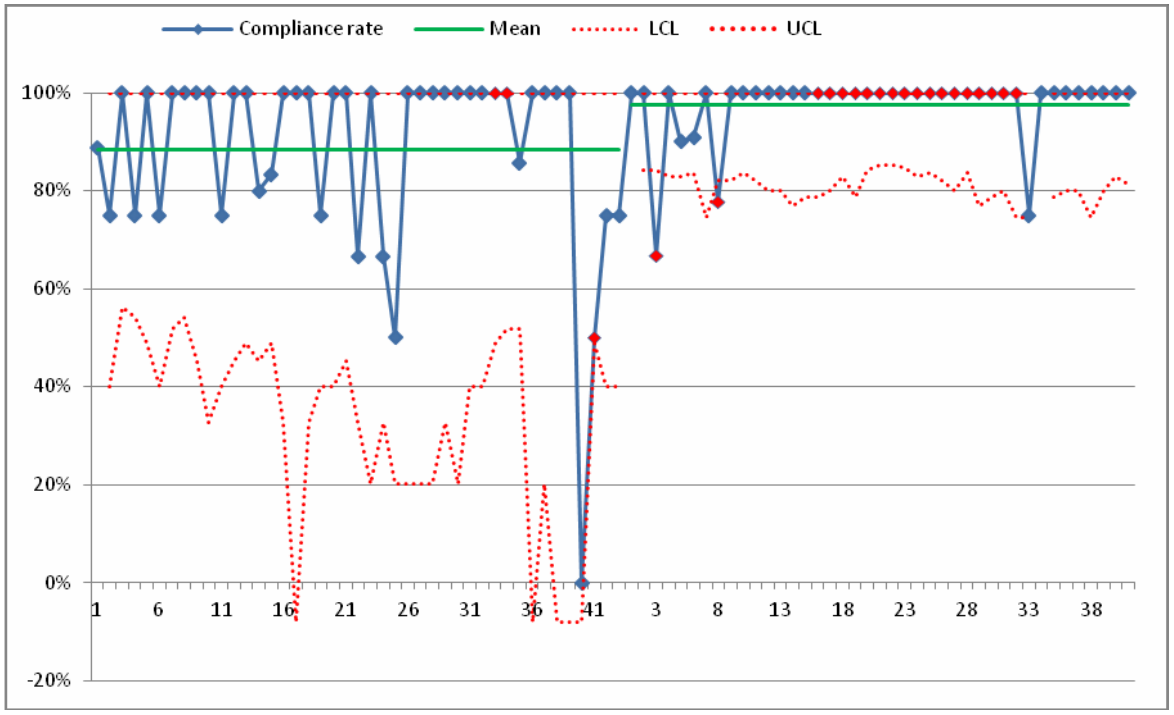


Rule violations

Study period	Day no.	Violations for points
Baseline	28	< -3 sigma
	28	2pts of last 3 below -2 sigma
	28	4pts of last 5 below -1 sigma
Intervention	13	< -3 sigma
	14	2pts of last 3 below -2 sigma
	40, 41	8 consecutive pts ^ centre line

Interpretation: Reduced variation in compliance is evident for the intervention period. The two consecutive 'outlier' data points (outside -2 to -3 sigma limits) during the intervention period were followed by consistently high levels of compliance. There was a 45% increase in fully-compliant days.

Figure 6.5 Compliance with sedation management over time

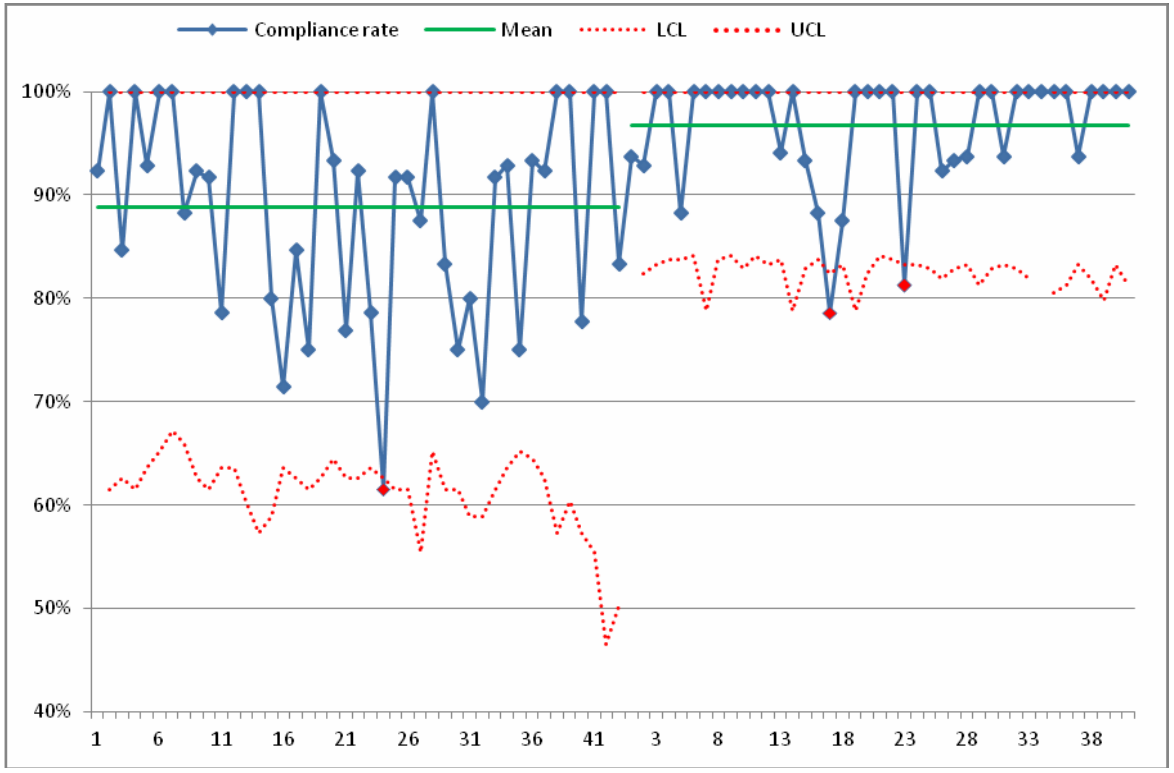


Rule violations

Study period	Day no.	Violations for points
Baseline	33-34	8 consecutive pts ^ centre line
	41	< -3 sigma
	41	2pts of last 3 below -2 sigma
Intervention	3, 8	< -3 sigma
	16-32	8 consecutive pts ^ centre line

Interpretation: Despite high average compliance rates during baseline the need for improvement was evident with two days displaying 50% compliance and one day zero compliance. During the intervention period the majority of days achieved 100% compliance (a 22% increase from baseline i.e. from 64-86%), with a subsequent improvement in average compliance noted.

Figure 6.6 ***Compliance with nutrition management over time***

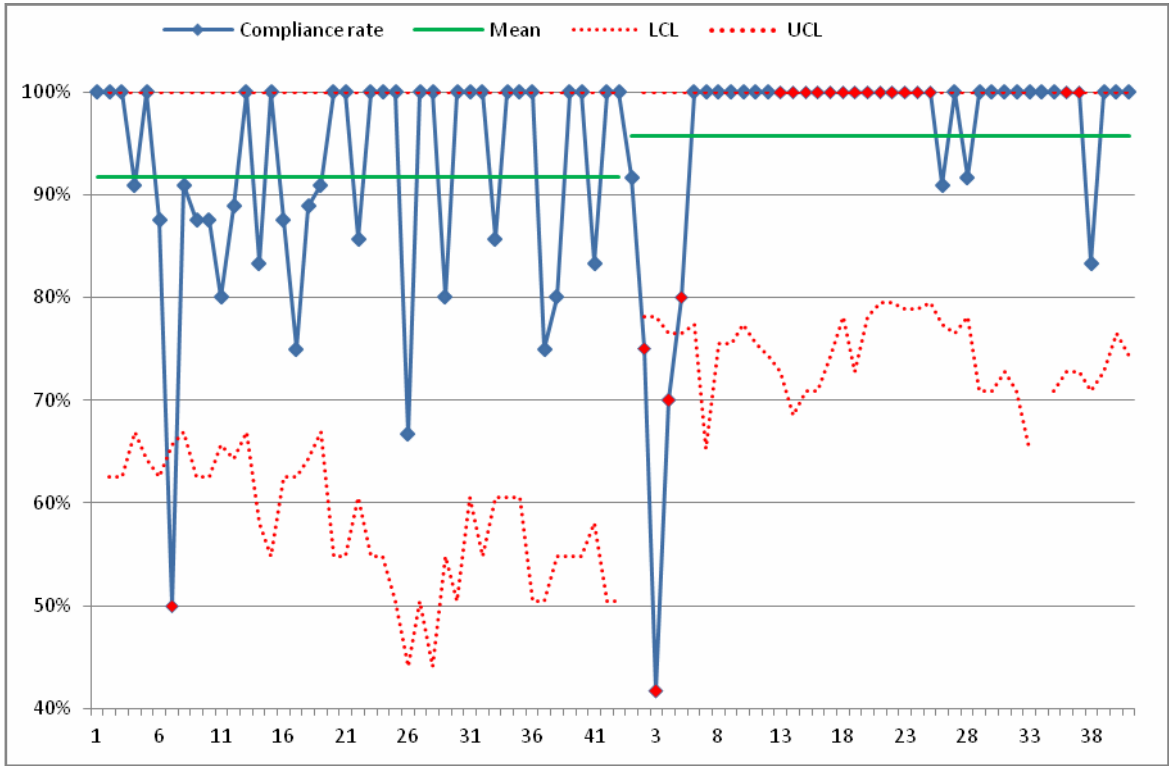


Rule violations

Study period	Day no.	Violations for points
Baseline	24	< -3 sigma
Intervention	17, 23	< -3 sigma

Interpretation: Improved levels of compliance, with reduced variability the during intervention period is evident, despite two days where unit compliance fell below 3 sigma limits – each instance was followed by improved compliance (within 3 sigma limits) the following day. There was a 33% increase in fully-compliant days from baseline to intervention.

Figure 6.7 Compliance with management of weaning off mechanical ventilation over time

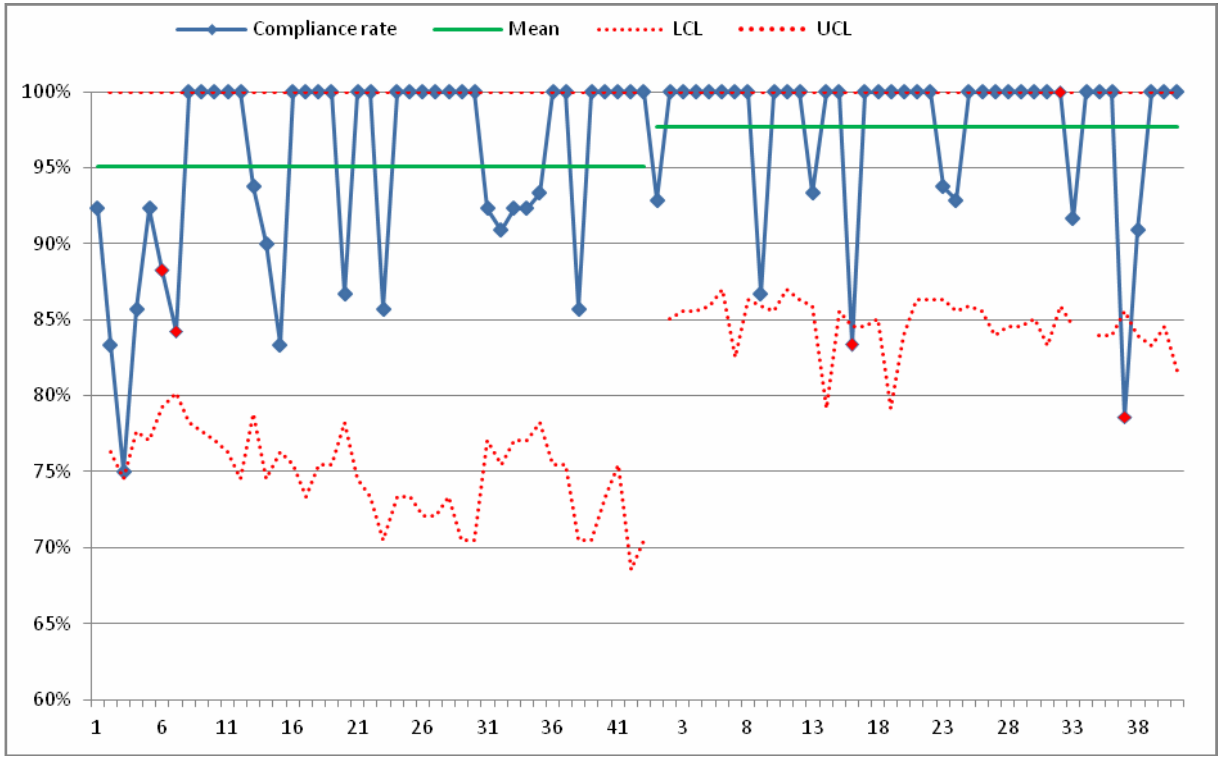


Rule violations

Study period	Day no.	Violations for points
Baseline	7	< -3 sigma
Intervention	2-4	< -3 sigma
	3-5	2pts of last 3 below -2 sigma
	5	4pts of last 5 below -1 sigma
	13-25, 36-37	8 consecutive pts ^ centre line

Interpretation: Considerable variability was evident during baseline. After a slow start to the intervention period, compliance improved dramatically displaying consistently high daily compliance rates for the remainder of the study period, including a 24% increase in fully-compliant days.

Figure 6.8 Compliance with stress ulcer prophylaxis over time

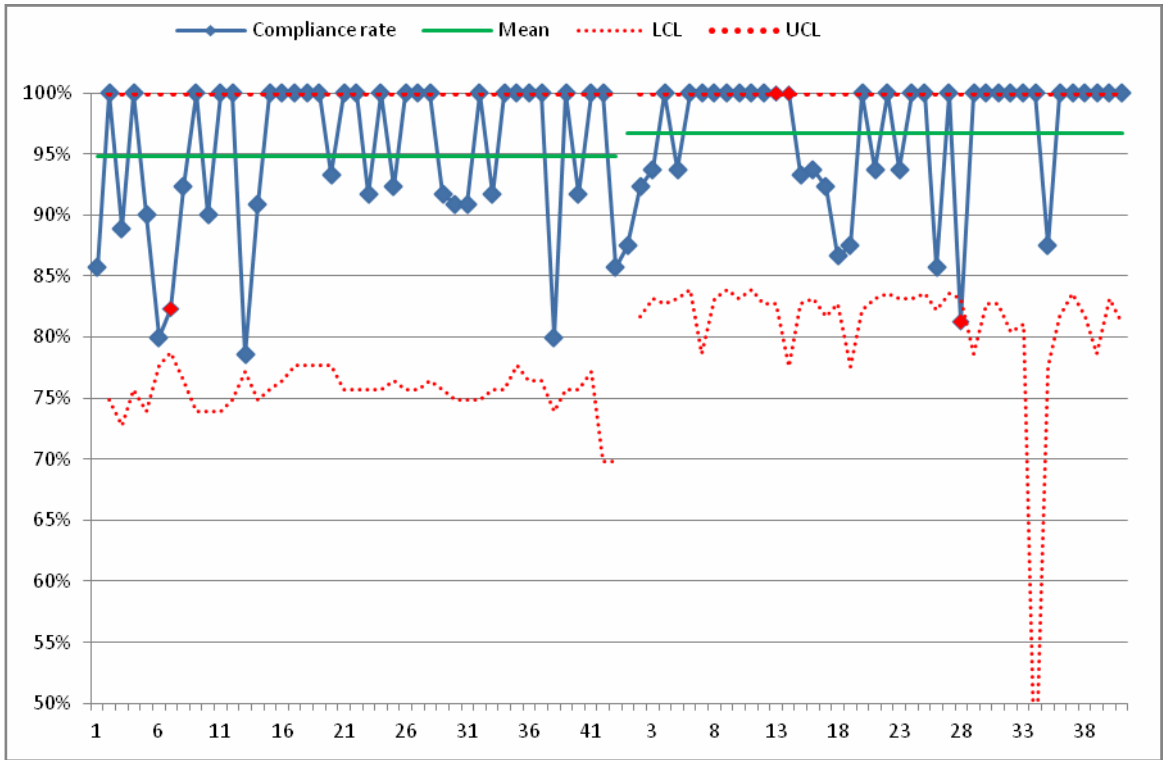


Rule violations

Study period	Day no.	Violations for points
Baseline	6, 7	4pts of last 5 below -1 sigma
Intervention	16, 37	< -3 sigma
	32	8 consecutive pts ^ centre line

Interpretation: Although average daily compliance improved from baseline to intervention, some variability continued during the intervention period. Notably, when compliance fell below the lower control (-3 sigma) limit, it returned to within control limits the following day. There was a 22% increase in fully-compliant days during the intervention period.

Figure 6.9 ***Compliance with DVT prophylaxis over time***

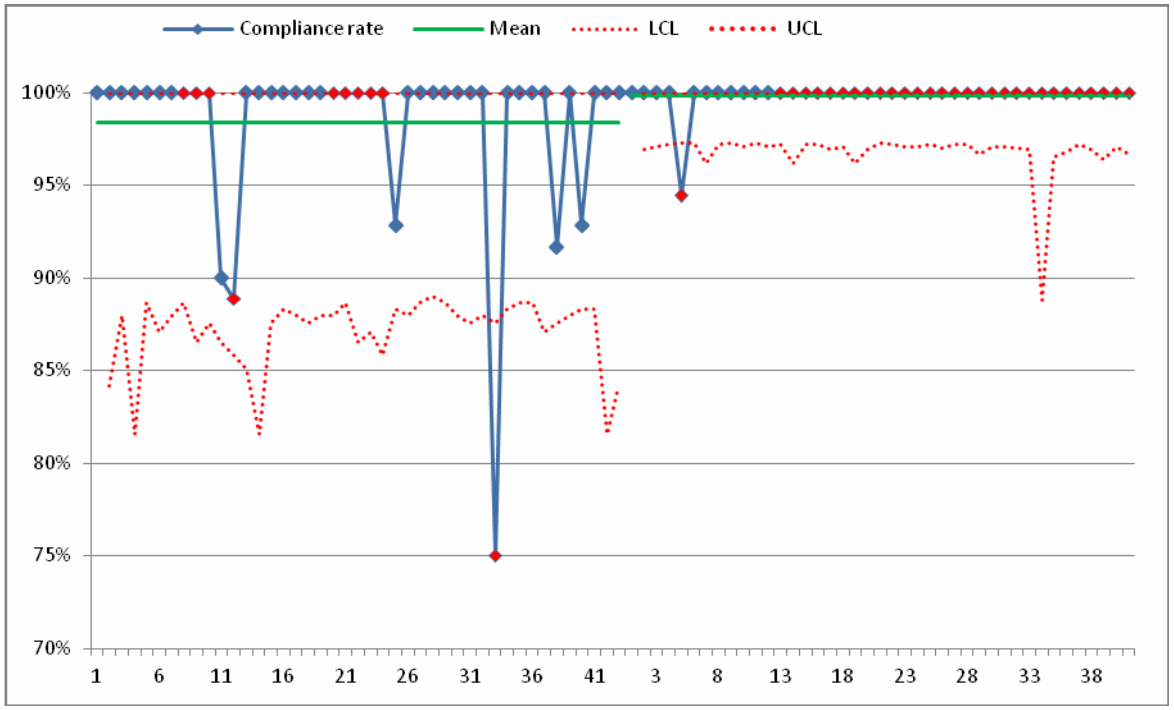


Rule violations

Study period	Day no.	Violations for points
Baseline	7	2pts of last 3 below -2 sigma
Intervention	13, 14	8 consecutive pts ^ centre line
	28	< -3 sigma
	28	2pts of last 3 below -2 sigma

Interpretation: High compliance levels at both times that was relatively stable and within control. Slight improvements in daily compliance during the intervention period, as illustrated by the mean line.

Figure 6.10 Compliance with medications management over time



Rule violations

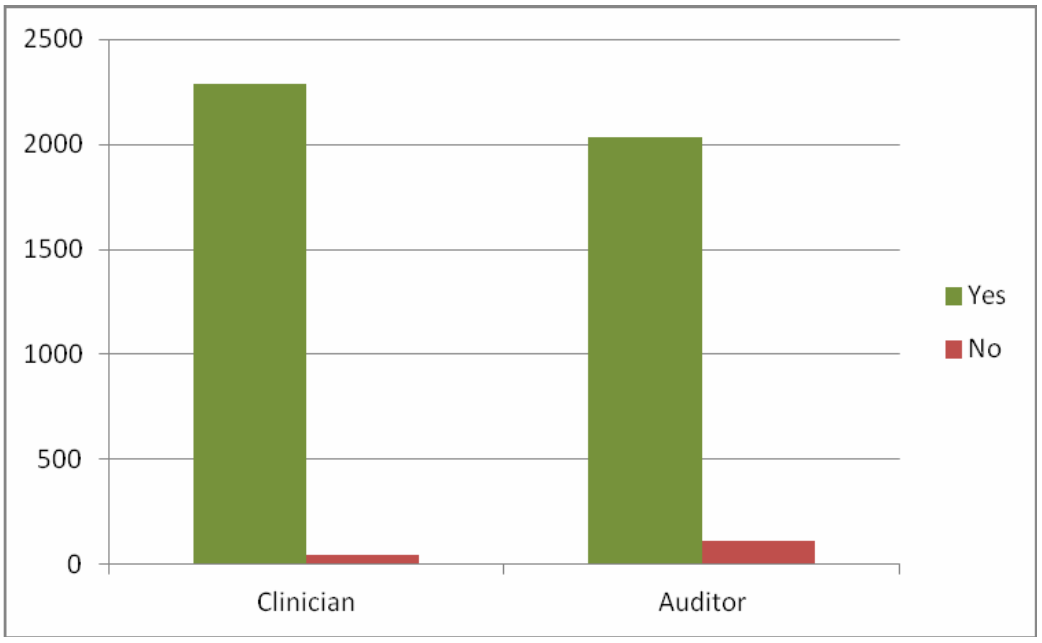
Study period	Day no.	Violations for points
Baseline	8-10, 20-24	8 consecutive pts ^ centre line
	12	2pts of last 3 below -2 sigma
	33	< -3 sigma
Intervention	5	< -3 sigma
	13-41	8 consecutive pts ^ centre line

Interpretation: Daily compliance during the baseline period was high, although there were several days where compliance dropped off. Only one instance was evident early in the intervention period, with 100% compliance recorded for the remainder of the time.

Checklist concordance with actual delivery of care

During the intervention period, frequency data revealed much higher proportions of 'yes' responses than 'no' responses for the checklist statements (see Figure 6.11). From a statistical perspective, this is indicative of prevalence bias (where a larger proportion of observed ratings fall under one category) (Byrt, Bishop & Carlin 1993).

Figure 6.11 Frequency distribution of all included checklist responses provided by physicians and auditors



With 'not applicable' responses excluded, the care components with the highest proportion of agreement between intensivists and auditors were medications (100%) and stress ulcer prophylaxis (99.57%), while those with the lowest agreement rates were pain (79.23%) and head of bed elevation (85.26%).

Calculation of both bias indices revealed the marginal distributions to be relatively free of bias between observers, but prevalence was high (very high rates of positive responses and very low to zero negative responses) (see Table 6.5). These figures supported use of Byrt's kappa to correct for chance and prevalence bias. As evident in Table 6.5, these kappa statistics better reflected the percent agreement figures in ranking care components from highest to lowest levels of concordance, but with more conservative estimates of agreement.

Table 6.5 Measures of concordance between physician and auditor checklist responses for each care component*

Care component	n	Proportion observed agreement	Bias Index	Prevalence Index	Byrt's Kappa	Proportion positive	Proportion negative
Medications	289	100	NA	NA	No variation	NA	NA
Readiness to wean	194	94.33	-.036	.933	.887	.971	.154
Glucose management	306	91.18	.082	.912	.824	.954	0
Nutrition	270	97.04	0	.956	.941	.985	.333
Stress ulcer prophylaxis	233	99.57	.004	.996	.991	.998	0
Thromboprophylaxis	255	98.82	.004	.988	.976	.994	0
Head of bed elevation	190	85.26	.126	.853	.705	.920	0
Sedation	150	92.00	.040	.92	.840	.958	0
Pain	207	79.23	.130	.783	.585	.883	.044

* concordance based on 2x2 contingency table

NA = not applicable due to no variation in marginal distributions

There were moderate to very high rates of agreement between the two respondent groups, with kappa values ranging from .585 for pain management to .991 for stress ulcer prophylaxis (note Byrt's kappa not calculated for Medications as there was no variation between the two respondent groups i.e. 100% agreement).

Post-hoc analyses conducted using the same measures of concordance for each physician designation revealed similar agreement (Consultant = .89, Senior Registrar = .84, Registrar = .92). Although Registrars displayed the highest levels of agreement, this finding should be viewed with caution given the smaller number of observations for this group (n=316) as compared to Senior Registrars (n=796) and Consultants (n=930). Detailed results can be found in Appendix T.

Patient outcomes including adverse events

At baseline, patient adverse event data was collected for 12 of the 42 days (conducted by the primary data collector – see study limitations for further detail), so only limited data was available. For the intervention period, the full 42 days of data were collected. Table 6.7 presents frequencies of adverse events and also the number of patients with an adverse event (per category) to illustrate when patients had repeated adverse events.

Table 6.7 Adverse events recorded at baseline and intervention

Adverse event	Baseline Event (patient) count	Intervention Event (patient) count
Hyperglycaemia	21 (15)	49 (29)
Other (not specified)	6 (5)	19 (15)
Ventilator-associated pneumonia[1]	6 (6)	5 (5)
Hypoglycaemia	1 (1)	4 (3)
DVT detected[1]	-	4 (4)
Unplanned extubation	1 (1)	1 (1)
Medication error	1 (1)	-
Gastrointestinal bleed	-	1 (1)

Adverse event	Baseline Event (patient) count	Intervention Event (patient) count
Re-intubation related to unplanned extubation	-	1 (1)
Hypoxic arrest after attempt to wake up patient[2]	-	1 (1)
Small graze/wound to left leg[2]	-	1 (1)
Total	*36 (29)*	*86 (61)*

Notes

[1] Recorded once per ICU stay

[2] 'Other' event specified by e-checklist user

During baseline there were 0.2 events per patient day (see Box 6.1 for calculation method). The maximum number of different events (i.e. excludes multiple of the same event type such as hyperglycaemia) recorded per patient stay was 3 – VAP, hyperglycaemia, other – not specified. Three patients had both VAP and hyperglycaemia recorded for the same time period.

Box 6.1 Calculation for events per patient day

Total number of events divided by average daily occupancy (during ward rounds) multiplied by the number of checklist days during each time period i.e. baseline = 36/(15x12); intervention = 86/(17x42)

During the intervention period there were 0.12 events per patient day. The maximum number of different events recorded per patient stay was 5 – VAP, DVT detected, unplanned extubation, hyperglycaemia, other – not specified.

Hyperglycaemia was the most common event during both time periods. The rate of hyperglycaemia in the sample (based on the number of events each patient day) was 11.7% at baseline and 6.9% at intervention.

Discussion

This section initially presents the key findings of the study, then synthesis and interpretation of the findings for each process-of-care, within the context of previous published studies and the study site practices and processes. The strengths and limitations of the study, implications for practice for both clinicians and policy-makers, and recommendations for further research are also presented.

Key findings

In addressing each of the three research questions, the following findings were demonstrated:

1. **Compliance** with all process-of-care checklist items improved significantly after implementation of the e-checklist. Reduced variation in daily cares delivered between the pre- and post-intervention was also evidenced.
2. **Concordance** between clinician and audit responses was high for the majority of care components, contributing evidence of the e-checklist's construct validity based on response processes.
3. Descriptively, there appeared to be an improvement in overall **adverse patient events** per patient day, however no statistical inferences could be made.

Interpretation & context

Findings for each of the care processes are discussed below, presented in order of highest to lowest improvements in compliance from baseline to intervention.

Pain management produced the largest change in compliance, but only moderate concordance (kappa=0.6) between clinician and auditor responses were achieved. There are multiple possible reasons for the lower rate of agreement including a lack of an agreed, standardised, objective pain assessment, particularly for non-communicative ICU patients (Li, Puntillo & Miaskowski 2008). This may potentially have lead to differences in medical and auditor responses (auditors indicated a higher rate of omissions for the pain care component than medical staff). This checklist item was also a multi-dimensional statement, adding complexity to the interpretation of responses.

Although it was clearly defined in the data dictionary (i.e. a 'yes' response required that at least a pain assessment was conducted; a pain management plan and progress review must also have been completed if applicable to the patient at the time of completing the checklist), it is possible that this strict definition was not adhered to. Given these results, medical staff may have selected 'yes' when one aspect of the checklist item was delivered but not all that were applicable to the patient at the time of completing the checklist e.g. a pain assessment had been completed however a pain management plan and/or progress review was not. Notably, two other checklist items that were similarly multi-dimensional (i.e. sedation and glucose control) had kappa values of less than 0.85, suggesting that perhaps greater checklist validity could be achieved by ensuring each item is uni-dimensional. These findings however are not definitive and the contemporary literature has not addressed the issue of multi-dimensional checklist items, therefore further study is suggested.

As demonstrated in the point prevalence study (Chapter 3), pain scores in Australian and New Zealand ICUs were poorly documented despite pain assessments taking place; this may have made it difficult for auditors to make an accurate assessment of whether all aspects of care was delivered when appropriate. Auditors reported that 19% of compliant cases were not documented correctly or completely during the intervention period; a lack of documentation for this aspect of care could have contributed to this discrepancy. This phenomenon has also been reported in emergency departments in the US (Chisholm et al. 2008)– an indication that this could be a widespread issue. Further, as demonstrated in the first construct validity study (Chapter 4.1) and in the literature e.g. (Payen et al. 2007), pain assessment rates have been shown to be lower than that of drug treatment for pain. Again, this could be due to a lack of documentation of pain assessments, or possibly an assumption by the medical staff that appropriate care was delivered.

This moderate kappa value however did not mitigate the large improvement in pain management compliance during intervention. Unit-level data revealed that during baseline only one day out of 42 reached 100% compliance, whereas there were 30/42 days fully compliant during the intervention period – a 69% increase. It therefore appears that the e-checklist improved pain assessment and management by the medical

team. Although findings from an earlier pilot study (Hewson & Burrell 2006) utilising a similar paper-based process-of-care checklist in this ICU suggested that perhaps pain management was less than desirable for post-surgical patients, post-hoc chi-square analysis of the data from this study revealed significantly higher levels of compliance at both baseline (60% vs 49%, $p<.01$) and intervention (100% vs 95%, $p<.05$) for post-surgical compared to non-operative ICU patients.

Overall compliance with pain assessment during the point prevalence study was 71% (Chapter 3); this ICU displayed lower levels of compliance at baseline (53%) but higher levels of compliance during the intervention period (96%). Given findings of deficiencies in pain assessment and management in ICUs around the world (Elliott et al. 2013; Erdek & Pronovost 2004; Payen et al. 2007), utility of a process-of-care checklist for this care component may be highly beneficial for ICUs globally.

Blood glucose level (BSL) management had the second largest improvement in compliance (22%). A reasonably high level of concordance (kappa = 0.82) was also noted, although there were 26 instances where the clinician response was 'yes' and the auditor response was 'no'; this may have been related to the noted difficulty of maintaining BSLs within defined limits (Ferenci et al. 2013). As highlighted previously, the highest number of recorded adverse patient events was hyperglycaemia for both time periods. This suggests that a once daily checking mechanism is only part of any solution for improvement in preventing adverse outcomes such as hyperglycaemia, where the need for constant vigilance in monitoring BSLs may be required. The checklist was never intended to be prescriptive, rather to be used in conjunction with unit policies, and can therefore only be effective as the application of these policies. Given the continued uncertainty around ideal blood glucose limits for critically ill patients (Bagshaw et al. 2009b; Kutcher et al. 2011) as well as suggestions that reducing variability in blood glucose levels may be more important in terms of mortality than maintaining pre-defined levels (Bagshaw et al. 2009a; Hermanides et al. 2010), it is unreasonable to expect no clinical practice variations. The substantial levels of improvement in compliance with the checklist item (i.e. BSLs have been assessed, limits set, and being managed to achieve those limits) however suggest that increased medical attention to this aspect of care on the morning ward rounds may complement

and enhance routine clinical practices to manage BSLs within clinically acceptable parameters.

A large improvement was also evident for head-of-bed (HOB) elevation (19%) with a moderate to high level of concordance (kappa = 0.71). The main source of discrepancy in concordance was 26 instances where the clinician response was 'yes' and the auditor response was 'no'. This may have been related to: patient position changes between ward round and audit; imprecision in the measurement tool to gauge head-of-bed angle (inclinometer measured angles in 5 degree increments); differences in where to measure the angle from due to the patient's body position on the bed; and the possibility of clinicians using personal judgement of angle rather than the measurement device – with the former overestimating HOB elevation (McMullin et al. 2002).

Given this care component was largely seen as the responsibility of nursing staff in this ICU (i.e. it formed a part of the nursing care prompt card and needed to be maintained by bedside nurses as appropriate), improvements evidenced may have been the result of increased attention paid by medical staff upon daily review of patients and the possibility of increased teamwork between the medical team and bedside nurses during ward rounds. Compared to earlier studies, this study revealed lower compliance rates at baseline than in the same unit during late 2004 (78 vs. 91%) (Hewson & Burrell 2006), but at a much higher rate than the average compliance rate for Australia and New Zealand in 2009 (78 vs. 40%) (Chapter 2). This is another care component that may benefit from regular checking mechanisms throughout the day.

Formal assessment of nutritional goals showed significant improvement even with high compliance at baseline (i.e. improved 7.4% from 89 to 96%), well above the prevalence rate of 67% for Australia and New Zealand (Chapter 2). Concordance was also very high (kappa = 0.94). Collectively, these results may have been influenced by the routine involvement of a dietitian in the assessment of ICU patients nutritional requirements in this ICU, with previous studies showing an association between dietitian involvement in patient care and improved nutritional support (Braga et al. 2006; Soguel et al. 2012) and decreased hospital length of stay (Braga et al. 2006). This would need confirmation through further evaluation.

Sedation assessment and management displayed results very similar to those for nutrition, with improvements (7.5%) resulting in a high level of compliance by the medical team on the ward rounds. Findings were also similar to compliance rates demonstrated in the point prevalence study. Although concordance between medical staff and auditors was lower than that for nutrition (kappa = 0.84), the number of observations was significantly less for sedation due to the applicable patient sample (i.e. only patients who were assessed for this item). Similar to the issue with pain management, minor discrepancies may have been due to a lack of documentation in the patient notes by clinical staff (Collins et al. 2011; DeGrado et al. 2011; Radtke et al. 2012).

Assessing patient readiness to wean from mechanical ventilation was completed in over 90% of cases at both times during this study. A considerable reduction in daily practice variation was however evident for the intervention period, including a 24% increase in the number of fully-compliant checklist days. These compliance rates were much higher than those evidenced for the point prevalence study; 60% overall but with considerable variability between ICUs (ranging from 35-100%). Given the evidence that daily weaning assessments reduce the duration of mechanical ventilation e.g. (Ely et al. 1996) and decreased adverse patient outcomes such as VAP (Dries et al. 2004; Marelich et al. 2000), reducing practice variation for this care component is highly desirable and the benefits of this forming a part of the daily ward round checklist appear substantiated. Notably concordance was also very high, providing further support to the validity of this item.

Similar to the Australia and New Zealand point prevalence data and previous studies (Keroack et al. 2006; Robertson et al. 2010; Robertson, Wilson & Cade 2008), stress ulcer and DVT prophylaxis had high compliance rates at baseline, followed by further improvement on implementation of the e-checklist. There was a notable improvement in compliance with these cares from the earlier paper-based checklist pilot study (Hewson & Burrell 2006) – compliance with DVT prophylaxis was 89% compared with 95% at baseline in this study; and stress ulcer prophylaxis was 85% compared with 94% at

baseline. This may have been due to the increasing number of QI studies e.g. (Ilan et al. 2007; Papadimos et al. 2008) that examined these aspects of care over time.

Concordance was also high for both DVT and stress ulcer prophylaxis, with checklist responses reflective of actual delivery of care. At the unit level however, some variation in daily practice continued during the intervention period for both care components. The potential reasons for this finding are unclear.

Unlike the point prevalence study, the possibility that practice variation in the delivery of stress ulcer prophylaxis was due to disparate views by clinicians regarding the target population, was discounted. In this study, the patient inclusion criteria specified patients ventilated (invasive or non-invasive) for greater than 48 hours and not contraindicated for stress ulcer prophylaxis, which is in line with recent recommendations (Alhazzani et al. 2012).

With consistently high compliance rates over time and 100% concordance rates, clinical utility of the medications checklist item is questionable. Based on advice from senior ICU clinicians (see Chapter 4.2) an item pertaining to the review of antibiotics on the ward round was expanded to include all medications. This resulted in the statement 'All medications have been checked and reviewed' with the data dictionary specifying that this referred to all medications being administered to the patient and required checking, confirming and reviewing the medications chart and ensuring all were correctly prescribed.

In this study, this item appears to have been too broad to provide meaningful data – during the intervention period there was only one omission of care. This does not however mean there is no room for improvement, as recent literature suggested that up to 38 adverse drug events and 498 medication errors per 1,000 patient days occur in developed countries' critical care units (Wilmer et al. 2010). Checking and reviewing medications therefore remains an ongoing and important aspect of the ward round that in the absence of other improvement strategies, should either be integrated into clinical processes as a prompt or be broken down into specific checklist items that have been identified as problem areas for the unit.

Although not a study outcome, comparing the delivery of cares related to the IHI ventilator bundle is noted here for completeness. A 23% improvement from baseline to intervention was noted, although there was no change in the recorded number of VAP cases (6 at baseline, 5 during intervention). A relationship between these was however unlikely due to the study not adopting the bundled approach to the intervention. Note also that the study sample size was not calculated to detect a difference in adverse event rates. This analysis was therefore conducted for descriptive purposes to reveal whether care improvements (to reduce the incidence of VAP) were noted in a subset of patients who were mechanically ventilated.

Study strengths and limitations

By incorporating learning from previous studies into the e-checklist intervention study, greater applicability, specificity and less ambiguity amongst the process-of-care checklist items was achieved (Table 6.8). As noted above for example, specifying the patient inclusion criteria regarding delivery of stress ulcer prophylaxis minimised practice variation related to individual clinician decisions.

This study also sought to address many of the limitations of previous intervention studies utilising checklists in clinical practice – as identified in the literature review (Chapter 2). Although not all limitations could be addressed in this study alone, most were addressed in some way enabling support for the strength of evidence for using checklists during the morning ICU ward rounds. The positive results achieved are particularly important given the intervention period coincided not just with the usual busy winter period, but also a swine flu epidemic which impacted on caseload and staffing levels in the local study site (Webb et al. 2009).

Table 6.8 Incorporating the lessons learnt from previous studies

Lessons learnt	**How incorporated into intervention study**
Sedation practices in Aus & NZ differ from those published in international literature – particularly around the daily 'sedation hold' (Ch 3)	Going into the second validation study (Ch 4.2) the proposed checklist statement for sedation did not include any reference to a daily 'sedation hold' to be consistent with ICU practice in Aus & NZ.
Ambiguity over target population for stress ulcer prophylaxis (Ch 3)	Patient inclusion criteria in this study was clearly specified so that only patients who were applicable for this care component were included.
Consideration of local ICU context particularly with regards to work processes and procedures was required (Ch 4.1)	Clinician interviews & modified Delphi technique (that included all intensivists who worked in the ICU) were conducted during checklist development to ensure content was relevant at the local level, observations of the morning medical rounds were carried out prior to implementation.
It was unknown if there was a difference between documentation of care and actual delivery of care (Ch 4.1)	When care was deemed to have been delivered, auditors were required to specify whether the care was documented or not documented. Results showed the majority of cares delivered were documented.
Repeated measurements for the same patient over time was not controlled for statistically (Ch 4.1)	GEE analysis of process data controlled for confounding variables including repeated patient measures, over time.
Further validity testing within a prospective research design was required (Ch 4.1)	To test the e-checklist's construct validity based on response processes concordance between physician and auditor responses to e-checklist were measured.
Local policies exist for some of the care processes (Ch 4.2)	Reference to relevant ICU policies were made as appropriate e.g. data definitions in e-checklist user manual.
Checklist items must be evaluated for their practical use, interpretation and clinical utility (Ch 4.2)	Analyses of checklist data and user feedback obtained (see Ch 7).

Aus = Australia; NZ = New Zealand

Methodological strengths of this study therefore included real-time prospective, electronic data collection at the point-of-care during both the baseline and intervention

periods. Process measures were based on physician and auditor responses provided via the e-checklist, and a multi-faceted approach to daily compliance measurement was undertaken i.e. comparing delivery of individual care components over time that factored in confounders at the checklist level, and statistical process control at the unit level. As the intervention data provided by physicians was self-reported, post-ward round audit data were collected during the same period to determine whether physician responses on the checklist matched those provided on audit as an indicator of actual care delivery. A high level of concordance between the two sets of responses provided evidence in support of the e-checklist's construct validity.

Further to the measure of compliance, detail on whether an omission of care was corrected upon detection or noted for correction post-ward rounds was also obtained via the e-checklist. In evaluating this data it was apparent that all omissions detected led to care delivery according to subsequent responses to the e-checklist either the next day or the day after, where applicable. This provides further confirmation that use of the checklist largely functions as intended – to ensure delivery of essential cares once omissions are detected.

In addition to capturing omissions, inclusion of 'not applicable' responses to the e-checklist allowed clinicians to exercise their clinical judgement and did not restrict them to a simple 'yes' or 'no' response that may have compromised accurate measurement and their acceptance of the tool. Patient safety was another important consideration – with an emphasis on delivering care where applicable, it was essential to build in options that ensured that unnecessary and potentially harmful treatments were not delivered to patients that were either not applicable or contraindicated for certain cares (Krimsky et al. 2009).

Although the study was limited to a single ICU, the sample size achieved was more than adequate with a total of 293 patients included when power calculations indicated 206 were required to detect significant differences in compliance over time. With an equivalent number of patients pre- and post-intervention that had similar patient demographics, it is evident that a good representation of the ICU patient population was

achieved. Findings from this study could therefore apply to other general combined ICU/HDUs with similar patient demographics.

The before–after study design precluded establishing a causal relationship between e-checklist use and improvement in the delivery of ICU processes of care, although there were factors that contributed strength to such an argument: patient cohorts were very similar, there were no other changes contributing to enhanced clinical practice at the time, improvement across all aspects of care covered by the e-checklist, and good levels of concordance with post-ward round audit data.

Restrictions on the amount of available resources meant that reliability testing did not form a part of the study, and post-ward round audits for the collection of concordance data could only be completed 4-days a week. As the aim was to audit on alternate days that varied from week-to-week (but including one weekend day), a fairly representative sample was likely to have been obtained despite this limitation.

As noted earlier, collection of adverse event data was not completed in full at baseline (main data collector overlooked this data point), and there were no resources available to collect the data retrospectively. Although the study was never adequately powered to detect a statistical difference in adverse patient events, the incomplete data collection limited discussion around implications for non-delivery of evidence-based processes of care and the potential relationship with adverse patient events.

The Hawthorne effect may have influenced findings to some extent. Although physician participants were not provided with information pertaining to the project until after baseline data was collected, there may have been heightened awareness associated with research nurses routinely conducting audits with the PDA after the ward rounds had been completed (in both stages of the study). As a quality improvement initiative, the intervention required providing clinicians with useful clinical information and obtaining their buy-in to the project. Physicians were therefore aware of the main aim of the research (i.e. to improve compliance with certain cares) and this may have influenced their behaviour during the intervention period. It is therefore unknown whether the same results would be obtained beyond the confines of the study (sustainability is discussed

further in Chapter 7). In order to minimise the impact of the Hawthorne effect physicians were informed that individual practice would not be evaluated or reported in any way. Only unit-level data was fed back to ICU clinicians regardless of their position.

Implications for practice

For clinicians, this study has demonstrated that an electronic process-of-care checklist can be used as a tool on the morning ward rounds to help ensure the delivery of essential daily cares. The need for such a tool can be determined in other ICUs by the presence of both patient-level and unit-level variability in the delivery of care, which can be identified via post-ward round audits of practice. These findings are in line with two recent systematic reviews: one recognised the effectiveness of checklists in improving patient safety (Thomassen et al. 2014); and after identifying evidence-informed best practices, the other recommended the development and implementation of a structured checklist for use during ward rounds in the ICU (Lane et al. 2013).

As the need for improvement in the delivery of important processes of care in ICUs has been demonstrated internationally e.g. (Alsadat et al. 2012; McGlynn et al. 2003; Scales et al. 2011), the implications for this work are likely to apply widely. The model of QI and knowledge translation (Pronovost, Berenholtz & Needham 2008) utilised in this study is also versatile and could be adopted in any healthcare setting. It acknowledges that each clinical unit has unique requirements such as different methods of documentation, technological infrastructure, available resources, staffing profiles, models of care, educational/training requirements, and culture. The successes of such QI initiatives are likely to be dependent on making local adaptations according to these requirements (more on project evaluation to follow in Chapter 7).

More specifically, findings suggested that development of uni-dimensional checklist items may increase precision of the tool and produce more interpretable data that has greater clinical utility. Pain, sedation and glucose control are examples of care processes that may need multiple or multi-level checklist items to ensure each component is properly addressed.

With the constantly evolving nature of technology, smartphones and other handheld devices such as tablets have superseded PDAs since commencement of this project. Other advances in healthcare technology will also impact on the delivery of e-tools in clinical settings such as purpose-built clinical information systems (CIS) where some checks can be automated and alerts sent to clinicians via bedside monitors and messaging services to email accounts or smart phones. A ward round checklist could be to be built into a module of the CIS that requires clinician interaction, particularly for aspects of care that cannot be automated (e.g. measuring head of bed elevation). Data pertaining to checks on automated care components (e.g. intravenous fluids) could also feed into the checklist to be signed-off by appropriate members of the clinical team to ensure they have reviewed all relevant aspects of patient care.

Policy makers and service administrators need to consider the process involved in achieving improvements in care delivery, and ensure resources are available to enable practice improvements. The mere existence and promulgation of guidelines and policies are insufficient for achieving improvements at the local level (Grimshaw et al. 2001; Sinuff et al. 2007; Weinert & Mann 2008). New QI projects require sufficient time and resources that go beyond what ICUs are currently funded for. Healthcare providers however, also need to be mindful of developing systems and processes that are sustainable without ongoing additional resources.

Recommendations for further research

There were a few findings and related issues identified that require further attention in future research. First, an evaluation of the effect that multi-dimensional checklist items compared to uni-dimensional ones have on process-of-care measurement would provide clarity around the development of future checklist statements. Second, given the complex nature of pain and sedation management in ICU and the challenges associated with measurement of these aspects of care, further exploration of the essential components of each as well as the relationship between the two may assist in evaluating compliance with these cares and contribute to the validity of related measures.

The third issue relates to evaluating the impact of certain ICU resources, staffing models, and standard work practices on compliance with cares such as the relationships

between: dietitian involvement and compliance with the assessment and review of nutritional goals; nursing practices and some of the routine cares particularly head-of-bed elevation and glucose control; participation of pharmacists in the morning handover or ward round and compliance with medication reconciliation.

Further research might also address the limitations of this study such as evaluating the reliability of the checklist – particularly inter-rater reliability, and conducting a larger multi-centre study utilising a stepped-wedge trial design (Brown & Lilford 2006) ensuring it is adequately powered to detect significant differences in patient outcomes such as adverse events over time, with a longer study period to evaluate durability of effect.

In light of advancements in technology, further work and study of the different modalities of delivering an e-checklist tool e.g. incorporation into CIS, PC tablet, iPad, smartphones is warranted. Different ICUs and other clinical settings have unique requirements that must be assessed at the local level during the planning process. It is also important to ensure that clinical support tools such as the e-checklist are as robust as possible and the ability to transfer and adapt them from one platform to another and perhaps from one clinical setting to another would broaden its appeal and have the potential to make even greater impact on the quality of patient care.

Conclusion

This before-after prospective intervention study demonstrated improved delivery of essential daily processes of care after implementation of an e-checklist used by physicians during the morning ward rounds in an ICU. Increased compliance with, and reduced variability in cares delivered over time offered evidence supporting the e-checklist as a tool that can assist in standardising and ensuring the delivery of important elements of patient care. There were generally very good rates of agreement between clinician and audit responses lending support to the validity of the e-checklist. In addition to having clinical utility, the e-checklist functioned effectively as a measurement tool – it was used to collect post-ward round audit data and the clinician tool captured the reasons care was not delivered in addition to the tick-box checklist

function. Due to different ICUs and other clinical settings having unique requirements, there is a need to test different modes of delivering e-checklist such as incorporating it into a CIS or using new handheld technology to suit the needs of users. Although the findings of this study demonstrate the benefits of an e-checklist to clinical practice, further work is required to ensure such tools are as robust as possible and can be transferred into practically any setting.

Chapter 7

Staff evaluation of the electronic checklist

Introduction

When attempting to change health professional's behaviour in order to improve the quality of health care, it is important to be cognisant that there are no "magic bullets" (Oxman et al. 1995)– no single intervention is universally capable of affecting sustainable change in clinical practice (Grimshaw et al. 2001). Studies need to factor in local practices and unit culture, implement multi-faceted strategies designed to improve targeted cares in that setting, and evaluate each component of complex interventions (Shojania & Grimshaw 2005).

Given the challenges of achieving clinical practice change at a local level, the e-checklist intervention study was designed with due consideration to contemporary evidence including the reported barriers and enablers to implementing evidence-based interventions (outlined in Chapter 2). Effective multi-faceted strategies suggested in the literature for achieving practice change were incorporated into the implementation model including reminder techniques (the e-checklist itself and prompts to use it), audit (post-ward round completed by research nurses) and feedback (via real-time, web-based reports and fortnightly summary reports), use of local opinion leaders (local ICU staff specialists), information technology (PDA, wireless technology, web-based server), education (information sessions, one-on-one training), and related materials (e.g. project summary information, data dictionary and instruction manuals, project tips).

As successful implementation of quality improvement strategies are largely dependent on clinician perception (Cabana et al. 1999; Leape et al. 2003), staff acceptance and satisfaction with the e-checklist and the associated implementation model, was necessary. All key components of the study therefore required targeted feedback from staff.

Evaluating the effectiveness of safety interventions can also be achieved by examining the safety culture of a unit as perceived by its employees. A positive safety climate in

the workplace has been associated with shorter hospital stays (Huang et al. 2010), lower risk of pressure ulcers (Taylor 2008), increased safe work practices (Gershon et al. 2000) and safety-related behaviours (in an Australian hospital) (Neal & Griffin 2006), although only one was conducted in an ICU, in the US (Huang et al. 2010). An assessment of an ICU's safety climate before and after the planned checklist intervention could therefore indicate whether this intervention influenced the unit's safety culture.

This chapter therefore extends upon Chapter 6 by describing the evaluation component to the e-checklist intervention study.

Study Aim and Research Questions

To evaluate an e-checklist designed to improve process-of-care during physician ward rounds in an ICU. The specific questions were:

1. What is the usability and staff satisfaction with the e-checklist intervention?
2. What is the impact of an e-checklist used during the ward rounds on staff perceptions of safety culture in the ICU?

Methods

Design

As detailed in Chapter 6, a prospective, mixed-methods design with a nested before-after intervention component was used to address the above research questions.

Participants

Participants for the usability and satisfaction survey were all medical staff involved during implementation and evaluation of the e-checklist project. Detailed description of the staffing profile was provided previously in Chapter 6 ('Participants' section). The 14 medical staff members with e-checklist logins and had used the e-checklist (four consultants, three senior registrars, six registrars, one resident medical officer) were the sampling frame for the interview study.

The sample for the safety culture survey was all ICU nursing and medical staff. At baseline the total clinical staff establishment was 141 (27 medical, 114 nursing) and post-intervention it was 128 (29 medical, 99 nursing).

Measuring instruments

The measuring instruments included user feedback surveys, participant interviews, and safety climate surveys.

User feedback surveys

Feedback from senior ICU medical staff evaluating the checklist procedure and the impact on processes of care using self-report questionnaires was undertaken twice (pre- and post-intervention). At baseline participants were asked about the frequency of attending to each of the care components, their experiences with handheld technology in clinical settings, the quality of project information, education and training received, and other information including the potential usefulness of the e-checklist in routine practice (see Appendix U).

At study completion, participants evaluated the utility of the checklist and work processes, the perceived impact on practice and care delivery, and an assessment on key elements and value of the intervention (see Appendix V). Respondents were also asked whether they would be willing to provide additional feedback on the project; those who responded 'yes' were included in the sample for interviews of key stakeholders.

Interviews

Semi-structured interviews were conducted with a purposive sample (n=3) of senior intensive care physicians who used the e-checklist and agreed to be involved, to obtain greater detail about the effectiveness of the project and its components. Potential participants were identified as being open, able to articulate their views and experiences with honest feedback and likely to offer different perspectives of the project. These participants were contacted via email and a suitable time for the interview was arranged.

An initial list of potential interview questions devised at the start of the project was revised after completion and consideration of responses to the user surveys. Topics included how the checklist was integrated into clinical practice, the benefits and

limitations of the checklist procedure and detailed feedback on the delivery of the e-checklist (see Appendix W for the interview schedule). The scheduled interview time was 30 minutes – sufficient time to cover all questions. Interviews were conducted in an administrative office away from the ICU so that there were no disruptions. All interviewees provided informed consent, including for audio recording of the interview and later transcription.

Safety culture survey

To assess the culture of safety in the ICU, a validated survey tool was sought. Due to the amount of information requested from ICU staff during this project and risk of respondent fatigue, it was decided to use the Safety Climate Survey (21 items) (Shteynberg, Sexton & Thomas 2005), a subscale of the Safety Attitudes Questionnaire (SAQ) ICU version (Sexton et al. 2006), both of which have been tested and validated in ICU settings (Kho, Carbone & Cook 2005; Sexton et al. 2011; Sexton et al. 2006). To ensure maximum benefit of this survey to the project, specific individual items from the SAQ were also selected as additional items for inclusion (i.e. collaboration and communication section) (see Appendix X for safety culture questionnaire used). Respondent demographics (job category, age, gender, years of experience in specialty, years worked in the ICU) and an item asking for the top three recommendations for improving patient safety in the ICU were also included. In total there were 51 items, estimated to take no longer than 10 minutes to complete.

The 5-point response scale for items 1-21 (Disagree Strongly, Disagree Slightly, Neutral, Agree Slightly, Agree Strongly) allowed transformation to a 100-point scale to enable calculation of normally-distributed data. A percent positive safety score was calculated separately using the proportion of respondents who agreed slightly or strongly (scores 4 and 5 respectively). As noted above, the survey was conducted twice (pre- and post-intervention) to measure any changes in staff attitudes to safety in their ICU as a result of the e-checklist intervention. A response rate of 60% or higher was recommended in the guidelines for administration of the SAQ (Sexton, Thomas & Grillo 2003) for appropriate sample representation.

Study Procedure

Pre-baseline

Completion of the adapted Safety Climate Scale occurred prior to education to gauge staff attitudes towards patient safety in the study unit. The questionnaire was sent to all ICU staff via personalised internal mail prior to the intervention. Two sealed post boxes were placed in separate staff-only areas of the ICU. A follow-up was scheduled at a ward meeting attended by both medical and nursing staff. Blank surveys with return-addressed internal mail envelopes were re-distributed by hand to those who hadn't already completed a survey and a sealed post box was placed outside the meeting room for those who completed the survey immediately. To reach staff unable to attend the meeting, research staff also handed out surveys to bedside nurses who had not yet completed one.

Pre-intervention

The pre-intervention user feedback survey was conducted after the e-checklist education sessions. Questionnaires were circulated at the meeting after the education session was completed, and sent out via email to senior medical staff not present at the meeting (questions related to the education session were deemed not applicable for these participants). Returns were received in person after the meeting, via internal mail or return email.

Post-Intervention

In evaluating the acceptance, utility and sustainability of the e-checklist and its impact on unit culture, follow-up safety climate and user feedback surveys, followed by semi-structured interviews with senior ICU physicians were conducted as for the pre-intervention phase.

Data management and analysis

Completed user feedback and safety climate survey responses were collated and entered into separate SPSS databases prior to analyses. Descriptive statistics were used for quantitative survey responses. For the user feedback survey data, calculation of percentages excluded 'not applicable' responses. Qualitative data derived from all open-ended survey questions (user feedback and safety climate surveys) were synthesised and

categorised using a qualitative descriptive approach (Sandelowski 2000; Sandelowski, Barroso & Voils 2007) where appropriate in order to summarise the findings.

One-on-one interviews with senior intensive care physicians were audio-taped and later transcribed by an independent administrative officer who checked content with the researcher when audio was not clear. Resulting qualitative data were categorised according to the topic question then synthesised for clarity, comprehension and brevity. Supporting quotations were selected to illustrate examples of common and uncommon themes and to ensure transparency of data interpretations.

For the Safety Climate surveys, respondent demographics were collected at both times (before and after intervention) and compared using two independent samples t-test for normally distributed interval data, Mann Whitney-U test for non-normally distributed interval data, and chi-square analyses for categorical data. Mean safety culture scores for individual survey items and the 100-point safety culture score were compared using two independent samples t-test. Percent-positive safety culture scores and the quality of collaboration and communication experienced with each position category were compared using chi-square analyses.

Results

Results are reported in alignment with the two research questions. Usability and staff satisfaction with the e-checklist intervention was evaluated with the before and after user feedback surveys. Semi-structured interviews with senior ICU clinicians also addressed this research. Staff perceptions of safety in the ICU were evaluated by the safety culture surveys.

User feedback surveys

Response rates for the user feedback surveys were 61% at baseline (five intensivists, three senior registrars, two registrars, one missing designation) and 47% post-intervention (three intensivists, two senior registrars, three registrars). Five respondents completed both surveys.

Baseline e-checklist user feedback survey

Of the 11 respondents, two completed only Part A of the questionnaire, on the perceived frequency that the ICU engaged in each of the care processes (both respondents were not present at the information session). There were a diverse range of perceptions on the frequency with which care components were completed, particularly for pain, sedation, head-of-bed elevation, blood sugar management, readiness to wean from mechanical ventilation and checking medications; responses ranged from 'infrequently' to 'always/almost always' (see Table 7.1). Respondents perceived that DVT and stress ulcer prophylaxis were completed more often, while pain and nutrition was perceived to be completed less frequently (two comments were noted however on the involvement of a dietitian in the ICU; i.e. high level of involvement/interventions).

Three respondents indicated they used some type of electronic device in the clinical setting (two intensivists, one registrar); an iPhone™ (used for a period of three months and prior to that a Palm™ handheld for four years); a Windows™ smartphone (used for one year); and an unspecified type of PDA (used for two years). Two respondents used their devices almost always (smartphone & PDA), and one used it often (iPhone™). Reported uses of these devices included MIMS (drug reference software) for prescribing information and drug interactions (n=3); note taking including history and daily progress (n=2); protocols (n=1); lab tests (n=1); and UpToDate – an evidence-based clinical decision support resource (n=1).

All three respondents reported that these electronic devices influenced their clinical decision making in the following ways:

- Accuracy and speed (saves time) (n=2)
- Better organisation/facilitates patient management (n=2)
- Reliable drug dosing & side effects
- Literature review

When asked about their personal level of acceptance of technology in the clinical management of a patient, 33% said it was moderate, 44% high, and 22% very high. One respondent elaborated: *"I believe that digitalisation of medical records is the way forward"*.

Table 7.1 Perceptions of the frequency the ICU engages in checklist care components for all applicable patients (n=11)

Care Processes	Infrequently (<50%)	Sometimes (50-79%)	Often (80-97%)	Always/Almost Always (>97%)	Comments (verbatim)
Nutrition goals formally assessed and progress reviewed	10	60	30	-	Default to dietitian High intervention of dietitian in this unit
Pain assessed, management plan set and progress reviewed	20	10	40	30	Done poorly Which drug to use? How often to assess
Sedation target set, sedation level assessed and managed	10	40	30	20	Rarely prescribed a score
Mechanical and/or drug DVT prophylaxis delivered	-	-	60	40	Done best If not, good reason e.g. liver laceration
Patients positioned with the head of the bed raised >30 degrees	10	30	40	20	If not, good reason e.g. spine not cleared
Stress ulcer prophylaxis delivered	-	20	60	20	Frequently missed
Blood sugar level (BSL) limits set and being managed to achieve those limits	10	20	60	10	Attempted rather than succeeding well Done well because of NICE[SUGAR study]
Patient's readiness to be weaned from mechanical ventilation assessed	10	10	50	30	Rarely fully assessed
All medications checked and reviewed	10	30	50	10	Cursory check survey

Note: Figures are percentages

Most respondents (89%) claimed they used some type of tool (e.g. checklists, mnemonics, or other methods) related to the delivery of care in the ICU. Two participants used FASTHUG (Vincent 2005), four used other mnemonics or their own checklist containing various recognised mnemonics, and one reported using a pre-printed ward round template that included a small list of basic prompts (as outlined in the Results of Chapter 6 under 'pre-study observations').

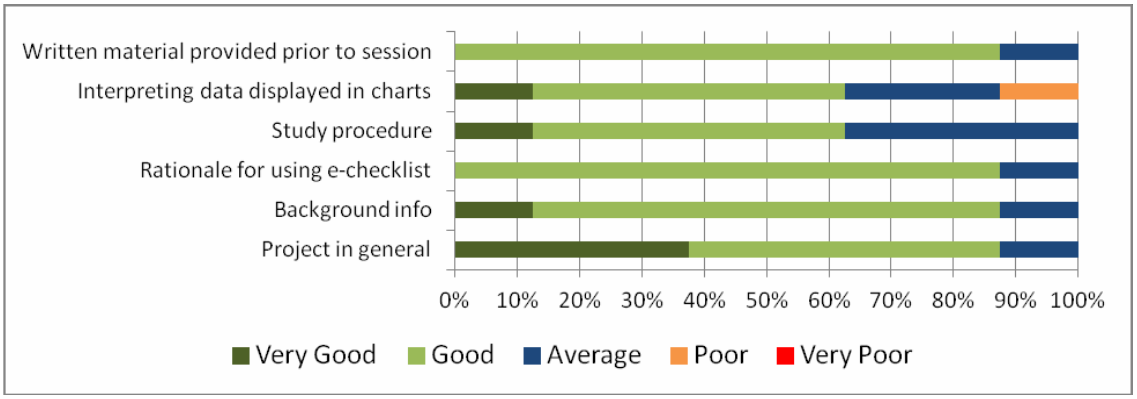
All except one respondent (89%) believed daily processes of care specified in the checklist could be improved in the ICU. Further, 78% believed the items in the checklist related 'well' / 'very well' to care processes that were expected in the ICU (22% of respondents were unsure).

Participants rated the e-checklist in terms of its perceived and potential usefulness:

- in ensuring daily processes of care are delivered – the majority (78%) indicated 'good' (n=6) or 'very good' (n=2) – one respondent (11%) said 'average';
- as opposed to using nothing/relying on memory – all indicated either 'better' (67%) or 'much better' (33%);
- as opposed to using a paper checklist – 63% thought it would be about the same, 38% thought it would be better.

Participants then rated the education and information session including whether they were provided with sufficient information about key aspects (see Figure 7.1). The only suggestion for improving the training provided was having a discussion group rather than a presentation (n=1). Three respondents provided additional comments about the project; one expressed concern that there would be an overlap between the e-checklist and current systems; one believed that data management would be very difficult and the interpretation of data was problematic (this was most likely in light of discussions had during the education session including: concern that the baseline audit data reflected compliance with documentation rather than compliance with actual delivery of care; the detection and measurement of adverse events, particularly VAP; and concern over some of the definitions and the potential for variation in interpretation); another provided support for the project i.e. '*Go ahead, good work*'.

Figure 7.1 How respondents rated aspects of education and information session (n=11)



Post-intervention user feedback surveys

Respondents largely thought that checklist items related to care processes expected within the ICU 'well' or 'very well' (87.5%). In comparing responses over time, two respondents who answered 'unsure' to this item at baseline responded 'well' post-intervention; one respondent rated it even better (from 'well' to 'very well'), one respondent rated it lower (from 'very well' to 'well'), another rated it the same (i.e. 'well') at both times.

In following up on the e-checklist's perceived usefulness prior to its use, participants reflected on its actual usefulness in the clinical setting:

- in ensuring daily POC were delivered – the majority (62.5%) indicated 'good' (n=4) or 'very good' (n=1) – one respondent (12.5%) said 'average', and two (25%) said 'poor';
- as opposed to using nothing/relying on memory – most (87.5%) indicated 'better' (n=6) or 'much better' (n=1), one said 'about the same';
- as opposed to using a paper checklist – 87.5% thought it was about the same, 12.5% thought it was better.

No significant differences between responses at baseline versus responses at post-intervention were detected (Pearson's chi-square). The five respondents who completed the survey at both times showed relative stability in responses over time, with just a few exceptions where responses changed:

- one respondent rated the e-checklist's usefulness in ensuring daily POC are delivered higher (i.e. from 'good' to 'very good'), one rated it lower (from 'good' to 'poor');
- one respondent rated the use of the e-checklist as opposed to using nothing/relying on memory lower (from 'better' to 'about the same');
- one respondent rated the use of the e-checklist as opposed to a paper-based one lower (from 'better' to 'about the same').

When asked to indicate the amount of time (on average) that it took them to complete the e-checklist for each patient, responses ranged from 2 to 7.5 minutes (median = 3.5, IQR = 2.13-6.13).

There was a diverse range of responses on the level of acceptance of the e-checklist technology for clinical management of a patient – 12.5% very high, 37.5% high, 25% moderate, 25% low. Three respondents elaborated on this question – two reported problems with the technology; one issue highlighted was the slow response time (i.e. between clicking on-screen and the action being registered); one noted that it would be better if this was quicker and the other thought it was a good idea but the wireless technology was 'poor'. The other issue raised by another respondent was that the wrong level of staff were targeted for checklist completion (but no suggestion for who should be targeted was provided). Despite this, later in the survey this particular respondent indicated that there were times when the checklist did serve as a reminder for cares that had not been addressed.

The majority (88%) indicated the probability of checking other routine processes of care that were not in the checklist was 'unchanged'. One respondent indicated they were more likely to check 'adequate use of antibiotics' as a result of using the e-checklist.

All respondents described their experience in adapting to the new process as either 'easy' (75%) or 'very easy' (25%). The majority of respondents (63%) noted that the e-checklist was supported by team members (including senior staff) 'moderately' (25% reported 'a lot', 12.5% was 'unsure').

Participants rated a number of elements pertaining to the e-checklist (see Table 7.2) Importantly, all thought that each item was appropriate, and most believed the statements were easily understood. The majority believed the checklist project protocols were good e.g. to be completed by senior medical staff at the end of each patient assessment as a 'challenge and answer' during ward rounds, and that electronic data capture as opposed to paper-based data collection was a worthwhile feature.

Most respondents (86%) believed training prepared them for implementation either 'moderately' (n=3) or 'a lot' (n=3). The majority (62.5%) of respondents believed delivery of care improved 'moderately' with the use of the e-checklist (25% were 'unsure', 12.5% indicated 'not at all'). Finally, participants indicated whether they believed the e-checklist was useful and worth continuing its use in the ICU; the majority (62.5%) indicated 'yes, possibly', one (12.5%) selected 'yes, definitely', and two (25%) selected 'probably not'.

Participants reported the perceived benefits (e.g. a reminder to complete cares) and limitations to using the e-checklist (e.g. slow response times to e-checklist action) as well as suggested improvements to implementation of the e-checklist project (e.g. improved program response time and reduce repetition by integrating the checklist into the medical record). Verbatim responses are provided in Appendix Y.

Interviews with ICU staff specialists

Following return of the evaluation user-surveys, seven of the eight respondents indicated their willingness to provide more detailed feedback (three intensivists, two senior registrars, and two registrars). Due to the involvement of senior intensive care physicians in the project (with a focus on the most senior positions due to the rotation of registrars and residents), and there being a shortage of senior registrars at both the time of intervention and evaluation, three intensivists were selected for interview. Two intensivists interviewed had also completed a post-intervention user-feedback survey. Findings from the collated interviews are presented below, with participant responses coded for confidentiality.

Table 7.2 Participant evaluations of e-checklist intervention elements (n=8)

	Very Good	Good	Unsure	Poor	Very Poor
Elements of checklist					
Appropriateness of items on checklist	-	100	-	-	-
Appropriateness of descriptors	-	86	14	-	-
Clarity of items i.e. are they easily understood?	-	87.5	-	12.5	-
Elements of checklist protocols					
To be completed during daily ward rounds for each patient	-	75	25	-	-
To be completed at end of patient visit as a direct "challenge & answer"	-	75	25	-	-
Senior medical staff to complete the checklist	-	62.5	25	-	12.5
Clarity of definitions in data dictionary	-	75	25	-	-
Elements of checklist software and PDA use					
Checklist design/ layout	-	75	25	-	-
Ease of use (PDA in general)	-	57	29	14	-
Ease of use (checklist software)	-	62.5	25	12.5	-
Ease of data entry	-	62.5	37.5	-	-
Navigating around checklist software i.e. between screens	-	37.5	50	12.5	-
Having the care process detailed in the information buttons	-	62.5	37.5	-	-
Having access to the data dictionary on the checklist server	-	75	25	-	-
User-generated reports via checklist server	-	29	71	-	-
Electronic data capture as opposed to paper-based data collection	-	71	29	-	-
Elements of data feedback					
Feedback reports circulated via email	12.5	75	12.5	-	-
Format of charts	-	62.5	37.5	-	-
Frequency of data feedback	12.5	62.5	25	-	-
Sense of ownership of process-of-care data	-	50	50	-	-
Usefulness of data feedback to my clinical practice	-	75	25	-	-

Note: figures are percentages

Summary and interpretation of responses

Using the e-checklist

The checklist was usually completed after routine activities during rounds - patient examination, history (if relevant), review of test results and charts, making plans, and completing documentation. The checklist was completed either in isolation by the checklist user (Intensivists A & C) or by both medical and nursing staff as a team at the end of each patient review before moving on to the next patient (Intensivist D). On very busy days however, the checklist was occasionally completed after finishing the complete ward round rather than at the end of each patient assessment. For this approach, the checklist still had utility but was not as efficient when something was forgotten or missed, as it involved returning to the patient to complete the information (Intensivist C).

The e-checklist was perceived to be most valuable at the end of each patient assessment when information pertaining to that individual was fresh (Intensivists C & D). Another perspective offered (Intensivist A) was that completion of the checklist at the end of each patient assessment was not ideal, but an additional task to complete; and if it raised issues then reverting back to previous steps would be required (e.g. patient examination, updating medical record).

While all participants reported using the e-checklist themselves, one noted that some of their colleagues did not do this:

> *"I tried to use it myself all the time. I know colleagues didn't necessarily do that – some got others to use it. To me that defeats the purpose of it"* [Intensivist C]

E-checklist limitations

Duplication in the ward round was mentioned as a limiting factor; this included an old pre-printed ward round template with items that overlapped with the e-checklist (Intensivist A). This template was not however used consistently and there were problems with interpretation given there were no definitions to the basic (i.e. usually one or two-worded) prompts (Intensivists C & D). Overlap with mental checks

pertaining to FASTHUG (Intensivist C) and more specifically, sedation and analgesia (Intensivist D) was also reported. It was however noted this was not necessarily applied by all senior physicians (Intensivist C).

There was an indication that there may have been a lack of awareness for some of what certain checklist items meant (e.g. assessment for weaning versus 'is the patient being weaned') despite it being clearly defined in the pre-implementation information, training and on the PDA itself (Intensivist D).

For those not familiar with the technology, using the e-checklist reportedly took longer to complete than the paper-based one they had used previously (Intensivist A). Those familiar with using handheld devices noted issues pertaining to the wireless technology; i.e. 'black spots', drop-outs, slow connectivity and response time; Intensivist C expected an immediate response when an action was performed instead of the 1-2 second delay whilst the PDA sent data to the networked server. Use of the PDAs also added an element to practice that may not be deemed a priority e.g. had to remember to pick it up, carry around, and enter data (Intensivist C).

Implementation issues and suggested improvements

It was generally thought that the e-checklist was integrated well considering the resources available at the time. Further to this, use of the e-checklist was not seen as problematic and one participant thought it should be available for use on an ongoing basis (Intensivist D). Suggestions for improving integration of the e-checklist into practice were noted; the e-checklist might be better utilised and less disruptive to ward rounds if completed at the bedside during the patient assessment (Intensivist A).

With the aim of improving the response time of the PDA in registering an action, a suggestion was made to run the checklist program off PDA-based software rather than a networked server. [Note this suggestion is problematic and is addressed in the Discussion section below].

For any future applications, suggestions were made for the integration of the checklist into a comprehensive electronic data collection system with all patient data centralised,

checks built into the system, and an immediate response to an action to be mandatory via the use of pop-ups screens that relate to patient data entered (Intensivists A & C). For example, one participant stated,

> *"I think it would be less disruptive if it was actually integrated into the actual ward round, even an electronic ward round. So say if somebody is at the bedside and they type the notes, because you still have to type some kind of text, a related question could then pop up… 'did you consider this, did you consider that…' and you can just answer yes or no with one stroke before moving on to the next item."* [Intensivist A]

The timing of the e-checklist implementation was also discussed in light of the implementation period coinciding with a busy winter season that included an unexpected outbreak of H1N1 flu virus that affected the workload of the ICU in terms of both patients and staff. All three respondents were of the general opinion that the ICU will always be busy.

> *"I actually think there is never a quiet time to implement something new"* [Intensivist D].

There were differences in opinion however, when it came to discussing the possible impact on this study. One respondent did not think this was problematic in terms of the e-checklist implementation, but thought that it required a longer lead time to cover all medical staff and allow time for them to be confident with use – suggesting that several months rather than several weeks might be required (Intensivist A). Timing may also have had a negative impact particularly on the busiest days where *"you're just running around putting out fires everywhere"* [Intensivist C], when catch-up with the e-checklist was required e.g. during lunch break. Similarly, another respondent (Intensivist D) noted that for some staff taking on another task during a busy time may have led to them being dismissive of it, potentially leading to errors, inconsistencies or lack of data collection. This intensivist also thought however that the greater the lead time the greater the potential for the project to be put aside and not carried forward.

Clinician buy-in, change management, ownership of data collection

The importance of obtaining clinician opinion on checklist content was highlighted (Intensivist A). Being able to adapt and adjust according to local context to ensure practice relevance was seen as an essential component to obtaining clinician buy-in. Although it was noted that the Delphi study (Chapter 4.2) addressed this issue, there was a time lag between content development and checklist implementation due to the software development process. It was suggested that clinician buy-in and sense of ownership may be improved if these two phases were brought closer together.

Technology that was used in isolation i.e. using the PDA solely for the purpose of delivering the e-checklist and collecting related process data, was identified as a barrier to obtaining full clinician buy-in (Intensivist C). It was further noted that overcoming this would however require major system change such as the implementation of a clinical information system (CIS) with a built-in checklist that essentially forced people to use it (Intensivist C).

Further opinions on this topic included the difficulties of getting people who were opposed to using this kind of strategy as a QI tool to change if they do not perceive it as important (Intensivist C); and the need to engage clinicians who believe in collecting data for audit to make a change (Intensivist D). Additionally, clinicians must believe the data they are collecting will make a difference, otherwise they will only see it as extra work to their already busy ward round and workload, and therefore not worth their time – despite evidence that suggests clear benefits (Intensivist D). It was clear that for the e-checklist to be implemented as an ongoing strategy it would need full buy-in of senior clinicians and management.

Benefits and limitations of the technology

Responses provided by the interviewees regarding the benefits and limitations of the technology implemented during the intervention study are outlined in Table 7.3 below. The identified benefits pertained mostly to features that ensured checklist completion was thorough, accurate and convenient for users. In addition to technical issues such as difficulties with connectivity, noted limitations also included the challenges and barriers to integrating the e-checklist into practice.

Table 7.3 Benefits and limitations of the technology used as identified by interviewees

Benefits	Limitations
- Updated and complete patient lists for commencement of morning ward rounds - Checklists were not deemed complete until every item was addressed and a list of patients who required checklist completion appeared when not in a checklist screen. This ensured all patients had a checklist completed every day in the ICU - Easy to use and integrate into ward rounds - Better than a paper version due to size, portability and function - Can be used for ready reference e.g. definitions appear when information buttons were tapped, whereas if it were paper-based there would be big, bulky documents that could be misplaced and not used because it is not readily available - Can be integrated into clinician's PDA (those who have one) - Can be integrated into a CIS and configured so that clinicians must address required care processes in appropriate ways	- Some items overlapped with paper documentation - More than one tap per question (i.e. reasons for a 'no' response) - Separate piece of equipment specifically for the purpose of completing the checklist with no utility beyond that (for the purposes of this study) - When clinicians don't interact with the data e.g. user-generated feedback reports, there is no real difference between ticking boxes on paper versus ticking boxes on a PDA screen - Wireless technology not completely reliable i.e. 'black spots', drop-outs, slow connectivity/response time - Challenging for those who are not familiar with technology or comfortable with change

Sustainability issues

It was generally felt that even though there were clear benefits of the e-checklist, its use would not be sustainable in this ICU given the identified constraints and current culture. Introduction of unconnected technology in addition to paper-based documentation was identified as problematic, despite the shortcomings associated with the latter. After indicating the e-checklist was easy to use and implement during the study period, one participant noted:

> *"I think it would be nice to have a fully electronic unit. Having paper and electronics confuses people and it does give the impression somewhat of duplication of work which never goes down very well. I think there's a case for it but I think it would be hard to actually convince people of that."* [Intensivist D]

Value of the e-checklist in the clinical management of ICU patients

All respondents commented that the e-checklist would be valuable particularly for senior medical staff (who are responsible for making sure everything is addressed and done properly), once a CIS was implemented. Consultants could instigate and co-ordinate its use, verbalise how it is to be used and what their thoughts were, however any member of the clinical team could input the data. It was noted that registrars have too many duties elsewhere e.g. MET calls, so the person completing it could be the person who is doing the recording – i.e. they can verbalise the questions and then enter the answers (Intensivist A). It was also noted that it must be flexible to accommodate the different ways in which ward rounds are run (depending on the team and clinical lead on the day); and more than one person should be able to take it over in the event that the initial person entering the data needed to leave the bedside.

Although it was thought the ideal situation would be to have one PDA per bedside, it was also noted that would be a resource issue (Intensivist D). Regardless of whether it was delivered electronically or not, it was generally thought some form of checklist should be integrated into ward rounds because although some clinicians have their own mental checklists that they do, this was not consistent throughout the ICU (Intensivist C). Further, integrating the setting of daily goals with the e-checklist was perceived to be of potential value (Intensivist C & D).

Suggestions for training clinicians on the use of the technology

The way in which the training was carried out prior to implementation i.e. one-on-one training including hands-on use of the PDA, was seen as most useful due to: the ways in which people learn; the fact that there were varying levels of familiarity with using PDAs (some were very comfortable as they used one regularly, others had never used one); allowing the opportunity for interaction and providing immediate user-feedback; and the difficulties of getting all or even most of the medical team together in one place. As one respondent stated:

> *"I think having hands-on [experience] is very useful so having someone come around – though it is very labour intensive, is time well spent. I actually find I get more information through the old route – if I am told how to do it and shown how to do it that has much more of an impact than reading a manual or receiving a lecture without actually using it. Having someone there to ask questions of whilst you are actually using it is also very good – to do that effectively you would have to be there on the ward round, and that would also give you good feedback as to what the difficulties of using it were."* [Intensivist A]

The impracticalities however of having someone complete one-on-one training was also raised (Intensivist D). The potential solution offered was to get key people involved, encourage them to champion the process and keep momentum going. This aspect of the study was reported as adequately considered and explained.

> *"I can't see what else you could have done to make it more thorough… I think you went through all the correct processes"* [Intensivist D].

Feedback reports

None of the respondents used the reports generated from e-checklist use on a regular basis – there was an emphasis on making sure things were addressed at the patient and checklist user level rather than unit level information during the study period. There was an overall perception that for the user-generated reports (i.e. those available via the web-based server) to be of any benefit to individual users they need to be simplified. All respondents however acknowledged the possible utility of feedback reports –

particularly when unit-level information that demonstrated changes and variations in practice were reviewed in quality (or similar types of) meetings.

Other suggestions were made for how feedback on process-of-care data should be provided including: concise, unit-level feedback summaries that could be presented at collegial group meetings; providing individual clinicians with the option to obtain their own data for review; and ensuring there is someone responsible for quality assurance (something this ICU was reportedly lacking), and reporting on relevant data in a similar way to mortality and morbidity data i.e. review of issues or problem areas. To enable on-going data feedback, a member of staff with some level of ownership or whose role encompassed quality assurance and related data collection systems was seen as a requirement (Intensivist C & D).

It was perceived that clinicians probably did not need daily feedback – regardless of the method of feedback it was generally thought that monthly data was sufficient. One respondent thought that it would be more useful to review checklist data over longer periods (i.e. monthly or longer) because *"there are variations from day to day that don't mean anything and tend to even out over a longer period of time"* [Intensivist C]. For feedback to be useful to clinical practice, it needs to form part of a cycle of continuous quality improvement – the checklist could therefore be one tool that assists in a quality management process (Intensivist C).

When problems are detected one approach would be to focus down (perhaps with a focus group) to find out what the barriers are to implementing an aspect of care (Intensivist A). It was also noted that checklist data alone does not provide information pertaining to why cares are being omitted – supplementary information is required to explore the reasons why: a) the checklist is not being used appropriately; or b) not getting the results you expect/want.

A potential shortcoming to providing feedback at the unit level was that some people would not see themselves as being part of an identified problem – so there may be a case for feeding back some individual data to those people after collegial discussion has taken place (Intensivist D).

Further to this, the need to show an association between deficient care and poor patient outcomes was highlighted and that unfortunately some people only take notice of deaths, but there are other detrimental events that can occur that should be evaluated. Ultimately feedback needs to be relevant, be associated with a patient outcome that can't be attributed to anything else, and have a high impact factor to make clinicians change their practice (Intensivist D).

Summary of findings from interviews

Feedback provided by participants offered insight into clinician experience with the e-checklist. The e-checklist was valued and integrated well into practice, although there were some variations in how this was achieved, highlighting the need for flexibility in implementing clinical support tools. Reported benefits of the technology were predominantly focused on features that ensured checklist completion was thorough (e.g. software would keep track of patients who had incomplete checklists), accurate (e.g. definitions readily available) and convenient (e.g. size, portability and function) for users. Other aspects of the intervention that were perceived as useful included one-on-one training, including hands-on use of the PDA and periodic unit-level feedback. Participants emphasised the importance of clinician engagement and although they thought there was a good case for continuing its use, there were currently too many constraints to enable this.

Some of the limiting factors of the e-checklist included: potential duplication of effort (although it was noted no other systematic method of checking processes of care was used consistently by all medical staff); increased time spent documenting care for those not used to the technology; and some performance issues with the technology. Suggested improvements included completing the checklist during patient assessment rather than after; engaging clinicians more in the data review process; and integrating the e-checklist into a CIS. It was generally thought that integration into a CIS would help alleviate many of the limitations identified and might be the only way of progressing this area of work in this ICU.

Safety Surveys

Response rates for the Safety Culture Survey were 48% at baseline (52% medical, 42% nursing) and 42% post-intervention (34% medical, 41% nursing). No statistically significant differences were identified in respondent demographics for the two measurements (see Table 7.4).

Table 7.4 Safety culture survey respondent demographics

	Baseline (n=68)	**Intervention (n=54)**	**P-value**
Gender (female)	40 (61.5)	37 (74)	.17
Age[a]	37 [28-45]	40.5 [30-45]	.43
Years experience in specialty	6 [2-11]	7 [3-13.5]	.41
Years experience in this ICU	4 [1-8]	5 [2-9]	.46
ICU job category:			
Nursing	48 (70.6)	41 (75.9)	.82
Medical	14 (20.6)	10 (18.5)	.82
Other	2 (2.9)	1 (1.9)	NA

Notes

[a] Descriptive data for age, years of experience, years of experience in this ICU are summarised using median and inter-quartile range (not normally distributed data). Missing data are excluded.

The mean and percent-positive scores for the survey items are listed in Table 7.5. No significant differences between pre- and post-intervention scores were detected for mean scores (t-test) or percent-positive scores (chi-square) for any of the items. Similarly, there was no significant difference between pre- (mean = 63.23; SD = 12.39) and post-intervention (mean = 62.56; SD = 10.96) scores ($F=1.44$, $df = 120$, $p=.76$) for the 100-point safety culture mean score calculated using 7 items from the questionnaire (as noted in Table 7.5; p values not included as no significance detected).

Table 7.5 Mean and percent-positive safety culture scores for survey items

Survey item	Pre-intervention		Post-intervention	
	Mean (SD)	**% Positive**	**Mean (SD)**	**% Positive**
The culture in this ICU makes it easy to learn from the errors of others [b]	2.46 (.78)	62	2.55 (.97)	57
Medical errors (any mistake in the delivery of care) are handled appropriately in this ICU [b]	2.49 (.92)	56	2.41 (.74)	63
The senior leaders in my hospital listen to me and care about my concerns	2.69 (1.08)	48	2.76 (1.13)	46
The physician and nurse leaders in my area listen to me and care about my concerns	2.19 (.99)	75	2.28 (.88)	69
Leadership is driving us to be a safety-centred institution	2.42 (.91)	49	2.52 (.86)	59
My suggestions about safety would be acted upon if I expressed them to management [b]	2.44 (.81)	62	2.44 (.82)	57
Management/Leadership does not knowingly compromise safety concerns for productivity	2.24 (.91)	70	2.40 (.93)	55
I am encouraged by my colleagues to report any patient safety concerns I may have [b]	1.98 (.81)	80	2.06 (.81)	76
I know the proper channels to direct questions regarding patient safety in this ICU [b]	2.03 (.79)	82	2.02 (.66)	85
I receive appropriate feedback about my performance [b]	2.59 (.98)	50	2.72 (.92)	41
I would feel safe being treated here as a patient [b]	2.29 (.95)	62	2.20 (.79)	72
Briefings (e.g. patient report at shift change) are important for patient safety	1.49 (.56)	97	1.39 (.49)	100
Thorough briefings are common in this ICU	2.25 (.78)	77	2.41 (.94)	65
I am satisfied with availability of Physician leadership	2.12 (.80)	77	2.13 (.71)	79
I am satisfied with availability of Nursing leadership	2.06 (.84)	81	2.20 (.88)	78
I am satisfied with availability of Pharmacy leadership	1.88 (.80)	85	1.87 (.58)	89
This institution is doing more for patient safety now, than it did one year ago.	2.55 (.81)	45	2.54 (.79)	48
I believe that most adverse events occur as a result of multiple system failures, and are not attributable to one individual's actions	2.15 (.78)	70	2.15 (.74)	72

Survey item	Pre-intervention		Post-intervention	
	Mean (SD)	% Positive	Mean (SD)	% Positive
All the personnel in my ICU take responsibility for patient safety	2.34 (.91)	71	2.56 (.97)	59
Personnel frequently disregard rules or guidelines (e.g. handwashing, treatment protocols/clinical pathways, sterile field etc.) that are established for this ICU [a]	2.76 (1.09)	52	2.91 (.92)	39
Patient safety is constantly reinforced as the priority in this ICU	2.32 (.91)	63	2.26 (.73)	65
I am aware that patient safety has become a major area for improvement in this institution	2.28 (.90)	61	2.20 (.74)	69
All the necessary information for diagnostic and therapeutic decisions are routinely available to me	2.31 (.82)	73	2.37 (.83)	65
I am provided with adequate, timely information about events in the hospital that might affect my work.	2.88 (.87)	40	2.70 (.82)	43
The physicians and nurses here work together as a well-coordinated team	1.93 (.76)	84	2.02 (.81)	80
Intensivists in this ICU are doing a good job	1.78 (.71)	90	1.67 (.55)	96
Interactions in this ICU are collegial, rather than hierarchical	2.43 (1.10)	59	2.36 (.98)	64
Important issues are well communicated at shift changes	2.30 (.78)	70	2.30 (.77)	69
There is widespread adherence to clinical guidelines and evidence-based criteria in this ICU	2.43 (.83)	59	2.26 (.68)	69
Communication breakdowns, which lead to delays in delivery of care, are common [a]	2.94 (.93)	34	2.96 (.91)	41
Communication breakdowns, which negatively affect patient care, are common [a]	2.81 (.95)	41	2.64 .(79)	51

Notes

[a] These items are reverse scored for calculation of means and % Positive = disagree & strongly disagree responses to these items only. All other % Positive = agree & strongly agree responses.

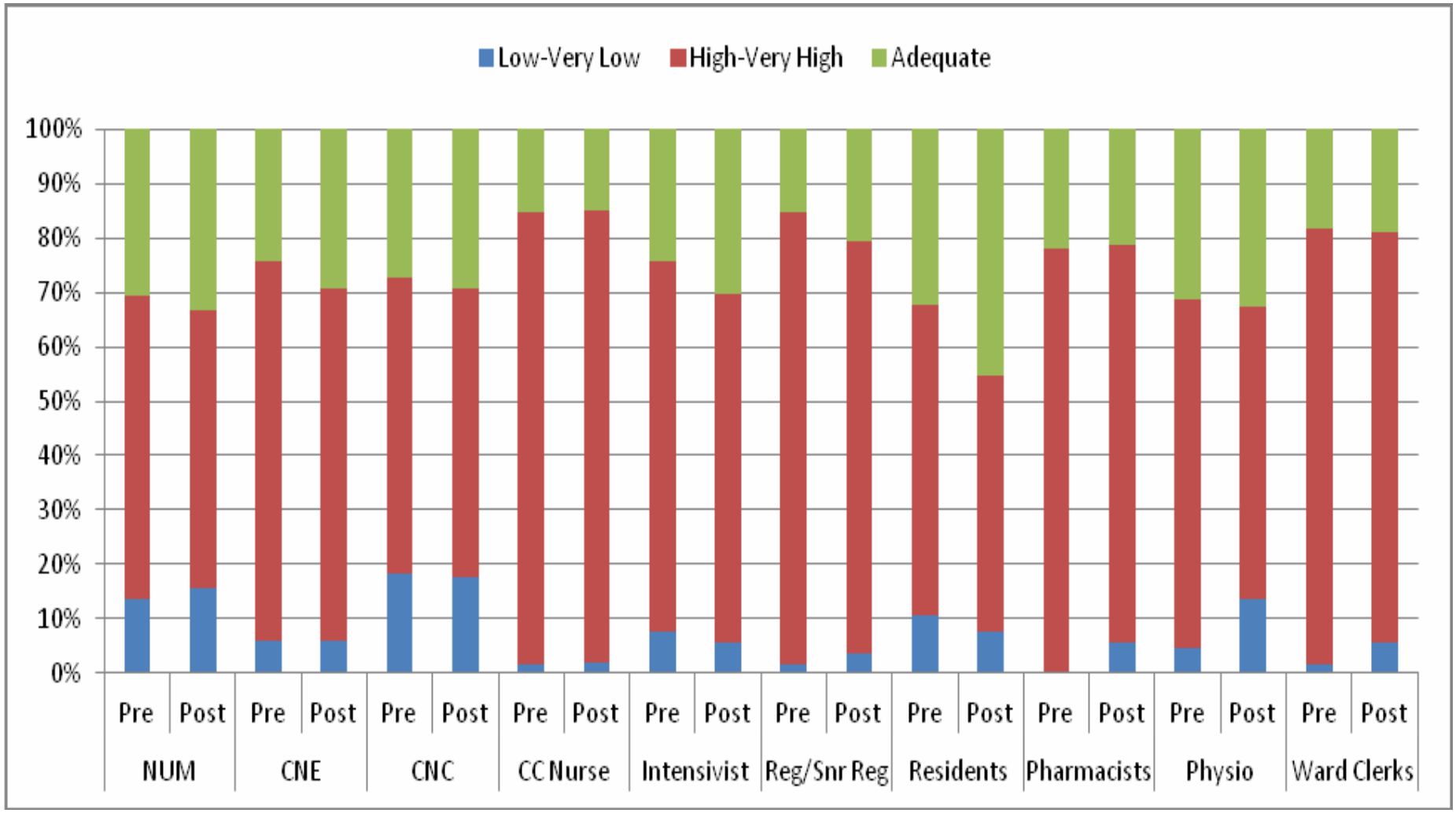
[b] Items comprising the Safety Culture Score

The quality of collaboration and communication experienced with each position category (i.e. nurse unit managers, clinical nurse educators, clinical nurse consultants, critical care nurses, intensivists, registrars/senior registrars, residents, pharmacists, physiotherapists, ward clerks) reported by respondents did not change over time when compared using chi-square analyses (see Figure 7.2).

In summarising and synthesising respondents' recommendations for improving patient safety in this ICU, several major categories were evident: clinical practice and management, communication and collaboration, education, environment, equipment, incident monitoring, safety culture, staffing/rostering, and performance management. Further detail can be found in Appendix Z where all major categories and sub-categories that contained more than two responses are outlined.

Responses pertaining to the method of survey completion (only asked at pre-intervention) revealed the majority (74%) thought it would be either 'easy' or 'very easy' to complete the Safety Culture survey online. Of those that responded, the majority would prefer to complete the survey at work (78%) as opposed to home (17%).

Figure 7.2 Percent ratings of the quality of collaboration and communication amongst staff: pre- and post-intervention



Discussion

Key findings

In addressing each of the three research questions, the following findings were demonstrated:

1. Overall acceptance and perceived utility of the e-checklist. Staff were generally satisfied with the intervention, with both benefits and limitations reported.
2. The e-checklist had face validity with ICU physicians who used the tool.
3. There were no detectable differences in staff perceptions of safety culture in the ICU as measured by the adapted Safety Climate survey pre- and post-intervention.

Interpretation and context

Key findings pertaining to utility of the e-checklist are elaborated below within the context of the current literature base. Issues explored include delivery of care, checklist face validity, user satisfaction, technology, and safety culture.

Delivery of care

Prior to the intervention, ICU physicians identified the need for improvement in the delivery of daily processes of care specified in the checklist. Nutrition and sedation practices were identified as being addressed least consistently in this unit. After comparing the responses from senior medical staff with data collected at baseline, it appeared there were discrepancies between perception and reality, a situation previously reported (Brunkhorst et al. 2008). In this study, clinical practices related to pain, head of bed elevation and glucose management were actually delivered less consistently than clinician perception. Conversely, nutrition, sedation and medication management were delivered more consistently than perceived. As previously noted in Chapter 6, some measurement issues may have impacted on the accuracy of compliance data, particularly for pain and medication management. Importantly, the need for accurate baseline measurement is

highlighted when differences between clinician perception and actual practice are detected (Brunkhorst et al. 2008).

Upon evaluation most respondents believed care improved with use of the e-checklist. Perception matched actual practice here, with improvements noted across all nine care components (as detailed in Chapter 6). With the success of QI interventions being heavily reliant on clinician acceptance (Cabana et al. 1999; Fitzpatrick et al. 2009), this feedback was key to establishing the ongoing utility of the e-checklist in an ICU setting.

Although few used technology at the bedside prior to this intervention, most used some type of clinical practice tool for example mnemonics. Given the improvements to delivery of cares noted in Chapter 6, it appears that the systematic use of an e-checklist was superior in terms of results than the diverse approaches being used routinely at baseline. This finding is consistent with an earlier Australian study conducted in an anaesthesia department of a tertiary hospital where approximately one-third of the required processes were not performed when physicians relied on memory alone (Hart & Owen 2005).

Checklist protocols rated well with participants e.g. being completed by senior medical staff at the end of patient assessment as a challenge and answer – although it was noted by interviewees that this was not always done (notably this could be another reason there were small discrepancies between physician and auditor responses to the checklist). Alternative suggestions for future checklist completion included integrating it into patient assessments as a prospective prompt or to be used as a review of the ward rounds after completion. Most previous studies evaluating the use of checklists or rounding forms in ICUs appeared to indicate they were completed during the ward round for each patient, although the issue of timing during the patient interaction was commonly not addressed e.g. (Byrnes et al. 2009; DuBose et al. 2008; Pronovost et al. 2003a). A more recent study evaluating the use of a daily goals form in an ICU observed that the form was primarily reviewed at the end of each patient assessment (Centofanti et al. 2014), an indication that this may be the best option in terms of workflow. Ultimately, timing of checklist completion would be largely dependent on its' intended purpose and ease of integration into local practice.

Checklist face validity

The majority of clinicians thought checklist items related well to the processes of care expected in the ICU, and this rating improved from baseline to post-intervention. Further, all respondents thought the checklist items were appropriate, and most believed the statements were easily understood. Collectively, these findings lend support to the e-checklist having face validity with ICU physicians – important for the uptake and sustainability of practice improvement tools in routine practice (Hales et al. 2008; Pittman & Bakas 2010).

As most respondents to the baseline survey indicated they used some type of reminder (e.g. mnemonics) to ensure routine processes of care were delivered, and interviewees reported some overlap with the existing checks they perform, there was the risk that the e-checklist would be considered redundant. Participants thought however, that use of the e-checklist was actually better than not using a tool or relying on memory alone, and pre-study observations revealed that checks were often interrupted and left unfinished. Together with findings of significant improvements to delivery of all cares covered by the checklist, there was a strong indication that the e-checklist enhanced existing clinical practices, which again adds evidence supporting the validity of the e-checklist.

Feedback from physicians also highlighted that they were unlikely to check for other routine processes of care not covered by the e-checklist. This emphasises the need to ensure that checklists address all aspects of care that require routine attention and/or improvement at the local unit level.

User satisfaction

User feedback was generally very positive – participants thought it was a worthwhile and effective intervention. A few respondents who replied to both surveys rated the e-checklist better on follow-up than they did at baseline – an indication that it functioned even better than initially perceived by ICU clinicians. This may have been achieved in part by addressing the concerns a few clinicians had pertaining to measurement and interpretation of process data. The further development work done in consultation with local ICU

clinicians, as well as disseminating and providing ready access to a data dictionary along with care statements embedded into the e-checklist tool, appeared to address participants' initial concerns.

Utility of the e-checklist also rated well with participants over time – it reportedly assisted in ensuring daily care processes were delivered, with adaptation to the implementation process easy, irrespective of their level of experience with handheld technology (see more on technology below). Key benefits reported included: a single tool that covered the important aspects of care to be considered for each patient; a reminder function to complete cares; imbedded, detailed checklist statements and an updated patient list indicating those requiring checklist completion; more functional than a paper version due its size, portability and utility; could be used to obtain rapid feedback allowing for self-assessment of clinical practice; and could be integrated into other devices and clinical information systems.

Time taken (on average) for physicians to complete a checklist was reported as two to around seven minutes. The longer times reported may have been due to unfamiliarity with the technology (as noted by one interviewed participant), interruptions to checklist completion or when identifying omissions – all of which could prolong the process. As noted in the observations taken during the pre-baseline phase and in previous studies (Alvarez & Coiera 2005; Lyons, Standley & Gupta 2010), disruptions to morning ward rounds are common, increasing the amount of time to complete routine care processes. Given a 'no' response to e-checklist statements required further clarification on the reason, and the philosophy behind the checklist was to correct omissions upon detection where possible, may have also contributed to checklist completion taking longer than a few minutes. Variation in time to complete any task in a clinical setting can be expected and may not be an entirely limiting factor; a recent study reported that increased time spent on completing a daily goals form was considered (by clinicians) necessary to ensure patient safety, and completion of the form brought clinicians back on task after being distracted (Centofanti et al. 2014).

Ratings of the education and information sessions provided to medical staff at baseline were generally positive. Although there appeared to be room for improvement in some of the ratings, it was hard to identify specific issues, as only one suggestion for improving the training was provided (i.e. a discussion group rather than presentation) and all interviewees were supportive of the approach taken.

Due to the lower rating given to 'interpreting data displayed in charts' at baseline, it was decided that feedback to clinicians be provided in a format that was familiar to them i.e. run charts, graphs and summary tables rather than SPC charts. Ratings of the feedback reports provided to medical staff via email during the evaluation phase were consequently positive with the content, format and frequency of reports useful to clinical practice. This feedback was unexpected as the reported benefits of using SPC largely outweighed the limitations (Thor et al. 2007), and the use of control charts has been widely promoted as a useful and effective method for measuring safety and quality in health care – particularly acute and critical care (Pronovost et al. 2004a; Thor et al. 2007). The reasons for clinician's preference in this study was unknown, and may need to be explored further prior to planning any future process improvement strategies.

Technology

Many elements of the e-checklist rated well with participants; checklist design and layout, ease of use (both the e-checklist and PDA in general), ease of data entry, having the care statement detailed in the information buttons, access to the data dictionary via the e-checklist server, and electronic data capture as opposed to paper-based data collection. Notably, only a few physicians had used an electronic device in the clinical setting prior to study commencement and there were no reports of these devices being used as a checking mechanism. It therefore appears that despite unfamiliarity with use of similar technology, participants believed the e-checklist was easy to use and had beneficial technological features.

Reported acceptance of technology in the clinical management of a patient however, rated slightly lower overall at evaluation than at baseline. There are a couple of potential reasons

for this finding: 1) there was a different sample at each time point due to changes in medical registrar rostering; and 2) for those who were proficient in using similar technology, the e-checklist did not perform exactly as expected i.e. response time was not instantaneous, there were occasional difficulties with the wireless connectivity, and more than one tap per question was required when a 'no' response was recorded (which was a function that enabled physicians to specify whether the care was not delivered because it was not applicable to the patient at the time e.g. clinical contraindication, or an omission that was either corrected at the time of detection or noted for rectification sometime after the ward rounds).

Some users provided suggestions for improving e-checklist performance. To improve response time and negate the issues with wireless technology, it was suggested that the e-checklist software could run off the PDA rather than the networked server that required the wireless connection. The reasons this was not appropriate for the study were: the need for data to be collected centrally, with two PDAs in use concurrently due to split ward rounds conducted across the two ICU pods (the e-checklist server prevented any doubling-up by removing patients from the 'to-do' list once completed), data security (if PDAs were lost they contained no patient-related information; the server was stored in a secure location and password protected), data integrity (the server was the 'source of truth'; all data recorded was stored in the server and data validation rules could be easily applied), data storage (the PDA's memory was insufficient for storing all data collected), and functionality of the PDA's was limited (i.e. unable to perform adhoc data reports and real-time data monitoring).

With constant advances in technology, all of these issues could be re-explored when implementing similar tools in the future. In this ICU for example, the wireless coverage was not 100%, so upgrading wireless connectivity could lead to improvements in PDA responsiveness. Other handheld devices such as PC tablets (which were not readily available at the e-checklist development stage) provide users with a larger surface with which to interact, enabling more content to be applied to the one screen; this could mean less 'taps' leading to improved time efficiencies and ease of use when completing the

checklist. This assumption has yet to be tested in healthcare settings however, with a lack of research published on the utility of PC tablets.

Although physicians were generally satisfied with unit-level summary feedback reports that were sent to them via email, the user-generated reports via the e-checklist web portal (that offered real-time unit-level data in graphical and tabular formats) were rarely accessed. Upon interview, intensivists thought greater utility of unit-level reports might be realised if they were fed back to physicians at collegial team meetings on a monthly basis rather than to rely on individuals seeking this information either during clinical or on their own time. This might also help with ownership of the data – particularly if review of data is led by physician(s) responsible for quality and safety assurance and forms a part of clinical practice improvement cycles. This finding demonstrates that although collecting and recording process data electronically assists with audit and feedback functions which have both been shown to be beneficial to QI initiatives e.g. (Tooher et al. 2005), the way in which this is implemented at the local level requires further testing and evaluation.

Using technology in one single aspect of care delivery was identified by a few participants as a concern. Use of the e-checklist in addition to routine documentation in the medical records may have contributed to the sense of duplication of effort. Feedback obtained from some of the participants highlighted the need to integrate all patient data (including but not limited to the e-checklist) into a comprehensive electronic data collection system. Undoubtedly, computerisation of information in intensive care units is the way forward, with uptake of clinical information systems (CIS) increasing internationally (Colpaert et al. 2010), and demonstrating benefits such as improved documentation, legibility, evidence based decision support, interdisciplinary communication, reduced duplication, documentation time and medical errors, and increased time spent on direct care activities (Bosman 2009; Mills et al. 2013). Development of a CIS for NSW ICUs is currently underway, (Ryan & Abbenbroek 2013) with plans to integrate a FASTHUG checklist although full implementation will take several years.

Safety culture

There were notably no differences to perceptions of safety culture in the study ICU between the two measurement points, with a number of possible reasons for this finding. First, a six-week intervention period was arguably not long enough to affect long held perceptions of safety in the ICU. A previous study demonstrating improvements in ICU safety culture tested the implementation of two different multifaceted interventions of evidence-based prevention practices (i.e. to reduce CR-BSI and VAP) and a daily goals checklist that spanned a period of 2 years before a follow-up safety climate survey was conducted (Sexton et al. 2011). This US study was also conducted in 127 ICUs providing much greater statistical power than for this single centre.

Second, due to nursing staff already having their own process in place, the e-checklist intervention purposely targeted medical staff; this limited the potential for culture change across the entire unit. Improvements in safety climate scores have been evidenced by staff who participated in an intervention to improve the safety culture of 23 clinical units in a tertiary-level teaching hospital, but no such improvements were evident for those who did not actively participate in the intervention (Thomas et al. 2005); this may have been a similar issue for nurses in this study.

Third, methodological aspects of assessing safety culture in hospital settings have been questioned including whether culture can be ascertained via questionnaires that ask individuals to rate their agreement with a number of statements (Pumar-Mendez, Attree & Wakefield 2014). This is a limitation of using just one tool and method for evaluating a complex construct such as the culture of safety in a clinical setting.

Fourth, response rates achieved at both time points were less than 50%, under the recommended response rate (60%) for obtaining a representative sample overall (Sexton, Thomas & Grillo 2003). It is unknown whether obtaining a higher response rate would alter the results. As the questionnaires were completed anonymously, it was also unknown how many respondents completed them at both time points.

Finally, there were several items on the safety culture survey that pertained to leadership at the hospital or institution level, indicating that staff were generally less positive towards these items than other aspects of safety culture. As this research was targeted at clinicians at the bedside and did not involve hospital leaders in any way, it is possible that exclusion of these items may have resulted in a measure more attuned to detecting cultural change as a result of the intervention.

Overall it appeared that use of the safety culture survey tool in a 6-week, single-centre intervention study that involved only medical staff did not provide valuable information on the impact of the e-checklist. It is likely that ICU safety culture was largely unaffected on a unit-wide scale.

Strengths and limitations

The strengths of this evaluation included obtaining staff perceptions of the intervention study's key components including the delivery of processes of care, e-checklist tool, implementation model, feedback mechanisms, and education/training. Comparing clinician perception and actual delivery of care provided insight into the differences between what cares physicians perceive are delivered consistently and what was actually delivered. Measures of user satisfaction provided feedback on what participants thought was more or less useful about the intervention. As documentation of patient-related clinical information was predominantly paper-based in the ICU, participants were able to make comparisons between that and electronic data capture. Interviews with senior ICU physicians enabled a more detailed evaluation of the intervention. The resulting data provided greater explanation of issues identified in the user surveys, adding further insight into e-checklist use and utility, and clinician perception.

Both the user surveys and interviews contributed important information on establishing face validity for the checklist items with physicians. Evaluating face validity of the e-checklist addressed a limitation of previous studies (identified in Chapter 2) that either did not seek or did not report clinician feedback on the tools implemented.

Limitations with this evaluation component of the study are also noted. Response rates achieved across all the surveys conducted were modest; the highest was for the user survey at baseline (61%), and the remaining response rates were below 50 percent. This could have been due to survey fatigue, a new rotation of registrars just prior to the intervention period commencing (who were not present for previous engagement strategies), or the workload on clinicians during the influenza pandemic. It is therefore unknown whether the responses obtained are representative of the entire ICU staff population. Further to the issue of the intervention coinciding with an influenza pandemic, it is also uncertain what impact this had on staff acceptance. Although this was explored with interviewees, it is uncertain whether their views would be reflective of their fellow intensivists and the registrars who report to them. The number of intensivists interviewed was another potential limitation – although this sample represented half of the intensivists, no registrars were interviewed due to medical staff shortages during this evaluation phase.

Due to the limited resources available, no formal observations of the ward rounds were conducted during the intervention period. Feedback on how the e-checklist was utilised was therefore dependent on self-report and retrospective accounts provided by physicians, which as previously noted, can differ from reality.

Implications for practice

The findings of the evaluation suggest that in addition to being an effective clinical practice tool, use of a systematic e-checklist was accepted by senior medical staff. The content developed for this tool proved clinically relevant for physicians on the morning ward rounds, it enhanced existing clinical processes, and was deemed better than relying on memory alone. Whilst there was an indication that completion of the e-checklist may be most beneficial at the end of each patient assessment whilst still at the bedside, consideration should be given to workflow, which could differ amongst clinical settings and ward round teams within an ICU.

As there are likely to be differences between clinician perception and actual practice, the recommendation is to collect objective baseline data establishing where improvements are

required. Demonstrating deficiencies in the delivery of care to physicians was key to gaining their initial engagement. E-checklist utility and ease of use appeared to be important in maintaining clinician acceptance.

Despite some limitations, integrating the checklist into a handheld electronic device had good clinical utility and advantages over paper documentation (as previously described). Improvements to technology (e.g. use of tablets, ensuring full wireless network coverage) and processes (e.g. replacing clinical tools that are not consistently or reliably utilised) may increase clinical utility of e-checklists even further. Automating data collection would most likely lead to improved efficiencies such as quality of patient care, staff time and related costs, particularly for ICUs that: 1) have similar paper-based clinical practice tools that are not routinely or fully utilised; 2) have a clinical information system that allows for a built-in checklist function; and 3) regularly conduct audits of practice.

The e-checklist therefore has the potential for even greater clinical utility than was realised in this study. There were some cases where omissions in care were detected but not corrected immediately upon detection. If processes were in place that actively encouraged clinicians to interact with the web-based server (which collected and reported on the process measures of care in real-time) sometime after the ward rounds had been completed, omissions could be identified and immediately rectified by clinicians upon review.

Recommendations for further research and evaluation

These findings highlighted areas that require further study. One is determining how the e-checklist is utilised in practice including where and when it is used, how long it takes to complete, and whether there are any disruptions or distractions to the process. This type of evaluation requires observational work and an electronic tool has been developed and validated in critical care settings that assist with the collection of this data (Ballermann et al. 2011). As an extension of this, comparing the utility of the e-checklist with similar clinical support tools or across different delivery platforms, would demonstrate the benefits and limitations of each approach, enabling clinicians to select tools that are most appropriate to them.

In addressing limitations of this evaluation, future studies might benefit from obtaining a larger sample of clinicians to provide feedback on the intervention; this could be done by conducting more interviews or organising focus groups, ensuring representation from all staff designations participating in the study. Further consideration should be given to improving response rates, such as avoiding the over-use of surveys. In this particular study, evaluation of the ICU's safety climate did not add valuable information pertaining to the impact of the e-checklist; it is therefore not recommended for use in studies that utilise the same methodology and time periods. Formative evaluation may also be required in future work for establishing clinicians' preferred methods of receiving data as feedback on clinical practice for the purpose of quality improvement.

Conclusion

In evaluating the multi-faceted implementation of an e-checklist intervention, a multi-method approach to evaluation was undertaken. This involved user feedback including staff satisfaction that was obtained via pre- and post-implementation surveys and follow-up interviews; and before and after safety culture surveys of all ICU staff. The findings revealed that physicians were satisfied with the e-checklist; they believed it was both an effective and worthwhile intervention. Although there were discrepancies between perception and reality regarding delivery of cares at baseline, almost all participants thought there was room for improvement and after the intervention phase the majority believed care delivery improved with use of the e-checklist.

The findings also lend support to the e-checklist tool having face validity with ICU physicians, which addressed a limitation of previous studies. Participants reported benefits, limitations and made suggestions for improvements to the technology used, though overall the e-checklist was considered easy to use and beneficial to clinical practice. The safety culture surveys demonstrated no differences in safety climate after the intervention, questioning the value of using this as an evaluative measure in this type of study with a short timeframe. Recommendations for further research and evaluation include

incorporating observations during the intervention phase and conducting focus groups to further explore user issues and impact on routine practice. This evaluation overall suggested that the e-checklist was an effective tool that was accepted by clinicians who were generally satisfied with the intervention, despite some noted limitations which could be addressed with improved technological performance and integration into available clinical information systems.

Chapter 8.

Synthesis of study findings and conclusion

Through a staged and iterative approach, this program of research explored the utility of an electronic process-of-care checklist to support the medical morning rounds in an ICU. Multiple methods were used to appropriately examine each research question. Results of earlier studies were used to inform the methodological approach and procedural detail for later ones, culminating in the intervention study, which also involved an evaluative component.

Major Findings

The literature review highlighted several key processes of care for inclusion in a ward round checklist, various approaches and strategies for improving care delivery, appropriate measurement methods for use in QI research, and the technological advancements in healthcare that assist in the delivery of clinical tools. The evidence-base suggested there was room for improvement in the delivery of ICU processes of care (Berenholtz et al. 2011; Hewson-Conroy, Elliott & Burrell 2010; Scales et al. 2011). Although there were notable gaps and limitations in the evidence, there was sufficient support for further evaluating process-of-care delivery in ICUs, and developing, implementing and evaluating the utility of an electronic process-of-care checklist for use by physicians on the morning medical rounds.

Although the evidence suggested that compliance with routine processes of care in ICUs was less than desirable, it was not known whether this was true for Australian and New Zealand practice. This led to a bi-national point prevalence study which measured the prevalence of routine care actually being delivered in a large sample of ICUs. Findings clearly demonstrated variability in the delivery of routine interventions at participating ICUs – wide variations in compliance were evident for the assessment of pain, sedation and nutritional goals, as well as head-of-bed elevation, ventilator weaning, pressure area and bowel management practices, which was consistent with previous international studies

(Crunden et al. 2005; Ilan et al. 2007; Keroack et al. 2006; Pronovost et al. 2003b). This provided the impetus for continuing this area of study.

The paucity and limitations of checklist validity testing in critical care settings highlighted the need for further validation studies. First, it was unknown whether completion of the checklist reflected actual delivery of care (its intended purpose). Examination of criterion-related concurrent validity of a process-of-care checklist ensued (Chapter 4.1) which involved comparing responses to a paper-based checklist (that was piloted prior to commencing this research) with care documented in the medical record (as an independent measure of care delivery). Results showed a strong and positive association between the two measures, demonstrating support for the concurrent validity of a process-of-care checklist, particularly its use as a tool for measuring and ensuring the delivery of daily cares in an ICU.

Second, the need to develop relevant checklist content that adequately covered the daily processes of care expected in ICU was also identified. The second validity study (Chapter 4.2) developed checklist items for daily use during ward rounds. Interviews with local clinicians and two rounds of a modified-Delphi technique with an expert clinician panel produced a series of clear, concise, and instructive checklist statements that represented relevant content for essential practices in the process-of-care for ICU patients. These statements, which addressed cares pertaining to nutrition, pain, sedation, DVT and stress ulcer prophylaxis, head-of-bed elevation, glucose and medication management, and readiness to wean, were subsequently included in the purpose-built e-checklist software for the handheld device (as described in Chapter 5).

Collectively, this accumulated preliminary work was consolidated and integrated into a prospective before-and-after intervention study designed to test the implementation of an electronic process-of-care checklist during medical ward rounds in an ICU. A combination of QI principles, methods of knowledge translation and point-of-care technology were used to implement and evaluate the e-checklist. The focus of measurement was on process data collected via the e-checklist. Key findings were: improved compliance with, and reduced

variability in cares delivered over time; very good rates of agreement between clinician and audit responses indicating checklist completion reflected actual delivery of care, which demonstrated evidence for validity of the e-checklist. In line with previous study findings (Scales et al. 2011), the greatest improvements were evidenced for aspects of care that had lower compliance at baseline i.e. pain (42% increase, OR = 23[14-38]), glucose (22% increase, OR = 14[7-27]) and sedation (7.5% increase, OR = 3.9 [1.8-8.4]) management, head-of-bed elevation (19% increase, OR = 11[5-22]) and nutrition assessment (7.4% increase, OR = 4.4[2.4-7.9]. There was also evidence to suggest that omissions of care detected by the checklist were subsequently delivered. The e-checklist was therefore fit-for-purpose; it functioned effectively as both a valid measurement and clinical practice tool that improved the delivery of essential cares to ICU patients.

The multi-method evaluation component of the intervention study explored the usability of, and staff satisfaction with the e-checklist and determined whether there was any impact on the ICU's safety culture. Physicians were generally satisfied with the e-checklist, the feedback received indicated that it was a worthwhile and effective intervention that improved their practice by ensuring essential cares were considered and delivered where appropriate. Importantly, the findings provided support to the e-checklist having face validity and clinical utility with physicians. Although there were no detectable differences in safety climate, the value of this evaluative measure was questionable in light of the limitations identified after completion of the study.

Study strengths and limitations

This entire programme of research sought to address evidence gaps and limitations of previous studies, particularly those testing and evaluating checklists in intensive care units. Although it was not possible to tend to everything, numerous issues were addressed (as outlined in Table 8.1) offering support for the strength of evidence for using checklists during the morning medical rounds in an ICU.

Table 8.1 Addressing the evidence-gaps and limitations of previous studies

Limitations of previous studies	How addressed in this research
Unknown compliance with a range of processes of care in ANZ ICUs unknown	Point prevalence study conducted in 50 ANZ ICUs measured care delivery at a single time point providing a snapshot of compliance (Hewson-Conroy et al. 2011)
Lack of detailed and rigourous QI intervention studies evaluating impact of checklists on practice adherence	E-checklist intervention study used evidence-informed implementation models for the design and methods, including an integrated evaluation component. Primary outcome of interest was compliance with daily processes of care.
Impracticalities of data collection - paper checklists and manual data collection labour intensive	Develop an electronic checklist which functions as both a checklist and data collection tool, is portable and can therefore be used at the bedside in real-time.
Establishing consistent definitions	Data dictionaries for both clinicians and auditors were developed in collaboration with each user group, then shared with all users with wide availability (hard copies in unit, soft copies on e-checklist server, PDA and distributed via email).
Extensive lists imposed additional burden on busy clinical staff	A list of nine essential processes of care identified as the most important and considered essential to routine care delivery during ward rounds (Conroy, Elliott & Burrell 2013a). All nine were visible on a single screen and required a 'Yes' or 'No' (if no, a single reason is requested) response.
Not using appropriate process measures	Process measures were based on responses provided to the e-checklist via clinical audit and physician use at the point-of-care.
Outcomes closely related to practices in the checklists not measured	Adverse events potentially related to the process measures were recorded.

Limitations of previous studies	How addressed in this research
Not controlling for extraneous variables that could impact on outcomes	GEE analysis of process data controlled for confounding variables over time.
Lack of baseline data for comparisons	Baseline data (audits of practice) were collected daily by research nurses prior to commencement of intervention.
Utility of checklist in detecting and correcting omissions or errors not evaluated	Data collected on whether an omission of care was either 'now corrected' or 'not yet corrected' and omissions were further evaluated.
Lack of formal validity and reliability testing of checklist	Tests for validity of the e-checklist were conducted prior to, during and after the intervention study. Demonstrated evidence for the following validity types: concurrent (criterion-related) (Conroy, Elliott & Burrell 2013b), content (Conroy, Elliott & Burrell 2013a), construct based on response processes, face. Reliability testing not a study aim.
Low inference study designs e.g. uncontrolled and retrospective	Whilst this before-after study design was uncontrolled, data was collected prospectively at the point-of-care and GEE analysis controlled for confounding variables.
Study designs that lack comparison with other methods	Whilst testing a concurrent method of improving processes of care was not feasible for this study, an earlier pilot study tested a paper-based checklist in the same ICU (Hewson & Burrell 2006).
Small or unknown sample sizes	Total sample size achieved (n=293) was more than adequate according to *a priori* power calculations (206 participants required to detect significant differences over time).

Limitations of previous studies	How addressed in this research
Limited representation of ICU population due to single centre studies	Although this was a single-centre study both the ICU and patient characteristics were detailed to enable comparison and applicability to other general ICUs.
Not evaluating the multi-faceted interventions or tools developed as part of the study	Evaluations of the multi-faceted aspects to this study including the e-checklist are outlined in Chapter 7.
Sustainability issues, particularly where data collection was resource intensive	Although sustainability was a consideration in development of the e-checklist, ICU culture at the local level, changes in state-based health care system and rapid advances in ICT has impacted on this (outlined in Chapter 7).

Abbreviations: ANZ = Australia and New Zealand; GEE = Generalised Estimating Equations; HDU = high dependency unit; ICT = information & communications technology; ICU = intensive care unit; PDA = personal digital assistant

There were limitations of the research; some were not able to be addressed due to limited resources and were therefore deemed beyond the scope of this project, others were methodological issues or a mix of the two. One methodological limitation, reliability testing, was not able to be assessed as it was not feasible to ask any more of the medical team at the time the intervention study; this was due to the impact of the swine flu epidemic on the unit which adversely affected staff availability and workload.

Although the point prevalence study had strengths in capturing a large number of ICUs across a wide geographic area (all of Australia and New Zealand), resources only allowed for a cross-sectional design with data collected on one single day at each participating unit; it also meant that participating units were likely to be those with existing resources such as research staff, hence the high participation rate of tertiary units but under-representation from metropolitan, rural, and private hospitals.

The intervention study utilised an uncontrolled study design and was not adequately powered to detect a statistical difference in patient-level adverse events over time. Although not a primary outcome of interest for this study, collection of patient events data were of minimal utility due to incomplete data collection at baseline. These limitations could be addressed in future research.

Overall, all the studies may have been subject to bias to varying degrees (detailed in each study chapter), response rates to surveys were generally only moderate, and feedback on how the e-checklist was utilised in the intervention study was limited to self-reported and retrospective accounts provided by physicians. These limitations could be addressed in future research through the use of a controlled research design, exploring alternative methods for improving response rates, and conducting observations of e-checklist use during the intervention phase.

Implications for practice

In addition to demonstrating that an electronic process-of-care checklist can be used as a clinical support tool on the morning ward rounds to help ensure the delivery of essential daily cares in an ICU, this research has demonstrated the versatility of an e-checklist. It also had utility as a real-time, portable measurement device at the patient's bedside and a method of auditing care delivery. ICUs can therefore implement e-checklists in different ways depending on their practice and quality improvement needs, available resources, and what aims they want to achieve.

Findings of this research also have applicability beyond the ICU. When the need for improvement in the delivery of care has been identified (e.g. via literature review and clinical audit), and a checklist is considered fit-for-purpose, content of the checklist can be developed using the methods outlined in Chapter 4.2. The implementation model utilised in the intervention study (Chapter 6) equally applies to any healthcare setting, and can be used on a wide scale.

The implications for health administrators are to understand that achieving improvements in health care delivery does not happen automatically; it takes significant time, concerted effort, additional resources and therefore has cost implications. As shown in the literature (Chapter 2), investment in QI can lead to both improvements in care and cost savings, for example by reducing the amount of patient time on mechanical ventilation and length of ICU stay. As the cost of improvement strategies will be additional to the costs of delivering current services, healthcare providers must demonstrate that any proposed interventions will provide value for money and that proposed changes to systems and processes are sustainable without ongoing additional resources. Although it was beyond the scope of this research to perform a costing analysis, the costs associated with this research programme were minimal, particularly in relation to the cost of running an intensive care service. Health services that have funded research and/or quality improvement positions would be able to replicate these studies with relative ease and at minimal additional cost. It is unknown whether economies of scale mean that smaller units will be able to follow suit; an

alternative option could involve them working together with a larger unit that may be able to offer support in achieving the same goal – improved quality of care delivered to patients.

Recommendations for further research

As evidenced in the results from the multi-centre point prevalence study and the single site intervention study, there was variability in practice both within and between ICUs. Further research could examine the reasons for this which would help to inform future QI strategies. It would also be useful to know what impact variability in practice has on patient outcomes as this would help prioritise further work in this area and where resources should be directed.

After reviewing the results of this research in conjunction with the existing evidence-base, it was apparent that additional studies around all care processes are required to ensure the right care is delivered to the right person, at the right time. This includes large pragmatic clinical trials focussing on processes of care where there is currently equivocal evidence. Quality and safety in intensive care is essentially a moving target – as clinical research evolves, so must quality improvement strategies.

In light of the findings from this research, there is more work to be done around evaluating the utility of checklists in clinical practice, including conducting a larger multi-centre study adequately powered to detect significant differences in patient outcomes e.g. adverse events. Such studies could incorporate observations of the ward rounds which would enable detailed description of checklist use in clinical practice including where and when it is used, how long it takes to complete, and whether there are any disruptions or distractions to the process. Reliability testing of the checklist is also required and as shown in the intervention study, can be built into prospective research designs. Given advancements in technology, testing the utility of checklists integrated into different electronic platforms such as smartphones, tablet PCs and clinical information systems is also recommended. Comparing an e-checklist with similar clinical support tools or across different delivery

platforms, would demonstrate the benefits and limitations of each, assisting clinicians to select the most suitable tool for integration into their routine clinical practice.

Conclusion

Use of an electronic process-of-care checklist during medical ward rounds in an ICU improved delivery of care to patients. With variability in practice demonstrated across Australia and New Zealand, increased use of clinical practice tools such as the e-checklist is recommended. In addition to demonstrating improvements to care delivery, this programme of research has provided a substantial amount of evidence in support of the e-checklist's validity, an important factor to consider prior to implementing any clinical practice tool. Although there is further work recommended, results of this research demonstrated that the e-checklist was effective in supporting intensive care practice and there may be even greater benefits to be realised with advancements in information and communication technologies.

References

Agarwal, S., Frankel, L., Tourner, S., McMillan, A. & Sharek, P.J. 2008, 'Improving communication in a pediatric intensive care unit using daily patient goal sheets', *Journal of Critical Care*, vol. 23, no. 2, pp. 227-35.

Alhazzani, W., Alshahrani, M., Moayyedi, P. & Jaeschke, R. 2012, 'Stress ulcer prophylaxis in critically ill patients: review of the evidence', *Polskie Archiwum Medycyny Wewnetrznej*, vol. 122, no. 3, pp. 107-14.

Alhazzani, W., Lim, W., Jaeschke, R.Z., Murad, M.H., Cade, J. & Cook, D.J. 2013, 'Heparin thromboprophylaxis in medical-surgical critically ill patients: a systematic review and meta-analysis of randomized trials', *Critical Care Medicine*, vol. 41, no. 9, pp. 2088-98.

Alsadat, R., Al-Bardan, H., Mazloum, M.N., Shamah, A.A., Eltayeb, M.F.E., Marie, A., Dakkak, A., Naes, O., Esber, F. & Betelmal, I. 2012, 'Use of ventilator associated pneumonia bundle and statistical process control chart to decrease VAP rate in Syria', *Avicenna Journal of Medicine*, vol. 2, no. 4, pp. 79-83.

Alvarez, G. & Coiera, E. 2005, 'Interruptive communication patterns in the intensive care unit ward round', *International Journal of Medical Informatics*, vol. 74, no. 10, pp. 791-6.

American Educational Research Association, American Psychological Association, Joint Committee on Standards for Educational and Psychological Testing & National Council on Measurement in Education 1999, *Standards for educational and psychological testing*, Americal Educational Research Association, Washington, DC.

Askarian, M., Kouchak, F. & Palenik, C.J. 2011, 'Effect of surgical safety checklists on postoperative morbidity and mortality rates, Shiraz, Faghihy Hospital, a 1-year study', *Quality Management in Healthcare*, vol. 20, no. 4, pp. 293-7.

Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2010, 'Acute pain management in intensive care', in P.E. Macintyre, D.A. Scott, S.A. Schug, E.J. Visser & S.M. Walker (eds), *Acute pain management: Scientific Evidence*, Third edn, ANZCA & FPM, Melbourne.

Australian Commission on Safety & Quality in Healthcare 2006, *Australian Government Department of Health and Ageing*, Web page, viewed 7 July 2009 <http://www.safetyandquality.gov.au/>.

Australian Commission on Safety & Quality in Healthcare 2007, *Update*, Australian Government Department of Health and Ageing, Canberra.

Australian Institute of Health and Welfare & The Australian Commission on Safety and Quality in Health Care 2007, *Sentinel events in Australian public hospitals 2004-05*, no. HSE 51, AIHW, Canberra.

Australian Wound Management Association 2001, *Clinical practice guidelines for the prediction and prevention of pressure ulcers*, Cambridge Publishing, West Leederville, WA.

Bagshaw, S.M., Bellomo, R., Jacka, M.J., Egi, M., Hart, G.K. & George, C. 2009a, 'The impact of early hypoglycemia and blood glucose variability on outcome in critical illness', *Critical Care* vol. 13, no. 3, p. R91.

Bagshaw, S.M., Egi, M., George, C. & Bellomo, R. 2009b, 'Early blood glucose control and mortality in critically ill patients in Australia', *Critical Care Medicine*, vol. 37, no. 2, pp. 463-70.

Ballermann, M.A., Shaw, N.T., Mayes, D.C., Gibney, R.T. & Westbrook, J.I. 2011, 'Validation of the work observation method by activity timing (WOMBAT) method of conducting time-motion observations in critical care settings: An observational study', *BMC Medical Informatics & Decision Making*, vol. 11, no. 32.

BBC News 2009, *Surgical checklist 'saves lives'*, news article, BBC News, viewed 29 July 2009 <http://news.bbc.co.uk/2/hi/health/7825780.stm>.

Beckmann, U., Bohringer, C., Carless, R., Gillies, D.M., Runciman, W.B. & Pronovost, P.J. 2003, 'Evaluation of two methods for quality improvement in intensive care: facilitated incident monitoring and retrospective medical chart review', *Critical Care Medicine*, vol. 31, no. 4, pp. 1006-11.

Benneyan, J., Lloyd, R. & Plsek, P. 2003, 'Statistical process control as a tool for research and healthcare improvement', *Quality & Safety in Health Care*, vol. 12, no. 6, pp. 458-64.

Berenholtz, S. & Pronovost, P. 2007, 'Monitoring patient safety', *Critical Care Clinics*, vol. 23, pp. 659-73.

Berenholtz, S. & Pronovost, P.J. 2003, 'Barriers to translating evidence into practice', *Current Opinion in Critical Care*, vol. 9, pp. 321-5.

Berenholtz, S.M., Dorman, T., Ngo, K. & Pronovost, P.J. 2002, 'Qualitative review of intensive care unit quality indicators', *Journal of Critical Care*, vol. 17, no. 1, pp. 1-12.

Berenholtz, S.M., Pham, J.C., Thompson, D.A., Needham, D.M., Lubomski, L.H., Hyzy, R.C., Welsh, R., Cosgrove, S.E., Sexton, J.B., Colantuoni, E., Watson, S.R., Goeschel, C.A. & Pronovost, P.J. 2011, 'Collaborative cohort study of an intervention to reduce ventilator-associated pneumonia in the intensive care unit', *Infection Control and Hospital Epidemiology*, vol. 32, no. 4, pp. 305-14.

Berwick, D.M., Calkins, D.R., McCannon, C.J. & Hackbarth, A.D. 2006, 'The 100,000 lives campaign: setting a goal and a deadline for improving health care quality', *Journal of the American Medical Association*, vol. 295, no. 3, pp. 324-7.

Bion, J.F., Abrusci, T. & Hibbert, P. 2010, 'Human factors in the management of the critically ill patient', *British Journal of Anaesthesia*, vol. 105, no. 1, pp. 26-33.

Biondo, P.D., Nekolaichuk, C.L., Stiles, C., Fainsinger, R. & Hagen, N.A. 2008, 'Applying the delphi process to palliative care tool development: lessons learned', *Supportive Care in Cancer*, vol. 16, no. 8, pp. 935-42.

Bishop, S., Young, H., Goldsmith, D., Buldock, D., Chin, M. & Bellomo, R. 2010, 'Bowel motions in critically ill patients: a pilot observational study', *Critical Care and Resuscitation*, vol. 12, no. 3, pp. 182-5.

Blackwood, B., Alderdice, F., Burns, K., Cardwell, C., Lavery, G. & O'Halloran, P. 2011, 'Use of weaning protocols for reducing duration of mechanical ventilation in critically ill adult patients: Cochrane systematic review and meta-analysis', *BMJ*, vol. 342, p. c7237.

Bliss, L.A., Ross-Richardson, C.B., Sanzari, L.J., Shapiro, D.S., Lukianoff, A.E., Bernstein, B.A. & Ellner, S.J. 2012, 'Thirty-day outcomes support implementation of a surgical safety checklist', *Journal of the American College of Surgeons*, vol. 215, no. 6, pp. 766-76.

Boberg, A.L. & Morris-Khoo, S.A. 1992, 'The Delphi method: a review of methodology and an application in the evaluation of a higher education program', *The Canadian Journal of Program Evaluation*, vol. 7, no. 1, pp. 27-39.

Bochicchio, G.V., Smit, P.A., Moore, R., Bochicchio, K., Auwaerter, P., Johnson, S.B., Scalea, T. & Bartlett, J.G. 2006, 'Pilot study of a web-based antibiotic decision management guide', *Journal of the American College of Surgeons*, vol. 202, no. 3, pp. 459-67.

Böhmer, A.B., Wappler, F., Tinschmann, T., Kindermann, P., Rixen, D., Bellendir, M., Schwanke, U., Bouillon, B. & Gerbershagen, M.U. 2012, 'The implementation of a perioperative checklist increases patients' perioperative safety and staff satisfaction', *Acta Anaesthesiologica Scandinavica*, vol. 56, no. 3, pp. 332-8.

Boorman, D. 2001, 'Today's electronic checklists reduce likelihood of crew errors and help prevent mishaps', *ICAO Journal*, vol. 56, no. 1, pp. 17-20.

Bosman, R.J. 2009, 'Impact of computerized information systems on workload in operating room and intensive care unit', *Best Practice & Research Clinical Anaesthesiology*, vol. 23, pp. 15-26.

Bourne, L.E. & Yaroush, R.A. 2003, *Stress and cognition: a cognitive psychological perspective*, National Aeronautics and Space Administration - Grant Number NAG2-1561, Boulder, CO.

Braga, J.M., Hunt, A., Pope, J. & Molaison, E. 2006, 'Implementation of dietitian recommendations for enteral nutrition results in improved outcomes', *Journal of the American Dietetic Association*, vol. 106, pp. 281-4.

Brook, A.D., Ahrens, T.S., Schaiff, R., Prentice, D., Sherman, G., Shannon, W. & Kollef, M.H. 1999, 'Effect of a nursing-implemented sedation protocol on the duration of mechanical ventilation', *Critical Care Medicine*, vol. 27, no. 12, pp. 2609-15.

Brown, C.A. & Lilford, R.J. 2006, 'The stepped wedge trial design: a systematic review', *BMC Medical Journal*, vol. 6, no. 54, pp. 1-9.

Brunkhorst, F.M., Engel, C., Ragaller, M., Welte, T., Rossaint, R., Gerlach, H., Mayer, K., John, S., Stuber, F., Weiler, N., Oppert, M., Moerer, O., Bogatsch, H., Reinhart, K., Loeffler, M., Hartog, C. & for the German Sepsis Competence Nework 2008, 'Practice and perception - a nationwide survey of therapy habits in sepsis', *Critical Care Medicine*, vol. 36, no. 10, pp. 2719-25.

Buckley, T.A., Short, T.G., Rowbottom, Y.M. & Oh, T.E. 1997, 'Critical incident reporting in the intensive care unit', *Anaesthesia*, vol. 52, no. 5, pp. 403-9.

Burrell, A.R., McLaws, M.-L., Murgo, M., Calabria, E., Pantle, A.C. & Herkes, R. 2011, 'Aseptic insertion of central venous lines to reduce bacteraemia: the Central line associated bacteraemia in NSW intensive care units (CLAB ICU) collaborative', *Medical Journal of Australia*, vol. 194, no. 11, pp. 583-7.

Byrnes, M.C., Schuerer, D.J.E., Schallom, M.E., Sona, C.S., Mazuski, J.E., Taylor, B.E., McKenzie, W., Thomas, J.M., Emerson, J.S., Nemeth, J.L., Bailey, R.A., Boyle, W.A., Buchman, T.G. & Coopersmith, C.M. 2009, 'Implementation of a mandatory checklist of protocols and objectives improves compliance with a wide range of evidence-based intensive care unit practices', *Critical Care Medicine*, vol. 37, no. 10, pp. 1-7.

Byrt, T., Bishop, J. & Carlin, J.B. 1993, 'Bias, prevalence and kappa', *Journal of Clinical Epidemiology*, vol. 46, no. 5, pp. 423-9.

Cabana, M.D., Rand, C.S., Powe, N.R., Wu, A., Wilson, M.H., Abboud, P.-A.C. & Rubin, H.R. 1999, 'Why don't physicians follow clinical practice guidelines?: a framework for improvement', *Journal of the American Medical Association*, vol. 282, no. 15, pp. 1458-65.

Camporota, L. & Brett, S. 2011, 'Care bundles: Implementing evidence or common sense?', *Critical Care*, vol. 15, no. 159.

Centofanti, J.E., Duan, E.H., Hoad, N.C., Swinton, M.E., Perri, D., Waugh, L. & Cook, D.J. 2014, 'Use of a daily goals checklist for morning ICU rounds: a mixed-methods study', *Critical Care Medicine*, vol. 42, no. 8, pp. 1797-803.

Chanques, G., Jaber, S., Barbotte, E., Violet, S., Sebbane, M., Perrigault, P.-F., Mann, C., Lefrant, J.-Y. & Eledjam, J.-J. 2006, 'Impact of systematic evaluation of pain and agitation in an intensive care unit', *Critical Care Medicine*, vol. 34, no. 6, pp. 1691-9.

Chisholm, C.D., Weaver, C.S., Whenmouth, L.F., Giles, B. & Brizendine, E.J. 2008, 'A comparison of observed versus documented physician assessment and treatment of pain: the physician record does not reflect the reality', *Annals of Emergency Medicine*, vol. 52, no. 4, pp. 383-9.

Cicchetti, D.V. & Feinstein, A.R. 1990, 'High agreement but low kappa: II. Resolving the paradoxes', *Journal of Clinical Epidemiology*, vol. 43, no. 6, pp. 551-8.

Clemmer, T.P., Spuhler, V.J., Oniki, T.A. & Horn, S.D. 1999, 'Results of a collaborative quality improvement program on outcomes and costs in a tertiary critical care unit', *Critical Care Medicine*, vol. 27, no. 9, pp. 1768-74.

Collins, S.A., Bakken, S., Vawdrey, D.K., Coiera, E. & Currie, L.M. 2011, 'Agreement between common goals discussed and documented in the ICU', *Journal of American Medical Informatics Association*, vol. 18, pp. 45-50.

Colpaert, K., Vanbelleghem, S., Danneels, C., Benoit, D., Steurbaut, K., Van Hoecke, S., De Turck, F. & Decruyenaere, J. 2010, 'Has information technology finally been adopted in Flemish intensive care units', *BMC Medical Informatics and Decision Making*, vol. 10, p. 62.

Commonwealth of Australia 2002, *The national strategy for quality use of medicines*, Commonwealth of Australia, Canberra.

Conroy, K.M., Elliott, D. & Burrell, A.R. 2013a, 'Developing content for a process-of-care checklist for use in intensive care units: a dual-method approach to establishing construct validity', *BMC Health Services Research*, vol. 13, no. 1, p. 380.

Conroy, K.M., Elliott, D. & Burrell, A.R. 2013b, 'Validating a process-of-care checklist for intensive care units', *Anaesthesia & Intensive Care*, vol. 41, no. 3, pp. 342-8.

Craig, A.E. 2007, 'Personal digital assistants: Practical advice for clinicians in 2007', *Topics in Advances Practice Nursing eJournal*, vol. 7, no. 1.

Crisp, J., Pelletier, D., Duffield, C., Adams, A. & Nagy, S. 1997, 'The Delphi method?', *Nursing Research*, vol. 46, no. 2, pp. 116-8.

Critical Care Clinical Practice Guidelines Committee 2009, 'Updated recommendations', *Clinical practice guidelines for nutrition support in the mechanically ventilated, critically ill adult*, <http://www.criticalcarenutrition.com/>.

Crunden, E., Boyce, C., Woodman, H. & Bray, B. 2005, 'An evaluation of the impact of the ventilator care bundle', *Nursing in Critical Care*, vol. 10, no. 5, pp. 242-6.

Davis, B., Welch, K., Walsh-Hart, S., Hanseman, D., Petro, M., Gerlach, T., Dorlac, W., Collins, J. & Pritts, T. 2014, 'Effective teamwork and communication mitigate task saturation in simulated critical care air transport team missions', *Military Medicine*, vol. 179, no. 8S, pp. 19-23.

de Vos, M., Graafmans, W., Keesman, E., Westert, G. & van der Voort, P.H.J. 2007, 'Quality measurement at intensive care units: which indicators should we use?', *Journal of Critical Care*, vol. 22, pp. 267-74.

Degani, A. & Wiener, E.L. 1990, *Human factors of flight-deck checklists: the normal checklist*, Ames Research Center, San Jose, CA.

DeGrado, J.R., Anger, K.E., Szumita, P.M., Pierce, C.D. & Massaro, A.F. 2011, 'Evaluation of a local ICU sedation guideline on goal-directed administration of sedatives and analgesics', *Journal of Pain Research*, vol. 4, pp. 127-34.

Dellinger, R.P., Levy, M.M., Carlet, J.M., Bion, J., Parker, M.M., Jaeschke, R., Reinhart, K., Angus, D.C., Brun-Buisson, C., Beale, R., Calandra, T., Dhainaut, J.-F., Gerlach, H., Harvey, M., Marini, J.J., Marshall, J., Ranieri, M., Ramsay, G., Sevransky, J., Thompson, T., Townsend, S., Vender, J.S., Zimmerman, J.L. & Vincent, J.-L. 2008, 'Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock: 2008', *Critical Care Medicine*, vol. 36, no. 1, pp. 296-327.

DeVon, H.A., Block, M.E., Moyle-Wright, P., Ernst, D.M., Hayden, S.J., Lazzara, D.J., Savoy, S.M. & Kostas-Polston, E. 2007, 'A psychometric toolbox for testing validity and reliability', *Journal of Nursing Scholarship*, vol. 39, no. 2, pp. 155-64.

Dobkin, E. 2003, 'Checkoffs play key role in SICU improvement: checklist helps team follow care plan', *Healthcare Benchmarks & Quality Improvement*, vol. 10, no. 10, p. 113-115.

Doig, G.S., Heighes, P.T., Simpson, F., Sweetman, E.A. & Davies, A.R. 2009, 'Early enteral nutrition, provided within 24 h of injury or intensive care unit admission, significantly reduces mortality in critically ill patients: a meta-analysis of randomised controlled trials', *Intensive Care Medicine*, vol. 35, pp. 2018-27.

Donabedian, A. 1966, 'Evaluating the quality of medical care', *Milbank Quarterly*, vol. 44, no. 3, p. 166-203.

Drakulovic, M.B., Torres, A., Bauer, T.T., Nicolas, J.M., Nogue, S. & Ferrer, M. 1999, 'Supine body position as a risk factor for nosocomial pneumonia in mechanically ventilated patients: a randomised trial', *Lancet*, vol. 354, no. 9193, pp. 1851-8.

Drennan, K., Hart, G. & Hicks, P. 2010, *Intensive care resources and activity: Australia and New Zealand 2007/2008*, Australia and New Zealand Intensive Care Society, Melbourne.

Dries, D.J., McGonigal, M.D., Malian, M.S., Bor, B.J. & Sullivan, C. 2004, 'Protocol-driven ventilator weaning reduces use of mechanical ventilation, rate of early reintubation, and ventilator-associated pneumonia', *Journal of Trauma - Injury, Infection and Critical Care*, vol. 56, no. 5, pp. 943-52.

DuBose, J.J., Inaba, K., Shiflett, A., Trankiem, C., Teixeira, P., Salim, A., Rhee, P., Demetriades, D. & Belzberg, H. 2008, 'Measureable outcomes of quality improvement in the trauma intensive care unit: the impact of a daily quality rounding checklist', *Journal of Trauma - Injury, Infection and Critical Care*, vol. 64, pp. 22-9.

Duffield, C. 1993, 'The Delphi technique: a comparison of results obtained using two expert panels', *International Journal of Nursing Studies*, vol. 30, no. 3, pp. 227-37.

Durieux, P., Nizard, R., Ravaud, P. & al, e. 2000, 'A clinical decision support system for prevention of venous thromboembolism: effect on physician behaviour', *Journal of the American Medical Association*, vol. 283, no. 21, pp. 2816-21.

Elliott, D., Aitken, L.M., Bucknall, T.K., Seppelt, I.M., Webb, S.A., Weisbrodt, L. & McKinley, S. 2013, 'Patient comfort in the intensive care unit: a multicentre, binational point prevalence study of analgesia, sedation and delirium management', *Critical Care and Resuscitation*, vol. 15, no. 3, p. 213.

Ely, E.W., Baker, A.M., Dunagan, D.P., Burke, H.L., Smith, A.C., Kelly, P.T., Johnson, M.M., Browder, R.W., Bowton, D.L. & Haponik, E.F. 1996, 'Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously', *The New England Journal of Medicine*, vol. 335, pp. 1864-9.

Erdek, M.A. & Pronovost, P.J. 2004, 'Improving assessment and treatment of pain in the critically ill', *International Journal of Quality in Health Care*, vol. 16, no. 1, pp. 59-64.

Eslami, S., Abu-Hanna, A., de Jonge, E. & de Keizer, N.F. 2009, 'Tight glycemic control and computerized decision-support systems: a systematic review', *Intensive Care Medicine*, vol. 35, pp. 1505-17.

Ferenci, T., Benyo, B., Kovacs, L., Fisk, L., Shaw, G.M. & Chase, J.G. 2013, 'Daily evolution of insulin sensitivity variability with respect to diagnosis in the critically ill', *PLOS One*, vol. 8, no. 2, p. e57119.

Fernandez Perez, E.R., Winters, J.L. & Gajic, O. 2007, 'The addition of decision support into computerized physician order entry reduces red blood cell transfusion resource utilization in the intensive care unit', *American Journal of Hematology*, vol. 82, no. 7, pp. 631-3.

Finfer, S., Chittock, D.R., Su, S.Y.-S., Blair, D., Foster, D., Dhingra, V., Bellomo, R., Cook, D., Dodek, P., Henderson, W.R., Hebert, P.C., Heritier, S., Heyland, D.K., McArthur, C., McDonald, E., Mitchell, I., Myburgh, J.A., Norton, R., Potter, J., Robinson, B.G., Ronco, J.J. on behalf of the NICE-SUGAR Study Investigators. 2009, 'Intensive versus conventional glucose control in critically ill patients', *The New England Journal of Medicine*, vol. 360, no. 13, pp. 1283-97.

Fitzpatrick, K.R., Pantle, A.C., McLaws, M.-L. & Hughes, C.F. 2009, 'Culture change for hand hygiene: Clean hands save lives, Part II', *MJA*, vol. 191, no. 8, pp. S13-S6.

Frutiger, A. 1997, 'Process quality in the intensive care unit', *Acta Anaesthesiologica Scandinavica*, vol. 41, no. 1 (Supplement 111), pp. 14-6.

Fulbrook, P. & Mooney, S. 2003, 'Care bundles in critical care: a practical approach to evidence-based practice', *Nursing in Critical Care*, vol. 8, no. 6, pp. 249-55.

Garland, A. 2005a, 'Improving the ICU: Part 1', *Chest*, vol. 127, pp. 2151-64.

Garland, A. 2005b, 'Improving the ICU: Part 2', *Chest*, vol. 127, no. 6, pp. 2165-79.

Garson, D. 2013, *Generalized Linear Models & Generalized Estimating Equations*, Statistical Associates Publishers, Asheboro, North Carolina.

Gawande, A.A. 2007, 'The checklist: if something so simple can transform intensive care, what else can it do?', *The New Yorker*, 10 December 2007.

Geisinger, K.F. 1992, 'The metamorphosis of test validation', *Educational Psychologist*, vol. 27, no. 2, pp. 197-222.

Gershon, R.R.M., Karkashian, C.D., Grosch, J.W., Murphy, L.R., Escamilla-Cejudo, A., Flanagan, P.A., Bernacki, E., Kasting, C. & Martin, L. 2000, 'Hospital safety climate and its relationship with safe work practices and workplace exposure incidents', *American Journal of Infection Control*, vol. 28, no. 3, pp. 211-21.

Goodwin, L. 2002, 'Changing conceptions of measurement validity: an update on the new Standards', *Nursing Education*, vol. 41, no. 3, pp. 100-6.

Grimshaw, J.M., Shirran, L., Thomas, R., Mowatt, G., Fraser, C., Bero, L., Grilli, R., Harvey, E., Oxman, A. & O'Brien, M.A. 2001, 'Changing provider behavior: an overview of systematic reviews of interventions', *Medical Care*, vol. 39, no. 8, pp. II2-II45.

Grol, R. 1997, 'Personal paper: beliefs and evidence in changing clinical practice', *BMJ*, vol. 315, no. 7105, pp. 418-21.

Grol, R., Dalhuijsen, J. & Thomas, S. 1998, 'Attributes of clinical guidelines that influence use of guidelines in general practice: observational study', *BMJ*, vol. 317, pp. 858-61.

Hales, B., Terblanche, M., Fowler, R. & Sibbald, W. 2008, 'Development of medical checklists for improved quality of patient care', *International Journal Quality Health Care*, vol. 20, no. 1, pp. 22-30.

Hales, B.M. & Pronovost, P. 2006, 'The checklist - a tool for error management and performance improvement', *Journal of Critical Care*, vol. 21, pp. 231-5.

Hallgren, K.A. 2012, 'Computing inter-rater reliability for observational data: an overview and tutorial', *Tutorials in Quantitative Methods for Psychology*, vol. 8, no. 1, pp. 23-34.

Hart, E.M. & Owen, H. 2005, 'Errors and omissions in anesthesia: a pilot study using a pilot's checklist', *Anesthesia & Analgesia*, vol. 101, pp. 246-50.

Hasson, F. & Keeney, S. 2011, 'Enhancing rigour in the Delphi technique research', *Technological Forecasting & Social Change*, vol. 78, pp. 1695-704.

Hasson, F., Keeney, S. & McKenna, H. 2000, 'Research guidelines for the Delphi survey technique', *Journal of Advanced Nursing*, vol. 32, no. 4, pp. 1008-15.

Hatler, C.W., Mast, D., Corderella, J., Mitchell, G., Howard, K., Aragon, J. & Bedker, D. 2006, 'Using evidence and process improvement strategies to enhance healthcare outcome for the critically ill: a pilot project', *American Journal of Critical Care*, vol. 15, no. 6, pp. 549-55.

Haynes, A.B., Weiser, T.G., Berry, W.R., Lipsitz, S.R., Breizat, A.-H., Dellinger, P., Herbosa, T., Joseph, S., Kibatala, P.L., Lapitan, M.C.M., A.F., M., Moorthy, K., Reznick, R.K., Taylor, B. & Gawande, A.A. 2009, 'A surgical safety checklist to reduce morbidity and mortality in a global population', *The New England Journal of Medicine*, vol. 360, pp. 491-9.

Haynes, A.B., Weiser, T.G., Berry, W.R., Lipsitz, S.R., Breizat, A.H., Dellinger, E.P., Dziekan, G., Herbosa, T., Kibatala, P.L., Lapitan, M.C., Merry, A.F., Reznick, R.K., Taylor, B., Vats, A., Gawande, A.A. & Safe Surgery Saves Lives Study Group 2011, 'Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention', *BMJ Quality & Safety*, vol. 20, no. 1, pp. 102-7.

Hermanides, J., Vriesendorp, T.M., Bosman, R.J., Zandstra, D.F., Hoekstra, J.B. & DeVries, J.H. 2010, 'Glucose variability is associated with intensive care unit mortality', *Critical Care Medicine*, vol. 38, no. 3, pp. 838-42.

Hewson-Conroy, K.M., Burrell, A.R., Elliott, D., Webb, S.A.R., Seppelt, I.M., Taylor, C. & Glass, P. 2011, 'Compliance with processes of care in intensive care units in Australia and New Zealand- A point prevalence study', *Anaesthesia and Intensive Care*, vol. 39, no. 5, pp. 926-35.

Hewson-Conroy, K.M., Elliott, D. & Burrell, A.R. 2010, 'Quality and safety in intensive care - A means to an end is critical', *Australian Critical Care*, vol. 23, no. 3, pp. 109-29.

Hewson, K.M. & Burrell, A.R. 2006, 'A pilot study to test the use of a checklist in a tertiary intensive care unit as a method of ensuring quality processes of care', *Anaesthesia and Intensive Care*, vol. 34, pp. 322-8.

Heyland, D.K., Cook, D. & Dodek, P.M. 2002, 'Prevention of ventilator-associated pneumonia: Current practice in Canadian intensive care units', *Journal of Critical Care*, vol. 17, no. 3, pp. 161-7.

Heyland, D.K., Dhaliwal, R., Drover, J.W., Gramlich, L., Dodek, P. & and the Canadian Critical Care Clinical Practice Guidelines Committee 2003, 'Canadian clinical practice guidelines for nutrition support in mechanically ventilated, critically ill adult patient', *Journal of Parenteral and Enteral Nutrition*, vol. 27, no. 5, pp. 355-73.

Huang, D.T., Clermont, G., Kong, L., Weissfeld, L.A., Sexton, B., Rowan, K.M. & Angus, D.C. 2010, 'Intensive care unit safety culture and outcomes: a US multicenter study', *International Journal for Quality in Health Care*, vol. 22, no. 3, pp. 151-61.

Huang, H.C., Lin, W.C. & Lin, J.D. 2008, 'Development of a fall-risk checklist using the delphi technique', *Journal of Clincial Nursing*, vol. 17, pp. 2275-83.

Hunt, D.L., Haynes, R.B., Hanna, S.E. & Smith, K. 1998, 'Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review', *Journal of the American Medical Association*, vol. 280, no. 15, pp. 1339-46.

Ilan, R. & Fowler, R. 2005, 'Brief history of patient safety culture and science', *Journal of Critical Care*, vol. 20, pp. 2-5.

Ilan, R., Fowler, R.A., Geerts, R., Pinto, R., Sibbald, W.J. & Martin, C.M. 2007, 'Knowledge translation in critical care: factors associated with prescription of commonly recommended best practices for critically ill patients', *Critical Care Medicine*, vol. 35, no. 7, pp. 1696-702.

Institute for Healthcare Improvement 2006, 'Getting started kit: Prevent ventilator-associated pneumonia: How-to guide', *Critical Care Nursing Quarterly*, vol. 29, no. 2, pp. 157-73.

Institute for Healthcare Improvement. 2010, *Getting Started Kit: Prevent Ventilator-Associated Pneumonia How-to Guide*, 5 Million Lives Campaign, Cambridge, MA.

Institute of Medicine Committee on Quality of Health Care in America. 2001, *Crossing the quality chasm: a new health system for the 21st century*, National Academy Press, Washington, DC.

Iregui, M., Ward, S., Clinikscale, D., Clayton, D. & Kollef, M.H. 2002, 'Use of a handheld computer by respirtory care practitioners to improve the efficiency of weaning patients from mechanical ventilation', *Critical Care Medicine*, vol. 30, no. 9, pp. 2038-43.

Jacobi, J., Fraser, G.L., Coursin, D.B., Riker, R.R., Fontaine, D.K., Wittbrodt, E.T., Chalfin, D.B., Masica, M.F., Bjerke, S., Choplin, W.M., Crippen, D., Fuchs, B.D., Kelleher, R.M., Marik, P.E., Nasraway, S.A., Murray, M.J., Peruzzi, W.T. & Lumb, P.D. 2002, 'Clinical practice guildelines for the sustained use of sedatives and analgesics in the critically ill adult', *Critical Care Medicine*, vol. 30, no. 1, pp. 119-41.

Kanji, S., Singh, A., Tierney, M., Meggison, H., McIntyre, L. & Hebert, P.C. 2004, 'Standardization of intravenous insulin therapy improves the efficiency and safety of blood glucose control in critically ill adults', *Intensive Care Medicine*, vol. 30, no. 5, pp. 804-10.

Kawamoto, K., Houlihan, C.A., Balas, E.A. & Lobach, D.F. 2005, 'Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success', *BMJ* vol. 330, pp. 765-73.

Kearns, R.J., Uppal, V., Bonner, J., Robertson, J., Daniel, M. & McGrady, E.M. 2011, 'The introduction of a surgical safety checklist in a tertiary referral obstetric centre', *BMJ Quality & Safety*, vol. 20, no. 9, pp. 818-22.

Keeney, S., Hasson, F. & McKenna, H. 2006, 'Consulting the oracle: ten lessons from using the Delphi technique in nursing research', *Journal of Advanced Nursing*, vol. 53, no. 2, pp. 205-12.

Keroack, M.A., Cerese, J., Cuny, J., Bankowitz, R., Neikirk, H.J. & Pingleton, S.K. 2006, 'The relationship between evidence-based practices and survival in patients requiring prolonged mechanical ventilation in academic medical centers', *American Journal of Medical Quality*, vol. 21, pp. 91-100.

Kho, A., Henderson, L.E., Dressler, D.D. & Kripalani, S. 2006, 'Use of handheld computer in medical education', *Journal of General Internal Medicine*, vol. 21, no. 5, pp. 531-7.

Kho, M.E., Carbone, J.M. & Cook, D.J. 2005, 'Safety climate survey: reliability of results from a multicenter ICU survey', *Quality & Safety in Health Care*, vol. 14, pp. 273-8.

Ko, H., Turner, T.J. & Finnigan, M.A. 2011, 'Systematic review of safety checklists for use by medical care teams in acute hospital settings - Limited evidence of effectiveness', *BMC Health Services Research*, vol. 11, p. 211.

Kohn, L.T., Corrigan, J.M. & Donaldson, M.S. 1999, *To err is human: building a safer health system*, Institute of Medicine, Washington, DC.

Kraemer, H.C., Periyakoil, V.S. & Noda, A. 2002, 'Kappa coefficients in medical research', *Statistics in Medicine*, vol. 21, pp. 2109-29.

Kress, J.P., Pohlman, A.S., O'Connor, M.F. & Hall, J.B. 2000, 'Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation', *The New England Journal of Medicine*, vol. 342, no. 20, pp. 1471-7.

Krimsky, W.S., Mroz, I.B., McIlwaine, J.K., Surgenor, S.D., Christain, D., Corwin, H.L., Houston, D., Robison, C. & Malayaman, N. 2009, 'A model for increasing patient safety in the intensive care unit: increasing the implementation rates of proven safety measures', *Quality & Safety in Health Care*, vol. 18, pp. 74-80.

Kutcher, M.E., Pepper, M.B., Morabito, D., Sunjaya, D., Knudson, M.M. & Cohen, M.J. 2011, 'Finding the sweet spot: identification of optimal glucose levels in critically injured patients', *Journal of Trauma*, vol. 71, no. 5, pp. 1108-14.

Lane, D., Ferri, M., Lemaire, J., McLaughlin, K. & Stelfox, H.T. 2013, 'A systematic review of evidence-informed practices for patient care rounds in the ICU', *Critical Care Medicine*, vol. 41, no. 8, pp. 2015-29.

Leape, L.L., Weissman, J.S., Schneider, E.C., Piana, R.N., Gatsonis, C. & Epstien, A.M. 2003, 'Adherence to practice guidelines: the role of specialty society guidelines', *American Heart Journal*, vol. 145, no. 1.

Levy, M.M. 2004, 'Computers in the intensive care unit', *Journal of Critical Care*, vol. 19, no. 4, pp. 199-200.

Li, D., Puntillo, K. & Miaskowski, C. 2008, 'A review of objective pain measures for use with critical care adult patients unable to self-report', *Journal of Pain*, vol. 9, no. 1, pp. 2-10.

Lilford, R., Mohammed, M.A., Spiegelhalter, D. & Thomson, R.T. 2004, 'Use and misuse of process and outcome data in managing performance of acute medical care: avoiding institutional stigma', *Lancet*, vol. 363, pp. 1147-54.

Lohr, K.N. & Schroeder, S.A. 1990, 'A strategy for quality assurance in medicare', *The New England Journal of Medicine*, vol. 322, no. 10, pp. 707-12.

Loughlin, K. & Moore, L. 1979, 'Using Delphi to achieve congruent objectives and activities in a pediatrics department', *Medical Education*, vol. 54, pp. 101-6.

Lu, Y.C., Xiao, Y., Sears, A. & Jacko, J.A. 2005, 'A review and a framework of handheld computer adoption in healthcare', *International Journal of Medical Informatics*, vol. 74, no. 5, pp. 409-22.

Lyerla, F., LeRouge, C., Cooke, D.A., Turpin, D. & Wilson, L. 2010, 'A nursing clinical decision support system and potential predictors of head-of bed position for patients receiving mechanical ventilation', *American Journal of Critical Care*, vol. 19, no. 1, pp. 39-47.

Lyons, M.N., Standley, T.D. & Gupta, A.K. 2010, 'Quality improvement of doctors' shift-change handover in neuro-critical care', *Quality & Safety in Health Care*, vol. 19, p. e62.

Mack, E.H., Wheeler, D.S. & Embi, P.J. 2009, 'Clinical decision support systems in the pediatric intensive care unit', *Pediatric Critical Care Medicine*, vol. 10, no. 1, pp. 23-8.

Marelich, G.P., Murin, S., Battistella, F., Inciardi, J., Vierra, T. & Roby, M. 2000, 'Protocol weaning of mechanical ventilation in medical and surgical patients by respiratory care practitioners and nurses: effect on weaning time and incidence of ventilator-associated pneumonia', *Chest*, vol. 118, no. 2, pp. 459-67.

Marik, P.E. & Zaloga, G.P. 2001, 'Early enteral nutrition in acutely ill patients: a systematic review', *Critical Care Medicine*, vol. 29, no. 12, pp. 2264-70.

Martin, C.M., Doig, G.S., Heyland, D.K., Morrison, T., Sibbald, W.J. & for the Southwestern Ontario Critical Care Research Network. 2004, 'Multicentre, cluster-randomized clinical trial of algorithms for critical-care enteral and parenteral therapy (ACCEPT)', *Canadian Medical Association Journal*, vol. 170, no. 2, pp. 197-204.

Martinez-Motta, J.C., Walker, R.G., Stewart, T.E., Granton, J., Abrahamson, S. & Lapinsky, S.E. 2004, 'Critical care procedure logging using handheld computers', *Critical Care*, vol. 8, no. 5, pp. R336-R42.

McCannon, C.J., Schall, M.W., Calkins, D.R. & Nazem, A.G. 2006, 'Saving 100 000 lives in US hospitals', *BMJ*, vol. 332, pp. 1328-30.

McGlynn, E.A., Asch, S.M., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A. & Kerr, E.A. 2003, 'The quality of health care delivered to adults in the United States', *The New England Journal of Medicine*, vol. 348, pp. 2635-45.

McKenna, H. 1994a, 'The essential elements of a practitioners' nursing model: a survey of psychiatric nurse managers', *Journal of Advanced Nursing*, vol. 19, no. 5, pp. 870-7.

McKenna, H.P. 1994b, 'The Delphi technique: a worthwhile research approach for nursing?', *Journal of Advanced Nursing*, vol. 19, pp. 1221-5.

McKinley, B.A., Moore, F.A., Sailors, R.M., Cocanour, C.S., Marquez, A., Wright, R.K., Tonnesen, A.S., Wallace, C.J., Morris, A.H. & East, T.D. 2001, 'Computerized decision support for mechanical ventilation of trauma induced ARDS: results of a randomized clinical trial', *Journal of Trauma*, vol. 50, no. 3, pp. 415-24.

McKinley, B.A., Parmley, C.L. & Tonneson, A.S. 1999, 'Standardized management of intracranial pressure: a preliminary clinical trial', *Journal of Trauma*, vol. 46, no. 2, pp. 271-9.

McMullin, J.P., Cook, D.J., Meade, M.O., Weaver, B.R., Letelier, L.M., Kahmamoui, K., Higgins, D.A. & Guyatt, G.H. 2002, 'Clinical estimation of trunk position among mechanically ventilated patients', *Intensive Care Medicine*, vol. 28, pp. 304-9.

Mickan, S., Tilson, J.K., Atherton, H., Roberts, N.W. & Heneghan, C. 2013, 'Evidence of effectiveness of health care professionals using handheld computers: a scoping review of systematic reviews', *Journal of Medical Internet Research*, vol. 15, no. 10, p. e212.

Miller, G.A. 1956, 'The magical number seven, plus or minus two: some limits on our capacity for processing information', *Psychological Review*, vol. 63, pp. 81-97.

Mills, J., Chamberlain-Salaum, J., Henry, R., Sando, J. & Summers, G. 2013, 'Nurses in Australian acute care settings: experiences with and outcomes of e-health. An integrative review', *International Journal of Management & Information Technology*, vol. 3, no. 1, pp. 1-8.

Minhas, M., Velasquez, A., Kaul, A. & Celi, L.A. 2013, '697: Do sedation protocols decrease mortality in the ICU: a systematic review & meta-analysis', *Critical Care Medicine*, vol. 41, no. 12, p. A171.

Minkman, M., Ahaus, K., Fabbricotti, I., Nabitz, U. & Huiisman, R. 2009, 'A quality management model for integrated care: results of a Delphi and concept mapping study', *International Journal for Quality in Health Care*, vol. 21, no. 1, pp. 66-75.

Mitchell, M.B. 2012, 'How mobile is your technology?', *Nursing Management*, vol. 43, no. 9, pp. 26-30.

Moreno, R.P., Rhodes, A. & Donchin, Y. 2009, 'Patient safety in intensive care medicine: the declaration of Vienna', *Intensive Care Medicine*, vol. 35, pp. 1667-72.

Morgan, P.J., Lam-McCulloch, J., Herold-McIlroy, J. & Tarshis, J. 2007, 'Simulation performance checklist generation using the delphi technique', *Canadian Journal of Anaesthesia*, vol. 54, no. 12, pp. 992-7.

Morris, A.C., Hay, A.W., Swann, D.G., Everingham, K., McCulloch, C., McNulty, J., Brooks, O., Laurenson, I.F., Cook, B. & Walsh, T.S. 2011, 'Reducing ventilator-associated pneumonia in intensive care: impact of implementing a care bundle', *Critical Care Medicine*, vol. 39, no. 10, pp. 2218-24.

Mostafa, S.M., Bhandari, S., Ritchie, G., Gratton, N. & Wenstone, R. 2003, 'Constipation and its implications in the critically ill patient', *British Journal of Anaesthesia*, vol. 91, no. 6, pp. 815-9.

Moyen, E., Camire, E. & Stelfox, H.T. 2008, 'Clinical review: medication errors in critical care.', *Critical Care*, vol. 12, no. 2.

Muscedere, J., Dodek, P., Keenan, S., Fowler, R., Cook, D., Heyland, D. & for the VAP Guidelines Committee and the Canadian Critical Care Trials Group 2008, 'Comprehensive evidence-based clinical practice guidelines for ventilator-associated pneumonia: Prevention', *Journal of Critical Care*, vol. 23, pp. 126-37.

Narasimhan, M., Eisen, L.A., Mahoney, C.D., Acerra, F.L. & Rosen, M.J. 2006, 'Improving nurse-physician communication and satisfaction in the intensive care unit with a daily goals worksheet', *American Journal of Critical Care*, vol. 15, no. 2, pp. 217-22.

Nassar, A.P.J., da Silva, F.M.Q. & de Cleva, R. 2009, 'Constipation in intensive care unit: Incidence and risk factors', *Journal of Critical Care*, vol. 24, no. 4, pp. 630.e9-.e12.

National Health and Medical Research Council 2009, *Clinical practice guideline for the prevention of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to Australian hospitals*, Melbourne.

Neal, A. & Griffin, M.A. 2006, 'A study of the lagged relationships among safety climate, safety motivation, safety behavior, and accidents at the individual and group levels', *Journal of Applied Psychology*, vol. 91, no. 4, pp. 946-53.

Needham, D.M., Sinopoli, D.J., Dinglas, V.D., Berenholtz, S.M., Korupolu, R., Watson, S.R., Lubomski, L., Goeschel, C. & Pronovost, P. 2009, 'Improving data quality control in quality improvement projects', *International Journal for Quality in Health Care*, vol. 21, no. 3, pp. 145-9.

Norgaard, K., Ringsted, C. & Dolmans, D. 2004, 'Validation of a checklist to assess ward round performance in internal medicine', *Medical Education*, vol. 38, pp. 700-7.

NSW Department of Health 2005, *Medical Records*, Corporate Government and Risk Management, NSW Department of Health, North Sydney.

NSW Department of Health. 2005a, *Medical records in hospitals and community care centres*, Corporate Government and Risk Management, NSW Department of Health, North Sydney.

NSW Department of Health. 2005b, *Records - Principles for creation, management, storage and disposal of health care records*, Nursing and Midwifery Office, NSW Department of Health, North Sydney.

NSW Therapeutic Advisory Group 2007, *Indicators for Quality Use of Medicines in Australian Hospitals*, NSW Therapeutic Advisory Group.

Osmon, S., Harris, C.B., Dunagan, C., Prentice, D., Fraser, V.J. & Kollef, M.H. 2004, 'Reporting of medical errors: an intensive care unit experience', *Critical Care Medicine*, vol. 32, no. 3, pp. 727-33.

Oxman, A.D., Thomson, M.A., Davis, D.A. & Haynes, R.B. 1995, 'No magic bullets: a systematic review of 102 trials of interventions to improve professional practice', *Canadian Medical Association Journal*, vol. 153, no. 10, pp. 1423-31.

Papadimos, T., Hensley, S., Duggan, J., Khuder, S., Borst, M., Fath, J., Oakes, L. & Buchman, D. 2008, 'Implementation of the "FASTHUG" concept decreases the incidence of ventilator-associated pneumonia in a surgical intensive care unit', *Patient Safety in Surgery*, vol. 2, no. 1, p. 3.

Payen, J.-F., Chanques, G., Mantz, J., Hercule, C., Auriant, I., Leguillou, J.-L., Binhas, M., Genty, C., Rolland, C., Bosson, J.-L. & for the DOLOREA Investigators 2007, 'Current practices in sedation and analgesia for mechanically ventilated critically ill patients', *Anesthesiology*, vol. 106, p. 4.

Payne, K.F.B., Wharrad, H. & Watts, K. 2012, 'Smartphone and medical related App use among medical students and junior doctors in the United Kingdom (UK): a regional survey', *BMC Medical Informatics and Decision Making*, vol. 12, no. 1, p. 121.

Peter, J.V., Moran, J.L. & Phillips-Hughes, J. 2005, 'A meta-analysis of treatment outcomes of early enteral versus early parenteral nutrition in hospitalized patients', *Critical Care Medicine*, vol. 33, no. 1, pp. 213-20.

Phipps, L.M. & Thomas, N.J. 2007, 'The use of a daily goals sheet to improve communication in the paediatric intensive care unit', *Intensive and Critical Care Nursing*, vol. 23, no. 5, pp. 264-71.

Piotrowski, M.M. & Hinshaw, D.B. 2002, 'The safety checklist program: creating a culture of safety in intensive care units', *Joint Commission Journal on Quality Improvement*, vol. 28, no. 6, pp. 306-15.

Pittman, J. & Bakas, T. 2010, 'Measurement and instrument design', *Journal of Wound Ostomy and Continence Nursing*, vol. 37, no. 6, pp. 603-7.

Prgomet, M., Georgiou, A. & Westbrook, J.I. 2009, 'The impact of mobile handheld technology on hospital physicians' work practices and patient care: a systematic review', *Journal of the American Medical Informatics Association*, vol. 16, no. 6, pp. 792-801.

Pronovost, P., Berenholtz, S., Goeschel, C.A., Needham, D.M., Sexton, J.B., Thompson, D.A., Lubomski, L.H., Marsteller, J.A., Makary, M.A. & Hunt, E. 2006a, 'Creating high reliability in health care organizations', *Health Research and Educational Trust*, vol. 41, no. 4, pp. 1599-617.

Pronovost, P., Berenholtz, S. & Needham, D.M. 2008, 'Translating evidence into practice: a model for large scale knowledge translation', *BMJ*, vol. 337, pp. 963-5.

Pronovost, P., Holzmueller, C.G., Needham, D.M., Sexton, J.B., Miller, M., Berenholtz, S., Davis, R., Baker, D., Winner, L. & Morlock, L. 2006b, 'How will we know patients are safer? an organization-wide approach to measuring and improving safety', *Critical Care Medicine*, vol. 34, no. 7, pp. 1988-95.

Pronovost, P., Needham, D.M., Berenholtz, S., Sinopoli, D., Chu, H., Cosgrove, S., Sexton, B., Hyzy, R., Welsh, R., Roth, G., Bander, J., Kepros, J. & Goeschel, C. 2006c, 'An intervention to decrease catheter-related bloodstream infections in the ICU', *The New England Journal of Medicine*, vol. 355, no. 26, pp. 2723-32.

Pronovost, P., Weast, B., Rosentein, B., Sexton, J.B., Holzmueller, C.G., Paine, L., Davis, R. & Rubin, H.R. 2005, 'Implementing and validating a comprehensive unit-based safety program', *Journal of Patient Safety*, vol. 1, no. 1, pp. 33-40.

Pronovost, P.J., Berenholtz, S., Dorman, T., Lipsett, P.A., Simmonds, T. & Haraden, C. 2003a, 'Improving communication in the ICU using daily goals', *Journal of Critical Care*, vol. 18, no. 2, pp. 71-5.

Pronovost, P.J., Berenholtz, S., Goeschel, C., Thom, I., Watson, S.R., Holzmueller, C., Lyon, J.S., Lubomski, L., Thompson, D.A., Needham, D.M., Hyzy, R., Welsh, R., Roth, G., Bander, J., Morlock, L. & Sexton, B. 2008, 'Improving patient safety in intensive care units in Michigan', *Journal of Critical Care*, vol. 23, pp. 207-21.

Pronovost, P.J., Berenholtz, S., Ngo, K., McDowell, M., Holzmueller, C., Haraden, C., Resar, R., Rainey, T., Nolan, T. & Dorman, T. 2003b, 'Developing and pilot testing quality indicators in the intensive care unit', *Journal of Critical Care*, vol. 18, no. 3, pp. 145-55.

Pronovost, P.J. & Berenholtz, S.M. 2002, *A practical guide to measuring performance in the intensive care unit*, VHA, Irving, TX.

Pronovost, P.J., Miller, M.R., Dorman, T., Berenholtz, S. & Rubin, H. 2001, 'Developing and implementing measures of quality of care in the intensive care unit', *Current Opinion in Critical Care*, vol. 7, pp. 297-303.

Pronovost, P.J., Nolan, T., Zeger, Miller, M.R. & Rubin, H. 2004a, 'How can clinicians measure safety and quality in acute care?', *Lancet*, vol. 363, pp. 1061-7.

Pronovost, P.J., Sexton, J.B., Pham, J.C., Goeschel, C.A. & Winters, B.D. 2009, 'Measurement of quality and assurance of safety in the critically Ill', *Clinics in Chest Medicine*, vol. 30, pp. 169-79.

Pronovost, P.J., Weast, B., Bishop, K., Paine, L., Griffith, R., Rosenstein, B.J., Kidwell, R.P., Haller, K.B. & Davis, R. 2004b, 'Senior executive adopt-a-work unit: a model for safety improvement', *Joint Commission Journal on Quality and Safety*, vol. 30, no. 2, pp. 59-68.

Pumar-Mendez, M.J., Attree, M. & Wakefield, A. 2014, 'Methodological aspects in the assessment of safety culture in the hospital setting: a review of the literature.', *Nurse Education Today*, vol. 34, pp. 162-70.

Puntillo, K.A., White, C., Morris, A.B., Perdue, S.T., Stanik-Hutt, J., Thompson, C.L. & Wild, L.R. 2001, 'Patients perception and responses to procedural pain: Results from Thunder Project II', *American Journal of Critical Care*, vol. 10, no. 4, pp. 238-51.

Puntillo, K.A., Wild, L.R., Morris, A.B., Stanik-Hutt, J., Thompson, C.L. & White, C. 2002, 'Practices and predictors of analgesic interventions for adults undergoing painful procedures', *American Journal of Critical Care*, vol. 11, no. 5, pp. 415-29.

Radtke, F.M., Heymann, A., Franck, M., Maechler, F., Drews, T., Luetz, A., Nachtigall, I., Wernecke, K.-D. & Spies, C.D. 2012, 'How to implement monitoring tools for sedation, pain and delerium in the intensive care unit: an experimental cohort study', *Intensive Care Medicine*, vol. 38, pp. 1974-81.

Resar, R., Pronovost, P., Haraden, C., Simmonds, T., Rainey, T. & Nolan, T. 2005, 'Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia', *Joint Commission Journal on Quality and Patient Safety*, vol. 31, no. 5, pp. 243-8.

Rhodes, A., Moreno, R.P., Azoulay, E., Capuzzo, M., Chiche, J.D., Eddleston, J., Endacott, R., Ferdinande, P., Flaatten, H. & Guidet, B. 2012, 'Prospectively defined indicators to improve the safety and quality of care for critically ill patients: a report from the Task Force on Safety and Quality of the European Society of Intensive Care Medicine (ESICM)', *Intensive Care Medicine*, vol. 38, no. 4, pp. 598-605.

Roberts-Davis, M. & Read, S. 2001, 'Clinical role clarification: using the Delphi method to establish similarities and differences between nurse practitioners and clinical nurse Specialists', *Journal of Clinical Nursing*, vol. 10, pp. 33-43.

Robertson, M.S., Nichol, A.D., Higgins, A.M., Bailey, M.J., Presneill, J.J., Cooper, D.J., Webb, S.A., McArthur, C., MacIsaac, C.M. & for the V. T. E. Point Prevalence Investigators for the Australian New Zealand Intensive Care Research Centre and Australian and New Zealand Intensive Care Society Clinical Trials Group 2010, 'Venous thromboembolism prophylaxis in the critically ill: a point prevalence survey of current practice in Australian and New Zealand intensive care units', *Critical Care & Resuscitation*, vol. 12, no. 1, pp. 9-15.

Robertson, M.S., Wilson, S.J. & Cade, J.F. 2008, 'Acute stress ulceration prophylaxis: point prevalence surveys in intensive care units in Victoria, 1997 and 2005', *Critical Care and Resuscitation*, vol. 10, no. 1, pp. 15-8.

Rose, L., Presneill, J.J., Johnston, L., Nelson, S. & Cade, J.F. 2009, 'Ventilation and weaning practices in Australia and New Zealand', *Anaesthesia and Intensive Care*, vol. 37, pp. 99-107.

Ross, T.K. 2009, 'A second look at 100 000 lives campaign', *Quality Management in Health Care*, vol. 18, no. 2, pp. 120-5.

Rothschild, J., Landrigan, C.P., Cronin, J.W., Kaushal, R., Lockley, S.W., Burdick, E., Stone, P.H., Lilly, C.M., Katz, J.T., Czeisler, C.A. & Bates, D.W. 2005, 'The critical care safety study: the incidence and nature of adverse events and serious medical errors in intensive care', *Critical Care Medicine*, vol. 33, no. 8, pp. 1694-700.

Rubenfeld, G.D. 2004a, 'Implementing effective ventilator practice at the bedside', *Current Opinion in Critical Care*, vol. 10, pp. 33-9.

Rubenfeld, G.D. 2004b, 'Using computerized medical databases to measure and to improve the quality of intensive care', *Journal of Critical Care*, vol. 19, no. 4, pp. 248-56.

Rubin, H.R., Pronovost, P.J. & Diette, G.B. 2001, 'The advantages and disadvantages of process-based measures of health care quality', *International Journal for Quality in Health Care*, vol. 13, no. 6, pp. 469-74.

Ruffell, A. & Adamcova, L. 2008, 'Ventilator-associated pneumonia: prevention is better than cure', *Nursing in Critical Care*, vol. 13, no. 1, pp. 44-53.

Runciman, W.B., Hibbert, P., Thomson, R., Van der Schaaf, T., Sherman, H. & Lewalle, P. 2009, 'Towards an international classification for patient safety: key concepts and terms', *International Journal for Quality in Health Care*, vol. 21, no. 1, pp. 18-26.

Ryan, A. & Abbenbroek, B. 2013, 'Intensive Care Clinical Information System (ICCIS) Program Overview', viewed 9/5/2014, <http://www.hss.health.nsw.gov.au/__documents/programs/iccis/iccis_hs12-07a_iccis-project-overview.pdf>.

Sackett, D.L., Rosenberg, W.M.C., Gray, J.A.M., Haynes, R.B. & Richadson, W.S. 1996, 'Evidence based medicine: what it is and what it isn't', *BMJ*, vol. 312, pp. 71-2.

Saleh, M., Anthony, D. & Parboteeah, S. 2009, 'The impact of pressure ulcer risk assessment on patient outcomes among hospitalised patients', *Journal of Clinical Nursing*, vol. 18, pp. 1923-9.

Sandelowski, M. 2000, 'Focus on Research Methods-Whatever Happened to Qualitative Description?', *Research in Nursing & Health*, vol. 23, no. 4, pp. 334-40.

Sandelowski, M., Barroso, J. & Voils, C.I. 2007, 'Using qualitative metasummary to synthesize qualitative and quantitative descriptive findings', *Research in Nursing & Health*, vol. 30, no. 1, pp. 99-111.

Scales, D.C., Dainty, K., Hales, B., Pinto, R., Fowler, R.A., Adhikari, N.K.J. & Zwarenstein, M. 2011, 'A multifaceted intervention for quality improvement in a network of intensive care units: A cluster randomized trial', *Journal of the American Medical Association*, vol. 305, no. 4, pp. 363-72.

Scriven, M. 2007, *The logic and methodology of checklists*, Western Michigan University, Kalamazoo.

Seiver, A. 2000, 'ICU bedside technology: past, present and future', *Critical Care Clinics*, vol. 16, pp. 601-21.

Sexton, J.B., Berenholtz, S.M., Goeschel, C.A., Watson, S.R., Holzmueller, C.G., Thompson, D.A., Hyzy, R.C., Marsteller, J.A., Schumacher, K. & Pronovost, P.J. 2011, 'Assessing and improving safety climate in a large cohort of intensive care units', *Critical Care Medicine*, vol. 39, no. 5, pp. 934-9.

Sexton, J.B., Helmreich, R.L., Neilands, T.B., Rowan, K., Vella, K., Boyden, J., Roberts, P.R. & Thomas, E.J. 2006, 'The Safety Attitudes Questionnaire: Psychometric properties, benchmarking data, and emerging research', *BMC Health Services Research*, vol. 6, no. 44, pp. 1-10.

Sexton, J.B., Thomas, E.J. & Grillo, S.P. 2003, *The Safety Attitudes Questionnaire (SAQ): Guidelines for Administration*, no. Technical Report 03-02, The University of Texas Centre of Excellence for Patient Safety Research and Practice, Austin, TX.

Sexton, J.B., Thomas, E.J. & Helmreich, R.L. 2000, 'Error, stress, and teamwork in medicine and aviation: cross sectional surveys', *BMJ*, vol. 320, pp. 745-9.

Shehabi, Y., Botha, J.A., Boyle, M.S., Ernest, D., Freebairn, R.C., Jenkins, I.R., Roberts, B.L. & Seppelt, I.M. 2008, 'Sedation and delirium in the intensive care unit: an Australian and New Zealand perspective', *Anaesthesia and Intensive Care*, vol. 36, no. 4, pp. 570-8.

Shepard, L.A. 1993, 'Evaluating test validity', *Review of Research in Education*, vol. 19, pp. 405-50, viewed 9 April, 2012, <http://rre.sagepub.com/content/19/1/405>.

Shiffman, R.N., Liaw, Y., Brandt, C.A. & Corb, G.J. 1999, 'Computer-based guideline implementation systems', *Journal of the Amerian Medical Informatics Association*, vol. 6, pp. 104-14.

Shojania, K.G., Duncan, B.W., McDonald, K.M. & Wachter, R.M. 2001, *Making health care safer: a critical analysis of patient safety practices.*, Evidence Report/Technology Assessment no. 43, Agency for Healthcare Research and Quality, Rockville, MD.

Shojania, K.G. & Grimshaw, J.M. 2005, 'Evidence-based quality improvement: the state of the science', *Health Affairs*, vol. 24, no. 1, pp. 138-50.

Shteynberg, G., Sexton, B.J. & Thomas, E.J. 2005, *Test retest reliability of the safety climate scale*, The University of Texas Center of Excellence for Patient Safety Research and Practice.

Silagy, C.A. 2001, 'Evidence-based healthcare 10 years on: is the National Institute of Clinical Studies the answer?', *Medical Journal of Australia*, vol. 175, no. 3, pp. 124-5.

Sim, I., Gorman, P., Greenes, R.A., Haynes, R.B., Kaplan, B., Lehmann, H. & Tang, P.C. 2001, 'Clinical decision support systems for the practice of evidence-based medicine', *Journal of the American Medical Informatics Association*, vol. 8, no. 6, pp. 527-34.

Sintchenko, V., Iredell, J.R., Gilbert, G.L. & Coiera, E. 2005, 'Handheld computer-based decision support reduces patient length of stay and antibiotic prescribing in critical care', *Journal of the Amerian Medical Informatics Association*, vol. 12, no. 4, pp. 398-402.

Sinuff, T., Cook, D., Giacomini, M., Heyland, D.K. & Dodek, P. 2007, 'Facilitating clinician adherence to guidelines in the intensive care unit: A mulitcenter, qualitative study', *Critical Care Medicine*, vol. 35, no. 9, pp. 2083-9.

Soeken, K.L. 2010, 'Validity of Measures', in C.F. Waltz, O.L. Strickland & E.R. Lenz (eds), *Measurement in Nursing and Health Research*, Fourth edn, Springer Publishing Company, New York, NY, pp. 163-202.

Soguel, L., Revelly, J.-P., Schaller, M.-D., Longchamp, C. & Berger, M.M. 2012, 'Energy deficit and length of hospital stay can be reducted by a two-step quality improvement of nutrition therapy: the intensive care unit dietitian can make the difference', *Critical Care Medicine*, vol. 40, no. 2, pp. 412-9.

Speroff, T. & O'Connor, G.T. 2004, 'Study design for PDSA quality improvement research', *Quality Management in Health Care*, vol. 13, no. 1, pp. 17-32.

Stahl, K., Palileo, A., Schulman, C.I., Wilson, K., Augenstein, J., Kiffin, C. & McKenney, M. 2009, 'Enhancing patient safety in the trauma/surgical intensive care unit', *Journal of Trauma and Acute Care Surgery*, vol. 67, no. 3, pp. 430-5.

Sucher, J.F. 2008, 'Computerized clinical decision support: a technology to implement and validate evidence based guidelines', *Journal of Trauma, Injury, Infection, and Critical Care*, vol. 64, no. 2, pp. 520-37.

Sutcliffe, K.M., Lewton, E. & Rosenthal, M.M. 2004, 'Communication failures: An insidious contributor to medical mishaps', *Academic Medicine*, vol. 79, no. 2, pp. 186-94.

Takala, R.S.K., Pauniaho, S.L., Kotkansalo, A., Helmiö, P., Blomgren, K., Helminen, M., Kinnunen, M., Takala, A., Aaltonen, R., Katila, A.J., Peltomaa, K. & Ikonen, T.S. 2011, 'A pilot study of the implementation of WHO surgical checklist in Finland: improvements in activities and communication', *Acta anaesthesiologica Scandinavica*, vol. 55, no. 10, pp. 1206-14.

Tanne, J.H. 2006, 'US campaign to save 100 000 lives exceeds its target', *BMJ*, vol. 332, p. 1468.

Taylor, J.A. 2008, 'Utility of patient safety case finding methods and associations among organizational safety climate, nurse injuries, and errors', John Hopkins University, Baltimore, Maryland.

Taylor, P.M. 2005, 'Use of handheld devices in critical care', *Critical Care Nursing Clinics of North America*, vol. 17, pp. 45-50.

The Clinical Excellence Commission 2007, *Projects and programs*, web page, Sydney, viewed 7 July 2009 <http://www.cec.health.nsw.gov.au/currentprojects.html>.

The George Institute for Global Health 2014, *Point Prevalence Program*, webpage, Sydney, viewed 31/10/2014.

Thomas, E.J., Sexton, B., Neilands, T.B., Frankel, A. & Helmreich, R.L. 2005, 'The effect of executive walk rounds on nurse safety climate attitudes: A randomized trial of clinical units', *BMC Health Services Research*, vol. 5, no. 28.

Thomassen, Ø., Storesund, A., Søfteland, E. & Brattebø, G. 2014, 'The effects of safety checklists in medicine: a systematic review', *Acta Anaesthesiologica Scandinavica*, vol. 58, no. 1, pp. 5-18.

Thompson, D.A., Holzmueller, C., Hunt, D., Cafeo, C., Sexton, B. & Pronovost, P. 2005, 'A morning briefing: setting the stage for a clinically and operationally good day', *Journal on Quality and Patient Safety*, vol. 31, no. 8, pp. 476-9.

Thor, J., Lundberg, J., Ask, J., Olsson, J., Carli, C., Harenstam, K.P. & Brommels, M. 2007, 'Application of statistical process control in healthcare improvement: Systematic review', *Quality & Safety in Health Care*, vol. 16, no. 5, pp. 387-99.

Thursky, K.A., Buising, K., Bak, N., Macgregor, L., Street, A.C., Macintyre, C.R., Presneill, J.J., Cade, J.F. & Brown, G.V. 2006, 'Reduction of broad-spectrum antibiotic use with computerized decision support in an intensive care unit', *International Journal for Quality in Health Care*, vol. 18, no. 3, pp. 224-31.

Tolentino-DelosReyes, A., Ruppert, S.D. & Shiao, S.-Y.P.K. 2007, 'Evidence-Based Practice: Use of the ventilator bundle to prevent ventilator-associated pneumonia', *American Journal of Critical Care*, vol. 16, pp. 20-7.

Tooher, R., Middleton, P., Pham, C., Fitridge, R., Rowe, S., Babidge, W. & Maddern, G. 2005, 'A systematic review of strategies to improve prophylaxis for venous thromboembolism in hospitals', *Annals of Surgery*, vol. 241, no. 2, pp. 397-415.

Torres, A., Serra-Battles, J., Ros, E., Piera, C., de la Bellacasa, J.P., Cobos, A., Lomena, F. & Rodriguez-Roisin, R. 1992, 'Pulmonary aspiration of gastric contents in patients receiving mechanical ventilation: the effect of body position', *Annals of Internal Medicine*, vol. 116, pp. 540-3.

Truran, P., Critchley, R.J. & Gilliam, A. 2011, 'Does using the WHO surgical checklist improve compliance to venous thromboembolism prophylaxis guidelines?', *Surgeon*, vol. 9, no. 6, pp. 309-11.

Ursprung, R., Gray, J.E., Edwards, W.H., Horbar, J.D., Nickerson, J., Plsek, P., Shiono, P.H., Suresh, G.K. & Goldman, D.A. 2005, 'Real time patient safety audits: improving safety every day', *Quality & Safety in Health Care*, vol. 14, pp. 284-9.

Valentin, A., Capuzzo, M., Guidet, B., Moreno, R.P., Dolanski, L., Bauer, P. & Metnitz, P.G.H. 2006, 'Patient safety in intensive care: results from the multinational Sentinel Events Evaluation (SEE) study', *Intensive Care Medicine*, vol. 32, pp. 1591-8.

Van Klei, W.A., Hoff, R.G., Van Aarnhem, E.E.H.L., Simmermacher, R.K.J., Regli, L.P.E., Kappen, T.H., van Wolfswinkel, L., Kalkman, C.J., Buhre, W.F. & Peelen, L.M. 2012, 'Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study', *Annals of Surgery*, vol. 255, no. 1, pp. 44-9.

Victorian Quality Council 2006, *State-wide PUPPS 3 Report 2006: Pressure ulcer point prevalence survey*, Department of Human Services.

Victorian Quality Council. 2005, *Pressure ulcer basics (PUBS) education program*, Internet, State Government of Victoria, Department of Health, <http://www.health.vic.gov.au/qualitycouncil/activities/ulcers.htm>.

Vincent, J.-L. 2004, 'Evidence-based medicine in the ICU: important advances and limitations', *Chest*, vol. 126, pp. 592-600.

Vincent, J.-L. 2005, 'Give your patient a FAST HUG (at least) once a day', *Critical Care Medicine*, vol. 33, no. 6, pp. 1225-9.

Wall, R.J., Ely, E.W., Elasy, A., Dittus, R.S., Foss, J., Wilkerson, K.S. & Speroff, T. 2007, 'Using real time process measurements to reduce catheter related bloodstream infections in the intensive care unit', *Quality & Safety in Healthcare*, vol. 14, pp. 295-302.

Wall, R.J., Ely, E.W., Elasy, T.A., Dittus, R.S., Foss, J., Wilkerson, K.S. & Speroff, T. 2005, 'Using real time process measurements to reduce catheter related bloodstream infections in the intensive care unit', *Quality & Safety in Health Care*, vol. 14, pp. 295-302.

Webb, S.A.R., Pettila, V., Seppelt, I., Bellomo, R., Bailey, M., Cooper, D.J., Cretikos, M., Davies, A.R., Finfer, S., Harrigan, P.W.J., Hart, G.K., Howe, B., Iredell, J.R., McArthur, C., Mitchell, I., Morrison, S., Nichol, A.D., Paterson, D.L., Peake, S., Richards, B., Stephens, D., Turner, A., Yung, M. on behalf of the ANZICS Influenza Investigators. 2009, 'Critical care services and 2009 H1N1 influenza in Australia and New Zealand', *The New England Journal of Medicine*, vol. 361, no. 20, pp. 1925-34.

Weber, S., Crago, E.A., Sherwood, P.R. & Smith, T. 2009, 'Practitioner approaches to the integration of clinical decision support system technology in critical care', *The Journal of Nursing Administration*, vol. 39, no. 11, pp. 465-9.

Weinert, C.R. & Mann, H.J. 2008, 'The science of implementation: changing the practice of critical care', *Current Opinion in Critical Care*, vol. 14, pp. 460-5.

Weiser, T.G., Haynes, A.B., Dziekan, G., Berry, W.R., Lipsitz, S.R. & Gawande, A.A. 2010, 'Effect of a 19-item surgical safety checklist during urgent operations in a global patient population', *Annals of Surgery*, vol. 251, no. 5, pp. 976-80.

Weiss, C.H., Moazed, F., McEvoy, C.A., Singer, B.D., Szleifer, I., Amaral, L.A.N., Kwasny, M., Watts, C.M., Persell, S.D., Baker, D.W., Sznajder, J.I. & Wunderink, R.G. 2011, 'Prompting physicians to address a daily checklist and process of care and clinical outcomes: a single-site study', *American Journal of Respiratory & Critical Care Medicine*, vol. 184, pp. 680-6.

Wentworth Area Health Service. 2003, *Prevention of venous thromboembolism in the critically ill*, ICU Management Committee, Department of Intensive Care Medicine, Nepean Hospital.

Wentworth Area Health Service. 2004, *Nutritional support in the Intensive Care Unit*, ICU Management Committee, Department of Intensive Care Medicine, Nepean Hospital.

Wentworth Area Health Service. 2005, *Prevention of upper gastrointestinal bleeding*, Protocol Committee, Department of Intensive Care Medicine, Nepean Hospital.

Westwell, S. 2008, 'Implementing a ventilator care bundles in an adult intensive care unit', *Nursing in Critical Care*, vol. 13, no. 4, pp. 203-7.

WHO Collaborating Centre for Patient Safety Solutions 2007, *Patient safety solutions preamble*, World Health Organization, Geneva.

Williams, S.C., Koss, R.G., Morton, D.J., Schmaltz, S.P. & Loeb, J.M. 2008, 'Case volume and hospital compliance with evidence-based processes of care', *International Journal for Quality in Health Care*, vol. 20, no. 2, pp. 79-87.

Wilmer, A., Louie, K., Dodek, P., Wong, H. & Ayas, N. 2010, 'Incidence of medication errors and adverse drug events in the ICU: a systematic review', *Quality & Safety in Health Care*, vol. 19, pp. 1-9.

Wilson, D., Ashton, C. & Wingate, N. 1995, 'Computerized support of pressure ulcer prevention and treatment protocols', *Proceedings of the 19th Annual Symposium on Computer Applications in Medical Care*, pp. 646-50.

Wilson, R.M., Runciman, W.B., Gibberd, R.W., Harrison, B.T., Newby, L. & Hamilton, J.D. 1995, 'The quality in Australian health care study', *Medical Journal of Australia*, vol. 163, pp. 458-71.

Winters, B.D., Gurses, A.P., Lehmann, H., Sexton, J.B., Rampersad, C.J. & Pronovost, P.J. 2009, 'Clinical review: checklists - translating evidence into practice', *Critical Care*, vol. 13, no. 6, pp. 210.

Woolf, S.H. 2008, 'The meaning of translational research and why it matters', *Journal of the American Medical Association*, vol. 299, no. 2, pp. 211-3.

Appendix A. Sydney West Area Health Service HREC approval for medical record audit study

SYDNEY WEST
Area Health Service

HUMAN RESEARCH ETHICS COMMITTEE
NEPEAN CAMPUS

Court Building, Ground Floor
P.O Box 63
Penrith NSW 2751

Tel: 47 34 3441
Fax 47 34 1368
Email: Ethics@wahs.nsw.gov.au or
CoetinM@wahs.nsw.gov.au

mc

October 11th, 2006

Dr. Tony Burrell
Intensive Care Unit
Nepean Hospital.

Dear Dr. Burrell,

Re: HREC Project 06/046: Auditing the process of care in a Tertiary Intensive Care Unit- Dr. Tony Burrell, Ms. Karena Hewson and Prof. Doug Elliott

Thank you for your response dated 11/10/06 and the required information. As all matters raised by the HREC have been addressed, we are pleased to inform you that your study now has final approval.

This approval is valid for a period of twelve months from the date of this letter.

Conditions of the approval of your study are that the Committee be kept informed of:

1. Any serious or unexpected adverse events, involving participants, as applicable to your study.
2. Changes to the research protocol (including if the project is not commenced, or is delayed in commencement by more than six months from the date of this letter; or is discontinued and giving reasons)
3. All current SWAHS policies relevant to your project must be fully complied with. These policies include, *Duty of Care, Infection Control* and *Occupational Health and Safety (as applicable to your study).*
4. The Committee is to be provided with immediate reports of any unforeseen events that might affect the ethical acceptability of the project.

5. A Final Report should be provided to this HREC on completion of the project.

The project approval becomes operative when the attached copy of this letter is signed, dated and returned to Maricita Coutinho, Research & Ethics Officer, at the address mentioned on this letterhead.

The HREC wishes you success with the project.

Yours sincerely,

Lw Wilkes

Prof. Lesley Wilkes
Deputy & Acting Chair
SWAHS HREC, Nepean Campus.

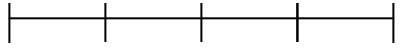
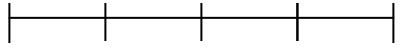
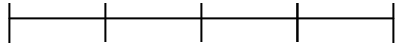
CC: Ms. Karena Hewson, ICCMU, C/- ICU Nepean.

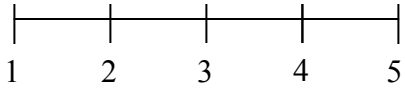
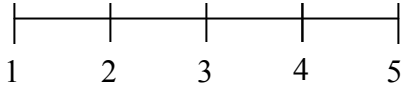
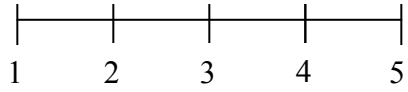
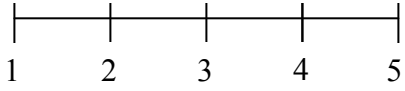
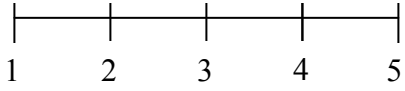
I accept, acknowledge and will comply with the conditions of approval for this project.

..... 16 oct 06

Chief Investigator/Designated Researcher (Date)

Appendix B. Modified Delphi survey – Round 1

Checklist Statements	Rating scale	Suggestions for improvement
These statements will appear when the information button next to each one-word descriptor (shown in bold) is selected.	1 = Strongly Disagree 2 = Disagree 3 = Neither Agree or Disagree 4 = Agree 5 = Strongly Agree	Please re-write the statement that you feel better describes the process-of-care in terms of clarity, conciseness and instructional value.
Feeding: Nutritional plan has been implemented and/or reviewed.		
Analgesia: Pain has been assessed and is being managed.		
Sedation: Sedation levels have been assessed and are being managed.		
Thrombo: DVT prophylaxis is being delivered.		

HOB>30: Head of the bed is raised 30-45 degrees.		
Ulcer prev: Stress ulcer prophylaxis is being delivered.		
Glucose: Blood sugar level (BSL) is within defined limits for this patient or if outside limits is being treated.		
Extubate: Patient's readiness to extubate has been assessed.		
Meds: All medications have been checked and reviewed.		

Appendix C. Modified Delphi survey – Round 2

Descriptor	Checklist Statements		Comments
	For each care component, select which of the 2 statements you think better describes the process-of-care in terms of clarity, conciseness and instructional value. Please select only **ONE** statement per care component.		Please make any comments you have about the statements in this column (click on the grey area & start typing).
Feeding	☐	Nutrition plan has been implemented, documented and reviewed	
	☐	Nutrition goals have been set and progress reviewed	
Analgesia	☐	Pain has been assessed and is being managed	
	☐	Pain has been assessed & documented, a management plan is set and progress reviewed	
Sedation	☐	Sedation levels have been assessed and are being managed	
	☐	Sedation levels have been assessed with target sedation score, a management plan is set and progress reviewed	
Thrombo-prophylaxis	☐	An appropriate means of delivering DVT prophylaxis has been chosen and is being delivered	
	☐	An appropriate means of delivering mechanical or pharmacological DVT prophylaxis has been chosen and is being delivered	

Descriptor	Checklist Statements		Comments
Head of Bed elevation	☐	Head of the bed is raised 30-45 degrees	
	☐	Head of the bed is raised greater than 30 degrees	
Ulcer prophylaxis		**Consensus reached on the following statement:** Stress ulcer prophylaxis is being delivered.	
Glucose	☐	Blood sugar level (BSL) is within defined limits for this patient or if outside limits is being treated	
	☐	Blood glucose limits have been defined and documented for this patient and BSL is within defined limits or if outside limits is being treated	
Extubate	☐	Patient's readiness to be weaned from mechanical ventilation has been assessed	
	☐	Ability of the patient to weaned from mechanical ventilation has been assessed and a ventilation plan has been set	
Medications	☐	All medications have been checked and reviewed	
	☐	Indications and dosing documentation for all current medications reviewed and correct	

Appendix D. Delphi responses – Round 1

Care Component	Checklist statements	Ratings (%)					Comments
		SA	A	U	D	SD	
Feeding	Nutritional plan has been implemented and/or reviewed.	67	11	0	22	0	• Nutrition (not nutritional) • Would review "and/or" from the sentence • Nutrition goals are set and progress reviewed
Analgesia	Pain has been assessed and is being managed.	56	33	11	0	0	• Possibly needs to be more definitive e.g. "Pain level assessed and documented and management plan in place and patient not in pain at rest."
Sedation	Sedation levels have been assessed and are being managed.	56	22	11	11	0	• Sedation score completed and documented and level of sedation appropriate. • The sedation level has been assessed and is appropriate • Sedation levels have been assessed, target sedation score has been set and management plan clear to team.
Thrombo-prophylaxis	DVT prophylaxis is being delivered.	33	44	11	11	0	• Patient is receiving DVT thromboprophylaxis • DVT prophylaxis (physical or pharmacological) is being delivered • Consider most appropriate means of delivering prophylaxis for a patient e.g. mechanical VS pharmacological. • This one is a bit more complicated- TEDS, calf compressors, SC heparin, LMW heparin. Heparin/LMWH prescribed and if contraindicated mechanical device being used?

							• There are no contraindications to DVT prophylaxis and an appropriate agent has been chosen and is delivered
Head of Bed elevation	Head of the bed is raised 30-45 degrees.	44	44	11	0	0	• "Head of bed is raised greater than 30 degrees" (so that say 60 degrees is not a failure for the pedants) • There are no contraindications and head of bed is raised 30-45 degrees.
Ulcer prophylaxis	Stress ulcer prophylaxis is being delivered.	66	33	0	0	0	• No comments
Glucose	Blood sugar level (BSL) is within defined limits for this patient or if outside limits is being treated.	66	11	11	11	0	• Blood glucose limits have been defined and documented for this patient and BSL is within defined limits or if outside limits is being treated. • Too cumbersome! Glucose is controlled.
Extubate	Patient's readiness to extubate has been assessed.	55	22	0	22	0	• The ability of the patient to being disconnected/weaned from mechanical ventilation has been assessed and plan has been made
Medications	All medications have been checked and reviewed.	55	22	22	0	0	• Indications and dosing documentation for all current medications reviewed and correct. • All medications have been reviewed.

Appendix E. Delphi responses – Round 2

Domain	Checklist statements	%	Comments
Feeding	Nutrition plan has been implemented, documented and reviewed	37	Replace “set” with “documented”. Think “goals” gives more instructional value than “plan”.
	Nutrition goals have been set and progress reviewed	50	
Analgesia	Pain has been assessed and is being managed	37	How about something even briefer- pain assessed and managed?*
	Pain has been assessed & documented, a management plan is set and progress reviewed	63	
Sedation	Sedation levels have been assessed and are being managed	13	Within target range
	Sedation levels have been assessed with target sedation score, a management plan is set and progress reviewed	75	Don't like either. Too ponderous. How about "sedation target set, sedation level assessed and managed"*
Thrombo-prophylaxis	An appropriate means of delivering DVT prophylaxis has been chosen and is being delivered	50	Neither. Too ponderous. "Mechanical and/or drug prophylaxis delivered today"*
	An appropriate means of delivering mechanical or pharmacological DVT prophylaxis has been chosen and is being delivered	37	

Head of Bed elevation	Head of the bed is raised 30-45 degrees	37	You may want to have your patient higher than 45 degrees
	Head of the bed is raised greater than 30 degrees	63	Can you use ">"?*
Glucose	Blood sugar level (BSL) is within defined limits for this patient or if outside limits is being treated	50	Neither- "BSL limits defined and managed within those limits"*
	Blood glucose limits have been defined and documented for this patient and BSL is within defined limits or if outside limits is being treated	37	
Extubate	Patient's readiness to be weaned from mechanical ventilation has been assessed	63	Neither- "Is the patient ready to be weaned from ventilation?"
	Ability of the patient to weaned from mechanical ventilation has been assessed and a ventilation plan has been set	25	
Medications	All medications have been checked and reviewed	63	Neither- "All medications reviewed"
	Indications and dosing documentation for all current medications reviewed and correct	25	

*These comments were factored into the final version of the checklist statements as they met the criteria of being clear, concise, and descriptive without losing meaning.

Appendix F. Business Requirement Document for PDA and server applications for e-checklist tool

Electronic Checklist Requirements

Introduction

This document will outline the functional requirements of a proposed system to track the completion of tasks and reasons for task omission to be undertaken by clinical care staff in a ICU environment.

The goal of the application will involve the data collection of task completion rates by clinical care staff via a handheld device and reasons for omission at the bedside. The data is to be collected and placed in a database.

The computer terminal hosting the database should include administrative abilities and reporting generation based on the data collected over time. It will take on the role of being the server to the PDA thin clients.

Scope & Assumption

ID	Description
ASPT-001	The system will exist as an independent entity from the site's clinical information systems, all patient data and administrative personnel information will be entered manually into control terminal.
ASPT-002	The environment will not necessarily facilitate a wireless environment, for the proposed component layout the requirements will be tailored to a continuous & wireless connected environment.
ASPT-003	The physical security and storage of the system components will be adequate and will not interfere in care delivery to patients.
ASPT-004	The time zone and time setting on both the PDA devices will be the same and will not change.
ASPT-005	The onsite location will have available an Internet connection >= ADLS speeds.
ASPT-006	When the device is connected to the Wi-Fi network, it will not power down to standby for 15 minutes.(See Appendix A.1)

Proposed System Components

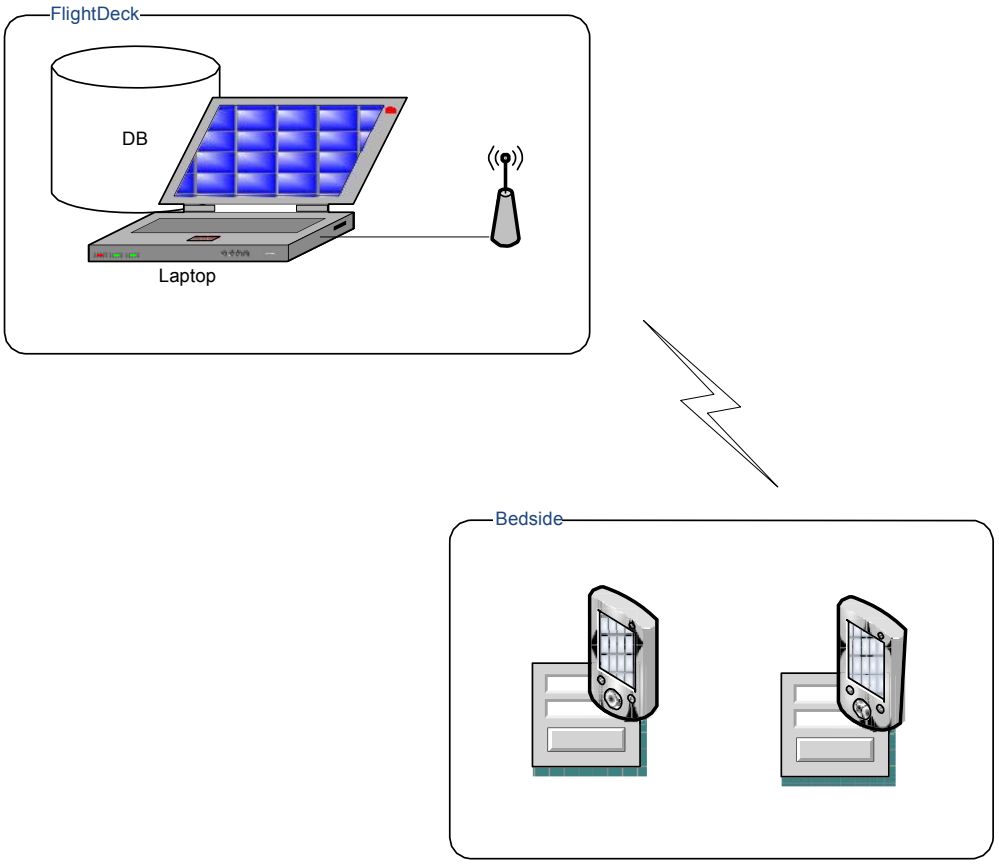


Figure 1 Component Layout and System Architecture

The system architecture will be a light weight client server design. The handheld devices will serve as thin clients communicating wirelessly to the server, querying the backend database for task lists, and provide client side authentication.

For simplicity and to maximise feasibility, a laptop with adequate RAM and a main AC power supply will be supplied at the site, this laptop will be installed with either a windows based or any Linux distribution. This laptop will then serve as the server side control terminal with the application and reporting capabilities.

The wireless router will be connected to the control terminal via the appropriate adapter (USB or otherwise). The network will maintain its isolation with a private subnet, accessible only by the devices. If there is however an Internet connection available at the control terminal then a remote control or monitoring software should be installed, and made available to administrative personnel for offsite monitoring of progress and troubleshooting.

The PDA devices will be Palm TX handheld PDAs. These are capable of Wi-Fi and Bluetooth connectivity. Contains 100mb of user accessible memory and has the capability of running Java applications (JavaVM has to be installed). Due to the lightweight processing power of these devices, the balance between device based storage versus network traffic load should be taken into to consideration.

*The requirements are biased towards a heavier network load than the amount of device hard coding.

High Level Requirements

ID	Description
HL-01	PDA Device thin client requirements.
HL-02	Server Side application requirements.

PDA Device thin client requirements (HL-01-*)

ID	Description	Priority
HL-01-01	Authentication and session management.	HIGH
HL-01-02	Data collection interface	MEDIUM
HL-01-03	Workflow requirements	HIGH
HL-01-04	Help Content	MEDIUM

HL-01-01-* Authentication and session management

ID	Description
HL-01-01-01	The login should consist only of the staff employee ID (numeric portion).
HL-01-01-02	The login ID will be displayed and attached in all transactions recorded in the database, this ID will be known as the username.
HL-01-01-03	The username will be authenticated each time the device is powered on from an off state.
HL-01-01-04	The login and logout options should be only displayed on the home screen of the application. Once logout is clicked by the user, a login screen should be immediately presented.
HL-01-01-05	Every time a device login attempt is made, it should be recorded. This record should show the username and the device used to attempt the login.
HL-01-01-06	User must re-enter their username after the device has been powered off or in the event of a network timeout.
HL-01-01-07	During any active session if the PDA is docked, then the application should log out any users and return to device main menu.
HL-01-01-08	If there is no available wireless connection within range then the PDA should not allow for any new login attempts. Since there is no way to authenticate.
HL-01-01-09	Users should be classified as either ‘Auditor’ or ‘Clinician’. A single user cannot be both types.

HL-01-02-* Data collection interface

ID	Description
HL-01-02-01	Every time there is a user input that requires a change or update to a checklist, the changes should be committed as a whole record instead of individual items. This ensures any change either gets written to the backend database or it fails in transfer. This type of atomicity minimises all risks of data corruption. Every instance where a state change occurs on any given checklist task event, then a transaction is to be sent to the server to synchronise the state with the database. This includes changes to the reason, status and login events.
HL-01-02-02	Any transactions outside of the connectivity zone will not be made to the database, and will be dropped with an error message. Once the connectivity is restored then user will resume the session provided it's still within the session time.
HL-01-02-03	Every patient may have up to 2 checklists generated - one to be completed by clinicians, and one to be completed by the auditors (if selected for audit). Any number of clinicians can complete the clinician checklist for the patient, and similarly the auditors for the auditor checklist.
HL-01-02-04	If there is a failure to write to the database for any given reason, an error should be displayed.

HL-01-03-* Workflow Requirements

ID	Description
HL-01-03-01	Logon - The User login into the device by entering in the numeric portion of their employee ID (which becomes their user-number) - The PDA should authenticate the user number against list available on the server. Allow the session to be created only if the user exists. - Once logged in, the user number should be displayed at the top of the checklist screen - The session type should identify whether the user is an auditor or a clinician. Depending on the user type the corresponding checklists will be loaded into the session. - No user can be both a clinician and auditor.
HL-01-03-02	Selecting the patient - Select the patient from the list of patients currently in the ICU, sorted by bed number. E.g. o 999818 (01) COMPLETE o 298793 (02) NOT STARTED o 398749 (04) INCOMPLETE - This list should show the patient MRN number and whether or not the checklist has been completed for that patient. The list of checklist status will be "NOT STARTED", "COMPLETED", "INCOMPLETE" - Once a patient is selected then the Server should send the list of tasks that's due for the patient. The task list is static for all patients and in the same order when opened.

HL-01-03-03	Selecting a Patient Checklist - The user must select one patient checklist from the table, the server should check whether the user is an auditor or a clinician, and load the corresponding checklist. - The MRN is to be displayed at the top of the checklist screen. - A completed checklist can be selected, enabling users to change a task item status as required. - The user can also reset the checklist status from either 'complete' or 'incomplete' back to the default state of 'not started'. - After each checklist completion, a window containing a list of remaining patients a checklist needs to be completed for will be displayed.
HL-01-03-04	Completing each task Item - As each item in the list is completed, the user is expected to tick either 'Yes' or 'No'. - If the user is an auditor when 'Yes' is selected they will be further prompted to choose either 'Yes - with documentation' or 'Yes - without documentation'. - If the user is a clinician when 'Yes' is selected, a green tick will appear immediately in the box selected. - When 'No' is selected in both modules (auditor and clinician), a "Choose a Reason" screen should appear containing a list of reasons for the 'no' response. There should only ever be one reason for any task that has a 'No' response. - If response is 'No' and a valid reason is given e.g. Not applicable, then a green cross symbol should appear in the 'No' column, next to the corresponding checklist item. If no valid reason is provided, a red cross will appear in the 'No' column. - A 'reset status' function that clears the reason selected in the event of a data input error is required

HL-01-03-05	Editing Task Status - If a task status was incorrectly entered, e.g. clicked 'Yes' instead of 'No', then the user should be allowed to change that selection by editing the task record for that checklist.
HL-01-03-06	Once all items in the checklist have a status attached, then the checklist screen should present a 'Finish' button which will bring the user back to the 'Select patient' screen.
HL-01-03-07	Navigation between each of the screens will be controlled by either the 'Back' or 'Next' button.
HL-01-03-08	The application should be retrieving data in real time, and does not store the data on the device in any caching methods.
HL-01-03-09	When completing a checklist for the patient, the device user should be able to record any inpatient adverse events that occur for that patient from a list of predefined events. Once the events have been recorded then an event record should exist in the DB, and the user should be able to add additional details on the event once they're finished with the checklist and back at the terminal.

HL-01-04-* Help Content

ID	Description	Priority
HL-01-04-01	On the main checklist tasks screen a help icon should be displayed. This should pop up in a modal window where by all other sections of the screen should be disabled, and the user should only be able to scroll and read or click 'OK' to return to the previous screen.	
HL-01-04-02	Every task has help content attached; this may include the task definition as well as other miscellaneous instructions. This should be updateable from the server side application.	

Server Side application requirements HL-02-*

ID	Description	Priority
HL-02-01	Patient level Information Management	HIGH
HL-02-02	User Level account management	HIGH
HL-02-03	Logging & Validation	MEDIUM
HL-02-04	Display & Reporting Requirements	HIGH
HL-02-05	Management of Tasks & Reasons	HIGH
HL-02-06	Devices Management	HIGH

HL-02-01-* Patient level Information Management

ID	Description
HL-02-01-01	MRNs can be manually entered or changed via the server.
HL-02-01-02	Allow users to add inpatient adverse events into the system. E.g. pulmonary embolism. A date-time stamp should be attached to each record physically entered into the system. The details of the event should be a mix of predefined events, and a free text field.
HL-02-01-03	Patients once added to the system should remain in the system until discharged manually.
HL-02-01-04	Inpatient events should be editable at a later date and an audit trail should be recorded on the database as to when the event was entered into the system, and whether the event was entered on the PDA or from the computer at the unit.

HL-02-02-* User Level account management

ID	Description
HL-02-02-01	Users can be added into the system
HL-02-02-02	Users can be (pseudo) removed from the system by changing their status from active to inactive, to maintain an audit trail.
HL-02-02-03	Produce a list of Active users and their most recent login time.
HL-02-02-04	Keep a list of user administration actions that contains the following information: - User id - Action = [Delete, Add] - Datetime stamp.
HL-02-02-05	Deletion of any users currently logged into a device should be prevented. This action will result in a warning box shown on the screen indicating "User Currently using Device #"
HL-02-02-06	The user management console was used exclusively by the clinicians, hence auditors were added to the system via the database. Their employee IDs were added prior to the implementation.

HL-02-03-* Logging & Validation

ID	Description
HL-02-03-01	The **Server side application** should maintain a log of all transactions. Maintaining the granularity of User, UserType, Patient, ChecklistID, Action, newValue.
HL-02-03-02	The server should maintain that any errors during the update of a record should be notified to the PDA as a transaction error, and any changes discarded. The atomicity of transaction should be strict.
HL-02-03-03	Any transaction errors should be logged with the details (if possible) of : - Timestamp - Device ID - Employee ID - Checklist ID

HL-02-04-* Display & Reporting Requirements

ID	Description
HL-02-04-01	The **Terminal Application** will be accessible by a single login and password combination and should not need any native user management controls.
HL-02-04-02	The summary table on the home page should show (as minimum) the following fields: - MRN - Status - StaffID - DeviceID
HL-02-04-03	Reporting modules will offer tables and graphs generated in real-time depending on user reporting parameters.
HL-02-04-04	The three pre-defined reports are: - Summary table - showing the completion rate of all applicable care items in the last 14 days, displayed on a line + column chart showing the number of applicable care task items, and the compliance rate (%). - Omissions Report - a tally of all omissions for the current day, week and all omissions 'to-date', showing each care item and the omission rate for each time period. - Compliance Report – display the compliance rate for each care item, i.e. the number of care items delivered divided by the number of applicable cares. This will also be aggregated to show compliance for the current day, week and 'to-date'. Weekly data is calculated from Monday to Sunday.

HL-02-05-* Management of Tasks & Reasons

ID	Description
HL-02-05-01	Maintain list of Default Tasks. This should be a once off event to maintain data uniformity overtime, but the ability for addition and alteration of task Descriptions and Help content are required. This could be done in the backend of the database.
HL-02-05-02	List of reasons for omissions should be maintainable. This should also be a once off event, but editing and addition capability should be made available.
HL-02-05-03	Allow administrator to maintain a relationship between applicable reasons and associated tasks.
HL-02-05-04	Care task shortcuts should be available on common item selections. e.g. patient is not in unit due to external procedures, or if the patient is not ventilated then certain items will be labelled as not applicable automatically.

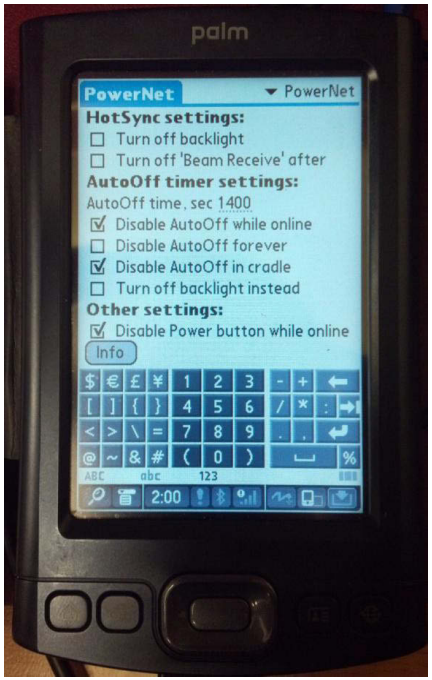
HL-02-06-* Devices Management

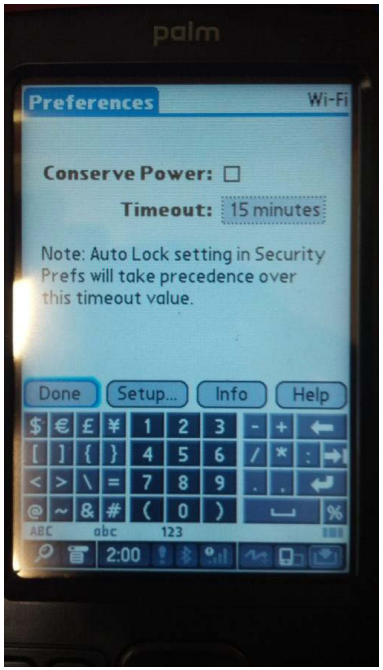
ID	Description
HL-02-06-01	Ensure that each device is identifiable and unique to the system.
HL-02-06-02	Each device's Identity is persistent from the minute it is activated within the system
HL-02-06-03	Check which user is currently using a specific device
HL-02-06-04	Check usage log of a specific device showing the following: - Timestamp - Action = [login/logout/update] - Username - MRN (only if the action was updated)
HL-02-06-05	The system should be able to add additional PDA devices.
HL-02-06-06	The system should be able to remove existing PDA devices.
HL-02-06-07	Once a device is removed from the system, the device status changes to "Deleted" only if the device was used to update a checklist record. Otherwise the device will not be shown in the Current Device Status.

A.1

Left: This is the PowerNet utility. This was installed to ensure the device did not go into standby in under 15 minutes. For the implementation we set it to 1400 seconds before going into standby. This ensured that the user did not have to reconnect after every 15 minutes.

Right: Wi-Fi setting, conserve power was turned off, and maximum of 15 minutes was selected. Due to PowerNet however, the 15 minute timeout doesn't occur and the device can be connected to the network far beyond the 15 minute time limit.





Appendix G. E-checklist manual for medical staff

Process of Care Checklist Project

6 July to 16 August 2009

Information Booklet for ICU Medical Staff

Contents:

- Research Protocol
- Data Dictionary
- PDA instructions
- Server instructions

Project Contact:

Ms Karena Hewson

Research & Quality Manager

NSW Intensive Care Co-ordination & Monitoring Unit

Extension 41584

SWAHS HREC Approval Number: 07/046

UTS HREC Approval Number: 2007-67A

Research Protocol

1. Collect the PDAs prior to the morning ward rounds from the ward clerk.
2. There are 2 PDAs for split ward rounds.
3. A senior medical staff member (Intensivist/Senior Registrar/ Registrar) is required to complete the E-checklist in consultation with the team on the morning ward round.
4. A checklist is to be completed for every patient in the ICU as a **challenge and answer after the patient assessment**.
5. Full checklist statements can be viewed by pressing on the care item label in the checklist e.g. 'Feeding'.
6. Answer each question with reference to the definitions provided in the following data dictionary.
7. After completing each patient's checklist, check the patient level events list and select/enter all that apply to the patient, as defined in the data dictionary.
8. If there are any patient level events that occur that may be relevant to the cares contained in the checklist, then please select 'Other' and provide detail of that event by using the 'Edit Event' function on the server (access via the COWs).
9. If a patient is not in their allocated bed area e.g. for a procedure, continue the ward rounds as you usually would and return to complete a checklist for the patient once they have returned and your routine patient assessment has been completed.
10. Once all patients have been completed, please return the PDAs directly to the ward clerks.

Data Dictionary

General response options:

YES = Care has been delivered according to the definitions outlined in the data dictionary.

NO = Care has not been delivered according to the definitions outlined in the data dictionary.

Reasons for NO- a reason for every '**No**' response must be provided. For every item on the checklist the following options are available:

- Omission- not yet corrected = care has not been delivered where appropriate, but has been flagged for rectification sometime after ward rounds.
- Omission- now corrected = care has not been delivered where appropriate, but was corrected during patient assessment or immediately upon checklist prompt.

Omissions are denoted on the checklist with a **red** cross.

For certain checklist items (see definitions below) other possible responses include:

- Not applicable
- Clinical contraindication

These responses are denoted on the checklist with a **green** cross.

Contact details:

If there are any problems/issues that you need assistance with please contact **Karena** (Research Officer, ICCMU) on **extension 41584** (office number).

The phone will be diverted to a personal mobile number out of hours and when away from the office.

Checklist items

Label	Checklist statement	Definition	Comment
Ventilated	Is the patient invasively ventilated?	Applies to patients with endotracheal or tracheostomy tubes only. Check '**Yes**' if the patient is invasively ventilated. Check '**No**' if the patient is not invasively ventilated. Note: if '**No**' is checked, the following care items are <u>not applicable</u> and will be completed automatically: • Head of bed elevation • Readiness to wean • Sedation A green cross will appear in the '**No**' column to indicate these cares are <u>not applicable</u> to patients who are not invasively ventilated. Complete the remaining **unchecked** items on the checklist.	If patient is not invasively ventilated, Check '**No**' and move to the next applicable care item on checklist.

Head of bed elevation	Patient is positioned with the head of the bed raised >30 degrees	An assessment on the angle of the head of the bed is to be made at the time of checklist completion using an inclinometer. Check '**Yes**' if patient is positioned with the head of bed > 30 degrees. Check '**No**' if patient is positioned with the head of bed < 30 degrees. Check '**No**' then Reason = '**NA- unit policy**' if the head of bed is not elevated for this patient due to unit policy.	**Applies to patients who are invasively ventilated only.** All patients should be nursed at 30 degrees head up unless haemodynamically unstable or needing large doses of noradrenaline, or prevented by unstable spinal or pelvic injuries.
Wean	Patient's readiness to be weaned from mechanical ventilation has been assessed	**Readiness to wean from mechanical ventilation** is determined by haemodynamic stability, manageable secretions, adequate gas exchange on FiO2 ≤ 0.4, capable of extended spontaneous ventilation & a level of consciousness that will allow the patient to maintain an airway, cough spontaneously & co-operate with physiotherapy. Check '**Yes**' if the patient's readiness to be weaned from invasive ventilation has been assessed Check '**No**' if the patient's readiness to be weaned from invasive ventilation has **not** been assessed	**Applies to patients who are invasively ventilated only.** The aim is to ensure medical staff have assessed readiness to wean and a plan and/or attempt has been made to move the patient towards liberation from the ventilator.

Sedation	Sedation target set, sedation level assessed and managed	Applies to patients that have an artificial airway and requires sedation for facilitation of ventilation. **Sedation target** is defined as a determination of appropriate sedation levels for the patient such as using a sedation score (e.g. RASS) or the 'calm, comfortable, collaborative' rule. **Assessment of sedation level** is defined as the current degree of sedation in relation to the sedation target. **Management of sedation** is defined as a medication strategy to maintain sedation at target levels. Check '**Yes**' if sedation target set, level assessed and managed (as appropriate) by ICU medical staff. Check '**No**' if any of these aspects has **not** been done. Check '**No**' then Reason = '**NA**' if the patient has not required sedation in past 24 hours.	**Applies to patients who are invasively ventilated only.** A '**Yes**' response requires the sedation target set, current sedation level assessed, and management to achieve sedation level within the defined range.

Analgesia	Pain has been assessed, a management plan set and progress reviewed	**Pain assessment** is defined as ICU medical staff gauging the patient's pain levels, ideally through use of a pain score. This includes recognition that a patient currently has no pain or it cannot be determined e.g. patient is unresponsive. **Pain management plan** is defined as a strategy for controlling the patient's pain. **Progress reviewed** is defined as ICU medical staff reviewing patient's pain after initial assessment and may include re-assessing pain levels and management plan. Check '**Yes**' if pain has been assessed, a management plan has been set and progress reviewed (where applicable) by ICU medical staff. Check '**No**' if any of these aspects have **not** been done. Check '**No**' then Reason = '**NA**' if pain assessment cannot be determined due to the patient's condition.	**Includes patients without pain as long as the assessment has been made.** A '**Yes**' response must have at least conducted a pain assessment. A pain management plan and progress review must also have been completed **if applicable** to the patient at the time of completing the checklist.

DVT prophylaxis	Mechanical and/or drug DVT prophylaxis is being administered or applied.	**Drug prophylaxis** includes the following: unfractionated heparin (sodium heparin, calcium heparin), low molecular weight heparin (enoxaparin = Clexane®, dalteparin = Fragmin® etc). For the purposes of this study also includes patients on therapeutic heparin/ clexane/ warfarin. **Mechanical prophylaxis** is defined as use of Sequential Compression Devices, **NOT** anti-embolism stockings. Check '**Yes**' if either mechanical OR drug DVT prophylaxis is being delivered. Check '**No**' if mechanical OR drug DVT prophylaxis is **not** being delivered. Check '**No**' then Reason = '**Clinical Contraindication**' if one exists for both forms of prophylaxis.	Anti-embolism or 'TED' stockings and similar are **not** mechanical DVT prophylaxis for the purpose of this study. If **neither** mechanical or drug DVT prophylaxis is being delivered check for clinical contraindication.

Stress Ulcer prophylaxis	Stress ulcer prophylaxis is being administered.	**Stress Ulcer prophylaxis** is defined as the administration of proton pump inhibitors (omeprazole, esomeprazole, pantoprazole etc) or H_2 antagonists (ranitidine, famiotidine etc) or sulcralfate. Includes patients on treatment for perforated peptic ulcers e.g. proton pump inhibitor infusion etc. Check '**Yes**' if Stress ulcer prophylaxis is being delivered or is prescribed. Check '**No**' if Stress ulcer prophylaxis is **not** being delivered or prescribed. Check '**No**' then Reason = '**Clinical Contraindication**' if one is present for the patient. Check '**No**' then Reason = '**NA- unit policy**' if Stress ulcer prophylaxis is **not** prescribed for this patient due to unit policy e.g. patient not mechanically ventilated for greater than 48 hours, patient is stable and tolerating enteral feeds.	**Applies to all patients mechanically ventilated (invasive or non-invasive) for > 48 hours and not contraindicated.** Check unit policy for indications.

Feeding	Nutrition goals have been formally assessed and progress reviewed	**Nutrition** is defined as any form of caloric intake i.e. enteral, parenteral, oral. **Formal assessment of nutrition goals** is defined as the prescription of a nutritional goal based on a combination of weight, demographics & biochemistry. **Progress reviewed** is defined as ICU medical staff reviewing the goals after formal assessment & may include re-assessing or re-defining goals. Check '**Yes**' if nutritional goals **have** been formally assessed & progress reviewed (if applicable) by either a dietitian or any member of the ICU medical staff. Check '**No**' if nutritional goals have **not** been formally assessed or progress reviewed (if applicable) Check '**No**' then Reason = '**NA**' if nutrition goals do not need to be assessed or reviewed for this pt e.g. withdrawing treatment, 'Nil by mouth' for gastrointestinal reasons, low acuity- patient expected to recover quickly, etc.	**Include patients who have had feeds suspended temporarily** e.g. fasting for surgery, planned percutaneous tracheostomy (response options for these patients = **Yes, No, NA**)

Glucose control	Blood sugar levels (BSL) have been assessed, limits have been set and are being managed to achieve those limits	**Blood sugar levels (BSL)** are to be assessed and if outside set limits are to be actively managed e.g. insulin infusion, to achieve prescribed limits. Check '**Yes**' if BSLs have been assessed and where appropriate, BSL limits have been set and the patient is being managed to achieve those limits. Check '**No**' if BSL limits either have **not** been set or are not being managed to achieve defined limits. Check '**No**' then Reason = '**NA**' if infrequent BSL monitoring was clinically appropriate or an intentional decision was made by the treating medical team.	Minimum requirement for '**Yes**' response = BSL was assessed and within acceptable limits.
Medications	All medications have been checked and reviewed	**Checking & reviewing** refers to all current medications on the medications chart confirmed as indicated and are correctly prescribed. Check '**Yes**' if all medications have been checked and reviewed. Check '**No**' if all medications have **not** been checked and reviewed.	**Includes all medications being administered to the patient.**

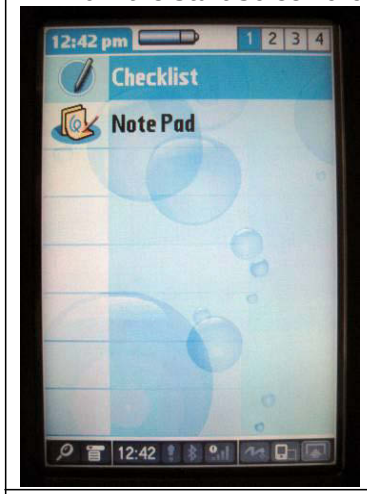
Patient Level Events

After completing checklist for each patient, check the patient level events list and select/enter all that apply to the patient, as defined below.

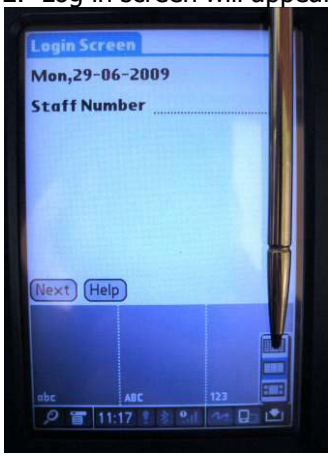
Event Name (max 50 Characters)	Description if needed
Ventilator-associated pneumonia (VAP)	Pneumonia is present in a patient who was intubated and ventilated at the time of or within 48 hours before the onset of infection. Identified via combination of radiologic, clinical and laboratory criteria (see CDC definition attached). **Needs to be recorded only once per ICU stay.**
Central line-associated bloodstream infection (CLABSI)	A blood stream infection (BSI) with no other apparent source of infection which occurs in a patient who has a centrally or peripherally inserted central line or has had a central line removed within 48 hours of BSI diagnosis. Identified via a combination of clinical and laboratory criteria. As indicated by clinical staff. **Needs to be recorded only once per ICU stay.**
Unplanned extubation	The unplanned/accidental removal of the endotracheal or tracheostomy tube by a mechanically ventilated patient.
Re-intubation related to unplanned extubation	Patient requires intubation after the unplanned/accidental removal of the endotracheal or tracheostomy tube.
Hyperglycaemia	Recorded blood sugar level of >10mmol/L.
Hypoglycaemia	Recorded blood sugar level of <2.2mmol/L.
Deep Vein Thrombosis (DVT) detected	Formation of a thrombus is detected via Doppler ultrasound. **Needs to be recorded only once per ICU stay.**
Pulmonary embolism detected	Blockage of the pulmonary artery or one of its branches is detected via (CT) pulmonary angiography. **Needs to be recorded only once per ICU stay.**
Gastrointestinal (GI) bleed	Hemorrhage (loss of blood) in the GI tract is detected.
Medication error	Select if one or more medication errors have occurred irrespective of type (where known).
Other	Optional free text field. Enter in any events related to cares covered by the checklist. Detail to be entered via the server.

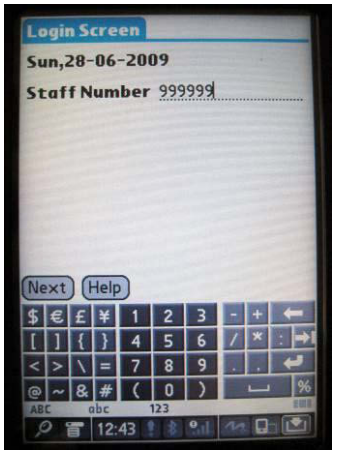
PDA Instructions

1. From the Start Screen click on '**Checklist**'



2. Log in screen will appear

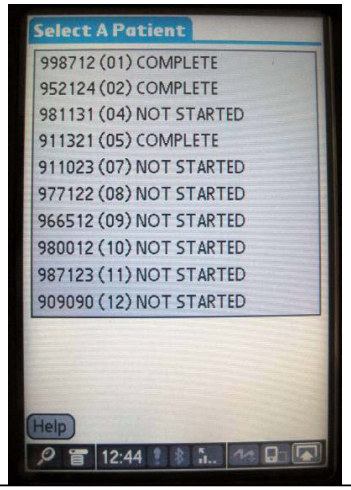




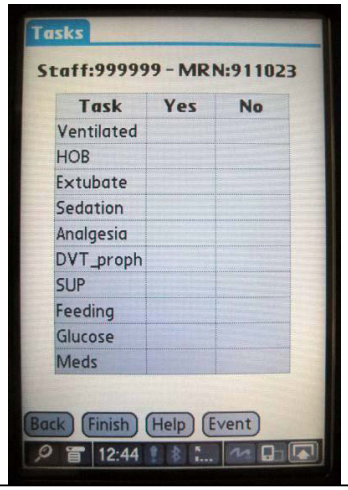
- Click on the line next to '**Staff Number**'
- Enter your staff number using keypad
  - To activate the key pad click on the icon in the bottom right corner. If numeric keypad does not appear press & hold icon until options appear, then select numeric keypad at top of dialog box
- Once your staff number is entered click on '**Next**'

3. Palm will then connect to the server

4. Select patient from patient list

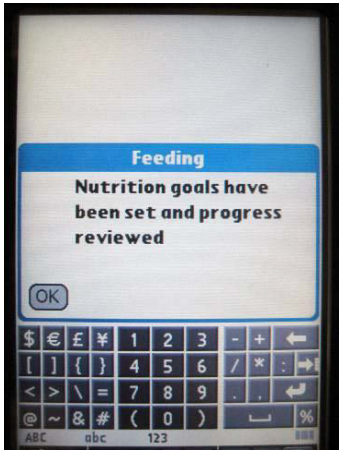


5. '**Tasks**' screen will appear



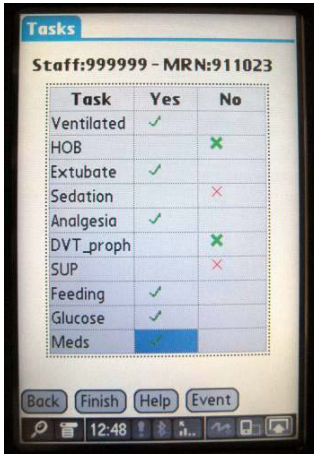
If keypad is still visible tap on icon in the bottom right corner once with stylus

6. To refer to the detailed checklist statement click on task name e.g. 'Feeding'.



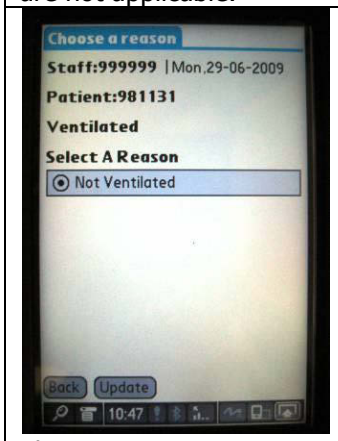
The statement will disappear automatically from the screen after a few seconds.

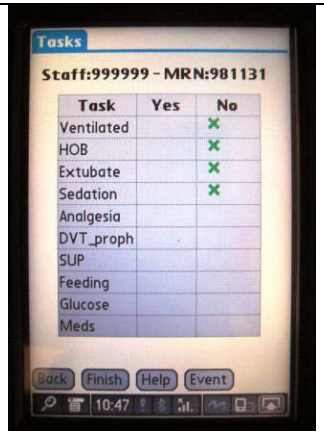
7. Complete the checklist



- For a **YES** response click in **'YES'** box, a **green tick** will appear.
- For a **NO** response click in **'NO'** box and select a reason for **NO** (refer to data dictionary)
- Click on '**Update**'
- If reason = 'Omission' a **red cross** will appear in the **NO** column
- If reason = 'Not Applicable' or 'Clinical Contraindication' a **green cross** will appear in the **NO** column

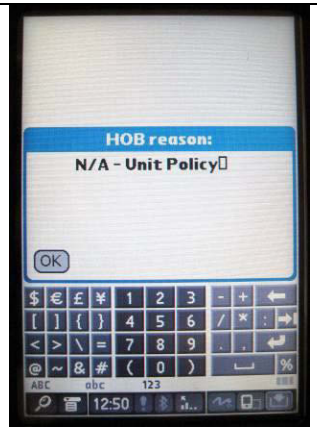
For patients **not** invasively ventilated, click '**NO**' next to 'Ventilated'. A **green cross** will appear next to items that are not applicable.





The remaining items are applicable to non- invasively ventilated patients and should be completed.

8. Checking completed items

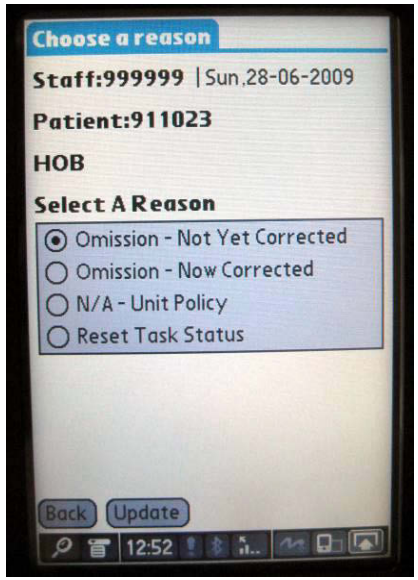


If you need to check the 'No' response, click on the cross and the reason will be displayed in a pop-up window.

Click on '**OK**' to return to the checklist.

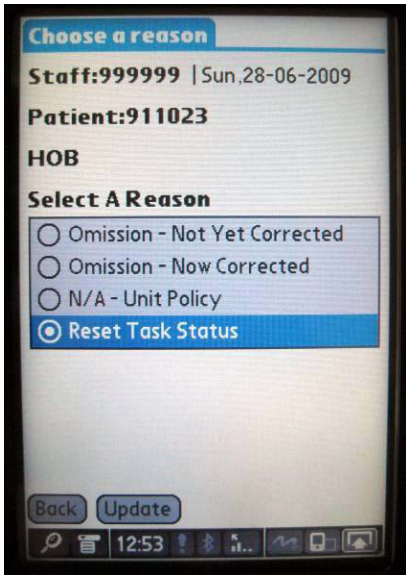
9. Editing a response

➢ Changing from 'Yes' to 'No'



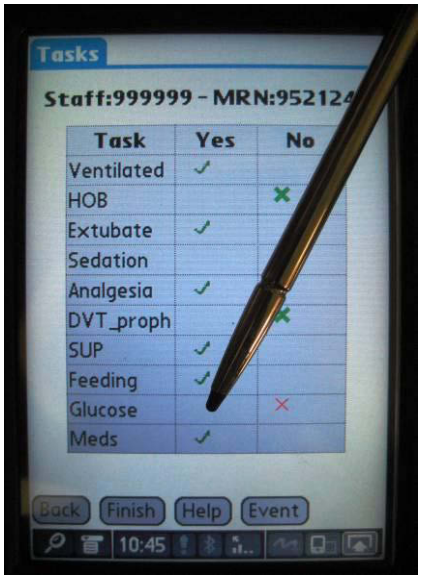
- Click on the '**No**' box beside the item you wish to change
- Select a reason for 'No'
- Click '**Update**'

➢ Changing from 'No' to 'Yes'



- Click on the '**Yes**' box beside the item you wish to change
- Click the '**Reset Task Status**' button
- Click '**Update**'

➢ Changing the reason for 'No'

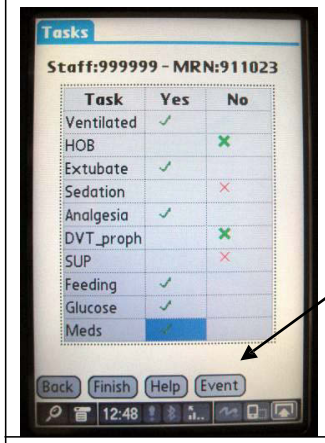


- Click on the '**Yes**' box beside the item you wish to change
- Select the new reason for 'No'
- Click '**Update**'

Clicking the '**Back'** button in the 'Select a reason' screen will return you to the checklist <u>without</u> making any changes.

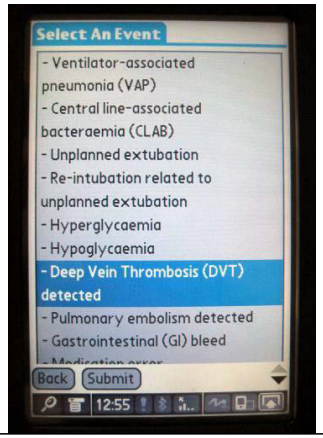
10. Enter patient level events

- Click on '**Event**' button at the bottom of the screen



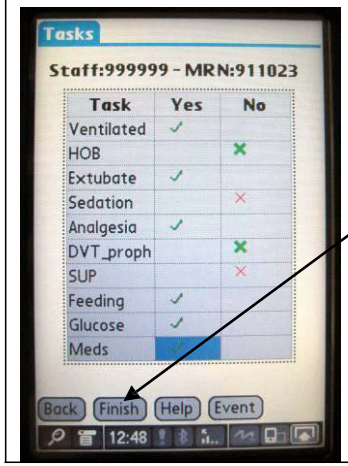
Click here

- Select an event from list by clicking on it.



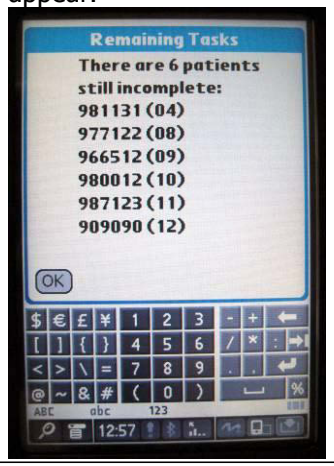
- '**Other**' events need to be specified at the server end.
- Click on '**Submit**'
- You will not be able to review entered events via the PDA, only via the server (see server instructions)
- If no events need to be recorded, click on the '**Back**' button.
- If more than one event, repeat above steps.

11. Completing the checklist



Click on '**Finish**'

A screen displaying incomplete patient checklists will appear.



Click '**OK**' to continue completing patient checklists.

When all patients have been completed the screen will display 'Finished. Thank you'.

Click '**OK**' to return to the patient list.

Press the '**Home**' function button on the bottom left corner of the PalmPilot to exit the program and return to the Start screen.

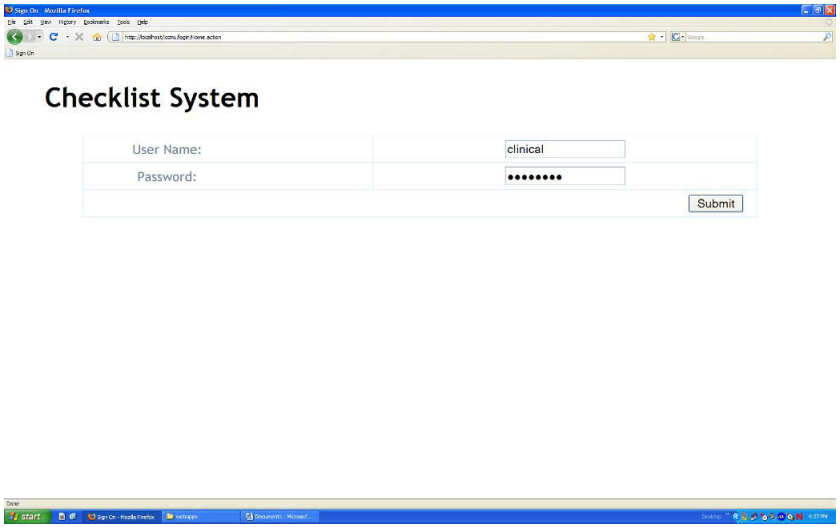
Please note: Power-off will automatically occur after 15 minutes of 'idle time' i.e. when PDA is not in use.
You will need to press the '**Home**' function button and re-enter your staff number to continue.

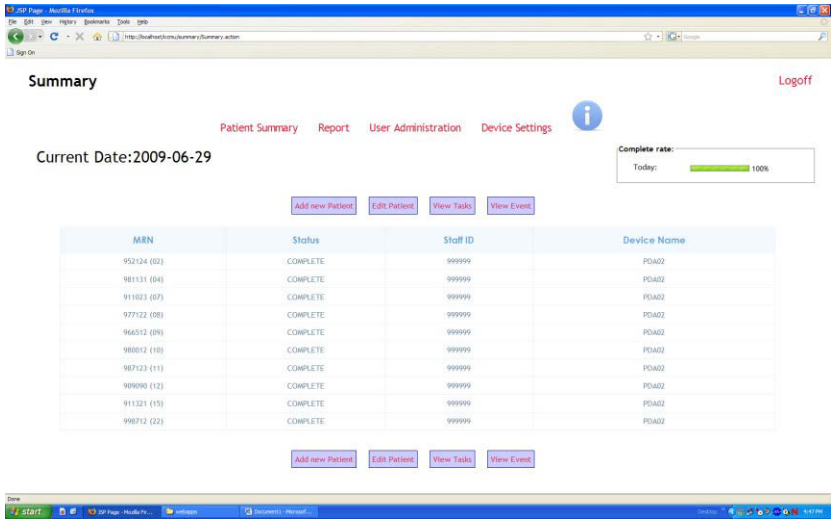
If the PDA freezes- press the reset button on the back of the PDA using the stylus.

Server Instructions

The Server can be accessed via the Computers on Wheels (COWs)

1. From the desktop, double click on the 'E-checklist' icon (shortcut to bookmarked address in Internet Explorer)
2. When login screen appears (see below) enter in username and password
3. Username = clinical
4. Password = clinical
5. Press Submit



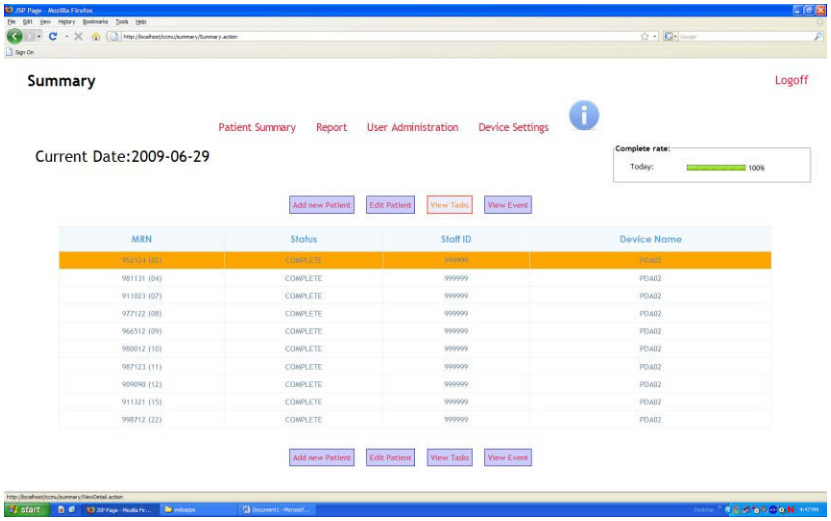


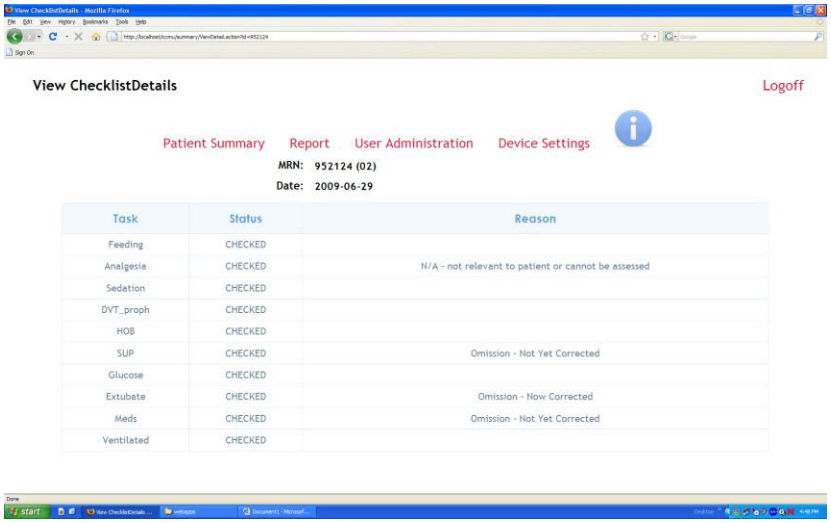
When you click on the  button, a copy of this information booklet will open in separate window.

Note: if you need to use Internet Explorer for other purposes, open up a new browser window.

Check Tasks Completed for Patient

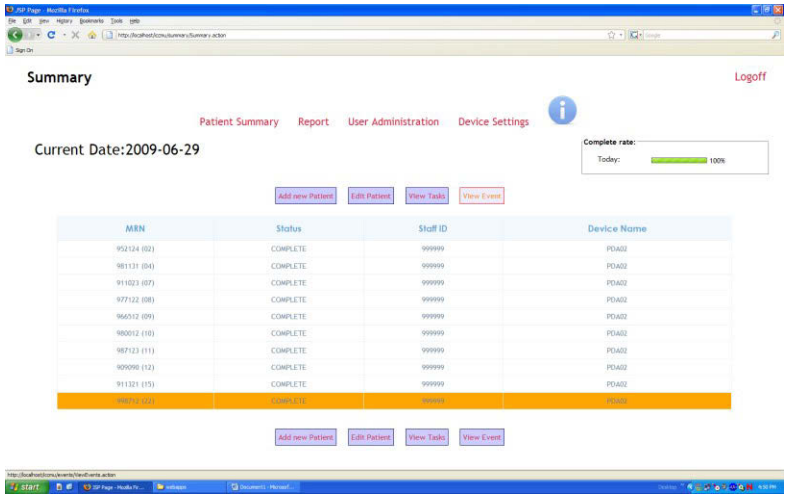
1. From the '**Patient Summary**' screen select the patient (patient will be highlighted in orange)
2. Click on '**View Tasks**' to view a summary of the tasks completed for the day
3. Click on '**Patient Summary**' to return to the main screen

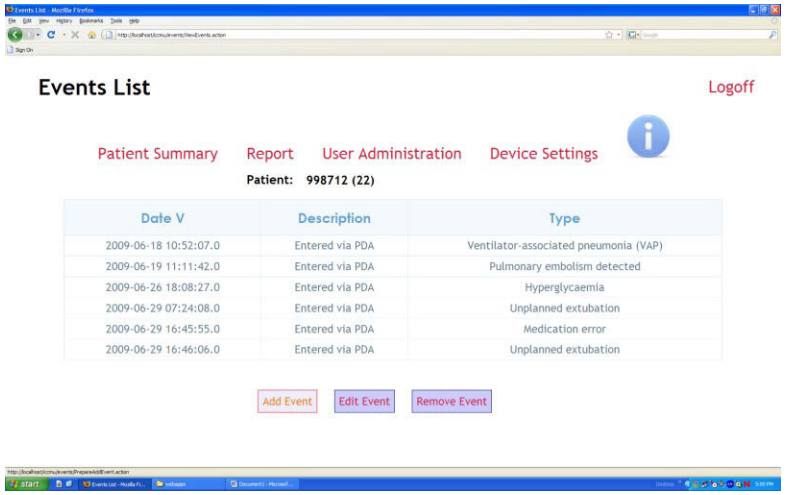




Add Patient Level Event

1. From the '**Patient Summary**' screen select the relevant patient (patient will be highlighted in orange)
2. Click on '**View Event**'
3. Click on '**Add Event**'

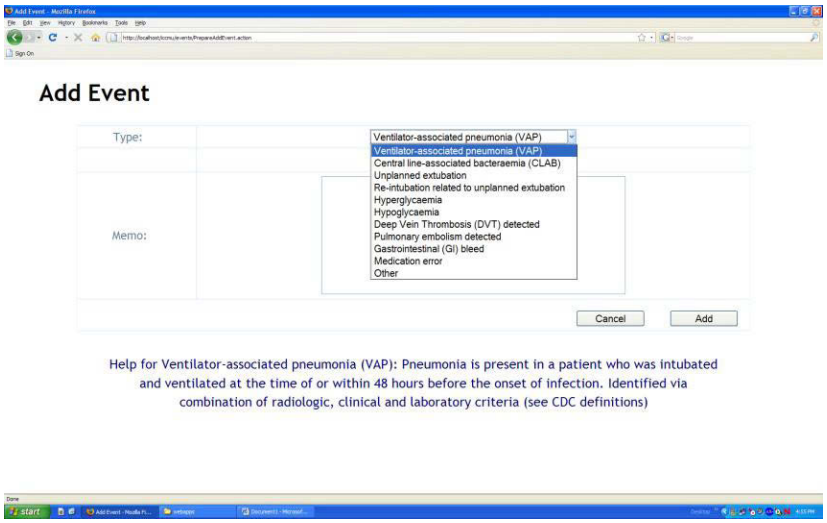


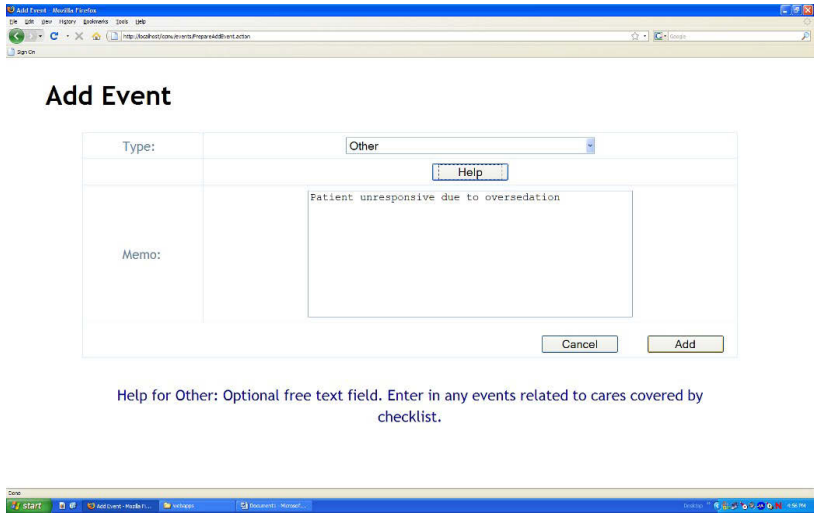


Instructions continued over page…

Add Patient Level Event (continued)

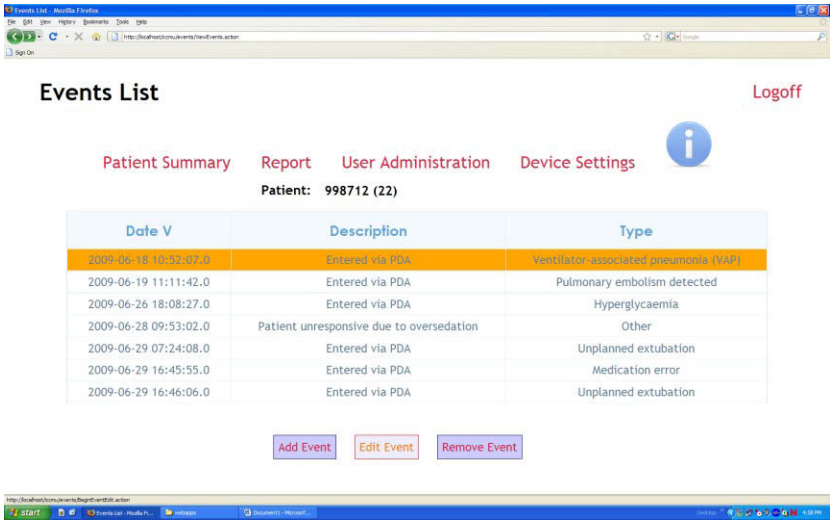
4. Select event you wish to add from the drop down list. If you select '**Other**' please specify in the '**Memo**' text box
5. Click on '**Help**' for event definition
6. If you would like to add a note about the event do so in the MEMO text box. This is not mandatory
7. Click on '**Add**'
8. Click on '**Patient Summary**' to return to the main screen

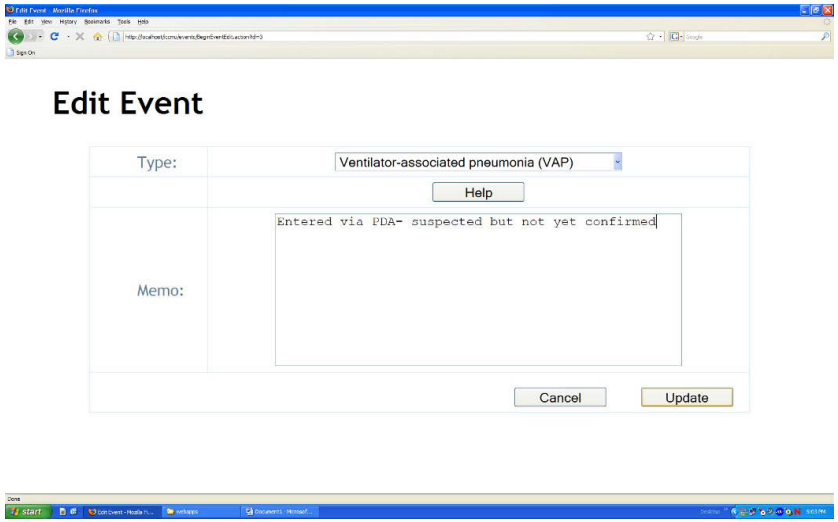




Edit Patient Level Event

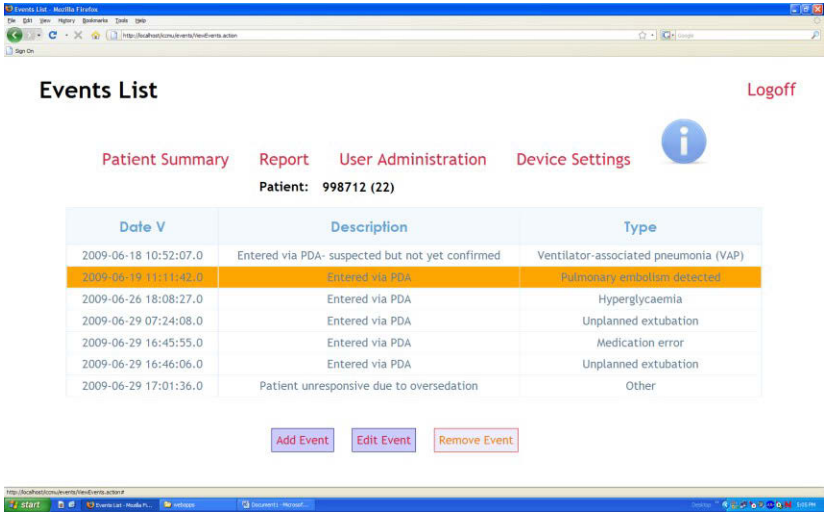
1. From the '**Patient Summary**' screen select the patient (patient will be highlighted in orange)
2. Click on '**View Event**'
3. Select event to edit (will be highlighted in orange)
4. Click on '**Edit Event**'
5. Edit event as required
6. Click on '**Update**'
7. Click on '**Patient Summary**' to return to the main screen

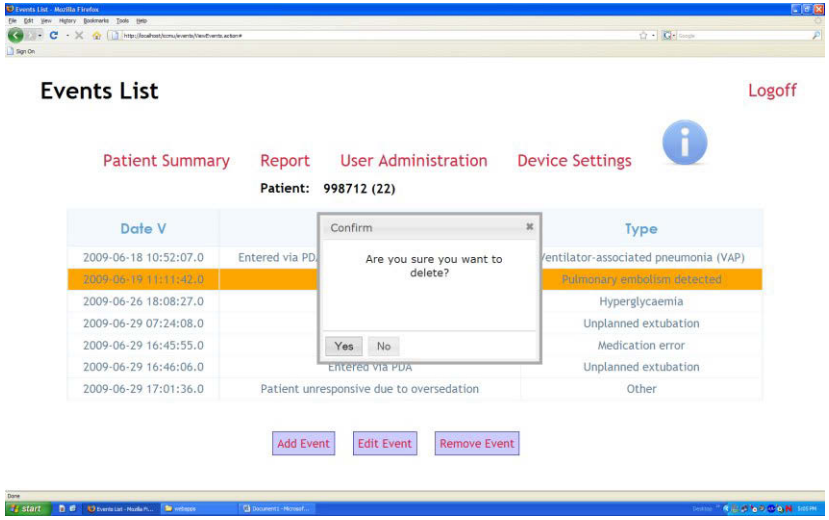




Remove Patient Level Event

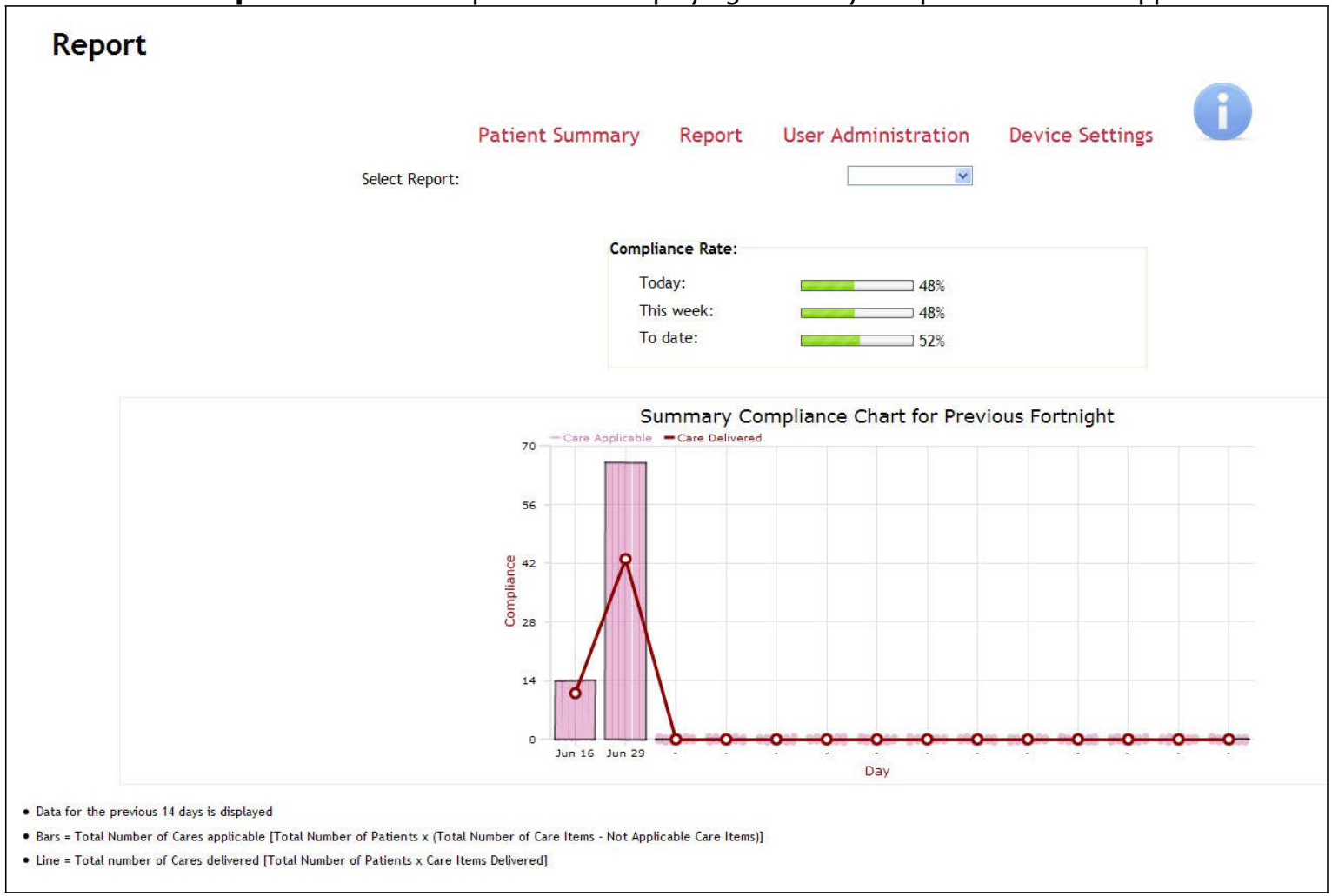
1. From the '**Patient Summary**' screen select the patient (patient will be highlighted in orange)
2. Click on '**View Event**'
3. Select event to edit (will be highlighted in orange)
4. Click on '**Remove Event**'
5. Confirm you are sure you want to delete the event
6. Click on '**YES**'
7. Event has been removed
8. Click on '**Patient Summary**' to return to the main screen



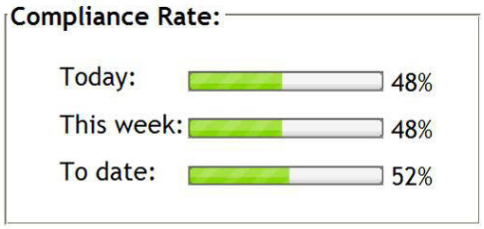


Data Reports

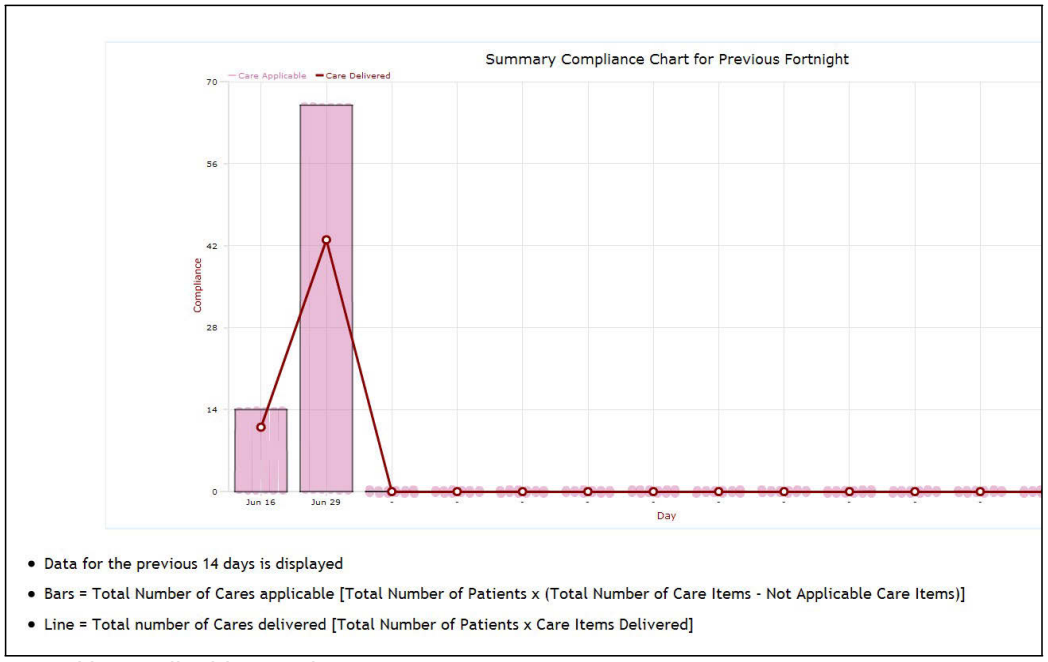
1. Click on '**Report**' – the main report screen displaying summary compliance data will appear.



2. The '**Compliance Rate**' progress bars display the **overall** percent compliance (i.e. cares delivered/cares expected*) for today, this week and total to date.

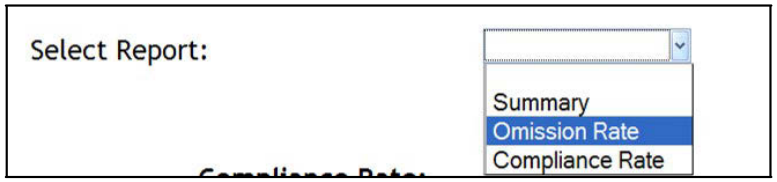


3. The '**Summary Compliance Chart**' displays the total number of cares applicable (bars) and the total number of cares delivered (line) for the past 14 days.

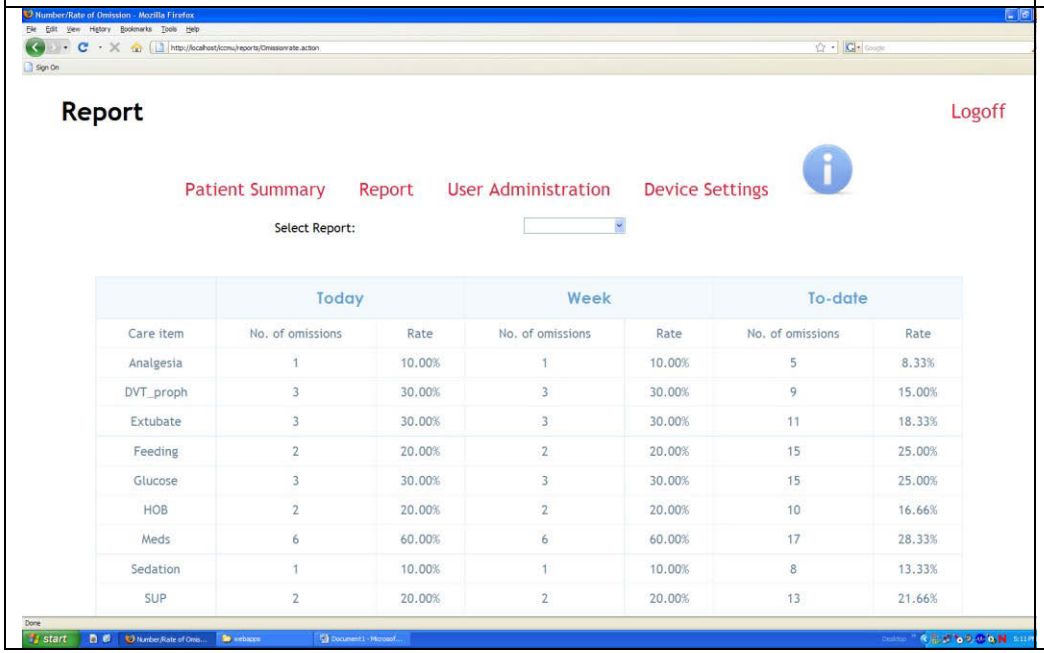


*Care expected = Total no. of care items – Not applicable care items

4. To choose a tabulated report, click on the drop down list box beside 'Select Report' and choose from the following:

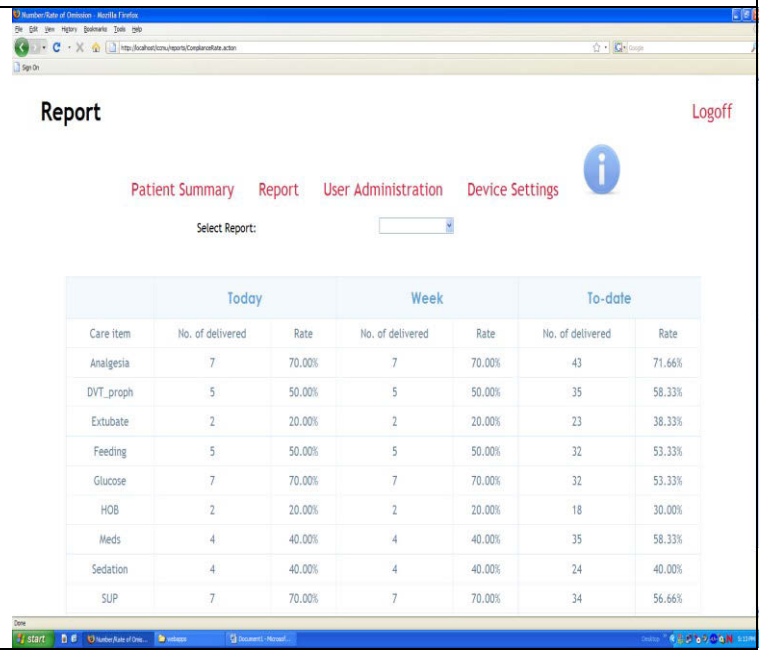


Omission rate – displays the number and rate of omissions by care item for today, the past week and to-date.



	Today		Week		To-date	
Care item	No. of omissions	Rate	No. of omissions	Rate	No. of omissions	Rate
Analgesia	1	10.00%	1	10.00%	5	8.33%
DVT_proph	3	30.00%	3	30.00%	9	15.00%
Extubate	3	30.00%	3	30.00%	11	18.33%
Feeding	2	20.00%	2	20.00%	15	25.00%
Glucose	3	30.00%	3	30.00%	15	25.00%
HOB	2	20.00%	2	20.00%	10	16.66%
Meds	6	60.00%	6	60.00%	17	28.33%
Sedation	1	10.00%	1	10.00%	8	13.33%
SUP	2	20.00%	2	20.00%	13	21.66%

Compliance rate – displays the number and rate of cares delivered for today, the past week and to-date.



	Today		Week		To-date	
Care item	No. of delivered	Rate	No. of delivered	Rate	No. of delivered	Rate
Analgesia	7	70.00%	7	70.00%	43	71.66%
DVT_proph	5	50.00%	5	50.00%	35	58.33%
Extubate	2	20.00%	2	20.00%	23	38.33%
Feeding	5	50.00%	5	50.00%	32	53.33%
Glucose	7	70.00%	7	70.00%	32	53.33%
HOB	2	20.00%	2	20.00%	18	30.00%
Meds	4	40.00%	4	40.00%	35	58.33%
Sedation	4	40.00%	4	40.00%	24	40.00%
SUP	7	70.00%	7	70.00%	34	56.66%

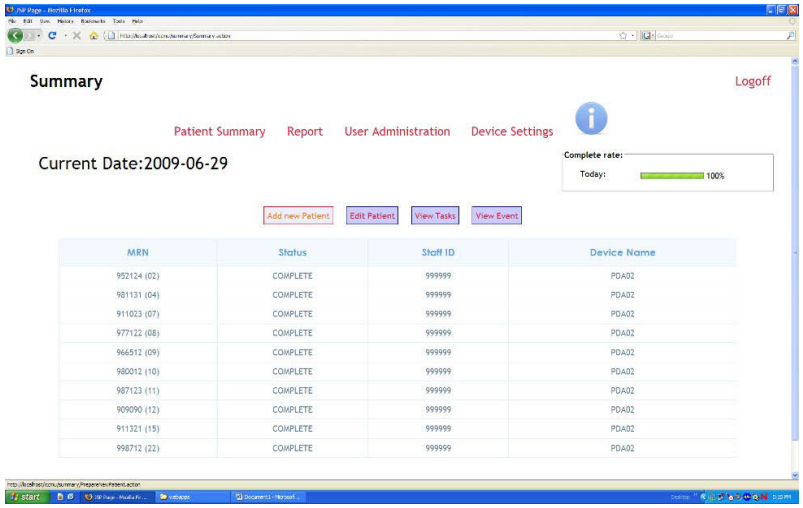
Summary – returns to the main report screen displaying summary compliance data.

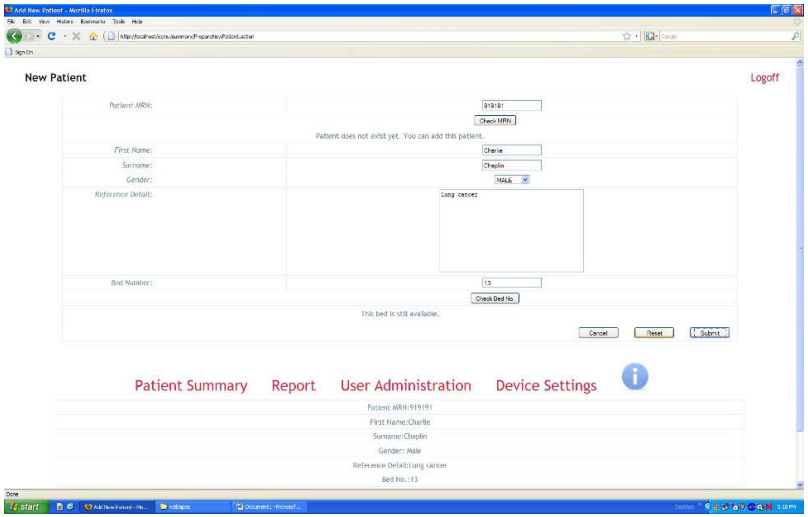
Add Patient

NOTE: Updating the patient list will be done by ward clerks <8am each day.

Before adding new patients ensure the '**Patient Summary**' screen is open and check the patient list.

1. Click on '**Add New Patient**'
2. Enter MRN (no spaces)
3. Click '**Check MRN**'
    - If patient exists then the patient should already be in the patient list displayed on the previous screen
4. Enter the patient's details. Any notes about the patient you may wish to make e.g. diagnosis should be added to the REFERENCE DETAIL text box. This field in not mandatory.
5. Enter the patients bed number (use leading zeros for beds 1-9 e.g. Bed 1 = "01")
6. Click on '**Check Bed No.**'
    - If the bed is still available click '**Submit**', the details will be confirmed in a summary table below the data entry form.
    - If the bed is not available there is already a patient in this bed and you will need to edit the existing patients details (see 'Edit a patient' instructions on next page)

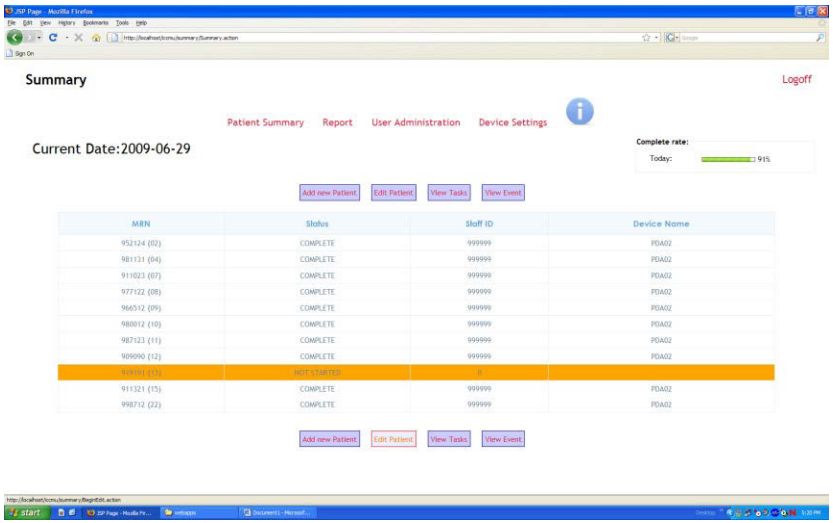


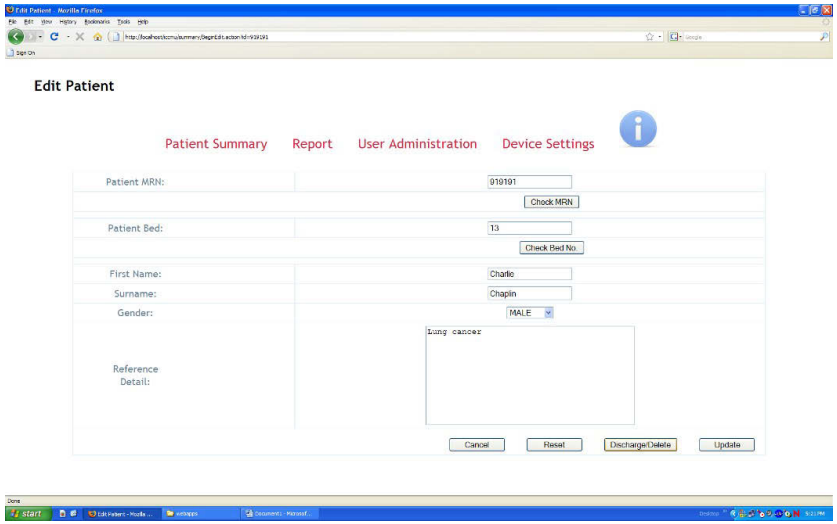


7. After the patient details have been confirmed click on '**Reset**' if you wish to add another patient (then follow the above steps)
8. Click on '**Patient Summary**' to return to the main screen

Edit Patient (e.g. change patient's bed number or remove patient from list)

1. From the '**Patient Summary**' screen select the patient you wish to edit (patient should be highlighted in orange)
2. Click on '**Edit Patient**'
3. Make necessary changes including bed numbers
4. Click on '**Update**' to confirm the change
5. If the patient is being or has been discharged from the unit click on '**Discharge/Delete**'





If you successfully delete a patient, a screen with 'Deleted' will appear.

Appendix H. E-checklist study information flyer for patients and their visitors

ICCMU Intensive Care Coordination & Monitoring Unit

UNIVERSITY OF TECHNOLOGY SYDNEY

SYDNEY WEST Area Health Service

Using a process of care checklist in the Intensive Care Unit (ICU)

Nepean ICU is currently implementing the use of an electronic checklist that aims to ensure that routine clinical care is provided to every patient, every day.

We would like to ensure the patients in our ICU are being kept safe whilst in our care. We are trialling the use of a checklist as a way of assisting our staff in delivering the best possible care to patients.

As part of the approval for our study, the Health Services Research Ethics Committee (HREC) at the University of Technology, Sydney (UTS) has requested we provide some information for patients and relatives.

The usual care and treatment that our patients/your relatives receive will not be influenced by our study.

The research does not involve the recruitment of patients for study.

If you have any questions relating to this study, please contact:
Ms Karena Hewson
Tel. (02) 4734 1584

If you have any concerns about the conduct of the study, you may contact the SWAHS Ethics Officer, Ms Paula Ewings on (02) 4734 3441 or email: Paula.Ewings@swahs.health.nsw.gov.au

Appendix I. E-checklist study information flyer for ICU staff

Using a process of care checklist in the Intensive Care Unit (ICU)

Nepean ICU is currently implementing the use of an e-checklist that aims to ensure that routine clinical care is provided to every patient, every day.

The e-checklist is being delivered via a handheld Personal Digital Assistant (PDA) linked wirelessly to a dedicated and secure server. The e-checklist will be completed by one of the senior medical staff at the end of each patient assessment during the morning ward rounds.

If you are using the e-checklist, please ensure you:

- receive one-on-one instruction on its use before commencing
- log-on to the PDA using your password and keep it with you during the rounds
- complete one checklist per patient at the end of each patient assessment as a "challenge and answer" process
- involve the team in completing the checklist
- after completing ward rounds press the 'Finish' button and return the PDA to its designated secure location.

Importantly, you can receive feedback on data collected at any time by accessing the reports function on the designated laptop computer. You can generate reports on care completion for any time period you wish.

This study has received ethics clearance from both SWAHS and UTS HRECs. Approval has also been obtained from ICU management.

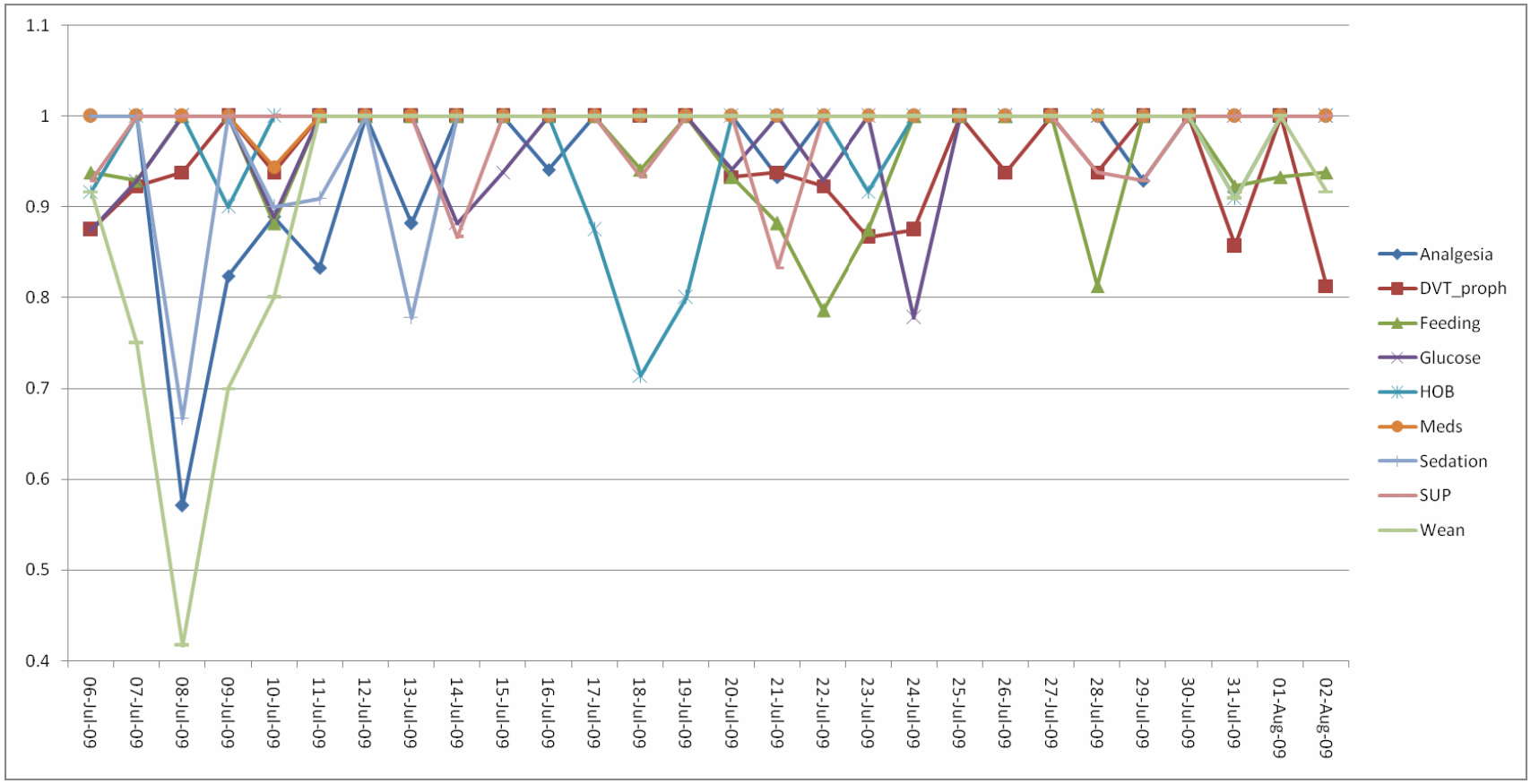
The research does not involve the recruitment of patients for study.

If you have any questions relating to this study, please contact:
Ms Karena Hewson
Tel. (02) 4734 1584

If you have any concerns about the conduct of the study, you may contact the SWAHS Ethics Officer, Ms Paula Ewings on (02) 4734 3441 or email: Paula.Ewings@swahs.health.nsw.gov.au

Appendix J. Example feedback report issued to ICU medical staff fortnightly

E-Checklist Project Fortnightly Feedback Report (3/8/2009)



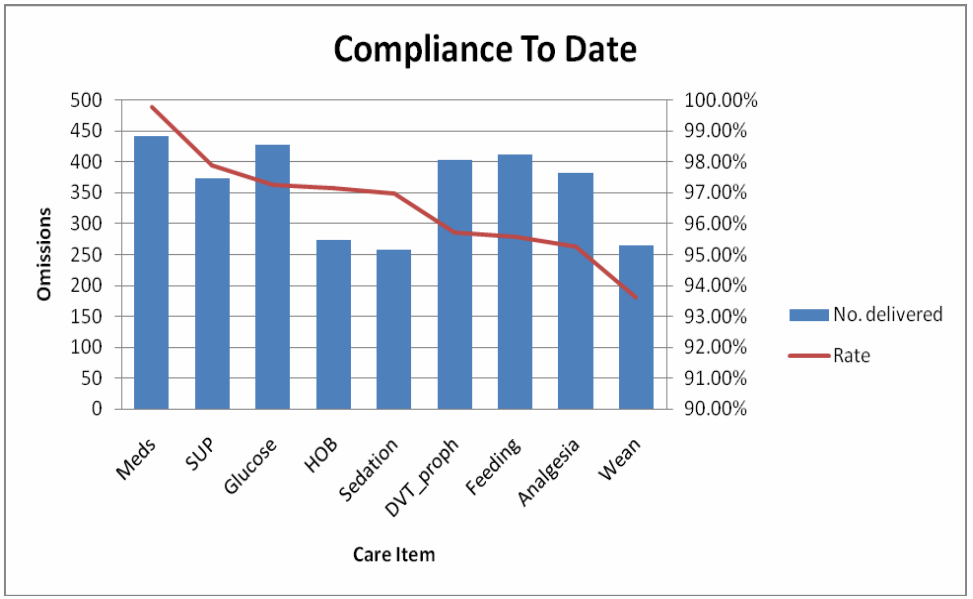
Note: Compliance rate = no of cares delivered / total cares applicable; i.e. 1.0 = 100% compliance.

- Overall, average compliance is very high (around 97%) - see compliance report below for more detail.
- However, there is some recent variability particularly around nutritional assessment and delivery of DVT prophylaxis.

Summary Reports as of 03 August 2009 (inclusive)

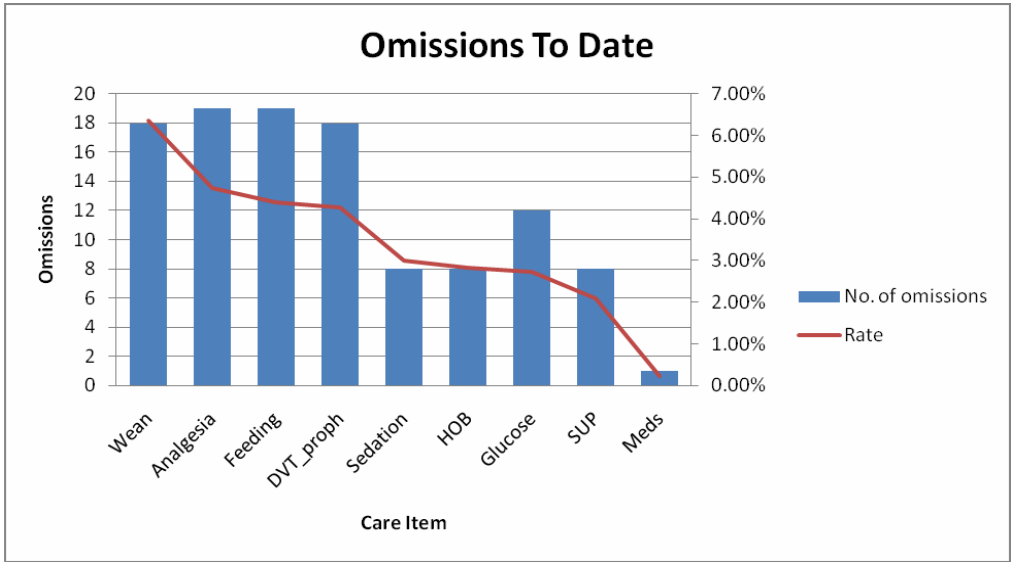
Compliance Report

Care item	No. delivered	Rate
Meds	441	99.77%
Stress ulcer proph	374	97.90%
Glucose	428	97.27%
HOB	274	97.16%
Sedation	258	96.99%
DVT prophylaxis	403	95.72%
Feeding	412	95.59%
Analgesia	382	95.26%
Wean	265	93.63%



Omissions Report

Care item	No. of omissions	Rate
Wean	18	6.36%
Analgesia	19	4.73%
Feeding	19	4.40%
DVT prophylaxis	18	4.27%
Sedation	8	3.00%
HOB	8	2.83%
Glucose	12	2.72%
Stress ulcer proph	8	2.09%
Meds	1	0.22%



Summary of Checklist Items and Response Options

Label	Checklist statement	Response Options
Ventilated	Is the patient invasively ventilated?	Yes/No
HOB>30	Patient is positioned with the head of the bed raised >30 degrees	Yes/No/NA (unit policy)
Wean	Patient's readiness to be weaned from mechanical ventilation has been assessed	Yes/No
Sedation	Sedation target set, sedation level assessed and managed	Yes/No/NA (has not required sedation in past 24 hours)
Analgesia	Pain has been assessed, a management plan set and progress reviewed	Yes/No/NA
DVT_proph	Mechanical and/or drug DVT prophylaxis is being administered or applied.	Yes/No/Clinical Contraindication
SUP	Stress ulcer prophylaxis is being administered.	Yes/No/NA (unit policy)/Clinical Contraindication
Feeding	Nutrition goals have been formally assessed and progress reviewed	Yes/No/NA
Glucose	Blood sugar levels (BSL) have been assessed, limits have been set and are being managed to achieve those limits	Yes/No/NA
Meds	All medications have been checked and reviewed	Yes/No

Note: The 'Ventilated' question is there simply to provide a filter for the checklist. When 'No' is selected, the following three statements are not applicable to patients who are not invasively ventilated so are completed automatically (i.e. NA = a **green** cross).

Remember these statements should be addressed and answered as a **challenge and answer at the end of patient assessment**. Wherever possible, cares that are identified as an omission should be corrected there and then e.g. DVT prophylaxis is not being administered when applicable, so an order should be written for it once identified. If the order is written immediately (i.e. upon checklist prompt) the answer should be '**omission- now corrected**'. If it is not feasible to correct it at that point in time the answer should be '**omission- not yet corrected**'.

Only press the '**Back**' button if you **do not** wish to save the data you have entered or the changes you have made.

Please refer to the data dictionary for detailed definitions (located on E-checklist server, on COWs and other unit computers)

Appendix K. Semi-structured observation tool for use in ICU

Part A. Pre-observation Interview

Position of person interviewed: _____

1. Type of unit
2. Layout of unit
3. Bed numbers (ICU/HDU)
4. Is there flexibility in the use of beds? Describe e.g. mix of ICU/HDU patients
5. Types of beds/rooms (e.g. isolation rooms etc)
6. Staffing structure per shift- positions, skill-mix, numbers
7. Rostering of medical staff
8. Routine practices/events during the day & across the week regarding organisation & general running of the unit e.g. handover, ward round, x-rays, meetings, etc.
9. Other notes on structure/resources of the unit

Part B. Observation tool for use during ICU ward rounds

1. Structure/layout of unit
   (in conjunction with pre-observation interview)

   1.1. Routine practices/events during the day & across the week regarding organisation & general running of the unit e.g. handover, ward round, x-rays, meetings, etc.
   1.2. Handover? (who is involved? Describe process. Nursing handover? Shift handover vs ward round)
   1.3. Other notes on structure/resources of the unit

2. Ward rounds
   2.1. Number of staff on morning ward rounds & their positions
   2.2. Describe the structure, flow and content of morning ward rounds.
   2.3. Note interactions- the type, the role of those involved, the purpose and whether it was initiated by the clinical lead. Note eye contact. Draw diagram depicting staff and their interactions.
   2.4. Levels of mobility of staff and are there differences between doctors and nurses?

3. Communication
   3.1. Assessment/evaluation of teamwork on ward rounds, noting verbal and non-verbal communication cues.
   3.2. Note whether thorough patient assessments are undertaken? Is this dependent on how familiar teams are with the patient?
   3.3. How do interruptions to ward rounds impact on information flow?
   3.4. Specific tools used e.g. Daily rounding forms/ care plans/ checklists etc?
   3.5. What is communicated during the rounds- does it follow a specific structure? How does this vary between teams? Do the dynamics change with a change in Intensivist lead? Verbal vs non verbal cues. Note patterns of communication and how it differs within the round and across teams.

4. Documentation
    4.1. Who documents what on the morning ward rounds?
    4.2. Who refers to the documentation?
    4.3. How thorough is documentation? Is this dependent on other factors e.g. is documentation less thorough when rounds are interrupted? (Consider having a nurse assist with this, check whether processes of care documented, randomly select 20% patients to review documentation after the ward rounds are complete).

5. Technology
    5.1. What devices other than medical equipment (e.g. PDAs, PC's, other electronic decision support) are used by the medical staff?
    5.2. What are they used for?
    5.3. Who uses them?
    5.4. How is technology integrated into patient care?
    5.5. What proportion is paper vs electronic documentation? Do the two overlap i.e. is there duplication? If so, what information is duplicated? (Note: not a focus, but document if overtly observed)

6. Other
    6.1. Note the limitations of the observational process, any barriers or difficulties encountered.
    6.2. Note the enablers to the observational process, what made it easier, how barriers were overcome etc.

Coding System for field notes

Code	Description
B#	Bed number
D1	Director, ICU
I1	Intensivist (use initial if more than one)
SR	Senior Registrar
R1	Registrar
R2	Resident
I2	Intern
MS	Medical Student
SP	Specialist (specify type)
NUM	Nurse Unit Manager
TL	Nurse Team Leader
CNS	Clinical Nurse Specialist
ON	Other Nurse Subcodes: CNC Clinical Nurse Consultant CNE Clinical Nurse Educator NE Nurse Educator
BN#	Bedside Nurse (with or without bed number)
NS	Nursing student
WP#	Wardspeople (number if more than 1)
WC#	Ward Clerks (number if more than 1)
AD	Administrative officers
CL	Cleaners
IC	Infection Control
AH	Allied Health Subcodes: PH Pharmacist PHYSIO Physiotherapist OT Occupational therapist ST Speech Therapist DIET Dietician RAD Radiology Technicians
PAS	Pastoral Care/ Religious Officer/Leader
R/F	Relatives & Friends

Appendix L. Sydney West Area Health Service HREC approval for e-checklist intervention study

SYDNEY WEST AREA HEALTH SERVICE | NSW HEALTH

HUMAN RESEARCH ETHICS COMMITTEE, NEPEAN CAMPUS

Court Building, Ground Floor
P.O Box 63
Penrith NSW 2751

Tel: 47 34 3441
Fax 47 34 1365
Email: Ethics@wahs.nsw.gov.au or CoutinM@wahs.nsw.gov.au

mc

June 20th, 2007

Dr. Tony Burrell
Director
Intensive Care Coordination & Monitoring Unit
North Block
Nepean Hospital.

Dear Dr. Burrell,

Re: HREC Project 07/046: Pilot Testing the Use of an Electronic Process of Care Checklist in a Tertiary Intensive Care Unit - Dr. Tony Burrell, Ms. Karena Hewson and Prof. Doug Elliott

The Sydney West Area Health Service HREC, Nepean Campus, at its meeting held on 12/6/2007, considered the ethical components of your research proposal that was scientifically reviewed and forwarded by our Scientific Review Committee.

We are pleased to inform you that your study was provisionally approved, subject to the following information and changes being returned for review and final approval:

1. Application section 3.5[b] indicates that research will be done on patients. Please clarify if this is correct and if not, amend and return page 8 of the application.

2. Application section 4.3[b] says that a Checklist will be given to all adult patients in ICU during the study period. Please clarify who the participants will be, amend page 10 of the application and return.

3. Application section 5.1 indicates that a Participant Information Sheet (PIS) will be given to participants; however application section 5.2 states that no consent will be obtained. The Committee requested the provision of a standard Consent Form.

4. Please also provide a standard Participant Information Sheet (PIS), as the PIS provided is non-standard (template attached).

5. Application section 7.1 indicates that information from state departments will be collected and additional information was provided under 7.1. The answer to 7.1 should be 'no' and the remaining information deleted. Please note that accessing data from a state department would be, for example, the linkage of data from NSW Health Dept's database, and this is certainly not the case. Please provide a revised page 14 of the application.

Please forward your response and amendments to the HREC office, Nepean Campus, for review and final approval.

Yours sincerely,

Dr. J Kalantar
Chair
SWAHS HREC, Nepean Campus.

CC: Ms. Karena Hewson, ICCMU.

Appendix M. UTS HREC approval for e-checklist intervention study

7 August 2007

Professor Doug Elliott
CB10.07.213
Faculty of Nursing, Midwifery and Health
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Doug,

UTS HREC REF NO 2007-67 – ELLIOTT, Professor Doug, BURRELL, Dr Tony (for HEWSON, Ms Karena PhD student) - "Electronic process of care checklist in the ICU"

Thank you for your response to my email dated 11 May 2007. Your response satisfactorily addresses the concerns and questions raised by the Committee, and I am pleased to inform you that ethics clearance is now granted.

Your clearance number is UTS HREC REF NO. 2007-67A

Please note that the ethical conduct of research is an on-going process. The *National Statement on Ethical Conduct in Research Involving Humans* requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9615.

Yours sincerely,

Professor Jane Stein-Parbury
Chairperson
UTS Human Research Ethics Committee

Appendix N. Participant Information Sheet

Title of Study
Electronic process of care checklist in the ICU

Names of Investigators
Dr Tony Burrell
Prof Doug Elliott
Ms Karena Hewson (PhD student)

Introduction
The ICCMU Research team, in association with UTS, is investigating the use of checklists to support evidence-based processes of care related to the ICU. As an extension of paper-based checklists piloted in 2004, a revision of content has been conducted and a new approach to data collection has been developed, as an electronic checklist via a Personal Digital Assistant (PDA), with accessibility to related unit policies and procedures. This research forms a part of Ms Hewson's doctoral thesis.

Aim of the Study
Our overall aim is to evaluate the implementation of a process-of-care checklist methodology in NSW Intensive Care Units (ICUs) as a way of ensuring evidence-based processes of care are performed routinely and systematically, ultimately improving the quality of care delivered to intensive care patients. Nepean ICU will be piloting this methodology, with the potential for rolling out to other ICUs statewide. It is therefore envisaged that Nepean ICU will become front-runners in implementing an innovative quality of care project that has implications for improving healthcare delivery.

Who will be invited to enter the Study?
All ICU medical staff will be asked to participate in this study.

What will happen on the Study?
There are two elements to this project that you will be asked to voluntarily participate in. The first involves the completion of two surveys - one prior to commencement of the checklist implementation, and another post-implementation. Each survey should take no longer than 10 minutes to complete. The second component is the completion of the PDA checklist for each patient on the morning ward rounds.

We hope that you will participate in activities that support the implementation of the checklist methodology. We plan to trial the use of the PDA checklist for a period of 6 weeks so as to explore any change in practice. Over this time, de-identified feedback on compliance with care components will be provided via control charts displayed in staff only common areas. If desired, this feedback can be discussed at Unit Quality Meetings.

What are the medical assessments to be conducted on participants?
We require one senior medical staff member to complete the PDA-based checklist daily for each patient on the morning ward rounds. The checklist will cover routine evidence-based cares that should be delivered to all patients (unless contra-indicated). The intention is to integrate this process into your normal work processes.

Do you have a Choice?
All medical staff have a choice in whether to participate in this study. As the aim of this project is to improve the quality of care delivered to intensive care patients, participation is strongly encouraged.

What are the participant's rights?

Although the study will not seek to collect any information of a sensitive or personal nature, any identifiable information obtained in connection with the study will remain confidential and disclosed only with your permission, except as required by law. Publishing of results will occur with your permission by signing the participant consent form. In any publication, information will be provided in such a way that you cannot be identified.

What if I decide not to go on the study?

There will be no repercussions for non-participation in this study. We only ask that if you decide not to participate in the study that this does not impede on those who are.

Complaints

If you have any concerns about the conduct of the study, you may contact the SWAHS Ethics Officer, Ms Paula Ewings on (02) 4734 3441 or email: Paula.Ewings@swahs.health.nsw.gov.au

Contact details

If you have any questions during business hours, please contact:
Ms Karena Hewson
Research & Quality Manager, ICCMU
Office telephone. 4734 1585

If you have any questions after hours, please contact:
Dr Tony Burrell
Director, ICCMU
Mobile number.

University contact:
Prof Doug Elliott
Director of Research, Faculty of Nursing, Midwifery & Health, UTS
Office telephone. (02) 9514 4832

Appendix O. Participant Consent Form

Name of Study: **Electronic process of care checklist in the ICU**

Principal Investigator/s: **Dr Tony Burrell, Prof Doug Elliott, Ms Karena Hewson (PhD student)**

I.....Name (please print)

of.....Address (please print)
give consent to my participation in the this research project.

In giving my consent I acknowledge that:

1. I may withdraw from the Study at any time and that my refusal to take part in the Study will not affect my employment at Nepean Hospital;

2. I understand that the Study will be conducted in a manner conforming with ethical and scientific principles set out by the National Health and Medical Research Council of Australia;

3. The study will be carried out as described in the attached information sheet and I acknowledge that I have read and understood the information sheet about the Study which was provided to me before I signed this consent and that I have received a copy of this consent form and information sheet;

4. The general purpose, method and demands and the possible risks, inconveniences and discomforts, which may occur to me during the Study, have been explained to me by Ms Karena Hewson, Research Officer, ICCMU.

5. I understand that I will not be identified in any way, and my personal results will remain strictly confidential to the extent permitted by the relevant privacy laws.

6. I agree that the research data gathered from this project may be published and will form part of a Doctoral thesis.

7. I have been advised that both the Sydney West Area Health Services Research Ethics Committee Nepean Campus and the University of Technology, Sydney Human Research Ethics Committee have approved the study.

8. I understand that if I have any complaints or concerns, I may contact the SWAHS Ethics Officer Ms Paula Ewings on (02) 4734 3441 quoting Registration No 07/046.

SIGNED: …… Date: ……

NAME: ……

WITNESS: …… Date: ……

Appendix P. Nurse unit manager's responses to pre-observation interview

1. Structure/layout of unit

1.1. Type of unit

General ICU (with HDU patients)

1.2. Layout of unit

- 2 physical pods each with separate nursing stations
- 1 procedure room
- 2 storage rooms- one for large equipment another for surgical/medical supplies
- 2 drug rooms (1 per unit)
- 1 room for dialysis equipment/plumbing
- 2 dirty utility rooms
- 1 bathroom
- 1 staff room
- 2 conference rooms (one large room divides into 2 with retracting wall)
- Overnight stay room
- 2 waiting rooms (1 serves as a family meeting room)
- Offices for senior nursing staff (NUM, Clinical NUMs, Research Nurses, CNEs)

1.3. Bed numbers (ICU/HDU)

19 beds (13 ICU, 5 HDU funded)

1.4. Is there flexibility in the use of beds? Describe e.g. mix of ICU/HDU patients

- Use as ICU/HDU as required- can flex up to 19 beds if needed
- Nurse-to-patient ratio - 1:1 (ICU) and 1:2 (HDU)

1.5. Types of beds/rooms (e.g. isolation rooms etc)

4 isolation rooms- negative pressure but no anti-chamber

1.6. Staffing structure per shift- positions, skill-mix, numbers

- 1 ICU Director (with clinical duties)
- 7 Consultants (not including Director)
- 4 Senior Registrars
- 8 Registrars
- 4 SRMO's
- 5 Residents
- 1 Nurse Unit Manager (Mon-Fri)
- Bedside nursing staff: 86 Registered Nurses (RN), 17 Clinical Nurse Specialists (CNS)
- 1 Access nurse (Senior RN)- when possible
- 6 Clinical NUMs (day) & Super-numery team leader (night) – 7 days
- 2 Clinical Nurse Educators (CNE) – cover 7 day roster
- 1 ICU Liaison Clinical Nurse Consultant (CNC) – mostly unit based (5 days), coordinates team of liaison nurses (7 day coverage)
- 1 Research Coordinator (1FTE CNC) and 3 Research Nurses who rotate and have other duties e.g. bedside nursing, CNE, organ and tissue donation (now on maternity leave)
- 1 Area CNC- covers Blue Mountains, Hawkesbury & Nepean with most time spent at Nepean.

1.7. Rostering of medical staff

Consultants:

- 7 day rotations with 2 consultants on call every day.
- Each has 1st and 2nd on-call duties per month (approx).
- Combination of two consultants per shift – usually different combination each rotation in any given month.

Senior Registrars – 4 x 10 hour shifts per week

Registrars – 7 x 12 hour shifts per 2 week block

Residents – 7 x 12 hour shifts per 2 week block

SRMOs – 7 x 12 hour shifts, 1 week on, 1 week off. 1 day shift & 1 night shift per month. 2 sets of day/night teams.

All medical staff in ICU are required to work on Public Holidays.

1.8. Routine practices/events during the day & across the week regarding organisation & general running of the unit e.g. handover, ward round, x-rays, meetings, etc.

- Nursing handover everyday at change of shift i.e. 7am, 2.30pm, 9.30pm.
- Central meeting with all nursing staff to give overview of all patients followed by bedside 1:1 detailed handover including review/update on charts.
- Medical handover at 8am (night to day staff) followed by ward rounds (approx 8.30am). Afternoon ward rounds (4pm). Evening handover at 8pm.

Meetings:

- X-ray meetings every day after/towards end of ward rounds depending on ICU activity (held at approx 1100-1200)
- Medical staff presentations – Tuesdays 0730-0830 (weekly)
- ICU Management meeting – Wednesdays 1100-1200. Attended by senior medical and nursing staff
- Clinical meeting, Thursdays 0900 – patients are selected by a consultant for case review

- Thursdays 1400 – rotate between Journal Club (2 per month), Mortality and Morbidity meeting (1 per month), Ward meeting (1 per month); attended by all interested medical and nursing staff
- Night duty ward meeting (0700 on different days, 1 per month)
- OH&S meetings (approximately every 2 months)
- Infection control meetings with infection control staff (monthly)
- Senior Nursing staff meetings (monthly)

1.9. Other notes on structure/resources of the unit

- 14 ventilators plus 1 transport ventilator
- Monitors at all beds
- 2 x computers on wheels (COWs)
- Computers and high resolution screens in ICU conference rooms for viewing scans & x-rays
- PACS computer against wall at Bed 10
- Computer and high resolution screens on back wall of ICU 1 for viewing scans and x-rays

Appendix Q. Checklist responses provided by auditors during *baseline* data collection phase (n=635)

Care component	Yes (care delivered & documented)	Yes (care delivered but not documented)	*Yes (total)*	Not applicable[b]	No (omission of care)	Not Ventilated [a]
Pain	311 (49.0)	28 (4.4)	*339 (53.4)*	-	296 (46.6)	-
DVT prophylaxis	483 (76.1)	5 (0.8)	*488 (76.9)*	120 (18.9)	27 (4.2)	-
Readiness to wean	254 (40.0)	7 (1.1)	*261 (41.1)*	-	26 (4.1)	348 (54.8)
Nutrition	455 (71.7)	10 (1.6)	*465 (73.2)*	112 (17.6)	58 (9.1)	-
Glucose management	461 (72.6)	20 (3.1)	*481 (75.7)*	-	154 (24.3)	-
Head of bed elevation	99 (15.6)	92 (14.5)	*191 (30.1)*	40 (6.3)	53 (8.3)	351 (55.3)
Medications[c]	487 (76.7)	7 (1.1)	*494 (77.8)*	133 (20.9)	8 (1.3)	-
Sedation management	149 (23.5)	8 (1.3)	*157 (24.7)*	460 (72.4)	18 (2.8)	-
Stress ulcer prophylaxis	442 (69.6)	-	*442 (69.6)*	167 (26.3)	26 (4.1)	-

Notes

Figures in brackets are percentages; missing data excluded.

[a] Auto-fill function in response to first checklist question 'Is the patient mechanically ventilated?' Sedation management not included at baseline ('not applicable' response was used).

[b] Includes clinical contra-indications.

[c] 'Not applicable' response to medications checklist item reflected auditors inability to determine whether a review of all medications was completed

Appendix R. Checklist responses provided by physicians during *intervention* phase (n=577)

Care component	Yes (care delivered)	Not applicable[b]	No (omission – not yet corrected)	No (omission now corrected)	*No (total)*	Not Ventilated [a]
Pain	504 (87.3)	50 (8.7)	21 (3.6)	2 (0.3)	*22 (3.8)*	-
DVT prophylaxis	522 (90.5)	36 (6.2)	6 (1.0)	13 (2.3)	*19 (3.3)*	-
Readiness to wean	326 (56.5)	-	17 (2.9)	2 (0.3)	*19 (3.3)*	232 (40.2)
Nutrition	541 (93.8)	16 (2.8)	13 (2.3)	7 (1.2)	*20 (3.5)*	-
Glucose management	562 (97.4)	2 (0.3)	4 (0.7)	9 (1.6)	*13 (2.3)*	-
Head of bed elevation	334 (57.9)	2 (0.3)	5 (0.9)	5 (0.9)	*10 (1.7)*	231 (40.0)
Medications	576 (99.8)	-	-	1 (0.2)	*1 (0.2)*	-
Sedation management	313 (54.2)	23 (4.0)	9 (1.6)	-	*9 (1.6)*	232 (40.2)
Stress ulcer prophylaxis	480 (83.2)	85 (14.8)	6 (1.0)	6 (1.0)	*12 (2.1)*	-

Notes

Figures in brackets are percentages; missing data excluded.

[a] Auto-fill function in response to first checklist question 'Is the patient mechanically ventilated?' Included 'sedation management'.

[b] Includes clinical contra-indications

Appendix S. Checklist responses provided by auditors during *intervention* phase (n=333)

Care component	Yes (care delivered & documented)	Yes (care delivered but not documented)	*Yes (total)*	Not applicable[b]	No (omission of care)	Not Ventilated [a]
Pain	137 (41.4)	62 (18.7)	*199 (60.1)*	95 (28.7)	37 (11.2)	-
DVT prophylaxis	271 (81.6)	-	*271 (81.6)*	58 (17.5)	3 (0.9)	-
Readiness to wean	195 (58.7)	6 (1.8)	*201 (60.5)*	-	3 (0.9)	128 (38.6)
Nutrition	258 (77.9)	21 (6.3)	*279 (84.3)*	43 (13.0)	9 (2.7)	-
Glucose management	284 (85.5)	7 (2.1)	*291 (87.7)*	8 (2.4)	33 (9.9)	-
Head of bed elevation	117 (35.1)	59 (17.7)	*176 (52.9)*	3 (0.9)	26 (7.8)	128 (38.4)
Medications	296 (89.4)	8 (2.4)	*304 (91.8)*	27 (8.2)	-	-
Sedation management	144 (43.4)	11 (3.3)	*155 (46.7)*	42 (12.7)	10 (3.0)	125 (37.7)
Stress ulcer prophylaxis	256 (77.1)	-	*256 (77.1)*	73 (22.0)	3 (0.9)	-

Notes

Figures in brackets are percentages; missing data excluded. Audits conducted four days per week.

[a] Auto-fill function in response to first checklist question 'Is the patient mechanically ventilated?' Included 'sedation management'.

[b] Includes clinical contra-indications

Appendix T. Measures of concordance* for all checklist items by physician designation

Care component	n	Proportion observed agreement	Bias Index	Prevalence Index	Byrt's kappa	Proportion positive	Proportion negative
Consultant	930	94.41	.045	.940	.888	.971	.071
Registrar	316	96.20	.019	.956	.924	.981	.143
Senior Registrar	796	92.09	.034	.918	.842	.959	.031

* concordance based on 2x2 contingency table

Appendix U. E-checklist user questionnaire – baseline

Process of Care Questionnaire: Part A

1. Please write your employee number here [ ]

2. Please place a cross (**X**) in the appropriate box to indicate the **frequency** that your ICU currently engages in **each** activity for **all** applicable patients.

There is space to provide comments if you wish to elaborate on any point.

	Infrequently (<50%)	Sometimes (50-79%)	Often (80-97%)	Always/almost always (>97%)	Comments
Care processes					
Nutrition goals formally assessed and progress reviewed					
Pain assessed, management plan set and progress reviewed					
Sedation target set, sedation level assessed and managed					
Mechanical and/or drug DVT prophylaxis delivered					
Patients positioned with the head of the bed raised >30 degrees					
Stress ulcer prophylaxis delivered					
Blood sugar level (BSL) limits set and being managed to achieve those limits					
Patient's readiness to be weaned from mechanical ventilation assessed					
All medications checked and reviewed					

Process of Care Questionnaire: Part B (Baseline)

Please complete the following questions as accurately as possible.

This survey will **not** report on any information that may identify you in any way. Employee numbers are only sought so that responses at baseline can be matched with responses post-implementation. Names will **not** be matched with employee numbers, and surveys will be stored in a secure location.

1. Your employee number: _____

2. Your current level of medical experience:

   1☐ Resident
   2☐ Registrar
   3☐ Senior Registrar
   4☐ Intensivist
   5☐ Other (specify)_____

3. Do you currently use an electronic device e.g. Personal Digital Assistant (PDA), Smartphone, in the clinical setting?

   0☐ No (go to Q4) 1☐ Yes

   If yes, please answer the following questions in relation to electronic device use in the **clinical setting** only.

3.1. What type of device do you use?	
3.2. How long (in months/years) have you been using it?	
3.3. How often do you use it for clinical work?	1☐ Almost always 2☐ Often 3☐ A few times 4☐ Rarely 5☐ Never
3.4. Describe how it is used in clinical work including what functions and programs you use.	
3.5. Has its use influenced your clinical decision-making?	0☐ No 1☐ Yes
3.5.1. If yes, in what way has it been influenced?	

4. How do you rate your own level of acceptance of technology in the clinical management of a patient?

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Very low	Low	Moderate	High	Very High

Comment:

_____

_____

5. Do you currently use any tools such as checklists, mnemonics, or other methods that relate to the delivery of care in the ICU?

0☐ No 1☐ Yes (specify)_____

_____

6. Do you believe that the daily processes of care specified in the checklist could be improved in this ICU?

0☐ No 1☐ Yes 2☐ Unsure

7. How well do the items in the checklist relate to the care processes that are expected to be delivered in this ICU?

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Not well at all	Not well	Unsure	Well	Very well

8. Please rate what you think the usefulness of this electronic checklist will be:

8.1. in ensuring daily processes of care are delivered

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Very poor	Poor	Average	Good	Very Good

8.2. as opposed to using nothing/relying on memory

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Much worse	Worse	About the same	Better	Much better

8.3. as opposed to using a paper checklist

1☐	2☐	3☐	4☐	5☐
Much worse	Worse	About the same	Better	Much better

9. Please rate the **training** provided including whether you were given enough information about the following:

9.1. the project in general

1☐	2☐	3☐	4☐	5☐
Very poor	Poor	Average	Good	Very Good

9.2. background information

1☐	2☐	3☐	4☐	5☐
Very poor	Poor	Average	Good	Very Good

9.3. the rationale for using an electronic checklist

1☐	2☐	3☐	4☐	5☐
Very poor	Poor	Average	Good	Very Good

9.4. the study procedure

1☐	2☐	3☐	4☐	5☐
Very poor	Poor	Average	Good	Very Good

9.5. interpreting data displayed in charts

1☐	2☐	3☐	4☐	5☐
Very poor	Poor	Average	Good	Very Good

9.6. the written material provided prior to session

1☐	2☐	3☐	4☐	5☐
Very poor	Poor	Average	Good	Very Good

10. Please make any suggestions for improving the training provided here.

_____

_____

_____

_____

11. Please make any comments you have here.

_____

_____

_____

_____

_____

Thank you for your time.

Appendix V. E-checklist user questionnaire – evaluation

Process of Care Questionnaire: Evaluation

The aim of this survey is to evaluate the use of the electronic process-of-care checklist in the ICU setting. It will take approximately 5 minutes to complete.

Please answer the following questions as openly and honestly as you can. This survey is anonymous and therefore it will **not** report any information that may identify you in any way. Employee numbers are only sought so that responses at baseline can be matched with responses post-implementation. Names will **not** be matched with employee numbers, identifiers will be **removed** once responses have been matched and all and surveys will be stored in a secure location.

1. Your employee number: _____

2. Your current level of medical experience:

   1☐ Resident
   2☐ Registrar
   3☐ Senior Registrar
   4☐ Intensivist
   5☐ Other (specify)_____

3. How well did the items on the checklist relate to the care processes expected within this ICU?

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Not well at all	Not well	Unsure	Well	Very well

4. Please rate what you think the usefulness of this electronic checklist was:

   4.1. in ensuring daily processes of care were delivered

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Very poor	Poor	Average	Good	Very Good

   4.2. as opposed to using nothing/relying on memory

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Much worse	Worse	About the same	Better	Much better

   4.3. as opposed to using a paper checklist

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Much worse	Worse	About the same	Better	Much better

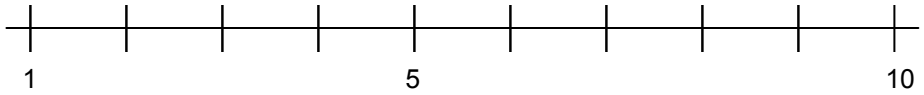
5. To what extent do you believe that overall, the delivery of care improved with the use of the e-checklist?

1☐	2☐	3☐	4☐	5☐
Not at all	A little	Unsure	Moderately	A lot

6. Was the use of the e-checklist supported by team members including senior staff?

1☐	2☐	3☐	4☐	5☐
Not at all	A little	Unsure	Moderately	A lot

7. On average, how long did it take to complete the e-checklist for each patient? (in minutes)



8. In your opinion, was using the e-checklist worth the time spent on its completion?

0☐ No 1☐ Yes 2☐ Unsure

9. After either using or witnessing the use of the checklist, how do you rate you own level of acceptance of this technology in the clinical management of a patient?

1☐	2☐	3☐	4☐	5☐
Very low	Low	Moderate	High	Very High

Comment:

_____

10. How would you best describe your experience in adapting to the new process?

1☐	2☐	3☐	4☐	5☐	6☐
Very Difficult	Difficult	Unsure	Easy	Very easy	Didn't get involved

11. During this project were you more or less likely to check other routine processes of care that weren't in the checklist?

1☐	2☐	3☐	4☐	5☐
Much less likely	Less likely	Unchanged	More likely	Much more likely

11.1 If **more likely** to check other processes, please specify which ones.

_____

_____

12. Please rate **each** of the following elements by ticking the box most appropriate to your response in the table below.

	Very Poor	Poor	Unsure	Good	Very Good
Elements of checklist					
Appropriateness of items on checklist					
Appropriateness of descriptors					
Clarity of items i.e. are they easily understood?					
Elements of checklist protocols					
To be completed during daily ward rounds for each pt					
To be completed at end of pt visit as a direct "challenge & answer"					
Senior medical staff to complete the checklist					
Clarity of definitions in data dictionary					
Elements of checklist software and PDA use					
Checklist design/ layout					
Ease of use (PDA in general)					
Ease of use (checklist software)					
Ease of data entry					
Navigating around checklist software i.e. between screens					
Having the care process detailed in the information buttons					
Having access to the data dictionary on the checklist server					
User-generated reports via checklist server					
Electronic data capture as opposed to paper-based data collection					
Elements of data feedback					
Feedback reports circulated via email					
Format of charts					
Frequency of data feedback					
Sense of ownership of process-of-care data					
Usefulness of data feedback to my clinical practice					

13. What do you believe were the benefits of using the e-checklist?

_____

_____

14. What do you believe were the limitations of using the e-checklist?

_____

_____

15. Did the training provided at commencement adequately prepare you for the implementation of the e-checklist project?

1☐	**2**☐	**3**☐	**4**☐	**5**☐
Not at all	A little	Unsure	Moderately	A lot

Comment:

_____

_____

16. Overall, do you believe the e-checklist is useful and worth continuing its use in the ICU?

1☐	**2**☐	**3**☐	**4**☐
No, definitely not	No, probably not	Yes, possibly	Yes, definitely

17. Please make any suggested improvements to the implementation of the checklist project here.

_____

_____

18. Would you be willing to give additional feedback on this project if required?

0☐ No 1☐ Yes 2☐ Unsure

Thankyou for your time.

Appendix W. Semi-structured interview questions for intensivists

1. First, ask about the process of using the e-checklist- how did you integrate it into your routine?
2. What are the problems/limitations to integrating the e-checklist into ward rounds?
3. What would make it easier- i.e. what systems, processes, implementation methods need to be in place?
4. Were there any barriers to providing the aspects of care covered in the checklist to patients (internal/external) e.g. absence of policy, awareness, etc?
5. What are your thoughts on gaining clinician buy-in, gaining acceptability in change of process? How do you get clinicians to drive or have a sense of ownership over routine process data collection?
6. Given most said the e-checklist was about as useful as a paper checklist and there were some limitations with the technology (slow, unresponsive, wireless network issues), in your opinion what were the pros and cons of the technology?
7. Is there a place for this technology in an ICU that is predominantly paper-based?
8. Can you see it being integrated into computer-based systems (e.g. via COWs)?
9. The e-checklist was implemented at a busy time, how much of an impact do you think this made to the project and in what way was it affected?
10. After piloting the use of the e-checklist, where do you see its value in the clinical management of a patient i.e. who should use and how should it be used?
11. What would be your suggestions for training clinicians on using the technology, taking them through the data dictionary and informing them about the project in general?
12. Did you use the user-generated reports via the checklist server? If yes, what did you think about the report functionality? How should this information be shared/used/communicated in the ICU?

13. If no, how should data be fed back to clinicians and how frequently? If this were to become an ongoing process, who should be responsible for data feedback?

14. How do you make the feedback useful to clinical practice? (e.g. what happens when a process is found to be lacking)

Appendix X. Safety culture questionnaire

Dear Colleagues

ICCMU in association with the University of Technology, Sydney is conducting this survey which has the potential to improve your unit's safety culture, ultimately improving patient care. Please answer the following questions with respect to the ICU where you received this survey.

This is an anonymous survey. Demographic information will only be used to group responses.

Safety Survey **Part A. Statements** Please circle the number corresponding to your response for each question	Strongly agree	Agree	Neutral	Disagree	Strongly
1. The culture in this ICU makes it easy to learn from the errors of others	1	2	3	4	5
2. Medical errors (any mistake in the delivery of care) are handled appropriately in this ICU	1	2	3	4	5
3. The senior leaders in my hospital listen to me and care about my concerns	1	2	3	4	5
4. The physician and nurse leaders in my area listen to me and care about my concerns	1	2	3	4	5
5. Leadership is driving us to be a safety-centred institution	1	2	3	4	5
6. My suggestions about safety would be acted upon if I expressed them to management	1	2	3	4	5
7. Management/Leadership does not knowingly compromise safety concerns for productivity	1	2	3	4	5
8. I am encouraged by my colleagues to report any patient safety concerns I may have	1	2	3	4	5
9. I know the proper channels to direct questions regarding patient safety in this ICU	1	2	3	4	5
10. I receive appropriate feedback about my performance	1	2	3	4	5
11. I would feel safe being treated here as a patient	1	2	3	4	5
12. Briefings (e.g. patient report at shift change) are important for patient safety	1	2	3	4	5
13. Thorough briefings are common in this ICU	1	2	3	4	5
14. I am satisfied with availability of Physician leadership	1	2	3	4	5
15. I am satisfied with availability of Nursing leadership	1	2	3	4	5
16. I am satisfied with availability of Pharmacy leadership	1	2	3	4	5
17. This institution is doing more for patient safety now, than it did one year ago.	1	2	3	4	5
18. I believe that most adverse events occur as a result of multiple system failures, and are not attributable to one individual's actions	1	2	3	4	5
19. All the personnel in my ICU take responsibility for patient safety	1	2	3	4	5

20. Personnel frequently disregard rules or guidelines (e.g. handwashing, treatment protocols/clinical pathways, sterile field etc.) that are established for this ICU	1	2	3	4	5
21. Patient safety is constantly reinforced as the priority in this ICU	1	2	3	4	5
22. I am aware that patient safety has become a major area for improvement in this institution	1	2	3	4	5
23. All the necessary information for diagnostic and therapeutic decisions are routinely available to me	1	2	3	4	5
24. I am provided with adequate, timely information about events in the hospital that might affect my work.	1	2	3	4	5
25. The physicians and nurses here work together as a well-coordinated team	1	2	3	4	5
26. Intensivists in this ICU are doing a good job	1	2	3	4	5
27. Interactions in this ICU are collegial, rather than hierarchical	1	2	3	4	5
28. Important issues are well communicated at shift changes	1	2	3	4	5
29. There is widespread adherence to clinical guidelines and evidence-based criteria in this ICU	1	2	3	4	5
30. Communication breakdowns, which lead to delays in delivery of care, are common	1	2	3	4	5
31. Communication breakdowns, which negatively affect patient care, are common	1	2	3	4	5
32. Have you completed this survey before?		Y		N	

Part B. **Use the scales to describe the quality of collaboration and communication you have experienced with:**	**Very low**	**Low**	**Adequate**	**High**	**Very High**	**Not applicable**
33. Nurse Unit Manager	1	2	3	4	5	6
34. Clinical Nurse Educators	1	2	3	4	5	6
35. Clinical Nurse Consultants	1	2	3	4	5	6
36. Critical Care Nurses	1	2	3	4	5	6
37. Intensivists	1	2	3	4	5	6
38. Registrars/Senior Registrars	1	2	3	4	5	6
39. Residents	1	2	3	4	5	6
40. Pharmacists	1	2	3	4	5	6
41. Physiotherapists	1	2	3	4	5	6
42. Ward Clerks	1	2	3	4	5	6
43. Other: specify (e.g. Occupational therapists, Speech Pathology, Dietitians, X-ray personnel)	1	2	3	4	5	6

44. ICU job category (mark one only):

❑$_1$ Nurse Unit Manager

❑$_2$ Clinical Nurse Educator

❑$_3$ Clinical Nurse Consultant

❑$_4$ Critical Care Nurse

❑$_5$ Intensivist

❑$_6$ Registrar/Senior Registrar

❑$_7$ Resident

❑$_8$ Ward Clerk

❑$_9$ Other: specify_____

45. Current age (e.g. 21):_____ 46. Gender: ❑ M or ❑ F

47. How many years of experience do you have in this speciality? (e.g. 4)_____years

48. How many years have you worked in this ICU? (e.g. 3) _____years

49. What are your top three recommendations for improving patient safety in this ICU?

_____

_____

_____

50. If this survey was online, how easy or difficult would it be to complete?

$_1$❑ Very easy $_2$❑ Easy $_3$❑ Unsure $_4$❑ Difficult $_5$❑ Very difficult

51. What location would you prefer to access the survey from?

$_1$❑ Work $_2$❑ Home $_3$❑ Other: specify_____

Thank you for completing this questionnaire, please place it in the designated post box in your unit.
Your unit will receive a summary of the results.

Appendix Y. Reported benefits and limitations to using e-checklist, suggested improvements to e-checklist implementation

Benefits	Limitations	Suggested improvements
• Served as a reminder to complete cares (n=2) • Easy to use • Covers important aspects of care to be considered for each patient • Cares to be checked integrated into a single tool • Possibility of rapid feedback • Self-assessment of clinical practice • Possibility of integration into clinical information systems • Improvements to delivery of care	• Slow response times to e-checklist actions (n=3) • Wireless network drop-outs • Some items overlapped with paper documentation • Not part of a single unified data management program • Need to use on every patient • Requires skill to operate PDA • PDA had poor battery life	• Improved program response time (n=2) • Need to computerise all ICU data/information • Reduce repetition by integrating into medical record (n=2) • Should not be performed by senior medical staff

Appendix Z. Summary of staff recommendations[1] for improving patient safety in the ICU

Pre-intervention categories	No. of responses	Example responses	Post-intervention categories	No. of responses	Example responses
Clinical practice and management					
Improve drug prescription and administration	4	Staff to verify treatment order with prescriber if there is any doubt	NA		
Improve pt care/management	4	Staff ignoring basic care, working with blinkers on	NA		
Review, develop and utilise evidence based guidelines/policies etc	4	Reviewing policy & procedure with evidence base; Decisions must be based on evidence	NA		
Computerised system for clinical information	3	Computerised: pt flow/management, charts, pharmacy; medical results/imaging	NA		
Improve handover and medical rounds	3	Regular multi-disciplinary rounds; Discuss the medical round & treatment plan nurse to doctor	Improve handover and medical rounds	3	Emphasise multi-disciplinary team approach; More efficient pt handovers
Improve hand washing	3	Adherence to hand washing	Improve hand washing	4	Hand washing still remains a huge problem especially with Drs, not just from ICU, some have little idea about sterile fields

Pre-intervention categories	No. of responses	Example responses	Post-intervention categories	No. of responses	Example responses
Use of checklists	3	Safety checklist on flow chart; Handover checklist to ensure pt safety, treatment & continuity; formalise daily goals	NA		
Communication and collaboration					
Achieve effective communication & collaboration between staff	9	Better communication with some of the medical team; Letting everyone in the unit what is happening and who is doing what	Achieve effective communication & collaboration between staff	10	Better communication of pt plans and direction; Change in communication strategy between ICU and other medical/surgical teams
Education					
Continue / extend / place emphasis on education	6	Educate staff on evidence-based policy & procedure; More regular education for nursing staff at least weekly in-services on topics such as drugs & ventilation in ICU	Continue / extend / place emphasis on education	4	More hands-on training of new staff (nursing/medical); More education/orientation programs
Increase / improve supervision of staff	2	More supervision for staff new to unit; Better supervision of Junior Medical Officers	Increase / improve supervision of staff	4	Increased clinical supervision targeting accountability for decision making around pt care

Pre-intervention categories	No. of responses	Example responses	Post-intervention categories	No. of responses	Example responses
Environment					
Supportive environment, positive reinforcement	3	Provide a system for dobbing in people who do a GOOD job - positive reinforcement works better than fear of reprisal	NA		
Equipment					
Access to more/adequate/suitable equipment e.g. beds that are readily available	4	More suitable beds; Better availability of some PPE items	Access to new/improved/ adequate equipment e.g. beds that are in working order	5	New beds that work e.g. Hillrom, in ALL bed areas; Working equipment and new chairs/lifters as all are broken
Incident monitoring					
Improve/increase reporting of incidents / near misses	5	Increasing incident reporting; encourage use of IIMS[2]	NA		
Increase debriefing sessions/feedback/follow-up of unsafe incidents	4	Provide feedback re: unsafe incidents; Review reasons & circumstances behind unsafe incidences to see how they could have been avoided	NA		

Pre-intervention categories	No. of responses	Example responses	Post-intervention categories	No. of responses	Example responses
Safety culture					
Improve / increase / encourage adoption of the safety culture within the unit	5	More pt safety centered discussions in academic fora. Bottom-Up strategy to gather ideas	Improve / increase / encourage adoption of the safety culture within the unit	2	Take it seriously (not just a token thing to be discussed and ignored)
No blame culture	2	Reduce 'blame one person' culture	Leadership & follow-up on safety issues	3	More follow-up from mgmt when nurses on floor voice concern about particular issues
Staffing/rostering					
Increased / better staffing and retention	5	Employ more senior nurses; Retention of senior staff from other disciplines	Adequate/ better staffing	5	Employing nursing staff who care more about pt safety and well-being
Appropriate/Improved skill mix	2	Educators needed on night duty; New grads should not be placed here on 1st rotation	Appropriate/Improved skill mix	5	Even skill mix for each shift especially night shift; Critically ill pt cared for by senior staff with experience in ICU - no new grads in ICU, must have 2 yrs on wards post-grad
Staff-to-patient ratio	2	Not accepting pts when there are no staff to care for them	Improve pt allocation including coverage during breaks	5	Not having team leader take a pt; Access nurses for break coverage

Pre-intervention categories	No. of responses	Example responses	Post-intervention categories	No. of responses	Example responses
Performance management					
Audit/evaluation and feedback	5	Reviewing team performance; Evaluation and feedback of pt cares	Audit/evaluation and feedback	7	Ongoing nursing audits of bed area and pt safety; Positive & negative feedback
NA	NA	NA	Appropriate action on performance issues	2	PRAISE high standards of care when they come to attention of leaders

[1] includes only those recommendations that were provided by more than one respondent

[2]IIMS = Incident Information Management System – a computer-based incident reporting tool