Improving Quality: Assessment of Risk, Interventions and Measuring Improvement in Critical Care

PhD by Published Work

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Abstract

Introduction

My ten published papers focus on two domains of the quality agenda, patient safety and patient experience, concentrating on how quality improvement can reduce the occurrence of serious consequences of patient harm and poor patient experience.

Aims

My goal was to design, test and discover how to make improvements in clinical practice in four areas: sleep deprivation, infection prevention, falls prevention and pressure ulcer prevention.

Literature Review

There was limited evidence of successful strategies for change to improve quality. Common quality improvement challenges were within the complex critical care environment and an urgency to act without the focus on well-designed methods.

Design and Methodology

A broad range of research methods was applied to evaluate the implementation of improvement interventions in critical care. These included: observational designs to uncover understanding on patient experience, activities and processes; before and after design; stepped cluster design and longitudinal time series design, utilised to increase confidence with attributable effect from the interventions.

Results

My appraisal of my ten publications showed quality varied. Process and outcome measures were used to determine the success, and I received national and local recognition for some of my work.

Discussion

My three main knowledge contributions were:

- practical ways to help nurses assess and improve patients' sleep
- risk assessment approaches
- translation and implementation of improvement methodology in critical care.

I discovered four cross-cutting themes which add to quality improvement knowledge and I developed an enhanced model for improvement. The four themes are:

- clinical leadership at a programme and local level
- using a bundle of technical and non-technical interventions
- undertaking patient risk assessment to guide interventions
- the value of data measurement and feedback

Conclusions & Recommendations

My work has improved patient experience and patient safety knowledge. With further testing this knowledge could greatly benefit other areas of healthcare.

Acknowledgements

I am fortunate to have worked with lots of people who have inspired me, challenged my thinking and supported me. All of my published work has involved working and collaborating with many great colleagues, too many to name individually. Nonetheless, a heartfelt thank you to all of them for their contributions and creating an enjoyable working environment. Special thanks to my loyal colleague and friend Robert Bullock who has reassured and encouraged me throughout my career and enabled me to progress and develop.

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Declaration

I declare that no outputs submitted for this degree have been submitted for a research degree of any other institution.

Signed …… Date ……15th February 2018……

Contents

1. Chapter One - Introduction to Quality Improvement, Patient Experience and Patient Safety

This chapter sets the scene by reviewing the origins of my ten published papers. It defines the key concepts of quality, safety and patient experience to put into perspective where my work sits within the quality of care agenda. My rationale to strive to improve patient experience and patient safety is explained, along with a review of the areas of focus: sleep deprivation, infections, falls and pressure ulcer damage to patients in acute and critical care.

1.1 Origins of my published papers

In England, the National Health Service (NHS) is currently facing immense challenges due to increasing financial and workload pressures and it cannot hope to meet the nation's healthcare needs without a commitment to quality improvement (Ham et al, 2016).

The delivery of high quality care has always been one of my personal commitments and it continuously drives me to seize opportunities to make improvements. My interest in improving patient experience and patient safety stems from concerns identified by patients and from what I observed in clinical nursing practice. My improvement leadership style can be described as a 'tempered radical', one who is willing to challenge the status quo and take responsibility for change (Meyerson, 2003). A key feature of this style is a desire to 'rock the boat' whilst at the same time 'stay in the boat' with those you are trying to change.

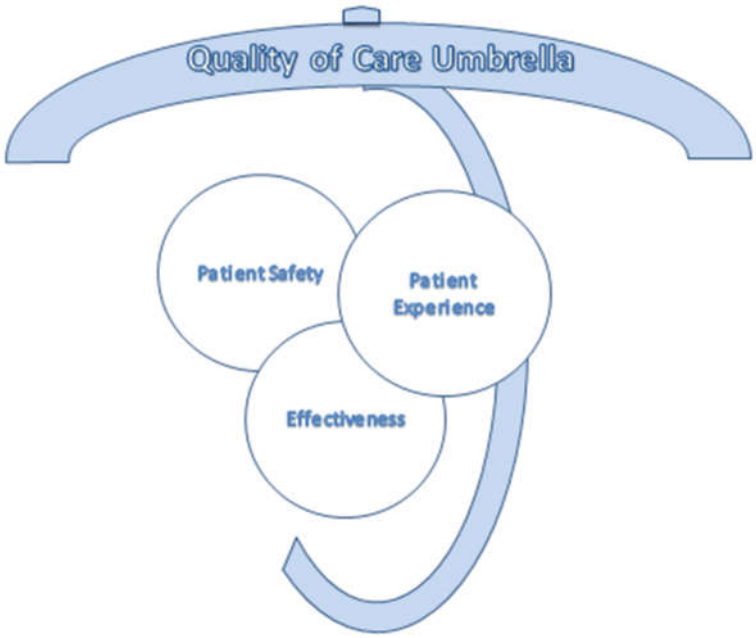
I have a great deal of curiosity about the prevalent evidence on techniques and approaches to improve care and outcomes, alongside an awareness of the practical difficulties with the implementation of this known evidence into practice. The application of proven successful improvement interventions and the opportunities for the translation of this evidence into practice in critical care was an obvious and relevant area for me to further evaluate.

To help review my work it is useful to highlight the two main areas of focus, patient experience and patient safety, and where they sit within the 'quality of care' agenda. The NHS identifies three quality domains: patient experience, patient safety and clinical effectiveness (NHS England, 2017) which are protected by legislation in the Health and Social Care Act (2012). Similarly, other

countries have defined safety and patient experience as priority areas within their quality agendas although the components vary. For example, Scotland and the United States of America (USA) use the same three domains but have added three more: efficient, equitable and timely (Scottish Government, 2010; Agency for Healthcare Research and Quality, 2016). It is worth noting that the terms quality and patient safety are often used interchangeably, as if they go hand in hand. However, quality is an umbrella term under which patient safety and patient experience sit.

Figure 1 has been developed with the three quality domains interlinked underneath a broad quality umbrella, with the understanding that problems in one domain impact on the other domains (Doyle et al, 2017; The Health Foundation, 2013).

Figure 1 - Quality umbrella and the interlinking domains



My work sits beneath the overall quality umbrella and originates from the domains of patient experience and patient safety due to my observations of poor patient experience and harmful patient events. Even though the work originates from these two domains, the third domain of clinical effectiveness plays an equally important part in improving quality of care.

Some definitions to help set the scene for the work are:

Patient safety is '*the absence of preventable harm to a patient during the process of health care'* (WHO, 2017b)

Patient experience is '*ensuring that people have a positive experience of care'* (The National Institute for Clinical Excellence, 2012, p. 4)

Clinical effectiveness is '*care which is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes*' (Healthcare Quality Improvement Partnership, 2015, p. 4).

Quality improvement is described as a logical approach using techniques to improve quality, and key elements of quality improvement are noted to include: the change or the improvement, a method or approach with appropriate tools and paying attention to context in order to achieve better outcomes (The Health Foundation, 2013).

Terms used such as 'improvement science' 'knowledge translation' and 'implementation research' all relate to the implementation of quality improvement. These terms are viewed as interchangeable with each other and with quality improvement research (Shojania and Grimshaw, 2016).

1.2 Rationale for focusing on patient experience and patient safety

Patient experience - Sleep promotion

My research began with quality improvement strategies to improve patients' sleep. Critical care is a noisy environment due to an array of medical devices such as monitors, ventilators and infusion pumps (Gabor et al, 2003). Most of these devices are fitted with audible alarms to alert staff to abnormalities. In addition, there are high numbers of multidisciplinary staff in close proximity to the patient due to the regular and intrusive nature of their care. A number of local complaints identified patients experiencing disturbed sleep at night due to noise.

A landmark report '*Crossing the Quality Chasm',* where patient experience and involvement in care became prominent, identified patient-centred care as one of the specific aims for improvement (Institute of Medicine, 2001). A number of years later, reports continued to identify that patients do not always have a positive healthcare experience (Shaller, 2007) and since the time my work began an emphasis on patient experience has continued. The specific effects of sleep deprivation were noted to be serious. Extensive studies have found that sleep deprivation can impact on patients' feelings and their recovery from illness. The effects include: irritability, tiredness, aggressive behaviour (Chuman, 1983), confusion (Dogan et al, 2005), respiratory dysfunction (Gabor et al 2001) and alteration to the process of weaning from a ventilator in intensive care (Mejer et al, 1994).

At a local level in the Trust where I work, improving patient experience by seeking their feedback had been made a key priority within the three-year Quality Strategy (The Newcastle upon Tyne Hospitals NHS Foundation Trust, 2015). The value of patient experience has recently been reinforced by evidence from a systematic review indicating positive associations between patient experience, patient safety and clinical effectiveness, across a range of disease areas, settings and patient groups. Positive patient experience was found to be associated with critical quality measures such as mortality and infections, and self-reported health and well-being outcomes such as functional ability, quality of life and anxiety (Doyle et al, 2017). The policy priorities and growing evidence boosts the need to concentrate on patient experience as a key component of quality.

Patient Safety - Infection, falls and pressure ulcer prevention

My subsequent work focused on reducing harm due to infection, falls and pressure ulcers.

Keeping patients safe is a fundamental responsibility for healthcare staff. Hippocrates (460-370 B.C.) 'the father of medicine' was credited with the Hippocratic Oath which includes the key message of 'do no harm'. In the 1850s Florence Nightingale demonstrated that making improvements to sanitation prevented infection and increased the survival of injured soldiers (Kudzma, 2006).

Despite the long history associated with keeping patients safe, over the last two decades the importance of preventing harm has intensified and become a key healthcare policy. Two influential reports, 'To Err is Human' (Institute of Medicine, 1999) and 'An Organisation with Memory' (Department of Health, 2000), both recognised that error was common with approximately one in ten patients experiencing harm from healthcare. It was also identified that healthcare was underperforming when compared to other industries, especially aviation, culminating in 2004 when the World Health Organisation (WHO) launched its 'World Alliance for Patient Safety' programme. Many countries responded and took action to establish organisations to focus on improving patient safety. Examples include the National Patient Safety Agency (NPSA) in England, the Agency for Healthcare Research and Quality (AHRQ) in the USA, the Canadian Patient Safety Institute and the Australian Commission on Safety and Quality in Healthcare (Shonjia and Panesar, 2014). These substantial investments demonstrated a genuine commitment to keeping patients safer. In Europe however, the focus on patient safety seems to have lagged behind. Following a two-year focus on patient safety strategies, some European countries were reported to have had variable success and called for a further commitment to patient safety (The European Commission, 2014).

The reported consequences of unintended harm are severe, emphasising the need to improve this area of practice. An English study reviewing over 1,000 hospital case notes found 110 patients experienced at least one adverse outcome. 21% resulted in impairment or disability lasting from one month to a year, 11% led to permanent disability and 10% contributed to patient death (Sari et al, 2007). Moreover, the emotional consequences of incidents can be significant for both patients and their families, including upsetting memories, mood disturbance, low self-esteem, depression

and anxiety. The families of patients who die due to an avoidable event may face traumatic and prolonged bereavement and difficulties in accepting the loss (Vincent and Coulter, 2002).

Staff involved in patient harm incidents can also suffer consequences. They often feel guilty, fear punishment and worry about the patient's anger (Wu, 2000). Sometimes the reaction of managers to blame the staff member involved can result in staff adopting dysfunctional ways to protect themselves, such as anger and defensive behaviour. Some staff lose their confidence, or use alcohol or drugs to cope (Wu, 2000).

Adverse events can also increase hospital length of stay. Sari et al (2007) found that on average, the stays were prolonged by 6.5 days per adverse event, thereby increasing cost. A meta-analysis of the financial impact of infections found an annual financial burden in the USA of $9.8 billion (£7.6 billion) (Zimlichman et al, 2013). An additional demand on organisations is the resource required to investigate and respond to complaints and claims associated with patient harm. A rigorous analysis of healthcare complaints over a period of almost 30 years showed 13% related to safety concerns (Reader et al, 2014). Similarly litigation costs are also vast. In the financial year 2014/15 the NHS Litigation Authority (NHSLA) paid out circa £1.1 billon to patients who suffered harm and their legal representatives. Consequently, the NHSLA have modified their approach to focus on supporting and learning from incidents (NHSLA, 2015).

Within my Trust, increasing attention is being placed on improving the quality of care through patient safety to the point whereby it has the highest priority within the Trust's overall three-year quality strategy (The Newcastle upon Tyne Hospitals NHS Foundation Trust, 2015). The patient safety priority areas identified include: infection prevention, falls prevention and pressure ulcer prevention.

My work on patient safety started with central venous catheter blood stream infections (CVC-BSI). A study in the USA concluded that the attributable mortality rates of CVC-BSI ranged from 0 to 35% (Frasca et al, 2010). Hospital lengths of stay increased by an attributable median of seven days (Leistner et al, 2014) with an estimated cost of between $4,869-$19,476 (£4,057-£16,230) per patient (Veenstra et al, 1999). More recently in Germany, higher costs of CVC-BSI have been reported at €29,909 (£24,924) per patient (Leistner et al, 2014). As a result of impressive findings from a study of 102 intensive care units in the state of Michigan it became NHS policy to refine and

replicate this practice from the USA to England. I was appointed nurse lead for the NPSA's 'Matching Michigan' national patient safety improvement programme. This two-year programme was established to minimise CVC-BSI across all critical care units in England.

Similarly, the consequences of falls were known to be the most common cause of death from injury in patients over 65 years old. Injuries associated with a fall include fractures, head injuries, bruising, loss of confidence and loss of independence (NPSA, 2007a). Furthermore, the cost of falls to the NHS is over £2 billion per year (Public Health England, 2014). This patient safety issue arose whilst I was working clinically on the critical care units and was driven by the Trust's target to reduce patient falls. A crucial step to prevent falls is to risk assess every patient so those with an elevated risk can be targeted with prevention interventions. Unfortunately, no risk assessment tool was available for critically ill patients, so the development of a tool became an important local priority.

My last five years' work has concentrated on pressure ulcer prevention; a national and local priority. The harm that can be caused by pressure ulcers has major patient, organisational and taxpayer impact. These include: a restricted lifestyle (Hopkins et al, 2006), pain and scarring, increased lengths of stay, mortality (Alderden et al, 2001), and a cost burden of £1.4 billion-£2.1 billion per annum (Bennett et al, 2004). Within my own Trust's critical care units I uncovered numerous patients suffering from pressure ulcer damage. I also discovered a staff culture that considered pressure ulcers as 'inevitable' rather than 'preventable'.

1.3 Aims

My objective was to design, test and understand how to make improvements in clinical practice. To do this I focused on four priority areas: improving patients' sleep, infection prevention, falls prevention and pressure ulcer prevention, all with acute and critically ill patients. This thesis explores the quality improvement techniques described in ten of my papers over a ten year period aiming to:

- Examine the development and testing of practical approaches to assist nurses assess and improve patients' sleep
- Examine the development and testing of risk assessment approaches in critical care
- Evaluate the translation and implementation of an infection prevention improvement methodology from the USA to England and then applied to pressure ulcer prevention.

2. Chapter Two - Quality Improvement Literature Review

This chapter reviews the literature relating to quality improvement to identify the level of knowledge and understanding before and during the publication of my papers.

At the start of my work the existing knowledge on quality improvement was limited despite a national directive to improve quality (Department of Health, 2008). This influential directive was focused on tackling variations in the quality of care, giving more information and choice to patients and accelerating change to improve quality.

When my first paper was published some models had already been developed to guide practitioners to improve quality by implementing evidence-based practice (EBP). An early framework 'the diffusion of innovation' was produced to guide implementation of research (Rogers, 2003). Rogers' work acknowledged that adopting and embedding a new idea, even one with obvious advantages, was extremely difficult. His framework defined diffusion as the process whereby an innovation or new idea is communicated through certain channels, over a period of time, and among the members of a social system (Rogers et al, 2003, p.11). This early work acknowledged that little was known about the optimum type and frequency of implementation strategies and that further attention was required to move the science forward (Titler, 2007).

Other approaches were available to assist the implementation of EBP. Common steps included: the topic, a critique of the evidence, adaption of the evidence for use in a specific practice environment, implementation of the EBP and evaluation of the effect on patient care processes and outcomes (Titler 2007). This type of EBP model worked unless the evidence was insufficiently sound to use in practice, leading to the consideration of conducting research to address the problem.

The most difficult part of the EBP model has always been the implementation stage. Implementation is regarded as one of the most challenging aspects of the translational medicine continuum, yet it is crucial for closing the gap between prolific scientific discoveries and lagging implementation knowledge (Waldman and Terzic, 2010). It was therefore unsurprising that evidence highlighted slow progress towards improving patient experience and reducing errors in healthcare in the United Kingdom (UK). Inpatient rating surveys from 2002 to 2009 highlighted improvements of less than 1%. Concerns with noise created by hospital staff were reported from

22% of patients in 2005 and 18% in 2009 (NHS Confederation, 2010). More recently, the serious shortcomings identified by the Mid Staffordshire Inquiry (Francis, 2013) suggested an urgent need to concentrate on improving patients' experiences.

Despite worldwide strategies and investment in patient safety, errors in healthcare continue to be reported. In hospitals the adverse error rate was 8.6%-11% (Sari et al, 2007) and in critical care it was double (Rothschild et al, 2005). In 2014, Shojania and Panesar identified that errors continued at a rate of 10%. These reports show that healthcare professionals need to take action.

Many reports describe the major challenges of bringing about improvements and why it is so difficult and slow. Ham et al (2016) describe the financial and workload pressures, often compounded by workforce shortages. Improvements rarely occur by chance; instead they require intentional actions (Ham et al, 2016). The complex interventions required to change behaviours are set in intricate organisational and policy contexts (Johnson and May, 2015). Many challenges are deep-rooted, but recognising their character helps to address them (Dixon-Woods et al, 2016).

Critical care is a very complex, busy and fast-moving environment, so making improvements within this area of healthcare is a challenge. My own observations of practice identified key challenges, such as a high reliance on rapidly advancing technology, difficulties in developing and maintaining a skilled and effective workforce and caring for extremely sick and unstable patients. Caring for the critically ill involves exposing them to extensive invasive testing, monitoring devices and the administration of multiple medications. This puts them at greater risk of preventable conditions such as infections and pressure ulcers (Barnhorst et al, 2015). These combined factors make introducing change within critical care difficult, with a need to identify effective ways to overcome the challenges.

A further barrier to improvement can be the urge to act without understanding the need for evidence to inform the action. As a result, staff make improvements unscientifically and results can often be counterproductive (Marshall et al, 2013). This is described as 'expediency versus rigor'; the urgency to improve is outweighed by rigorous design, (Shojania and Grimshaw, 2016). Early work identified approaches to overcome these challenges and make improvements. A comprehensive review of 102 trials to determine the effectiveness of different types of interventions to improve health professional performance found 'no magic bullets'. Moreover, they did discover that using a

range of interventions, especially a combined multimethod approach, could lead to notable improvements in professional practice and patient outcomes (Oxman et al, 1995). This multimethod 'bundle' approach was tested on ventilator-associated pneumonia and was successful in reducing pneumonia rates (Resar et al, 2005). In 2007 the Department of Health produced several 'High Impact Interventions' which were evidence-based practice bundles and two focused on intensive care (Department of Health, 2007a; Department of Health, 2007b). My observations identified that these technical evidence-based processes were not always embedded into practice and confirmed that solitary technical interventions had limited impact.

Johnson and May's (2015) systematic review to identify successful change interventions categorised four main approaches to change behaviour. They demonstrated that the most successful interventions were those based on action, such as audit, feedback and reminders, and various types of education. A key finding was that a combination of these interventions is likely to change behaviour the most effectively (Johnson and May, 2015).

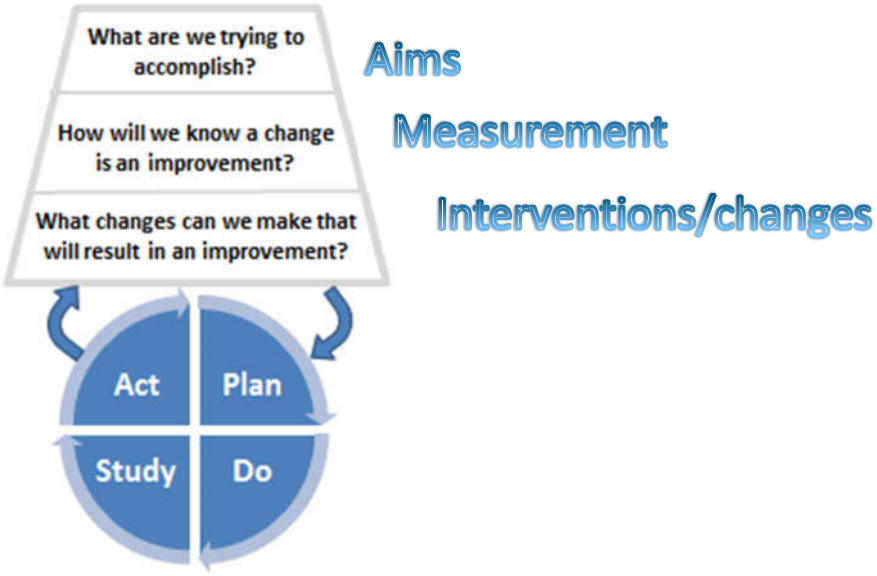
More wide-ranging quality improvement themes were recently uncovered from a review of five quality improvement programme reports combined with a literature review on improvement and organisational change (Dixon Woods et al, 2016). Ten key challenges were identified with a range of tactics to overcome each challenge. The ten challenges were divided into three broad themes: designing and planning improvement interventions; dealing with organisational context, professions and leadership; and sustainability and spread beyond the initial intervention period. The overarching message was that no single solution improves the quality of healthcare and that improvement requires strong leadership and multiple approaches.

The Institute for Healthcare Improvement (IHI) promotes a practice-based 'Model for Improvement' to guide healthcare staff through the process of improving quality (IHI, 2017). It is a worldwide, simple and scientific method to accelerate quality improvement. Its three fundamental elements are: aims, measurement and interventions. Key questions accompany each element to guide those leading improvement through the model. The 'Model for Improvement' is followed by the Plan/Do/Study/Act (PDSA) cycle to test the change (Figure 2) (IHI, 2017). The PDSA cycle includes:

- 'Plan' for the change to be tested
- 'Do' the implementation of change

- ‘Study’ the review of data before and after change
- ‘Act’ further change implemented and an amended cycle of change.

Figure 2 - IHI Model for Improvement



During my ten-year research period another improvement strategy was uncovered. Øvretveit (2009) identified effective leadership is required at different levels and stages to initiate and maintain improvement. The components of leadership include the building of alliances for change, continuously working to raise the possibility of a ‘better way’, creating systems and changing procedures (Øvretveit, 2009). A more recent study identified the need to invest time and effort in building relationships, seeking out new ways of delivering care and being optimistic about the potential for change (Bevan, 2014). These leadership components are also useful when dealing with common challenges such as hostility towards improvement, staff too busy and staff feeling threatened by the improvement (Dixon-Woods et al, 2012).

Before my papers were published, knowledge was already available suggesting that using risk assessments to target interventions could be effective in some healthcare situations. A meta-analysis of randomised control trials regarding the prevention of falls in older adults uncovered that a multifactorial risk assessment followed by a management programme to be very effective (Chang et al, 2004). Another controlled clinical trial targeting preventative strategies using six risk factors was successful in preventing delirium (Inouye, 2000). This evidence strongly supports the benefit of using risk assessments to guide the implementation of interventions. The NPSA suggested it was better to focus on the risks that really mattered and to keep risk assessment simple (NPSA, 2007b).

Despite the value of risk assessments being clearly beneficial, it was not well understood how nurses should undertake them on the critically ill in practice.

In summary, at the beginning of my work quality improvement knowledge was limited, especially successful strategies for change. This limited evidence was a likely contributing factor to the slow progress with improvement. A number of practice challenges associated with introducing improvements existed and ways to overcome the difficulties were being uncovered. Within the complex environment of critical care, the need to continually examine quality improvement strategies was of great importance. Therefore, principal intentions were to uncover the most effective approaches to provide higher quality care and optimise resources, and the need to advance knowledge and strengthen the adoption of scientific methods to make improvements.

3. Chapter Three - Design and Methodology

Prior to my ten papers being published, my own observations exposed many examples of practice changes being implemented without planned methods and no measurement of outcomes. This resulted in a poor understanding of which changes worked and which did not. The urge to act to fix a problem was something I resisted. Instead, I applied research methods to learn about improvement and gain a better understanding about what worked. Notwithstanding, the time required to plan and design the most robust methods was generally not available to me. I therefore explain the rationale for the choice of design and methods employed in each paper and offer a critique to identify the main strengths and limitations.

Paper 1 - A descriptive comparable pilot study was designed. This design is viewed as useful to observe, describe and document aspects of a situation (Polit and Beck, 2014). The observational design was chosen to compare two groups, nurses' assessment of sleep to that of patients. No objective measures of sleep were taken and the sample was from only two hospital sites, so the findings should be interpreted with caution. Despite these limitations I developed practical tools to evaluate patients' sleep and provide valuable insights into these solutions.

Paper 2 – This study was established as a pilot to evaluate patients' experience of sleep when wearing earplugs and eye masks compared to when not wearing them. It was a case control design aimed to investigate cause and effect. This is regarded as a relatively cheap and quick way to obtain results (Bowling, 2014). As with Paper 1 some limitations are acknowledged, such as no objective measures of sleep, small sample size and patients on only one type of critical care unit. These issues put constraints on the validity and generalisability of the findings. Nonetheless, important understanding about the interventions, such as comfort and benefits was uncovered from the qualitative data captured. This qualitative design is a strength as it allows the capture and consideration of different points of view and the extent to which the interventions can be implemented (Portela et al, 2015).

Paper 3 – This was designed as a quasi-experiment before and after study that allowed for the intervention to be implemented and data subsequently collected to assess effectiveness. This un-randomised quasi-experimental design is weaker than a randomised design, but still offers a strong design due to the collection of baseline data before the change (Polit and Beck, 2014). This design is

viewed as practical but establishing causality may be challenging (Poterla et al, 2015). No attempts were made to hide the recording equipment, no control group was used and all staff received the intervention. Consequently, other confounding factors could have impacted on the results. Since a small sample of only three wards was used the generalisability of the results is limited.

Paper 4 - A prospective stepped cluster design was used as ethical issues, such as best practice, were already well established and isolating the intervention from controls was not possible. This was a sequential rollout so that by the end of the study all participants received the intervention. This research design is viewed as robust if designed appropriately (Fan et al, 2010). The design involved clusters joining in a pre-determined sequence, with each successive cluster acting as a de facto control for the preceding cluster, thereby providing a robust approach. However, it is subject to a number of threats to internal validity, such as causal mechanisms during a time of general raising of awareness, policy directives and the emergence of professional and scientific consensus, which were widely publicised. To increase the validity and reliability of data, a verification process of consistency between intensive care units in identifying and reporting CVC-BSI in relation to reporting behaviours was conducted. An additional strength was the large number of critical care units involved and the inclusion of adult and paediatric units.

Paper 5 – This study was designed to compare the performance of four dressing techniques in three phases. No randomisation was undertaken so some allocation bias could have been introduced. However, the prospective large sample has a reduced chance of sampling error (Polit and Beck, 2014) and data was taken from adult and paediatric critical care units, so the findings should be generalisable to a broader population. An evaluation of the cost of each dressing and the time taken to change it adds valuable economic information. This assessment allows for judgements to be made on whether the programme benefits outweigh the monetary costs (Polit and Beck, 2014).

Paper 6 - A thematic content analysis was conducted as little was known about the risk factors associated with falls in critical care. This design proved beneficial since analysis of two years of existing data uncovered risk factors not previously known. This method is useful to identify patterns across a dataset in the practice arena (Braun and Clarke, 2014). Its limitations were associated with the subjective reporting of falls, resulting in a lack of confidence in likely contributing factors.

Paper 7 - A literature review was chosen to understand all the available evidence on pressure ulcer risk assessments and to identify known risk factors associated with pressure ulcer development in critical care. This was indicated due to low confidence in the tool being used in practice. This method identified risk factors unique to critically ill patients and aided the design of a practical assessment tool. This non-systematic review is limited by the subjective review and assessment of the publications (Bowling, 2014). The tool then underwent face validity testing, to evaluate the extent to which it measured what it was meant to measure (Polit and Beck, 2014). Content validity testing was also undertaken to check the items in the tool adequately representing the population (Polit and Beck, 2014), in this case critically ill patients. Both add strength to the appropriateness of the tool I designed. If a quality appraisal tool had been used to evaluate the evidence, the likelihood of each risk factor influencing pressure ulcers would be more robust. Also, if inter-rater reliability testing had been undertaken to check nurses' consistency and judgements it would have strengthened the tool. Furthermore, testing the weighting of each risk factor may have made the tool more accurate at predicting risk.

Paper 8 – This was designed as an observational study to evaluate compliance against local standards and process. It was chosen as process evaluations provide an understanding of improvement interventions in practice (Poterla et al, 2015). This design provided an opportunity to watch and report what happened, with the limitation that the observations could be subject to confounding variables. Caution is therefore required regarding the generalisability of the findings, particularly with the small number of staff opinions. Nonetheless, these methods served to add to the previously unknown pressure ulcer incidence rates, the assessment tool implementation and another important risk factor.

Papers 9 – An observational study was designed to watch and report what happened with the development of a regional benchmarking group to compare pressure ulcer prevalence and develop practice standards. Observing activities is a useful tool for understanding complex situations (Bowling, 2014). As with Paper 8, the main limitation was that the observations could be subject to confounding variables. However, this method served to uncover and add value to the previously unknown information about pressure ulcer prevalence across a number of critical care units in part of the UK.

Paper 10 – This quality improvement study utilised a time series design by using multiple monthly time periods, including outcome measures for six months before the interventions and twelve months afterwards. Key strengths of this method are how it conveys the extent of background variation and indicates any trends before the intervention (Shojania and Grimshaw, 2005). The time series design is seen as a useful quality improvement research method for evaluating the effects of interventions when it is difficult to randomise or identify a control group (Eccles et al, 2003). A limitation with this approach included interventions being implemented in parallel with national policy to prevent pressure ulcers. This attention therefore could have had an effect on the local outcomes.

My ten papers demonstrate that I was able to apply research methods and techniques to generate transferable knowledge and learning, despite being subject to the usual day-to-day urgency to solve problems.

4. Chapter Four - Results

My ten papers demonstrate research in the acute and critical care environment using a range of improvement approaches. Risk assessments were developed, interventions implemented and a variety of techniques used to measure the improvement. The areas of focus include sleep deprivation, infections, falls and pressure ulcer damage.

4.1 My ten published papers

Paper 1: Richardson, A., Crow, W., Coghill, E., Turnock, C. (2007) 'A comparison of sleep assessment tools by nurses and patients in critical care'. Journal of Clinical Nursing, 16, pp. 1660–1668.

Paper 2: Richardson, A., Coghill, E., Allsop, M. (2007) 'Ear Plugs and Eye Masks: do they improve critical care patients' sleep?' Nursing in Critical Care, 12(6), pp. 278-286.

Paper 3: Richardson, A., Thompson, A., Coghill, E., Chambers, I., Turnock, C. (2009) 'Development and implementation of a noise reduction intervention programme: a pre and post audit of three hospital wards'. Journal of Clinical Nursing, 18, pp. 3316–3324.

Paper 4: Bion, J., Richardson, A., Hibbert, P., Beer, J., Abrusci, T., McCutcheon, M., Cassidy, J., Eddleston, J., Gunning, K., Bellingan, G., Patten, M., Harrison, D. (2012) ''Matching Michigan': a two-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England'. BMJ Quality & Safety, 22(2), pp. 110-123.

Paper 5: Richardson, A., Melling, A., Straughan, C., Simms, L., Coulter, C., Elliot, Y., Reji, R., Wilson, N., Byrne, R., Desmond, C., Wright, S.E. (2015) 'Central venous catheter dressing durability: an evaluation'. Journal of Infection Prevention, 16(6), pp. 256-261.

Paper 6: Richardson, A. and Carter, R. (2015) 'Falls in critical care: a local review to identify incidence and risk'. Nursing in Critical Care, DOI: 10.1111/nicc.12151

Paper 7: Richardson, A. and Barrow, I. (2015) 'Part 1: pressure ulcer assessment - the development of Critical Care Pressure Ulcer Assessment Tool made Easy (CALCULATE)'. Nursing in Critical Care, 20(6), pp. 308-314.

Paper 8: Richardson, A. and Straughan, C. (2015) 'Part 2: pressure ulcer assessment: implementation and revision of CALCULATE'. Nursing in Critical Care, 20(6), pp. 315-321.

Paper 9: McBride, J. and Richardson, A. (2016) 'A critical care network pressure ulcer prevention quality improvement project'. Nursing in Critical Care, 21(6), pp. 343–350.

Paper 10: Richardson, A., Peart, J., Wright, S.E., McCullagh, I.J. (2017) 'Reducing the incidence of pressure ulcers in critical care units: a 4-year quality improvement programme'. International Journal of Quality in Healthcare, 29(3), pp. 433-439.

Appendix 1 provides an overview of my ten papers utilising the WHO's suggested evaluation and monitoring activities for quality improvements (WHO, 2017). This overview provides the context for each of the studies, in particular the number of centres used, the research methodologies, the participants for each study and the data measurement techniques used to assess the outcomes. The interventions implemented to make changes are also identified and categorised into single or multifaceted interventions. The key results, outcomes and limitations of each study allow judgements to be made about the success of the intervention.

Appendix 2 appraises my ten papers using the critical appraisal instrument for assessing specific features of quality improvement publications, the Quality Improvement Minimum Quality Criteria Set (QI-MQCS) (Hempel et al, 2015). This valid and reliable critical appraisal instrument is applicable to a broad range of quality improvement intervention evaluations in healthcare, and has 16 content domains to evaluate the quality of improvement publications. The QI-MQCS scoring guidance was used as a structured way to assess whether or not the minimum standard for each domain was met for each publication. Table 1 provides the overall assessment for each publication and Chapter Five discusses the main strengths and limitations.

Publications of the highest quality are those which meet the minimum criteria for all 16 domains (Hempel et al, 2015). The quality of my publications varies as the number of domains met ranges from 9 to 16. Paper 4 met all the domain criteria indicating the highest quality publication, closely followed by Paper 10 with a score of 15.

The interventions implemented in my ten papers are summarised in Appendix 3 and draw attention to the frequency and type of interventions used. A mixture of multifaceted interventions (Papers 3, 4, 5, 8, 9 and 10) were used in most studies with four focused on a single intervention (Papers 1, 2, 6 and 7).

Table 1 - QI-MQCS Domains and assessment of minimum criteria

Paper	OM	IR	ID	OC	I	SD	C	DS	T	A/F	HO	OR	P/R	Su	Sp	L	Total
1	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	X	X	X	X	X	✓	10
2	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	X	X	✓	X	X	✓	11
3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	X	X	X	✓	12
4	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	16
5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	X	✓	13
6	✓	✓	✓	✓	X	X	✓	✓	X	X	✓	✓	X	X	X	✓	9
7	✓	✓	✓	✓	X	X	✓	✓	X	X	X	✓	X	X	✓	✓	9
8	✓	✓	✓	X	✓	✓	✓	✓	X	✓	✓	✓	X	X	✓	✓	12
9	✓	✓	✓	✓	✓	X	X	✓	X	✓	✓	✓	✓	✓	✓	✓	13
10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	15
Total	**10**	**10**	**10**	**9**	**8**	**7**	**9**	**10**	**4**	**8**	**6**	**8**	**3**	**3**	**5**	**10**	

Domain Description

OM Organisational motivation
IR Intervention rationale
ID Intervention description
OC Organisational characteristics
I Implementation
SD Study design
C Comparator
DS Data source
T Timing
A/F Adherence/fidelity
HO Health outcomes
OR Organisational readiness
P/R Penetration/reach
Su Sustainability
Sp Spread
L Limitations

Key

√ met criteria
X did not meet criteria

4.2 Evaluating the impact of my papers

> *'Measurement of quality to drive improvement is the sine qua non of a high-performing health care system'* (Raleigh and Foot, 2010, p. 23).

This quote captures the essential requirement of any improvement initiative. The overall impact of my work has been taken from a number of sources. Firstly, improvement measures require careful selection (Fan et al, 2010) so that once the changes have been implemented an assessment can be made to establish if they have resulted in improvement (Norman and Norman, 2014). The Medical Research Council (MRC) recommends both outcome and process measures as vital to the evaluation of complex intervention studies (MRC, 2006). The measurement column in Appendix 1 highlights the different measures used to evaluate each study. Eight of the ten papers used both process and outcome measurements (Papers 2, 3, 4, 5, 6, 8, 9 and 10). Two studies used only outcome measures (Papers 1 and 7) as they did not implement interventions and one was a literature review (Paper 7). One was a comparative study of assessment tools (Paper 1). Table 2 summarises the main outcome measures from each paper.

Table 2 - Summary of the main outcomes from each paper

	Main Outcomes
Paper 1	No sleep assessment tool produced a close association between nurses' assessment and patients' assessment of sleep (gamma values: tool one 0.334, tool two 0.452, tool three 0.345). Patient feedback identified preferred and easier tools.
Paper 2	Quantity of sleep: sleep in the lowest number of hours (0-4 hours) - 'non–intervention' group 65%, 'intervention' group 56%. Sleep quality: sleep rated positively 'non-intervention' group 7%, 'intervention' group 18%. Cost of earplugs and eye masks £2.50, comfort varied widely. Sleep disturbing factors: noise and heat. Sleep promoting factors: earplug/eye masks, tiredness.
Paper 3	Achieved a significant reduction in peak noise levels from 96.48 dB(A) to 77.52 dB(A) $p< 0.001$ post intervention.
Paper 4	Adults: mean CVC-BSI rate decreased over 20 months from 3.7 to 1.48/1000 catheter days ($p=<0.0001$) for all clusters. Paediatric: rate reduction from 5.65 to 2.89 ($p=0.625$). Number of pre-ICU acquired infections declined. Criterion-referenced case note review showed high agreement between adjudicators (k 0.706). Wide variation in blood sampling rates, CVC utilisation and infection control practices.
Paper 5	No dressing lasted the recommended standard of seven days. One dressing lasted longer (median 68.5 hours) compared to 43.5 hours, 46.0 hours and 40.5 hours for other three dressings. Lowing rates of CVC-BSI observed throughout the programme.

Paper 6	Critical care risk factors identified for inclusion in falls assessment.
Paper 7	Seven risk factors identified and developed into a pressure ulcer risk assessment tool called 'CALCULATE'.
Paper 8	Pressure ulcer incident rate 3.4/100 patient admissions. CALCULATE revised from seven to eight risk factors. CALCULATE was easy to use, small adjustments identified to improve the understanding of risk factors. Majority of assessments every 24 hours and a minimum of every two days.
Paper 9	Unit participation increased from 33% to 100%. Pressure ulcer rates were reported between 5% - 8.9% over 2 years and 9 months. Network wide practice standards developed and branded 'SKIN' bundle.
Paper 10	Pressure ulcer rates reduced significantly from 8.08/100 patient admissions to 2.97/100 patient admissions. Overall rate reduction of 63% in four years. Reduction in the most severe category of PU (category IV and BN). Estimated cost saving £2.6 million (range £2.1 - £3.1).

External assessments further evaluate the impact of my work, including influential external reviews. My work on sleep promotion (Papers 1, 2 and 3) won a national Nursing Times award in the category of 'Back to Basics' (Cowan, 2007). It also won a Newcastle upon Tyne Hospitals NHS Foundation Trust 'Nursing Achievement Award' for sleep research.

In 2016 the Care Quality Commission (CQC) inspected The Newcastle upon Tyne Hospitals NHS Foundation Trust. A large team of CQC inspectors, including specialist advisors in critical care, assessed the Trust's core critical care service. Their final report highlighted my work as outstanding practices and helped contribute to the Trust's overall rating of 'Outstanding' (Care Quality Commission, 2016a). My work was described as:

> *'The critical care pressure ulcer surveillance and prevention group had developed a critical care dashboard for pressure ulcer incidence. A new pressure ulcer assessment tool was developed and implemented this had led to a major reduction in pressure injury'* (Care Quality Commission, 2016a, p. 3).

> *'Pressure ulcer incidence had reduced by 60% in the last 4 years. The work of the pressure ulcer prevention group in critical care had made a significant impact on practice and incidence.'* (Care Quality Commission, 2016b, p. 70).

In 2016, my work on pressure ulcer prevention (Paper 10) was shortlisted for a national Health Service Journal award in the category of 'Patient Safety' (Health Service Journal, 2016).

Informal recognition of my work has also been received via emails and visits from nursing colleagues from the UK across the world, including requests to use my sleep assessment tools (Paper 1) and my pressure ulcer risk assessment tool (Papers 7 and 8).

5. Chapter Five - Discussion

Both acute and critical care in any hospital are complex environments making the introduction of improvements a challenge. Despite this complexity there is a need to constantly improve care to accommodate increasing financial and workload pressures. Over the last decade, my ten papers demonstrate research into this environment using a range of improvement approaches and, where possible, the use of high quality data to measure and evaluate success. The value of formal evaluations of improvement efforts is positive as it enables improvements to be treated as learning opportunities and contributes to improvement science (Dixon-Woods et al, 2012).

The appraisal of my ten papers using the valid and reliable QI-MQCS framework (Hempel et al, 2015) identified the quality of the publications to be high. The main strengths of all ten papers were the motivation for the intervention, the interventional description, the data sources and the acknowledged limitations of each study. Other positive features included the reporting of the implementation, organisational characteristics, the comparator care processes and the adherence to the intervention. Together this high level focus on quality improvement increases the ability of researchers and practitioners to identify and learn from my studies (Hempel et al, 2015).

5.1 Research journey & original contributions

The ten papers have been considered together as a research journey and have been reviewed with the aim of identifying their original contribution to understanding in three knowledge topics under two domains of the quality umbrella.

Quality Domain: Patient Experience

- **Knowledge Topic One - Practical approaches to assist nurses assess and improve patients' sleep (Papers 1 – 3)**

My paper on sleep assessment (Paper 1) reviewed existing sleep assessment tools and produced three new tools to assess critically ill patients' sleep on a day-to-day basis. Previous tools used either complex and expensive technology (Tamburri et al, 2004) or involved scales too difficult to use with critically ill patients (Richardson, 1997). Observer bias was also uncovered due to nurses relying on their own observations to assess patients' sleep. The tools I developed were next applied

to an interventional study to assess the impact of using earplugs and eyes masks to improve sleep (Paper 2). This study offered a simple and cost effective way of promoting patients' sleep together with patients' views on the comfort of these interventions. My study to reduce noise levels on acute care wards (Paper 3) tested multiple interventions to promote sleep. Leadership commitment was identified as one of the influencers towards successful implementation of the interventions. Other successful influencers were evidence-based sleep promotion guidelines, noise awareness training for staff and sleep promotion posters.

Domain: Patient Safety

- **Knowledge Topic Two - Risk assessment approaches in critical care: an important step to reduce harm (Papers 6 – 8)**

Lessons learnt from the sleep promotion activities were used to develop new approaches to risk assessment for falls and pressure ulcers (Papers 6 and 7). The importance of assessments specific to critically ill patients had been highlighted previously and was incorporated into my next stream of work. In addition, the application of several different interventions to change practices, such as clinical leadership, guidelines and staff training, were included and further developed in the pressure ulcer assessment implementation phase (Paper 8).

My three papers in this knowledge topic concentrate on the role of risk assessment, which is essential to identify patients at an elevated risk of harm and to target interventions (Chang et al, 2004; Inouye, 2000). The first important patient safety area was falls (Paper 6). The risk factors most likely to contribute to a fall in critical care were identified by analysing two years' worth of falls data. This gave a much better understanding of the reasons why critically ill patients fall and contributed to the development of a local falls risk assessment approach. These risk factors were also used to develop a set of interventions to guide critical care nurses in the prevention of falls and were included in the nursing care plan documentation. Furthermore, the analysis of the data provided an opportunity to compare the varying falls rates in critical care locally and with national rates.

The second patient safety area investigated was pressure ulcers. I developed a practical, easy to use pressure ulcer risk assessment tool called 'CALCULATE' which was tested for content and face validity as an initial step in the prevention of pressure ulcers (Paper 7). Again, this tool was

implemented using multiple improvement approaches, followed by data analysis of the types and risk factors associated with pressure ulcers. I evaluated then revised the tool (Paper 8) and found it to offer a straightforward way to assist in identifying patients at risk of pressure damage. The measurement of outcomes generated a pressure ulcer incident rate and allowed comparisons to be made among different care settings.

Quality Domain: Patient Safety

- **Knowledge topic three - Translation and implementation of improvement methodology from the USA to England and then from infection prevention to pressure ulcer prevention. (Papers 4, 5, 9 and 10)**

The approaches to improve sleep promotion and patient assessment were developed and refined for infection and pressure ulcer prevention. These approaches used multiple interventions including clinical leadership, the development of evidence based guidelines, assessment of risk and the measurement and feedback of data.

My personal development in improving quality accelerated when I was appointed lead nurse for the national 'Matching Michigan' programme. Opportunities arose to learn from the highly successful work to reduce CVC-BSI in over 100 American intensive care units in the state of Michigan (Pronovost et al, 2006). My responsibility within the leadership team was to translate the Michigan's critical care CVC infection prevention programme to England (Paper 4). This programme significantly improved rates of CVC-BSI in English critical care units. The main aspects of the USA programme were replicated using a combination of technical and non-technical interventions supported by continuous measurement. Small adaptations were required such as amendments to materials, more precise infection definitions and a government/clinician directed leadership model. The continual CVC-BSI measurement approach from the 'Matching Michigan' programme was then used to monitor CVC-BSI rates in a separate study to improve CVC dressing durability (Paper 5). The ongoing care of the CVC dressings had been one of the technical interventions to minimise infections (Loveday et al, 2014) and I found a better and more cost-effective approach.

Paper 9 offers insight into a network-wide approach to develop pressure ulcer prevention standards for critical care. It was initiated to better understand good practice and prevalence rates across a number of different critical care units. The multiple methods employed included project leadership

and the benchmarking of practice standards, along with the measurement and sharing of pressure ulcer rates. The result was a consensus of standards for pressure ulcer prevention.

The final paper (Paper 10) draws on many aspects and learning from my previous work. It demonstrates that the CVC-BSI prevention methodology tested in the USA could be applied in England to address an unrelated patient safety problem. The results demonstrated a significant and sustainable improvement in the prevention of pressure ulcers. I therefore identified that the strategies used are transferable to other patient safety areas.

5.2 Quality improvement challenges

Recognising and reporting on the complex challenges when making improvements is a useful way to maximise learning, avoid similar pitfalls and can accelerate future progress (Dixon-Woods et al, 2012). Acknowledging the key challenges with my improvement work adds value to improvement leaders of the future.

The primary challenge I faced throughout my ten years of research was to improve care using the evolving evidence available at the time of undertaking each study. At the beginning of my work, little was known about the best frequency and type of implementation strategies, therefore requiring attention to improve the science (Titler, 2007). More recent quality improvement evidence has found some well-designed studies have not always produced good results (Dixon-Woods and Martin, 2016). This limited implementation evidence supports the need for more testing to uncover what works in practice. My three knowledge contributions add to the understanding of the types and effectiveness of strategies for critical care.

My second challenge was resisting the urge to take action immediately a problem was uncovered. Instead I focused on designing, implementing and measuring change. This 'expediency versus rigor' challenge (Shonjia and Grimshaw, 2005) was overcome by employing a broad range of study designs over ten years. Some of the research designs chosen were observational (Paper 1, 8 and 9) and uncovered important understanding of patient experience (Paper 1) and activities and processes to reduce harm (Papers 8 and 9). Process evaluations have a valuable role in practice improvement (Poterla et al, 2015) so they contribute to this part of knowledge within the critical care environment. The more robust studies were the before and after design used to evaluate a

multimethod interventions to reduce noise (Paper 3), the stepped cluster design (Paper 4) and the longitudinal time series design (Paper 10). Although none were randomised, these approaches offer rigorous quality improvement methods (Hemming et al, 2015) and increase confidence with attributable effect from the intervention (Ecceles et al, 2003).

The third challenge I experienced was sustaining the improvement work, which can often be difficult to achieve. The MRC identified long term follow up as a key function to determine whether short term changes persist (MRC, 2006). For sustainability it is important to demonstrate clinical effectiveness, efficiency and that the changes are supported in processes and systems (Dixon-Woods et al, 2012). Key strengths were identified with sustainability in the third knowledge contribution. This included presenting 12 months of ongoing data after the implementation of the pressure ulcer quality improvement interventions, plus a measure of efficiency with the estimated cost savings of £2.6 million (Paper 10). Paper 4 recommended a national system for continual CVC-BSI benchmarking to ensure sustained attention to CVC-BSI.

The final challenge was making improvements within the complex environment of critical care. This complexity consisted of: patients presenting with elevated risks of potentially preventable conditions (Barnhorst et al, 2015), many competing care demands and compounded by a culture where some staff viewed patient safety problems as 'inevitable' rather than 'preventable'. In undertaking my research I have discovered four cross-cutting themes applied to the complex critical care environment to implement successful quality improvement. These four themes add to the knowledge and understanding of improvement science and draw attention to important components for critical care.

Theme one: Clinical leadership

I have identified that effective clinical leadership is essential for the successful implementation of change. Leadership is crucial at every level and involves different staff and functions.

Clinical leadership was vital to the success of making changes. The real value was that these leaders were experienced, credible and actively encouraged change in their area of practice. They led by example (Paper 3 and 10) and influenced a change of culture within their units from viewing harmful events as 'inevitable' to 'preventable' (Paper 10). Further improvement research has

uncovered the need for effective leadership to consistently raise the possibility of a 'better way', creating systems and changing procedures (Øvretveit, 2009). Leaders should be nominated and can include staff at all levels, such as matrons, sisters and staff nurses. This discovery has been supported by the requirement for effective improvement leadership at different levels (Øvretveit, 2009).

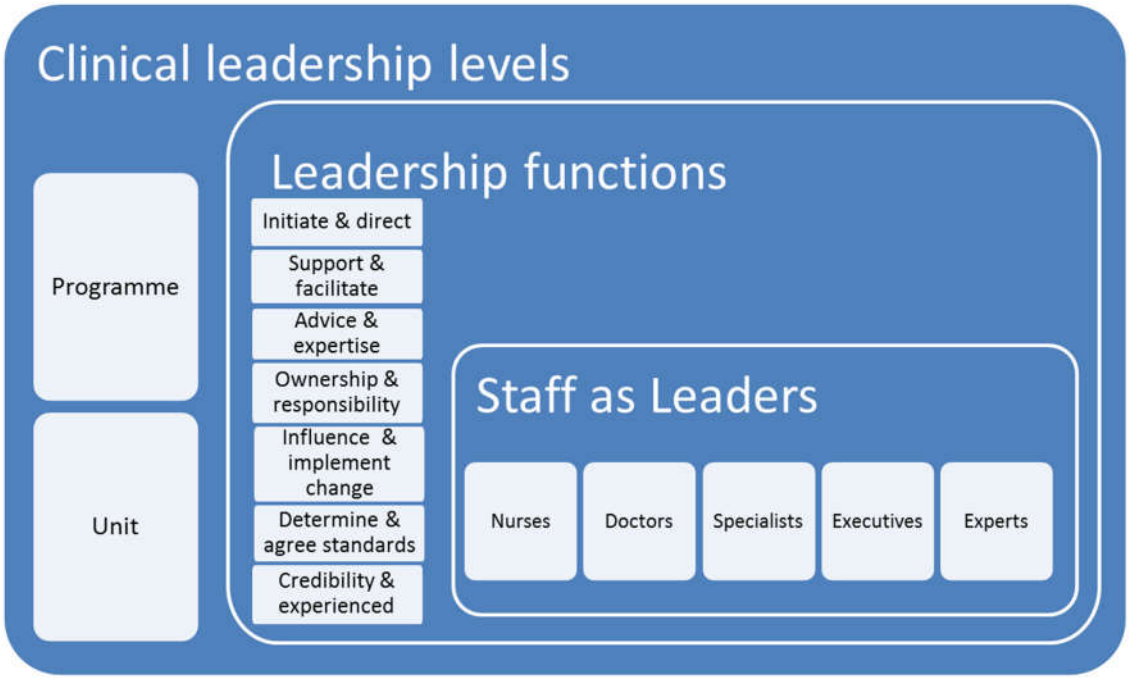
Successful leaders were credible through their critical care expertise enabling them to influence and convince staff of a need for change (Paper 8). In addition, nominating a nurse to represent a unit encouraged local responsibility and ownership of the project (Paper 5). These leadership characteristics involve investing time and effort in building relationships, seeking out new ways of delivering care and being optimistic about the potential for change (Bevan, 2014). A team of leaders was key to the infection reduction programme and included a lead nurse, lead physician, an infection control specialist and a director (Paper 4).

My papers also identify that overarching programme leadership is an important success factor to make changes effectively. Appointing a nurse to lead, guide, direct and facilitate the overall programme across four units over four years was a key strength of the pressure ulcer prevention programme (Paper 10). Overall programme leadership at a clinical level was also identified as important in the network-wide programme (Paper 9). This paper highlighted that leadership across 23 units was able to agree common goals, reach consensus on practice standards and enabled share and learn across organisational boundaries. Within the national improvement programme (Paper 4), the local unit leaders were supported and directed by programme leadership comprising professional and government leaders, including the original experts from the Michigan project. A central strategy team of a nurse and a physician was also crucial to the adult and paediatric improvement success across five critical care units (Paper 5).

Regular team meetings throughout the improvement programmes (Papers 3, 4, 5, 8, 9 and 10) brought together the clinical leaders and allowed time for improvement work, raising better ways and developing systems to promote improvement. Supporting my findings is the improvement work of Dixon-Woods et al (2012) who found forums as an opportunity to discuss and debate evidence, expose the work to challenge and ensure the acceptability of interventions (Dixon-Woods et al, 2012).

I have designed a Critical Care Leadership Framework (Figure 3). This framework adds to the existing knowledge and shows the importance of leadership at both a unit and a programme level, together with the functions and staff groups to consider.

Figure 3 - Critical care leadership framework: levels, functions and staff groups



Theme two: A bundle of technical and non-technical interventions

A mixture of multifaceted implementation interventions was used in most studies (Papers 3, 4, 5, 8, 9 and 10) with four using a single intervention (Papers 1, 2, 6 and 7). My papers show that a comprehensive multimethod approach of technical interventions (evidence-based) and non-technical interventions (cultural and behavioural) successfully translated from an infection prevention programme in the USA (Pronovost et al, 2006) to England (Paper 4), and then from infections prevention to pressure ulcer prevention in critical care (Paper 10). Combining technical and non-technical interventions increases the external validity of this improvement methodology.

More recent support of my research is the work by Johnson and May (2015) whereby a systematic review into behaviour change identified a combination of interventions as more effective than a single intervention. Also supporting this approach is the early investigation of different types of interventions by Oxman et al (1995). They found that using a range of interventions, especially a combined multimethod approach, was more likely to lead to notable improvements (Oxman et al, 1995).

Theme three: Assessment of the critically ill

At the beginning of my work it was understood that nurses have a duty to assess patients and keep clear and accurate records (Nursing and Midwifery Council, 2008) and that using risk assessments to target interventions could be an effective way of improving healthcare (Chang et al, 2004; Inouye, 2000). My personal observation was that there were limited practical tools to assess the sleep of critically ill patients. My papers add to the understanding of how to assess critically ill patients sleep and the effectiveness of earplugs and eye masks as interventions (Paper 3).

My observations uncovered that there was no tool to undertake falls risk assessment on the critically ill and that the risk assessment tool for pressure ulcers was unsuitable for these patients. Consequently, patients were not being identified to be at risk and requiring prevention interventions. The development and implementation falls risk factors (Paper 6) and CALCULATE (Papers 7 and 8) contributed to the existing evidence on what to include in a risk assessment. The data from critical care patients informed a more appropriate and suitable guide to improvement interventions. An evaluation of my papers (Papers 6, 7 and 8) found a number of components which contribute to increasing the knowledge in this area.

Falls risk factors (Paper 6):

- Falls risk factors relevant to critically ill patients based on falls data
- Specific patient groups on which to target falls prevention interventions

CALCULATE (Papers 7 and 8):

- A tool that is easy to incorporate into nurses' daily activities
- A valid assessment of pressure ulcers in critically ill patients informed by risk factors
- Allows targeted interventions to prevent pressure ulcers

Since my papers were published a systematic review of the literature identified risk factors predictive of pressure injury in critical care patients (Alderden et al, 2017). Many of the factors concur with CALCULATE (Paper 7) thereby supporting my contribution to the knowledge.

Theme four: Data measurement and feedback

I have always considered data measurement and feedback fundamental to improvement. At the same time my work was being undertaken, it was suggested that data should illustrate the scale of a quality problem (Dixon-Woods et al, 2012) and be used to determine the impact of changes (Davidge, 2014). Feeding data back to staff has also been found to convince them of a problem and the need for change (Dixon-Woods et al, 2012). Moreover, feedback has been shown to lead to actual improvements (Johnson and May, 2015), thereby serving as an improvement intervention itself.

My papers demonstrate many practical ways of delivering data measurement and feedback and build upon the developing knowledge. The care processes and patient outcome measures used in my work highlight a variety of ways to evaluate improvements. The papers also used data feedback to overcome challenges and enable improvement by influencing staff's acceptance of the need for change. An example was when noise level measurements from pre-audit data was fed back to staff at training sessions and another was through sleep promotion posters displayed on the nurses' station. This approach increased their awareness of high noise levels and helped adherence to the guidelines (Paper 3). In the national infection programme (Paper 4) data was analysed centrally and units were informed of their infection rates. This encouraged changes in behaviour and more reliable adherence to infection prevention practices. A theory-oriented evaluation of the original Michigan programme also uncovered similar behaviour changes when CVC-BSI data was fed back to units anonymously and compared with those of the entire cohort. Staff attitudes changed from refusing to accept there was a problem to taking action (Dixon-Woods et al, 2011).

My next papers added practical ways to deliver data measurement and feedback. Infection data was monitored monthly before and during the dressing durability programme (Paper 5). This data was fed back to staff and found to contribute to making improvements. The network pressure ulcer quality improvement programme (Paper 9) extracted data from a national measurement tool and presented data back to unit staff on run charts. Posters of the data run charts made trends easy to spot and helped assess for shifts, stability and comparisons over a large network-wide area.

Utilising varying types of data has been suggested. It should include hard facts to convince staff a problem exists and softer patient stories to secure emotional engagement (Dixon-Woods et al,

2012). The four-year pressure ulcer prevention programme (Paper 10) used a mixture of data feedback techniques to four critical care units. The monthly reports of the number and category of pressure ulcers enabled staff delivering the care to gauge the effects of changes. Regular feedback helped maintain staff's commitment to data collection and allowed them to make comparisons between units. The hard facts were supplemented by descriptive case presentations, including unpleasant but powerful photographs. This added greatly to staff's emotional commitment of the need for change. Another technique involved sharing evidence-based appraisals of best practice at the pressure ulcer prevention task group meetings.

The data feedback functions uncovered in my papers are supported by growing independent evidence, which enhances my contribution. The data feedback functions have been summarised into a new list of important checks (Figure 4) to assist improvement leaders. In addition, I have categorised the data into four categories, a balance of which should be used to influence improvement (Figure 5).

Figure 4 - Data feedback functions

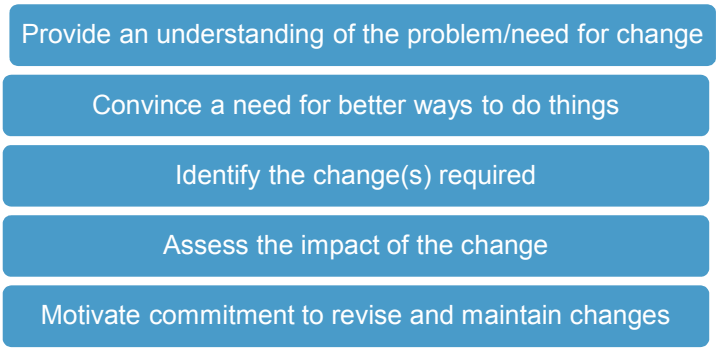
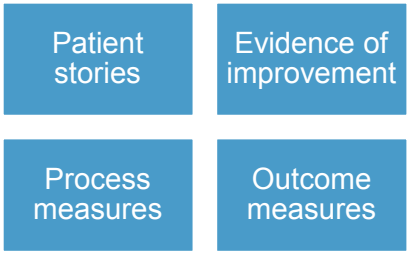


Figure 5 - Types of measurement data

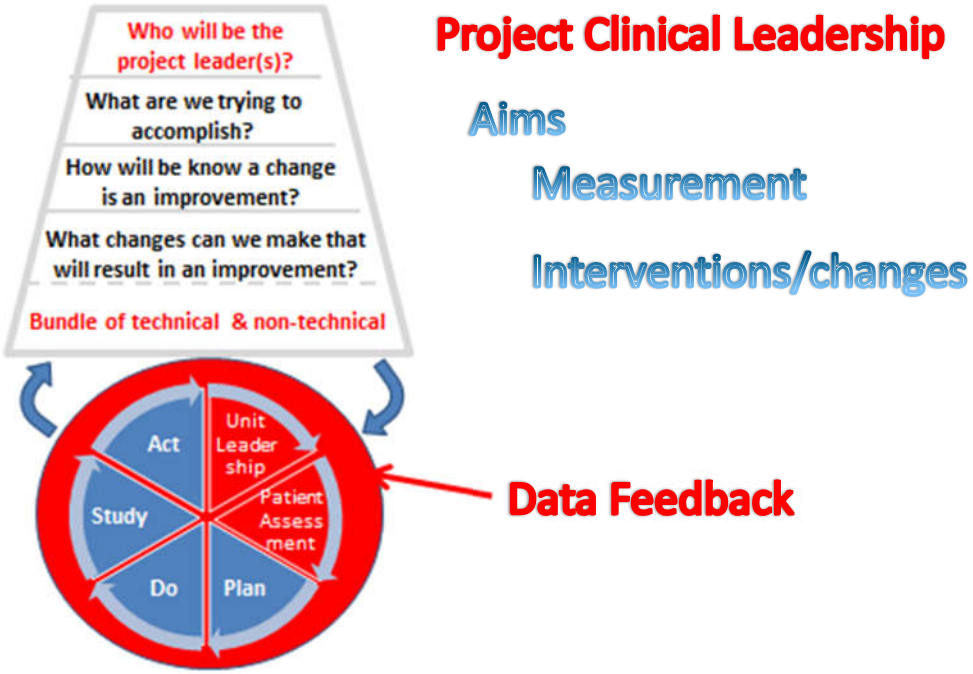


Incorporating the four cross-cutting themes into the Model for Improvement

I have used evidence from my papers to develop an Enhanced Model for Improvement (Figure 6) for use in critical care, although it may also be valid for other healthcare settings. My enhanced model applies the multimethod improvement approach. My enhancements (highlighted in red) are:

- Project and unit clinical leadership
- A bundle of technical and non-technical interventions
- Patient assessment to guide interventions
- Data feedback

Figure 6 - Enhanced Model for Improvement



Project clinical leadership is at the top of the model to signify the importance of establishing credible clinical leadership from the outset. The bundle of technical and non-technical interventions has been included at the interventions level to emphasise the importance of using both types. The PDSA cycle now includes leadership at unit level and patient assessment. Data feedback surrounds the entire PDSA cycle because it is required at every stage.

5.3 Limitations

It is important to acknowledge a number of limitations associated with my work. None of my studies used randomisation which is regarded as 'the gold standard method for evaluating healthcare interventions' (Eccles et al, 2003). It is an optimal strategy to reduce bias (Fan et al, 2010) with the aim of determining effects more precisely. This limits the reliability of my findings and the generalisability of my papers. However, non-randomised, quasi-experimental designs were used which are appropriate where there are political, practical or ethical barriers to conducting a randomised experiment (Eccles et al, 2003).

As acknowledged in Chapter 3 and Appendix 1 all designs had their limitations. A common limitation however, was the potential for exposure to other confounding factors which could have contributed to the desired improvements. This risk of bias limits the generalisability of some of the findings and needs to be considered when interpreting the outcomes.

All papers except Papers 4 and 5 used small samples on four critical care units which limit their generalisability; but the variety of critical care units involved adds methodological strength. This included the following types of units: cardiothoracic, neuro/trauma, burns, transplantation, mixed medical and surgical, and adult and paediatric units.

The appraisal of my ten publications highlighted in Table 1 using the QI-MQCS framework (Hempel et al, 2015) identified the least reported features. These were the reported timings of the intervention, the penetration/reach of the intervention, the sustainability of the intervention and the ability to be spread or replicate the intervention. One of the least reported features was reported sustainability. No long-term follow-up was acknowledged in the first two knowledge contributions nor was it undertaken due to time constraints and other clinical demands. Ensuring the long term sustainability of a quality improvement programme is a well-recognised challenge (Dixon-Woods et al, 2012; Jeffcott, 2014; Vincent and Amalberti, 2016) as the improvement often suffers dwindling interest as new priorities arise (Dixon-Woods et al, 2012). If the outcomes had continued to be measured it could have further strengthened the quality of the publications.

Unfortunately, although the lesser reported features such as timings, penetration/reach and spread were known at the time, they were not reported, thereby reducing the quality of these

publications. Therefore the opportunity for other researchers and practitioners to learn from these comments was limited.

6. Chapter Six – Recommendations and Conclusions

6.1 Recommendations

Recommendations focus on three areas: quality improvement appraisal, practice and research.

Quality improvement appraisal recommendations

To enable researchers and practitioners to identify important aspects of quality improvement and increase the chance of learning from studies, they should appraise their work using an appropriate framework such as the QI-MQCS (Hempel et al, 2015).

Practice recommendations

Within critical care the following components should be used to make changes to improve quality:

- A multimethod improvement approach, including clinical leadership at a local and programme level
- A bundle of both technical interventions (evidence-based practices) and non-technical interventions (cultural and behavioural) to make changes
- Apply appropriate risk assessments to target interventions
- Carefully select data feedback methods that influence, motivate and evaluate changes
- Follow the Enhanced Model for Improvement to guide quality improvement work

Research recommendations

It is important for continual research to enhance existing understanding and discover new knowledge, including:

- Testing the inter-rated reliability and further validity testing of CALCULATE
- Further investigating the translation and implementation of improvement methodologies from one care setting to another
- Using mixed research methodologies to clarify causal mechanisms underpinning quality improvement interventions to identify those most likely to promote best practice throughout healthcare

6.2 Conclusions

My personal journey has always been to improve the quality of patient care, experience and safety. I observed that some patients were being exposed to variations in quality of care, often due to the difficulties of putting known evidence into practice. My clinical concerns, areas for improvement and knowledge contributions were with improving sleep and reducing blood stream infections, falls and pressure ulcers.

Throughout the ten-year period my papers were being published, progress in quality improvement was slow but means of evaluating the impact of improvements were starting to be discovered. This emphasised the need for a greater understanding of the strategies required to implement change in critical care. My work adds to this understanding and signposts practitioners to useful and effective strategies to change practice and improve outcomes.

Two of my publications were identified as high quality publications (Paper 4 and 10) and should be considered by quality improvement leaders for replication. My other papers met many of the recommended reporting features of quality publications and provide major learning to help others influence successful change in the future.

My combined works demonstrate that I overcame the common challenge of 'expediency versus rigor' by taking time to design robust methods, measure outcomes and acknowledge limitations. Together these increase the confidence of the interventions.

Within the complex critical care environment, I identified three knowledge contributions. The first was inexpensive, practical approaches to help nurses assess and improve patients' sleep. Secondly were valuable insights into more valid and appropriate risk assessment tools to identify patients at elevated risk so that interventions could be targeted to minimise harm. Thirdly, that translation and implementation of improvement methodologies are most successful when supported by clinical leadership, a bundle of technical and non-technical interventions, all of which is underpinned by continuous data measurement and feedback.

Adding to the knowledge and understanding of improvement science, my papers uncover themes supporting how to undertake successful quality improvement within critical care. I identified four

cross-cutting themes within the multimethod improvement approach. First is leadership at a local and programme level. A number of leadership functions and the involvement of different types of clinical leader are presented in a new framework that enhances the knowledge contribution. The second theme was to use a bundle of technical interventions (evidence-based) and non-technical interventions (cultural and behavioural) to make changes. This supports early evidence that a single intervention is rarely the most effective. Thirdly, using risk assessments to target interventions was identified as a cross-cutting theme. The importance of risk assessments was known, but adapting these for the critically ill and making them practical was an original contribution. The final cross-cutting theme is that delivering data feedback is a key part of a quality improvement programme. An original checklist of data feedback functions has been created to assist improvement leaders.

Embedding and sustaining quality improvement can be difficult, but my papers provide measures to show long term improvement. This adds strength to the improvement approaches and highlights the type of data to be selected, the functions of data feedback and offers effective ways to influence motivate and evaluate change.

My work has been used to enhance the IHI Model for Improvement and PDSA cycle. This Enhanced Model for Improvement may be transferrable to other patient safety topics to prevent harm.

Most of my papers were developed within critical care. However, Paper 3 studied acute care wards and therefore some contributions are worthy of wider consideration, particularly the practical approaches to improve patients' sleep.

Overall, my published papers have added to the patient experience and patient safety improvement knowledge within critical care. With further testing, the new insights and knowledge have the potential for much wider implications by contributing to quality improvement in other areas of healthcare.

7. Appendices

7.1 Appendix 1 - Overview of papers

No	Year	Topic/ Short title	Context/setting Single centre (S) Dual centre (D) Multicentre (M)	Method/participants	Measurement: outcome measures (OM) process measures (PM)	Intervention/change Single (S) or Multifaceted (M)	Limitations	Key results/outcomes
1	2007	Sleep/ Comparison of sleep assessment tools	4 adult CC units/2 hospitals (D)	Descriptive comparable pilot study. Structured interviews. Convenient sample: 82 patients, compared to 82 nurses.	OM: 1. Gamma test to measure degree of association 2. Patient satisfaction	• Tested 3 sleep assessment tools (S)	No objective measure of sleep. Small numbers in two centres. Patient recall. No examination of day time sleep or comparisons to other night's sleep. Nurse's experience not measured.	No tool produced a close association between nurses assessment and patients' assessment of sleep (gamma values: tool one 0.334, tool two 0.452, tool three 0.345). Patients preferred/found easier two of the three tools: tool one and tool two.
2	2007	**Sleep**/ Ear Plugs and Eye Masks to improve sleep	Cardiothoracic high dependency unit (S)	Pilot interventional study quasi-experimental. Case control. Tested Earplugs and eye masks-using questionnaire. Sleep and comfort rating scales. 64 patients (34 intervention only)	OM: 1. Reported experiences of sleep 2. Cost (£) 3. Comfort of ear plugs and eye masks PM: 1. Factors disturbing and promoting sleep	• Ear plugs and eye masks (S)	No objective measure of sleep. One centre, small convenience sample. Bedside nurse inexperience with data capture. No patient past medical history obtained.	Cost of ear plugs and eye masks £2.50. Quantity of sleep: slept for lowest number of hours (0-4hrs) non –intervention group 65%, intervention group 56% . Sleep quality: rated sleep in the two most positive bands- intervention group 18%, non-intervention group 7%. Comfort varied widely. Disturbing factors: noise, heat Promoting factors: earplug/eye masks, tiredness

3	2009	**Sleep/** Noise reduction intervention programme	3 acute inpatient wards, medical, surgical and orthopaedic. 1 hospital (S)	Controlled before and after study on 3 wards in 3 phases: 1. pre audit of noise levels 2. development, implementation and delivery of noise reduction interventions 3. post-audit of noise levels	OM: 1. Noise measured using a sound meter PM: 1. Numbers of ward staff trained	5 stages (M) • development of guideline • review of ward environment • staff education and awareness raising • staff education and awareness raising follow up • posters displayed	Small sample. No attempts to hide the recording equipment. All staff did not receive the intervention.	Achievement of a significant reduction in peak noise levels. From 96.48 dB(A) to 77.52 dB(A) p< 0.001 post intervention.
4	2012	**Infections/** Matching Michigan' 2 year programme to minimise CVC infections	National critical care programme: adult and paediatric in England (M)	Prospective, 2-year, four cluster, stepped, non-randomised, interventional, time series study. 215 adult and paediatric intensive care units (196 adult, 19 paediatric)	OM: 1. Random-effects Poisson regression modelling 2. CVC-BSI/1000 catheter days PM: 1. Data verification: inter-rated agreement using kappa coefficient	• Technical interventions- evidenced based CVC checklist, evidence summary sheet, frequently asked questions. CVC insertion trolley and pack • Non-technical interventions- teaching resources and training, how to learn from incidents, executive-clinician partnership, teamwork and communication. • CVC-BSI measurement and data feedback (M)	No randomisation. Many confounding variables. National exposure of interventions to waiting clusters. No measures of the adoption of interventions and compliance with best practice.	Adults: mean CVC-BSI rate decreased over 20 months from 3.7 to 1.48 CVC-BSI/1000 catheter days (p=<0.0001) for all clusters. Paediatric: from 5.65 to 2.89 (p=0.625). Pre-ICU acquired infections declined Criterion-referenced case note review showed high agreement between adjudicators (k 0.706). Wide variation in blood sampling rates, CVC utilisation and infection control practices.

5	2015	**Infections**/ CVC dressing durability: an evaluation	5 CC units 4 adult/1 paediatric 2 hospitals (D)	Prospective cohort. 1229 dressings observed using a Proforma. 12 months in 3 phases (4 months for each dressing). Time in motion.	OM: 1. CVC infections 2. Cost (£) PM 1. Dressing duration median (days/hours) 2. Nursing time (minutes)	• Training sessions • 'how to guides' developed • Meeting/ discussions • Tested 3 dressing techniques • Nurses at bedside collected data- self monitoring (M)	No randomisation. Judgements on why dressing removed made by nurses, providing some variability between nurses. Data collection was patchy at times.	No dressing lasted the recommended standard of 7 days. One dressing lasted longer (median 68.5hr) compared to 43.5, 46.0, 40.5hr for other 3. Low rates of CVC-BSI observed.
6	2015	**Falls**/ Falls review to identify incidence and risk	4 adult CC units 2 hospitals (D)	2 year retrospective review, thematic analysis of 42 local incident reports.	OM: 1. falls incidence rate 2. falls related injuries PM: 1. frequency of risk factors: confusion/agitation, mobilising against advice, age, environment.	• Falls risk assessment and interventions to minimise risk	Small population of patients. Primary data source provided inconsistent information so factors could have been missed.	Critical care risk factors identified. Recommended fields to be included in falls incident reporting system.
7	2015	**Pressure Ulcers**/ Part 1: PU assessment - development of CALCULATE	4 adult CC units 2 hospitals. (D)	Literature appraisal from 2000 to2011, 3 databases.	PM: 1. face validity and content validity testing of the risk factors by expert nursing consensus group	• pressure ulcer risk assessment tool	No systemic appraisal of the literature. Tool did not allow for weighting of each risk factor.	7 risk factors identified and developed into a risk assessment tool called 'CALCULATE'.

8	2015	**Pressure Ulcers**/ Part 2: PU assessment: implementation and revision of CALCULATE	4 adult CC units 2 hospitals. (D)	Observational review. Implementation and refinement of CALCULATE.	OM: 1. PU incidence (%) per 100 patient admissions. PM: 1. 4 months review of PU numbers and types of risk factors (using CALCULATE) 2. Frequency of risk assessments 3. User feedback (16 nurses) using rating scale and open comments	• Nursing leadership • Staff training • Development of tools and guidance (M)	Sample samples, over a short period. No measures of the change strategies chosen. No comparison to data on patients without pressure ulcers.	PU incident rate 3.4%. CALCULATE revised from 7 to 8 risk factors. Frequency of assessments: majority every 24 hours and a minimum of 2 days. Staff found tool easy to use and a need to improve the definitions of the risk factors.
9	2015	**Pressure Ulcers**/ Network PU prevention QI project	23 CC units across a CC Network in Northeast of England (M)	Observational. Development of a benchmarking group. Telephone review using standard proforma of practice standards.	OM: 1. Monthly NHS Safety Thermometer PU prevalence data PM: 1. PU practices.	• Leadership meetings • Benchmarking • Sharing information • Standard setting (M)	No validation of the data. Prevalence data not incidence data and only categories 2-4 collected so not a full picture of harm. Compliance against standards not measured.	Unit participation in data submission from 33% to 100%. PU rates between 5-8.9% over a 2 year 9 month period. Practice standards developed –called 'SKIN' bundle.

10	2017	**Pressure Ulcers/** Reducing PUs 4-year QI programme	4 adult CC units 2 hospitals. (D)	Prospective, 4 year, non-randomised, interventional, before and after, time series	OM: 1. PU rate/100 patient admissions 2. PU numbers and grades 3. Cost (£) 4. Number of days without PU PM: 1. Staff training numbers 2. Audit of use of bowel management system 3. Audit of compliance against 12 hourly PU assessment standards	• Technical interventions-review of evidence, implemented guidelines, new mattresses, developed new PU risk assessment tool • Non-technical interventions- task group-clinical Leadership, staff training, shared learning from incident investigation of PU • PU data measurement and feedback (M)	Some confounding and temporal factors not reviewed. Interventions implemented as same time as national policy and attention which could have had an effect. Not able to retrospectively check data prior to September 2012.	PU rates reduced significantly from 8.08/100 patient admissions to 2.97/100 patient admissions. Overall rate reduction of 63%. Reduction in the most severe category of PU (category IV and BN). Estimated cost saving £2.6million (rage £2.1-£3.1).

7.2 Appendix 2 - Appraisal of papers using QI-MQCS

Domain	Paper 1 - Short title: Sleep/ Comparison of sleep assessment tools	Not met or met
Organisational motivation	Sleep assessment undertaken in an unsystematic manner within organisations' critical care units.	Met
Intervention rationale	No studies published compare the nurses' assessment with the patients' perception of sleep. To examine three sleep assessment tools and identify the most effective tool for assessing sleep within a critical care environment	Met
Intervention	To test three sleep assessment tools that nurses could use to assess and record sleep of individual patients	Met
Organisational characteristics	Four multispecialty critical care units in one large teaching trust. Specific details of each of the 4 critical care units provided.	Met
Implementation	Pilot testing of three sleep assessment tools. Patients asked to nominate the tool they found easiest to complete. Enlarged versions of the sleep assessments tools were printed and laminated so patients could easily see and point to the scale.	Met
Study design	Descriptive comparable pilot study.	Met
Comparator	Compared the judgement of nurses and the experiences of patients with regards to sleep using three separate sleep assessment tools	Met
Data source	Data source: collected by 4 critical care nurse researchers not directly involved in patient care. Demographic data from medical and nursing notes. Data collection method: Structured interviews with 30 patients. Convenient sample: interviews with 82 patients and 82 nurses. Outcome of interest: level of agreement between patients and staff for each tool using the Gamma test. Patients views on ease of completion.	Met
Timing	Pilot data collected from March to July 2004. No timelines on when fully implemented or follow up period.	Not met
Adherence/ fidelity	No adherence data identified. Fidelity data provided on patient preferences as to which tools were the easiest to complete and comparisons between nurses and patients.	Met
Heath outcomes	Not reported.	Not met
Organisational readiness	Not reported.	Not met
Penetration/ reach	Four eligible units participated. No data on number eligible.	Not met
Sustainability	Not reported.	Not met
Spread	Not reported.	Not met
Limitations	No objective measure of sleep. Small numbers in two centres. Patient recall. No examination of day time sleep or comparisons to other night's sleep. Nurse's experience not measured.	Met

Domain	Paper 2 - Short title: Sleep/ Ear Plugs and Eye Masks to improve sleep	Not met or met
Organisational motivation	Patients report sleep disturbance as one of the most stressful components of their critical care experience. Causes inpatient dissatisfaction while in hospital. Sleep deprivation has massive physiological consequences for critical care patients and noise has been found as one of the main factors disrupting sleep.	Met
Intervention rationale	An increasing number of patients requesting to use earplugs to help them sleep based on their experiences of wearing them at home or while travelling. No studies could be found combining earplugs and eye masks to improve critical care patients sleep within or outside the critical care setting. Only 2 previous studies tested earplugs – not with critically ill patients, very small samples. Studies showed when light is used to strengthen the circadian timing system, this increased quality in subsequent night-time sleep.	Met
Intervention	Set out to identify factors that influenced sleep in critical care. To evaluate the usefulness of two sleep interventions - eye masks and earplugs.	Met
Organisational characteristics	High-dependency planned and emergency admissions to a cardiothoracic intensive care.	Met
Implementation	Pilot testing of earplugs and eye masks, involved patients by asking their reported experiences of their sleep to evaluate the interventions.	Met
Study design	Pilot intervention study. Used a two group post-test quasi-experimental design. Case control. Tested Earplugs and eye masks-using questionnaire. Sleep and comfort using rating scales. Convenience sample of 64 patients.	Met
Comparator	Potential participants were shown the earplugs and eye masks to discern if able to accept and tolerate the interventions. If participants could not tolerate the interventions, they continued in the study as this provided a non-intervention group that could be used as a non-intervention control group.	Met
Data source	Data source: demographic data, including location in the unit, reason for and length of stay in the unit, pain management, blood pressure monitoring and night sedation. Data collection method: questionnaire of closed and open questions by bedside nurse with 64 patients. Outcome of interest: Patient's views on the factors aided and prevented sleep and ratings of sleep experiences and comfort of the interventions.	Met
Timing	Pilot data collected in 2005. No timelines on when fully implemented or follow up period.	Not met
Adherence/ fidelity	64 of the 34 patients chose to use the intervention. Patients rated the comfort of the intervention.	Met
Heath outcomes	Not reported.	Not met
Organisational readiness	Not reported.	Not met
Penetration/ reach	Only one eligible unit participated. Within one unit 64 patients were eligible and 34 agreed to participate.	Met
Sustainability	Cost of a set of earplugs and eye masks cost £2.50. No other reports of sustainability.	Not met
Spread	Not reported.	Not met
Limitations	No objective measures of sleep. One centre, small convenience sample. Bedside nurse inexperience with data capture. No patient past medical history obtained.	Met

Domain	Paper 3 - Short title: Sleep/ Noise reduction intervention programme	Not met or met
Organisational motivation	Sleep deprivation reported as detrimental to patients with acute illness and sleep disturbance and may have long-term detrimental effects on health outcomes and patient morbidity. Exposure to noise is a cause of sleep disturbance and many causes of noise identified. Guidance for noise levels in the hospital setting recommended levels of 45 dB(A) for day time noise and 35 dB(A) for night time noise.	Met
Intervention rationale	No studies examining ward based inpatient noise reduction. Strategies to reduce noise levels critical care based, indicating noise can be reduced when interventions such as nurse education, training, quiet time policy, co-ordinated care routines to reduce key activities.	Met
Intervention	Noise reduction programme. Behaviour changes expected included reducing ward noise by turning down telephones at night or switched to vibrate & carried by a member of staff, thus reducing ringing volume, wearing soft soled shoes, alteration of nurse call alarm at night.	Met
Organisational characteristics	Large UK Teaching NHS Hospitals Foundation Trust, 3 different speciality wards described, number of beds and number of staff on each ward.	Met
Implementation	Five stages: development of a sleep promotion clinical guideline, Review of ward environment, development and delivery of a staff noise awareness and education programme, staff follow up after awareness raising and education, display of sleep promotion posters.	
Study design	Pre and post noise levels data compared. Sound measurements subjected to descriptive (mean noise levels) and inferential (paired sample t-test) statistical analysis. To evaluate the significance of any difference significance was set at $p < 0.05$.	Met
Comparator	Existing ward environment reviewed on factors influencing noise	Met
Data source	Data source: Noise levels were measured using a Norsonic NOR-116 sound meter. Data collection method: sound meter was situated in the corner of a six-bedded bay, 1 m from the ground and 1 m from the wall, standing on its own tripod and plugged into the mains electricity supply. Outcome of interest: Noise levels measured, equivalent continuous A-weighted sound pressure level defined as the constant value having the same amount of acoustic energy as a given noise event (Aleq) and peak sound pressure defined as the maximum absolute value of instantaneous sound pressure (Apeak).	Met
Timing	Baseline noise levels measured in February/March 2007before first stage of intervention. Guideline agreed May 2007, 3 weeks following the development, implementation and delivery of a noise reduction intervention programme noise levels measured on same 3 inpatient wards.	Met
Adherence/ fidelity	Data provided on numbers of staff receiving the noise awareness and education programme. Numbers of staff emailed on strategies for noise reduction highlighting emails read, emails sent back with a refused delivery notice and email accounts were not accessed.	Met
Heath outcomes	Not reported.	Not met
Organisational readiness	Facilitators: establishment of a ward based nursing group to develop the guidelines assisting in the adherence to the guideline in practice, ward charge nurses or sisters supportive of the need for change providing a leadership commitment and the development and delivery of a staff noise awareness and education programme. Due to staffing levels and to ensure nurses stayed within the patient environment, one to one sessions were delivered to ward staff at convenient times. Reminders delivered using email and sleep promotion posters displayed in prominent positions on the wards. Barriers: limited time available for staff education overcome by delivering the programme whilst ward staff undertaking nursing activities.	Met
Penetration/reach	Three eligible wards participated. No data on number eligible.	Not met
Sustainability	Not reported.	Not met
Spread	Not reported.	Not met
Limitations	Small sample. No attempts to hide the recording equipment. All staff did not receive the intervention.	Met

Domain	Paper 4 - Short title: Infections/ Matching Michigan' 2 year programme to minimise CVC infections	Not met or met
Organisational motivation	Blood stream infections from CVCs increase morbidity and estimated to increase mortality risk plus incur costs of care. Body of evidence suggests rates of CVC infections are modifiable. 103 intensive care units in the USA reported a major reduction in CVC infections using a complex intervention targeting specific technical practices combined with support for cultural, behavioural and systemic change. National policy recommended a 'national patient safety initiative to tackle CVC-BSI drawing lessons from USA.	Met
Intervention rationale	To minimise CVC-BSI rates in adult and paediatric ICUs in England to at least the mean level (1.4 per 1000 CVC-patient days) seen in the USA Michigan- project.	Met
Intervention	Three components: technical interventions to ensure consistent use of evidence-based measures for reducing risks of CVC infections; non-technical interventions to intervene in culture and systems; and establishment of a standardised national reporting system for CVC infections.	Met
Organisational characteristics	223 Adult and Paediatric ICUs of which 176 (79%) were general adult ICUs, 21 (9%) paediatric, and 26 (11.6%) subspecialty. All specialities. 32 (23%) university hospitals .Mean (range) number of ICU beds per unit was 12 (3–43); mean (range) annual admissions 685 (166–2423).	Met
Implementation	All participating sites invited to take part in two training sessions, first focused on data collection, second focused on technical and non-technical interventions. Teleconference calls and internet-based teaching sessions offered over course of the programme. Guidance provided by telephone, email and on-site visits by two quality improvement facilitators. The Patient Safety First website hosted information on the interventions and on the programme. The project clinical leads provided additional ad hoc support and guidance when required	Met
Study design	A prospective, interventional, nonrandomised stepped, four-cluster, 2-year quality improvement project with continuous feedback of results to participating ICUs. All (139) acute hospitals in England with ICUs participated.	Met
Comparator	Clusters joined in a pre-determined sequence, each successive cluster acting as a de facto control for the preceding cluster.	Met
Data source	Data source: ICU staff collected and submitted infection data monthly. Data collection method: Measures of exposure were recorded through a daily census in each ICU involving a count of the number of CVCs in situ at a set time each day, this and infection data was submitted to a specially created web-based system. A survey on generic infection control practices was collated by each unit. Outcome of interest: Definitions for CVC-BSI rates/1000 catheter days were provided. Infections were reported as either CRBSI or CABSI were summed to calculate infection rates.	Met
Timing	Each cluster was invited to attend two training days, the first on data definitions developed for the programme and the second some months later on the technical and non-technical interventions. ICUs started baseline data collection as soon as possible after the first training day.	Met
Adherence/ fidelity	Compliance information on staff attendance at training days, units submitting infection data and completion rates of infection control practices survey	Met
Heath outcomes	Aggregated adult and paediatric ICU infection rates diminished with time from a first month rate of 4.4 CVC-BSI/1000 CVC-patient days for cluster 1, to 1.7 CVC-BSI in December 2010 (all clusters). Verification of consistency between ICUs in identifying and reporting CVC-BSI was undertaken in a purposive sample of ICUs.	Met
Organisational readiness	Facilitators were with the establishment of a national project team and an External Reference Group representing professional and governmental organisations. The scientific leads from the original Michigan-Keystone project acted as advisors and provided their improvement tools. Chief executive officers (CEOs) of all acute hospitals with ICUs invited to participate in the programme. Participating hospitals agreed to appoint a local project team comprising an ICU physician, an ICU nurse, a microbiologist or infection control specialist and an executive or non-executive director. The Patient Safety First website hosted information on the interventions and on the programme. On-site visits by two quality improvement facilitators (ICU nurses). Amendments to some of the programme materials to ensure contextual	Met

	relevance in England and definitions of CVC-BSI were specified more precisely than Michigan.	
Penetration/ reach	The study sample represented 223 ICUs, (96.4%, 215) ICUs submitted at least some infection data.	Met
Sustainability	A national clinician-directed system for sustained continuous CVC-BSI benchmarking ensures continued attention to CVC-BSI, and could provide a platform for monitoring other healthcare-associated infections with linkage to patient outcomes.	Met
Spread	A large roll out with interventions widely publicised on the Patient Safety First website.	Met
Limitations	No randomisation. Many confounding variables. National exposure of interventions to waiting clusters. No measures of the adoption of interventions and compliance with best practice. concurrent and preceding improvement efforts and to the consciousness-raising effect of a nationwide programme	Met

Domain	Paper 5 - Short title: Infections/ CVC dressing durability: an evaluation	Not met or met
Organisational motivation	Unresolved issue identified locally and supported by others was CVC dressing durability. Audit day indicated non-adherence seemed a particular problem. Local approach to CVC dressing use was very variable, with wide practice variation in both the type of dressing and method of application.	Met
Intervention rationale	Skin organisms at the insertion site are frequently implicated in central venous catheter blood stream infections (CVC BSIs) yet few studies have compared the durability of CVC dressings in critically ill patients. Dressing usage was high.	Met
Intervention	Evaluate 4 different commercially available, sterile, transparent, semi-permeable polyurethane dressings against the 7-day standard including a 'window' technique to improve durability of a CVC dressing and costs of the various CVC dressings and techniques	Met
Organisational characteristics	five critical care units (4 adult and 1 paediatric)	Met
Implementation	Staff received training on CVC dressing evidence-based practices and a 'how to guide' was implemented. at the beginning of each phase of the evaluation including unit-based and one-to-one teaching sessions, The educational content included: current clinical evidence and guidelines for CVC dressings; dressing design (permeability, adhesiveness); dressing technique; and how and when to change a CVC dressing	Met
Study design	Prospective study in 3 phases (4 months for each dressing) evaluation of costs and time.	Met
Comparator	Three phases: a first phase was the standard dressing and the second two phases evaluated two further dressing techniques.	Met
Data source	Data source: unit staff were trained on how to accurately complete the data collection form. A project nurses from each critical care unit recorded the time it took for them to change a CVC dressing. Data collection method: Data were collected prospectively using a pro forma which had been designed and tested. Outcome of interest: primary outcome measure was the average duration in hours that a CVC dressing remained in place.	Met
Timing	Over a 12-month period between December 2012 and December 2013. 3 phases of 4 months each. CVC-BSI rates were monitored routinely during the 12 months before and the 12 months during the dressing evaluation.	Met
Adherence/ fidelity	Of the 1229 dressing changes 304 (24.7%) did not have the type of dressing recorded so were excluded from the analysis. Numbers of CVCs and dressing changes by unit provided. Training was provided to the clinical teams at the beginning of each phase of the evaluation.	Met
Heath outcomes	CVC-BSI rates were monitored routinely during the 12 months before and the 12 months during the dressing evaluation.	Met
Organisational readiness	A small central strategy team was set up to direct and facilitate the evaluation. Each unit identified one or two experienced project nurses to participate in the evaluation. Training was provided to the clinical teams at the beginning of each phase of the evaluation.	Met
Penetration/ reach	Five critical care units (4 adult and 1 paediatric) participated. No data on number eligible.	No met
Sustainability	Time taken to change dressing and costs associated with changing dressings provided. No discussion of sustainability.	Not met
Spread	Five units participated. No data on number eligibility.	Not met
Limitations	No randomisation. Judgements on why dressing removed made by nurses, providing some variability between nurses. Data collection was patchy at times.	Met

Domain	Paper 6 - Short title: Falls/ Falls review to identify incidence and risk	Not met or met
Organisational motivation	Patient falls are the most common adverse event in hospitals, resulting in devastating physical, psychological and financial consequences. The emphasis on falls assessment and prevention is a key priority in the prevention of falls. NICE guidelines recommending a multifactorial assessment of risk to be carried out on patients at risk of falling.	Met
Intervention rationale	Little known about falls risk factors within critical care. Informal review of the assessment process within critical care the suitability was questioned	Met
Intervention	Falls risk assessment and interventions to minimise risk	Met
Organisational characteristics	Large teaching acute hospital organization in the UK. 4 critical care units and the number of beds and specialities provided. The four critical care units admitted both intensive care and high dependency patients	Met
Implementation	No implementation of change	Not met
Study design	Retrospective review of a local incident reporting system.	Not met
Comparator	Care process described was a multifactorial falls risk assessment lacking suitability due to the inability to adequately identify patients at risk of falls using the local assessment criteria. An example was with the identification of the risk factor called 'on medication's', this factor would trigger with almost all patients as this did not focus on the types of medications which could increase the risk of falling. Another example was with the ability to appropriately assess the risk factors 'balance, transfer and walking', this assessment was viewed by some staff as limited due to the critical nature of the patient's illnesses and the majority of time spent lying in bed.	Met
Data source	Data source: hospital online incident reporting system 'DATIX' (DatixWeb 12.3.1). Data collection method: not provided. Outcome of interest: Falls incidences, age, common themes, location of the fall, injuries and risk factors.	Met
Timing	No intervention timeline. Baseline falls data provided from a 2-year review.	Not met
Adherence/ fidelity	No adherence data.	Not met
Heath outcomes	Falls incidence/1000 bed days.	Met
Organisational readiness	Local falls risk assessment process used. Part of a local quality improvement project.	Met
Penetration/ reach	Not reported.	Not met
Sustainability	Not reported.	Not met
Spread	Not reported.	Not met
Limitations	Small population of patients. Primary data source provided inconsistent information so factors could have been missed.	Met

Domain	Paper 7 - Short title: Pressure Ulcers/ Part 1: PU assessment - development of CALCULATE	Not met or met
Organisational motivation	At a local level, pressure ulcer prevention was identified as a key quality improvement priority. European National & European recommendations to establish a structured approach to risk assessment to identify individuals at risk of pressure ulcers. The tool used in practice within the local organization was unable to adequately highlight elevated risk with critical care patients.	Met
Intervention rationale	The assessment of patients at risk was seen as an important first step in the quest to tackle pressure ulcer prevention with critically ill patients. Assessment scales in general are recommended for raising the awareness of risk factors in the clinical setting and for providing a minimum standard for risk assessment and documentation.	Met
Intervention	To identify a valid and reliable pressure ulcer risk assessment tool for critical care. In the absence of a suitably valid and reliable tool, to identify critical care risk factors to inform the development of a pressure ulcer risk assessment tool for critical care patients.	Met
Organisational characteristics	Within a large health care provider organization. Critically ill patients.	Met
Implementation	No change described.	Not met
Study design	Literature search using three electronic databases. No evaluation of an intervention	Not met
Comparator	Care process described was with the Braden tool used for all patients; when applied to the critically ill most patients had a very low Braden score so Braden was unable to adequately highlight elevated risk with critical care patients.	Met
Data source	Data source: existing evidence from a literature review Data collection method: Two members of the pressure ulcer prevention task group were involved in the review and appraisal of the evidence Outcome of interest: studies identifying pressure ulcer assessment scores, scales or risk factors and studies relating to adult critical care patients.	Met
Timing	No intervention implementation timeline.	Not met
Adherence/ fidelity	No adherence information.	Not met
Heath outcomes	No outcome data.	Not met
Organisational readiness	In the four local critical care units, nursing leaders from the units agreed to establish a pressure ulcer prevention task group. This task group was set up to direct, facilitate and review all aspects of critical care pressure ulcer prevention as part of a quality improvement programme.	Met
Penetration/ reach	Not reported.	Not met
Sustainability	Not reported.	Not met
Spread	Produced a pressure ulcer risk assessment tool CALCULATE with a definition for each risk factor.	Met
Limitations	No systemic appraisal of the literature. Tool did not allow for weighting of each risk factor.	Met

Domain	Paper 8 - Short title: Pressure Ulcers/ Part 2: PU assessment: implementation and revision of CALCULATE	Not met or met
Organisational motivation	Critically ill patients are a vulnerable group at very high risk of developing pressure ulcers. Incidence rates at a local level within critical care were unknown.	Met
Intervention rationale	A successful patient safety improvement approach was applied to critical care units in the USA and achieved substantial reductions in central venous catheter infections (Pronovost *et al.*, 2006). Key to their success was senior leadership in each critical care unit, standardisation of available evidence procedures, communication improvements, training tools to improve safety culture and measurement of infections.	Met
Intervention	Implementation of the pressure ulcer assessment tool CALCULATE	Met
Organisational characteristics	Four adult critical care units- only one characteristic reported	Not met
Implementation	Strategies included, nursing leadership, the provision of definitions for each risk factor, information laid out on posters at each patient's bedside, changes to pre-printed nursing documentation and a 30-min focused training package.	Met
Study design	Two audits. One to review of the number and types of risk factors (using CALCULATE) occurring in patients with pressure ulcers. One to review the frequency of the assessments against the 12-h standard and to gain feedback on the usability in practice.	Met
Comparator	Prior to the implementation of CALCULATE, the standard process for assessments were, on admission and then every week.	Met
Data source	Data source: pressure ulcers and moisture lesions were included from the DATIX system. Critical care risk factor information was taken directly from the nursing records. Frequency of the reported risk factors, reported risk factor scores and the frequency of risk assessments against local standard. Data collection method: risk factor data collected by the critical care nurse responsible for pressure ulcer prevention and tissue viability on each unit. Nurses from the four critical care units were asked their opinion on the use of the tool in practice. Outcome of interest: pressure ulcer incidence as a percentage of patient admissions.	Met
Timing	Timing of intervention explained- the pressure ulcer risk factor tool was implemented in May 2013, and 1 month after implementation, the task force group identified a requirement to audit two elements of the application in practice. No baseline data provided.	Not met
Adherence/ fidelity	Frequency of the reported risk factors audited for compliance against standard.	Met
Heath outcomes	Pressure ulcer incidence.	Met
Organisational readiness	Facilitators of implementation included a lack of confidence in the use of the existing tool, nursing leadership with credible critical care nursing expertise from each of the four units and a critical care pressure ulcer prevention expert group to direct, facilitate and review all aspects of the quality improvement program. Staff training and nursing guidance.	Met
Penetration/ reach	Four units participated. No data on number eligibility reported.	Not met
Sustainability	Not reported.	Not met
Spread	Produced a revised pressure ulcer risk assessment tool CALCULATE with a definition for each risk factor.	Met
Limitations	Sample samples over a short period. No measures of the change strategies chosen. No comparison on patients without pressure ulcers.	Met

Domain	Paper 9 - Short title: Pressure Ulcers/ Network PU prevention QI project	Not met or met
Organisational motivation	Critical Care Networks well placed to facilitate quality improvement across a number of critical care departments. Key function of networks is to develop common standards across critical care specialities within a geographical area. Network provided an ideal opportunity for nurses within critical care units to work in a cohesive and collaborative manner and to tackle the problem.	Met
Intervention rationale	National focus on pressure ulcer prevention provided an increased awareness to work together to maximise sharing and learning, and to prevent pressure ulcer damage. Nursing leaders were keen to understand and compare pressure ulcer prevalence rates within the Network and to set region wide standards to help prevent pressure ulcers.	Met
Intervention	To share pressure ulcer rates and practices	Met
Organisational characteristics	Critical care Network in the North of England, 23 critical care units, three main critical care specialities.	Met
Implementation	Establishment of a cross-organisational pressure ulcer prevention group and a benchmarking exercise of current practices. The National Safety Thermometer tool was used to measure pressure ulcer prevalence rates. Best available evidence was used to develop local consensus using another Critical Care Networks' bundle of interventions to develop a local pressure ulcer prevention standards	Met
Study design	Not provided.	Met
Comparator	Care process from the benchmarking exercise highlighted differences in the clinical practices. No details were provided on the existing standards of care.	Not met
Data source	Data source: the pressure ulcer prevalence data was taken from the national NHS Safety Thermometer tool. Data collection method: telephone interview data used a proforma to capture benchmarking practices from each critical care unit. Outcome of interest: Pressure Ulcer Prevalence rates.	Met
Timing	No timelines on intervention and evaluation.	Not met
Adherence/ fidelity	Compliance data for unit submission to the NHS Safety Thermometer measured overtime.	Met
Heath outcomes	Pressure ulcer prevalence.	Met
Organisational readiness	Project leadership and nursing representation from all critical care units within the region was available. The Network supported and coordinated the group. The national NHS Safety Thermometer data requirements were already established for each organisation. A document was produced with four key elements known as a 'SKIN' bundle and launched at a Network Lead Nurse clinical forum meeting.	Met
Penetration/ reach	Data provides number of eligible units as 23 units in the network and data on those submitting data. Initially eight critical care units (33%), this increased to 20 units (83%) then 23 units (100%).	Met
Sustainability	Potential for sustainability described as future plans for the Network to continue to collect the monthly pressure ulcer prevalence rates from the NHS Safety Thermometer for each critical care unit and to share and compare the data on a quarterly basis.	Met
Spread	Produced a Network guidance document called 'reducing pressure ulcers for critically ill patients'.	Met
Limitations	No validation of the data. Prevalence data not incidence data and only categories 2-4 collected so not a full picture of harm. Compliance against standards not measured.	Met

Domain	Paper 10 - Short title: Pressure Ulcers/ Reducing PUs 4-year QI programme	Not met or met
Organisational motivation	The NHS identified pressure ulcer prevention as a quality improvement target. Locally a high incidence of pressure ulcers in the four adult critical care units was identified.	Met
Intervention rationale	Other critical care quality improvement programmes demonstrated impressive patient safety improvements when a bundle approach was implemented. Evidence pointed towards multiple small interventions being important so chose a bundled approach.	Met
Intervention	Bundle approach of technical and non-technical interventions implemented supported by clinical leadership, process and outcome measures.	Met
Organisational characteristics	Setting for the improvement programme was four adult critical care units (intensive care and high dependency beds) within a NHS organization on two acute hospital sites. Data provided on the number of beds and case-mix for each unit.	Met
Implementation	Overall programme leadership provided. A pressure ulcer task group to lead direct and facilitate the implementation of the improvement programme. Three 12-month phases: first 12 months focused on appraisal of published evidence to identify parts of the bundle for implementation. A review of National & European clinical guidelines on valid pressure ulcer assessment turning regimes, seating regimes, mattress choice, skin care and incontinence management. Topics shared out within the task group, each member of the group reported back on their appraisal of important aspects of pressure ulcer prevention at the monthly task group meetings. Revision of the existing nursing care plan and nursing documentation, developed a new pressure ulcer risk assessment tool, updated the pressure ulcer prevention guidance and introduced a new pressure relieving mattresses for the highest risk patients. The use of bowel management systems, skin care and development of a critical care Bowel Management Assessment Tool. Second 12 months: 30-minute training session aimed at new and existing staff delivered. Third 12 month: period of refinement of the interventions, the pressure ulcer risk assessment tool was revised, 'flash training', continuous measurement of pressure ulcer incidence and rewards issued.	Met
Study design	Before and after study design. Data collected continuously over 4 years	Not met
Comparator	Standard care before the intervention included foam and gel mattresses and the use of the Braden Scale to assess pressure ulcer risk.	Met
Data source	Data source: local DATIX® incident reporting system. Data collection method: all pressure ulcers reported by unit staff, assessments and categorizations were based on the National Pressure Ulcer Advisory Panel definitions and checked and verified by a Tissue Viability Nurse Specialist. Outcome of interest: Incidence of pressure ulcers in critical care per 100 admissions by pressure ulcer category.	
Timing	Clear timelines provided on baseline data, when interventions implemented and evaluation after implementation.	Met
Adherence/ fidelity	Process measures included an audit of compliance with the 12 hourly pressure ulcer assessment standards, compliance against the bowel management assessment tool guidelines and numbers of staff trained.	Met
Heath outcomes	Incidence of pressure ulcers.	Met
Organisational readiness	Facilitators were a multidisciplinary, pressure ulcer task group with members who influenced and encouraged the application of the changes on each of the critical care units. Data feedback to critical care staff to maintain staff commitment. Time was invested to provide staff training to increase understanding of the importance of pressure ulcer damage.	Met
Penetration/ reach	Four units participated. No data on number eligibility reported.	Not met
Sustainability	Observed significant and sustained reduction in pressure ulceration over 4 years. The average estimated cost saving was calculated to be £2.6 million (range £2.1–£3.1).	Met
Spread	Bundle of interventions described plus the content and format of each intervention provided.	Met
Limitations	Some confounding and temporal factors not reviewed. Interventions implemented as same time as national policy and attention which could have had an effect. Not able to retrospectively check data prior to September 2012.	Met

7.3 Appendix 3 - A summary of the interventions used in the published papers

	Technical interventions (Evidence based)					Non-technical interventions			Data	
Paper	**Risk Assessment**	**Guidelines**	**Standards**	**Checklists**	**Equipment /materials**	**Consensus meetings**	**Education /training sessions**	**Reminders e.g. posters, emails**	**Measurement**	**Feedback**
1	✓								✓	
2					✓				✓	
3		✓			✓	✓	✓	✓	✓	✓
4		✓		✓	✓	✓	✓		✓	✓
5		✓			✓	✓	✓	✓	✓	✓
6	✓									
7	✓									
8		✓		✓		✓	✓		✓	✓
9			✓			✓			✓	✓
10		✓		✓	✓	✓	✓	✓	✓	✓

7.4 Appendix 4 - Published Papers

7.4.1 Paper 1

Richardson, A., Crow, W., Coghill, E., Turnock, C. (2007) 'A comparison of sleep assessment tools by nurses and patients in critical care'. *Journal of Clinical Nursing,* 16, pp. 1660–1668.

CRITICAL CARE

Journal of
Clinical Nursing

A comparison of sleep assessment tools by nurses and patients in critical care

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RICHARDSON A, CROW W, COGHILL E & TURNOCK C (2007) *Journal of Clinical Nursing* **16**, 1660–1668

A comparison of sleep assessment tools by nurses and patients in critical care

Aim. The aim of this critical care sleep assessment pilot study was to evaluate the usefulness of three sleep assessment tools to identify which, if any, provided the closest comparison between the nurses' judgement and the patients' experience of their sleep. The study objectives were to: (i) compare patients' and nurses' assessment of sleep using three different rating tools. (ii) Ascertain patients' preferences with non-interventional, user friendly, practical tools in critical care. (iii) Recommend changes and improvements to the way that sleep is assessed and documented.

Background. Sleep is important for promoting critical care recovery and sleep disturbance is known to cause irritability, aggression and increased stress levels. The availability and use of valid critical care sleep assessment tools is limited.

Design. A descriptive comparative study using three sleep assessment-rating scales were constructed to provide easy to understand tools for completion by both patients and nurses in critical care.

Methods. Structured interviews were undertaken with 82 patients and 82 nurses using a convenience sample from four multispecialty critical care units in one large teaching trust. Patients were included in the study if they met a list of pre-defined criteria to obtain responses from lucid orientated patients.

Results. No tool produced a close association between the nurses' assessment of the patients sleep and the patients' assessment of their sleep. Patients found two of the three tools easy to use when rating their sleep.

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Discussion. Objective invasive measurements of sleep as well as complex subjective tools appear inappropriate to be used as a part of daily critical care practice. The application of simple rating scores has a high degree of error when nurses assess patients' sleep, even though high levels of patient observation and assessment are practiced in critical care.
Conclusions. More research is needed to examine the assessment of sleep in critical care, particularly linking rating scales to alternative methods of physiological assessment of sleep. Findings indicate nurses are unable to accurately assess critical care patients' sleep using rating assessment tools. However patients were found to prefer two sleep assessment tools, one banded in hours to assess sleep quantity and one as a comparison against normal sleep to assess sleep quality.
Relevance to clinical practice. This study reviews the importance of sleep assessment and the diverse methods available for assessing sleep focussing on the critically ill patient. More noteworthy it highlights how nurses sole judgements of patients sleep is not a reliable method in clinical practice, however it provides some indication on the application of 'easy to use' tools to assist in the patients assessments of their sleep.

Key words: assessment tools, critical care, nurses, nursing, patients, sleep

Introduction

Sleep is important for promoting hospitalized-patients' recovery (Richards 1998). It is well recognized that the disturbance of sleep is detrimental to patients with an acute illness (Aurell & Elmqvist 1985, Wilson 1987, Soehren 1995, Perez de Ciriza *et al.* 1996) and sleep disturbance may have long-term effects on health outcomes and patients' morbidity (Tamburri *et al.* 2004). Specifically, within intensive care, many studies have identified that critically ill patients' report sleep disturbance as one of the biggest cause of stress (Aurell & Elmqvist 1985, Wilson 1987, Soehren 1995, Perez de Ciriza *et al.* 1996).

Many diverse methods are available to measure and assess sleep in hospitalized acutely ill patients. The most reported methods are polysomnography, actigraphy, self-report, observation, sleep charts and interviews (Closs 1988, Redeker 2000). Despite tools being available, an informal review by the research team of sleep assessment practices within four critical care areas found sleep assessment was often undertaken in an unsystematic manner. Nurses' assessment of patients' sleep, was regularly based on their own interpretation of the patients' sleep, occasionally supplemented by asking the patient. Only one of the four critical care units informally reviewed had an available sleep assessment tool, which had been designed at a local level. This tool was designed for nurses to measure periods (in minutes) when patients' eyes were shut to judge sleep, without directly measuring or asking patients about their sleep.

The purpose of this paper is to review the literature to examine available sleep assessment tools and to present a research study to test and identify the most effective tool for assessing sleep within a critical care environment.

Why sleep is important?

Sleep is a physical need for all humans. Sleep quality is seen as precious because complaints regarding sleep quality are common (Dogan *et al.* 2005), plus, sleep promotes recovery in the hospitalized patient (Richards 1998).

Studies have also shown that when sleep is reduced you become more irritable, tired and aggressive (Chuman 1983), more likely to have confused reactions (Dogan *et al.* 2005) and pain tolerance is decreased (Weitzman *et al.* 1974). Eveloff (1995) and Gabor *et al.* (2001) discovered that sleep actually had an impact on respiratory function, with disrupted sleep causing respiratory dysfunction, which may prolong mechanical ventilation support.

A study by McGonigal (1986) found that hospital staff did not allow for the importance of sleep when planning patient care even though effective sleep assessment by nurses can help to measure improvements in patients' sleep patterns (Richardson 1997). Snyder-Halpern and Verran (1987) found this could be due to nurses having no access to a reliable and valid tool to help them assess their patients sleep patterns fully. A recent study evaluating sleep quality in the hospitalized patient recommended nurses should develop a way of collecting data to determine and assess patients' sleep quality (Dogan *et al.* 2005).

Sleep assessment tools

Over the years, the assessment of sleep has been examined within the laboratory setting and the hospital environment. Objective and subjective methods have been used to assess both healthy volunteers' sleep patterns within the laboratory and the hospital environment and the hospital patient in the ward and critical care environment. The majority of the studies that have been undertaken in laboratory settings have used objective physiological measurements (Snyder-Hapern & Verran 1987). These polysomnograph sleep measurements include electroencephalogram (EEG) the measurement of electrical brain activity, electromyogram (EMG) the recording of muscle activity during sleep and electroculogram (EOG) the monitoring of eye movements. These measurements have been seen as the most effective and accurate way to assess the physiological attributes of sleep (Chuman 1983, Tamburri *et al.* 2004). However, polysomnograph methods are difficult to use outside the laboratory setting (Snyder-Hapern & Verran 1987) and are expensive and difficult to access (Richardson 1997), limiting their use in critical care areas (Tamburri *et al.* 2004). An alternative, less invasive behavioural measurement of sleep, is actigraphy (Tamburri *et al.* 2004) involving a small wrist or leg worn device to record gross motor activity, but this has similar interpretation and access problems.

However, it may not be necessary to use such invasive methods. Closs (1988) felt that there is evidence to show subjective sleep assessment results that compare closely with EEG measurements. Knabb and Engel-Sittenfeld (1983) suggested physiological assessment methods cannot accurately measure the subjective nature of sleep. However, Rdeker *et al.* (1998) disagreed, believing subjective measures cannot replace objective sleep measures, but they may complement each other.

Many subjective sleep assessment tools have examined sleep patterns over the years and again have been tested within and outside the hospital environment. An early study by Baekeland and Hoy (1971) assessed the sleep of 21 healthy adults in their own homes and the laboratory setting. This was evaluated using an 11-item multiple choice and short answer sleep log using complex rating scores on a scale assessing items such as soundness of sleep, movement during sleep and rest upon wakening.

A subjective sleep tool called the St. Mary's Hospital Sleep Questionnaire (SMH) was designed specifically to assess patients' sleep while in hospital. This SMH tool was a 14 item multiple choice and short answer instrument, which examined individuals' previous nights sleep. Patients within this study were not from the critical care environment, but were from surgical, medical and psychiatric wards in a general hospital unit. A further group of healthy volunteers was included to test the tool's reliability and validity (Ellis *et al.* 1981).

Another subjective sleep assessment tool, developed by Snyder-Hapern and Verran (1987) called the VSH sleep scale, measured sleep patterns in relation to visual markers in healthy volunteers in their own homes. This tool was adapted from early work measuring self-reported sleep patterns (Atkin 1969, Herbert *et al.* 1976, Parrott & Hindmarch 1978). The tool's validity was tested by using it in conjunction with the Baekeland and Hoy sleep log and the SMH. The VSH Sleep Scale required participants to place a point between a 100-cm line and zero scale (100 was deep sleep and zero no sleep) for eight items relating to their sleep. The higher the total score, the better the quality of sleep. Snyder-Hapern and Verran (1987) recommended that the scale should be repeated in a non-hospitalized population as well as a clinical population and to test its validity against the objective measurements obtained from polysomnography.

The VSH tool was retested within the hospital environment and many difficulties were found. Patients reported problems seeing or reading the tool because of medication side effects, position and tubes and dressings that interfere with the use of reading glasses. Patients also had difficulties in writing because hands and arms were often immobilized by monitoring, treatment and illness (Richardson 1997). Despite these difficulties, Richardson (1997) found this tool could be used in the critically ill and tested its use with quadriplegic patients. The tool was applied by the nurse who held the scale at right angles to the patient's face, and each item was read to them. The nurse then indicated the position on the scale with a pencil once confirmed by the patient. This method was found to be a useful approach in the critical care clinical environment, but presented no information regarding the tool's reliability and validity when used in this 'by proxy' manner (Richardson 1997).

An early study using a four-point sleep behavioural tool found nursing observations of sleep correlated with patients' polysomnograph data (Fontaine 1989). Another study compared a staff nurse observation tool with polysomnograph using a three-point check list (sleep, no asleep or unable to determine) on 21 critically ill patients and found nurse observations were correct 74% of the time (Edwards & Schuring 1993). Similarly, a study by Aurell and Elmqvist (1985) compared nurses' assessment of sleep with patients' polygraphic data. However, their findings discovered nurses overestimated patients sleep time. Another study by Freedman *et al.* (1999) used a questionnaire to examine sleep disturbances in four intensive care units (ICU). Patients were asked to rate

their sleep quality on a scale of 1–10 (1 = poor, 10 = excellent) and the degree of daytime sleepiness on a scale of 1–10 (1 = unable to stay awake, 10 = fully alert and awake). This subjective examination was unable to determine patients' true sleep architecture and the reliability and validity were reported as limitations of the tools, which may have been due to the study making no comparison with patients' polysomnographic data. A later study using the Freedman *et al.* (1999) subjective questionnaire to measure perception of sleep along with objective polysomnography measurements discovered that participants' perception of their sleep disruption did not match the polysomnograghy data (Gabor *et al.* 2003).

Other studies have developed simple rating scales for nurses to assess patients' sleep with the critically ill (Olsen *et al.* 2001). They used the tool previously developed and validated by Edwards and Schuring (1993) where nurses were asked to indicate patients sleep following a five-second observation of patients at eight pre-determined periods throughout 24 hours. Difficulties were encountered by nurses undertaking the assessment because of their need to be close to the patient resulting in waking the patient during their sleep. They suggested more objective methods should be used to enhance the validity of sleep assessment methods.

A review of the literature has identified a number of key issues, influencing the development and use of sleep assessment tools with critical care patients. These key issues include the fact that critically ill patients often experience difficulties in communicating and recalling information and writing may be difficult as their hands/arms may be weakened or immobilized by monitoring devices and intravenous access. Patients have difficulty responding to detailed visual analogue scales and many critical care patients have been anaesthetized, sedated and are often intubated resulting in an inability to speak. Therefore the development and testing of simple, easy tools for patients to understand and complete in critical care was considered desirable by the research team.

While simple subjective sleep assessment tools exist for nurses to assess patients' sleep and tools have been used for patients to assess their own sleep, no studies have been published that compare the nurses' assessment with the patients' perception of sleep. The requirement to ensure that users are involved in decisions and service developments (Department of Health 1999, 2000, 2001) support the need to ask patients their views on sleep assessment.

Aims

The aim of this critical care sleep assessment pilot study was to evaluate the usefulness of three sleep assessment tools to identify which, if any, provided the closest comparison between the nurses' judgement and the patients' experience of their sleep.

The study outcomes were to:

- Compare patients' and nurses' assessment of sleep using three different rating tools.
- Ascertain patients' preferences with non-interventional, user friendly, practical tools in critical care.
- Recommend changes and improvements to the way that sleep is assessed and documented.

Design/methodology

This was a pilot study attempting to test three sleep assessment tools that nurses could use to assess accurately and record sleep of individual patients in four critical care units. The study compared the judgement of nurses and the experiences of patients with regards to sleep using three separate sleep assessment tools (see Appendix 1). Three different tools were chosen to provide a variety of ways to assess sleep in terms of both quantity and quality of sleep experienced. As shown in Appendix 1.

These tools were designed by the research team using a similar format to sleep assessment tools identified in the literature review (Snyder-Hapern & Verran 1987, Richardson 1997), while acknowledging the known difficulties associated with assessment of sleep in the critically ill. The rating scores were constructed to provide an easy to understand tool for completion by both patients and nurses in critical care.

Enlarged versions of the sleep assessments tools were printed and laminated so patients could easily see and point to the scale. If individual patients' were unable to point, talk or see the scale then the researcher used a number of ways to obtain the patients' response. These included the researcher pointing to the score and asking the patient for confirmation using facial gestures, obtaining verbal responses and reading out the scores to patients. A large, easy to visualize, clock was placed at each patient's bed area to help them in their assessment of their own sleep.

Sample/participants

This was a pilot study in which the lack of previous research prevented the research team from making a power calculation. However, following advice from a statistician, it was agreed that to make inferential statistical analysis possible a minimum quota sample of 50 different patients and 50 different staff was believed to be necessary for the pilot study. In reality, 82 patients and 82 nurses participated in the study.

A convenience sample was used to collect data from four multispecialty critical care units in one large teaching trust. The four units sampled were:

1 Cardiothoracic intensive care unit: specializing in post-cardiac and thoracic surgery including heart and lung transplantation.
2 Neuro intensive care unit: specializing in neurosurgery, neurology, trauma, oral and maxillofacial surgery, home ventilation and infectious diseases.
3 General intensive care unit: specializing in vascular surgery, renal and liver transplantation, hepatobiliary and pancreatic surgery, ENT, general medicine and general surgery.
4 General intensive care unit: specializing in upper and lower gastro-intestinal surgery, burns and plastics, obstetrics and gynaecology, cardiac surgery and endocrine medicine and surgery.

Data collection

Four critical care nurse researchers not directly involved in patient care collected the data from March to July 2004. Each researcher obtained background demographic data from the patients' medical and nursing notes. Then the participating nurse (nurse caring for the patient overnight) participated in a short structured interview to identify their assessment of the patient's sleep using the three rating scales. Subsequently the patient also participated in a short structured interview, which was independent of the nurse interview and normally less than five minutes duration, to identify their assessment of their own sleep using the same rating scales. The data were collected from the nurse at the end of their night shift between 7.00–7.30 AM and then from the patient when awake, at a convenient time between 7.30–9.30 AM, so that neither nurse nor patient was aware of the other's rating.

Inclusion criteria, guided by previous sleep studies, aimed to select from lucid orientated patients able to provide the most appropriate responses using the criteria identified by Cooper *et al.* (2000). It was important to ensure patients were not still under the effects of an anaesthetic or intravenous sedation so a period of 24 hours was set as an appropriate length of time to wait following administration of these drugs. In addition, due to many disturbances associated with the admission of patients to critical care and to allow time to become familiar with a new environment, a length of stay in the ICU greater than 24 hours was set, which is an approach supported by Baekeland and Hoy (1971). As resources available for translation were limited, participants unable to speak and read English were excluded from the study, although all potential participants spoke English as their first language.

Therefore the sleep assessment criteria for inclusion into the study were defined as:

- More than 24 hours following any intravenous sedation.
- Length of stay greater than 24 hours.
- More than 24 hours since a general anaesthetic.
- A judgement made by the nurse caring for the patient that the patient is sufficiently lucid to understand the nature of the study and indicate a decision as to whether or not they wish to participate.

Once patients were identified as fulfilling the criteria for inclusion, nurse participation was limited to those nurses caring for the patient for a full night shift who would be responsible for assessing their patients' sleep.

Ethical considerations

Approval for this study was gained in a number of ways. Ethical approval for the study was obtained from the Trust, University and Local Research Ethics Committee.

Consent was obtained from all participants. The study was discussed with each participant, a written information sheet was provided and this was followed by written consent. A small number of patient participants were unable to provide written consent because of limb weakness so written assent was obtained from the patients' next of kin once the patient indicated, either verbally, by head movement or by pointing to a word board, that they were agreeable to participation.

Data analysis

Data analysis was undertaken by an independent researcher not involved in data collection. The data analysis began after the collection of 52 subjects. Findings from this analysis led to development of the data collection methods to capture additional information. Data were entered into the Statistical Package for Social Science (SPSS 11.0, SPSS Inc., Chicago, IL, USA). Descriptive statistics such as percentages and frequency counts were used to summarize data.

As the purpose of the study was to compare similarity between patient and nurse sleep assessment using a specific tool, data collected from the patient and the nurse for a specific rating scale were analysed comparing the level of agreement between patients and staff for each tool using a measure of association for ordinal data, Gamma test. This test measured the degree of association between two ordinal variables, i.e. patient and nurse assessment for a specific sleep assessment tool. The test compares patient and nurse assessments on a case-by-case basis to calculate the level of association between assessors by producing a value on a scale from -1 to $+1$. A value of 1 indicates a strong relationship

Table 1 Length of patient stay in ICU

Length of stay	Number	Percentage
1–3 days	34	41·5
4–6 days	20	24·4
7–9 days	5	6·1
10–12 days	3	3·7
13 –15 days	4	4·9
More than 15 days	15	18·3
Unknown	1	1·2
Total	82	100

Table 2 Grade of nurse

Grade of nurse	Number	Percentage
D	27	32·9
E	39	47·6
F	1	1·2
Bank nurse	15	18·3
Total	82	100

between the two variables, patient and nurse assessment, while a value of zero indicates little or no association between assessors. A value of −1 indicates an inverse relationship between assessors.

Findings

Eighty-two patients and 82 nurses participated in the study. Forty-five (54·9%) patients were male and 37 (45·1%) were female. Fifty-five (69·6%) patients were extubated, 22 (27·8%) had a tracheostomy and two (2·5%) were either orally or nasally intubated. Data on the nature of three patients' airways were not collected. Length of patients' stay in the ICU varied; although the greatest proportion had only been in the unit for no more than three days, (Table 1).

The nurse caring for the patient during the night of patient participation was either a D grade, E grade, F grade or bank nurse. As Table 2 indicates, the majority of nurses taking part in the study were E grades (Table 2).

Table 3 Similarity of nurse–patient assessment of sleep for each tool

Sleep assessment tool	Gamma value of association
Tool one: 0–2 hours; 2–4 hours; 4–6 hours; 6–8 hours; > 8 hours	0·334
Tool two: much less than average; less than average; average; more than average; much more than average	0·452
Tool three: 1 (no sleep); 5 (average sleep); 10 (slept well)	0·345

Table 4 Patients' preference of assessment tool

Sleep assessment tool	Number	Percentage
Tool one: 0–2 hours; 2–4 hours; 4–6 hours; 6–8 hours; > 8 hours	10	33·3
Tool two: much less than average; less than average; average; more than average; much more than average	9	30·0
Tool three: 1 (no sleep); 5 (average sleep); 10 (slept well)	4	13·3
None particular preference	7	23·3

Table 5 Patients' reasons for preference of assessment tool

Sleep assessment tool	Reasons stated
Tool one: 0–2 hours; 2–4 hours; 4–6 hours; 6–8 hours; > 8 hours	'Gives you hours' 'Put into hours' 'Because you can count hours' 'Easier to look at clock'
Tool two: much less than average; less than average; average; more than average; much more than average	'Able to compare to normal' 'Easiest to use' 'Can base it on usual experience' 'Easiest to relate to own sleep'
Tool three: 1 (no sleep); 5 (average sleep); 10 (slept well)	No quotes
None particular preference	'All the same' 'All easy to answer'

The following findings indicate that any possible effect of the order that the rating tools were presented to participants did not influence either the level of nurse–patient association or patient preference, as no specific tool was significantly different to any other.

The results for all three-assessment tools indicated a slight degree of association between patient and nurse assessment of the nature of the patients' sleep (Table 3).

While tool two had the greatest level of association, it was not appreciably greater than either of the other two. Furthermore, the findings suggest no tool produced a significantly close association between patient and nurse in making judgements about the nature of sleep experienced by a patient.

After data collection on 52 patients, interim analysis indicated no association, therefore, the study was extended

by a further 30 patients. Two questions were added and patients were asked to nominate the tool they found easiest to complete. As Table 4 indicates, there was the similar degree of preference for both assessment tools one and two at 33·3% and 30·0%. It is worth noting the low level of preference for tool three (13·3%).

Patients were also asked for reasons why their preferred tool was easiest. Table 5 presents the most common responses.

Discussion

Previous studies have examined how sleep has been assessed using many different objective and subjective assessment tools and in different settings (Baekeland & Hoy 1971, Snyder-Hapern & Verran 1987, Richardson 1997). However, many of the available sleep assessment tools use intrusive methods to obtain objective measurements and seem inappropriate to use as a part of daily critical care practice.

Subjective methods are available but their validity has been questioned and their use in critical care areas may also be difficult. The application of complex tools in critical care has been found to be problematic due to difficulties patients encounter understanding and completing the tool as well as the nurses' ability to interpret the information (Snyder-Hapern & Verran 1987, Redeker & Tamburri 1999). This study, using three different, easy to complete, sleep assessment tools, found no close association between nurses' assessment of patients sleep compared with the patients' perception of their sleep. Therefore this questions the nurses' ability to judge accurately patients' sleep using the sleep assessment tools.

Results of this study conflict with previous research where nurses can assess the actual number of patients' sleep episodes experience (Fontaine 1989, Edwards & Schuring 1993). This research indicated nurses were inaccurate at judging quantity (based on number of hours) of sleep and quality (based on average) of sleep. Similar nurse inaccuracies were found in critical care with nurses' ability to assess critical care patients sleep correctly (Freedman *et al.* 1999, Gabor *et al.* 2003). Although these studies were conducted in critical care, with a high nurse to patient ratio and high levels of patient observation throughout the night, patient observation by the nurse alone has a high degree of error when assessing patients' sleep. It may well be that the most accurate way for nurses to assess patients' perceptions of their sleep should be to ask the patient to rate their own sleep.

This observer bias finding when assessing patients' sleep reported in other studies (Redeker 2000) may be associated with patients who are not moving very much or have their eyes closed for a large proportion of the 24-hour period. It could be that nurses have difficulty making a judgement of exactly when these patients are asleep or awake. Also, because of the open nature of the ICU environment, often associated with open bedded bays in critical care, nurses are very aware of the activity and noise level throughout the night. Such awareness may have an impact on the nurses' judgement, resulting in an inaccurate assumption of when patients are able or unable to sleep in this environment. Therefore, the daily practice of nurses assessing patients' sleep, based on how long their eyes are shut or open, appears to be an inaccurate subjective measurement of sleep.

Of the three tools tested in this study, tool two had the closest association between the patient and nurse and would, therefore, be more appropriate than the other two tools if nurses assess patients' sleep solely in this way. Therefore nurses' assessment of patients sleep using tool two may be informative only with patients who are unable to respond and complete a subjective assessment tool.

Involving patients in this study found critical care patients preferred tool one and two as these were the easiest to complete, therefore, both may be useful to assist with the measurement of patients perceptions of their sleep.

Limitations

This study did not measure objective sleep measurements so no comparisons were made with the patient's physiological sleep pattern compared with the nurse and patient perception of their sleep pattern. In addition, no examination of the patient's previous nights sleep or the sleep experienced through the day was undertaken. Freedman *et al.* (1999) found 40–50% of an intensive care patient's sleep actually occurs during the day, so this needs to be considered when interpreting the data.

Participants were critical care patients who were awake and orientated limiting generalizability of findings to all critical care patients. Because of some patients, immobility and inability to speak because of their critical illness, the researchers may have introduced some observer bias when obtaining the patients perspective. Although this is recognized as a limitation the researchers were experienced and trained to communicate with the critically ill.

A further limitation may have been experienced with patients recall bias (Fontaine 1989, Richardson 1997). However, patients were only selected for the study if they had not received a general anaesthetic or had not received intravenous sedation for 24 hours and it is typically this group who do not remember much of their ITU stay

(Freedman *et al.* 1999). Also, subjects were asked about their previous night's sleep during the next morning to maximize the opportunity for recall. The study did not attempt to control the nature of patient sedation or analgesia as this would introduce an unacceptable degree of influence upon clinical-decision making that met the diverse range of patient needs in the participating units.

The ICU illness is complex particularly with the effects of illness itself and/or the affects of medications administered, making it difficult to know and control how these factors affect patients in different ways. Consequently, an awareness of this should be taken into account when interpreting the results from such a complex patient population.

The study did not examine any possible correlation between the nurses length of critical care experience and their ability to assess patients sleep.

Conclusions

This study measured the association between patients' perceptions and nurses' judgements of sleep, plus the patients' views on three sleep rating scales. The study made no association between patients' self-assessment of sleep with the physiological measures of sleep, as the aim of the study was to ascertain the usefulness of non-interventional, user friendly, practical tools in critical care. Despite the effectiveness of polysomongraphy (Chuman 1983, Tamburri *et al.* 2004) as a detailed physiological assessment of sleep, the expense and intrusiveness of such invasive techniques were not seen as feasible for use in every day critical care practice.

Further studies could focus on testing the tools in this study with patients' vital signs or actigraphy to provide more valid subjective tools to assess sleep. In addition, assessment over a complete 24-hour period plus making comparisons with the environmental noise and light could prove to be informative in the critical care environment.

The tools tested for use, which indicated patients' preferences within the critical care environment, were seen as a first step in understanding and measuring practical solutions to assessing patients' sleep in the future. It is suggested that tool one could assist in the assessment of patients' perception of their sleep quantity and tool two to assist in the assessment of patients' perception of their sleep quality, but it is stressed that nurses, where possible, should ask the patient to rate their sleep using these tools.

Contributions

Study design: AR, CT, WC; data analysis: AR, CT, WC, EC, MD and manuscript preparation: AR, CT, EC.

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Appendix 1

1. A rating on the number of hours slept (banded in hours)
Assessment tool one

	0-2 hours	2-4 hours	4-6 hours	6-8 hours	More than 8 hours
Nurse					
Patient					

2. A rating based on a comparison with their normal/average sleep
Assessment tool two

	Much less than Average	Less than Average	Average	More than Average	Much more than Average
Nurse					
Patient					

3. A numerical rating score (1–10)
Assessment tool three

	No Sleep 1	2	3	4	Average Sleep 5	6	7	8	9	Slept Well 10
Nurse										
Patient										

7.4.2 Paper 2

Richardson, A., Coghill, E., Allsop, M. (2007) 'Ear Plugs and Eye Masks: Do they improve critical care patients' sleep?' *Nursing in Critical Care,* 12(6), pp. 278-286.

Earplugs and eye masks: do they improve critical care patients' sleep?

Annette Richardson, Micheala Allsop, Elaine Coghill and Chris Turnock

ABSTRACT

Disturbed sleep and sleep deprivation is common in patients in critical care settings. Noise and inappropriate use of light/dark cycles are two of the causes of sleep interruptions. The purpose of the study was to evaluate eye masks and earplugs to help control patients' exposure to noise and light within the critical care environment. An intervention study using a two group post-test quasi-experimental design of high dependency patients within a cardiothoracic critical care unit was undertaken by a group of critical care nurses. Sleep assessment rating scales and open-ended questions were used to obtain patients' reported experiences of their sleep. Patients self-selected into either an intervention or non-intervention group. Sixty-four patients consented to take part in the study, 34 patients tried the interventions earplugs and eye masks and many found they improved sleep. However, noise was still a factor preventing sleep for both groups of patients. Mixed reports were found with the interventions from very comfortable to very uncomfortable. At a cost of £2·50/patient, earplugs and eye masks were a relatively cheap intervention with notable improvements for some critically ill patients. Further research is required with a larger sample size, plus an examination of both earplugs and eye masks separately. Offering patient's earplugs and eye masks to improve sleep should be considered as a matter of routine nursing practice, this should include time to show patients how to use and try them out for comfort.

Key words: Critical care • Earplugs • Eye masks • Sleep

BACKGROUND

Patients report sleep disturbance as one of the most stressful components of their critical care experience (Novaes *et al.*, 1997). Disturbances at night-time have been reported, through patient satisfaction surveys, as one of the causes of inpatient dissatisfaction while in hospital (Commission for Patient and Public Involvement in Health, 2007). As well as the reported patients' experiences of disturbed sleep, sleep deprivation has been well researched, particularly how common this is in patients in acute care settings (Parker, 1995; Wallace *et al.*, 1999; Cooper *et al.*, 2000; Redeker, 2000). This sleep deprivation is scientifically supported by polysomnographic studies (Honkus, 2003). Therefore, it is of no surprise that patients who leave the critical care environment often spend the first 2 or 3 days on a ward sleeping for prolonged periods (Reishtein, 2005) alarming relatives and ward staff.

The effects of sleep abnormalities in healthy subjects have been studied and found increased oxygen consumption and carbon dioxide production (Bonnett *et al.*, 1991), as well as result in a significant reduction in attention, short-term memory, verbal recall and problem-solving activity (Bonnett, 1989). The detrimental effects of sleep deprivation on patient recovery have also been studied. Sleep deprivation has massive physiological consequences for critical care patients as lack of sleep has been shown to affect upper airway musculature dysfunction and blunting of hypercapneic and hypoxic ventilatory responsiveness (Eveloff, 1995), and altering the process of weaning (Mejer *et al.*, 1994). In addition, lack of sleep in critically ill patients causes a decreased ability to fight infection and tissue repair (Snyder-Halpern, 1985). Patient experiences and the effects of sleep deprivation have raised the importance of sleep and the need to improve on sleep

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disturbance for patients in critical care; however, in order to improve sleep for patients, an understanding of the causes of sleep deprivation was indicated.

Many views exist on the causes of sleep disruption within a critical care setting. Reishtein (2005) summarizes the causes as ventilator dysynchrony, noise, interventions related to care, anxiety, underlying acute or chronic disease, circadian rhythm disturbances, light, noxious odours and effects of medication.

As the care of the critically ill relies on many types of highly technical equipment with safety alarms and high staffing levels resulting in frequent conversations, noise has been found as one of the main factors disrupting sleep in the case of the critically ill (Gabor *et al*., 2003). This is supported by a study, which correlated critical care noise levels and arousal frequencies, where findings have shown a relationship between sound levels and suppression of rapid eye movement (REM) sleep. This study highlighted the important link with a reduction in REM sleep and signs of confusion, suspiciousness, withdrawal and poorer recall (Topf and Davis, 1993). Likewise, Wallace *et al.* (1999) found that exposure to critical care noises increased the number of awakenings and decreased sleep time. An early study reported on excess noise and the effects on sleep within critical care, the average night-time noise was recorded at 56 decibel units dB(A), with maximum peaks of 86 dB(A) (Topf, 1992). Recent emphasis on noise reduction and recording noise levels at work, particularly with the European Directive that came into effect at the end of 2005 recommending the requirement of ear protection for employees at levels in excess of 87 dB(A) and various actions with levels in excess of 80 dB(A) (Dawson, 2005). It remains alarming that noise levels in critical care units still frequently exceed these high levels of noise, often with night-time peaks greater than 80 dB(A) (Monsen and Edell-Gustafsson, 2005).

A number of causes appear to produce excess noise levels, which disrupt sleep. Gabor *et al.* (2003) from subjective data found that conversation and alarms were the most disruptive noises, whereas polysomnography data suggested that alarms and conversation were only responsible for 20–25% of arousals and awakenings. Virtually all haemodynamic monitors and ventilators cause noise alarms that act as a safety system to alert staff when patients' observations and respiratory function move outside safe alarm parameters. Sleep in critical care single rooms has been found to improve significantly with both total sleep time and nocturnal sleep time because of reductions in noise intensity, irritating noises and visual distractions (Gabor *et al*., 2003). Interestingly, the same study concluded that noise and patient care activities only contributed to less than 30% of sleep disruption, and that the majority of disruption to ventilated patients' sleep was unexplained.

Another important issue worth considering is that during a 24-h period, sleep and wakefulness are maintained by circadian rhythms. The most significant external cue for this rhythm is light and darkness, although other cues include meal times, core body temperature, sleep–wake rhythms and social interactions (Hood *et al.*, 2004). Studies have shown that when light is used to strengthen the circadian timing system, there has been increased quality in subsequent night-time sleep of aged patients (Campbell *et al.*, 1993; Shochat *et al.*, 2000; Wakamura and Tokura, 2001).

In the practice setting, lights are always present in critical care and although the dimming of lights overnight is encouraged, the degree to which this can be safely maintained is often dependent on the stability of the patients. Bright lights can be required to enable accurate assessment of patient observations, plus this is supplemented by further raising of light levels in order to carry out procedures and patient care activities such as line replacements, chest drain insertions and essential pressure area care. Further light increases can occur at night when patients are admitted or transferred out and events such as emergency procedures.

Interventions to improve sleep

A number of techniques have been tested to assist patients' sleep such as reducing unnecessary patient care interventions and clustering patient care activities (Redeker, 2000). Drugs are commonly used as an intervention to encourage sleep in critical care units; however, a recent review of drugs used with critically ill patients indicated that although a wide variety of drugs are available to treat sleep disorders, they may not improve sleep (Bourne and Mills, 2004). Hypnotic drugs may also be helpful to assist sleep although other less controversial methods such as music (Guzzetta, 1989) and massage (Richards *et al*., 2000) may assist patients to sleep. Redeker (2000) suggests reducing pain and anxiety can promote the relaxation response and therefore lead to improvements in sleep.

Approaches incorporating environmental controls to reduce the impact and incidence of sleep disturbance are limited to a small number of studies with small sample sizes. Haddock (1994) studied 18 patients of which 9 used earplugs within a surgical/gynaecology ward and found a significant improvement in the quality of sleep by patients. A later study by Wallace *et al.* (1999) involved a small pilot study using six healthy participants exposed to noise from audiotapes simulated by the intensive care unit, and found earplugs worn during the exposure to the noise resulted in more

REM sleep. The two studies testing earplugs on sleep found that, in general, earplugs were comfortable and easy to apply (Haddock, 1994; Wallace *et al.*, 1999). All six users in the Wallace study found them to be either 'somewhat comfortable' or 'very comfortable' and four of the six reported that the earplugs were 'very easy to use'. In the Haddock study, all nine patients testing the use of earplugs found them to be comfortable and had no problems inserting and removing them.

Another small study was carried out by Wallace *et al.* (1998), assessing patients' sleep using polysomnography with seven critically ill patients, where lights were dimmed and nursing interventions continued as needed. Results indicated improvements in REM sleep and sleep efficiency indices, but because of the small size, they recommended the need to conduct a larger study.

In practice, an increasing number of patients have been requesting to use earplugs to help them sleep based on their experiences of wearing them at home or while travelling. Both earplugs and eye masks are regularly offered to travellers on long-haul night-time flights to improve sleep in aeroplanes' light and noisy environment. No studies could be found combining the two methods to improve critical care patients sleep within or outside the critical care setting. Therefore, the research team undertook a pilot observational study to examine the impact of simple interventions, such as earplugs and eye masks, upon the sleep experiences of critical care patients.

AIMS

The overall aims of this Critical Care Sleep Intervention study were to:

- Identify factors that influence sleep in critical care.
- Evaluate the usefulness of two sleep interventions, namely eye masks and earplugs by critical care patients.

THE STUDY

Design/methodology

This pilot intervention study used a two group post-test quasi-experimental design to collect information on patients' reported experiences of their sleep to evaluate the impact of two sleep interventions, eye masks and earplugs.

Ethical considerations

Ethical approval was sought from the Central Office for Research Ethics Committee and obtained from the Local Research Ethics Committee. Consent was obtained from all participants by discussing the study with each participant and providing an information sheet detailing the study. Potential participants were shown the earplugs and eye masks to discern if they will be able to accept and tolerate the interventions. If participants could not subsequently tolerate the interventions, they continued in the study as this provided a non-intervention group that could be used as a non-intervention control group. Consent and information were discussed during daytime between 1600 and 1800 h by two of the research team, and data collected the next morning between 0800 and 1200 h, once the patient was sufficiently awake and able to make judgements of their sleep. Consent was either obtained within the Critical Care setting to include non-elective admissions or on the preadmission wards to include elective admissions. Patient anonymity and confidentiality was maintained at all times.

Sample/participants

As this was a pilot study, a convenience sample of 64 patients was selected to participate in the study. The population was obtained from high-dependency planned and emergency admissions to a cardiothoracic intensive care.

Inclusion criteria were set in line with previous research undertaken on sleep with critical care patients (Richardson *et al.*, in press) to ensure selected patients were lucid orientated participants familiar with a new environment and no longer experiencing the effects of an anaesthetic or intravenous sedation.

The need for patients to apply earplugs and eye masks and the likelihood that patients would need to remove them at times when awake throughout the night-time meant participants had to demonstrate they could apply and remove the interventions themselves. Finally, because of the complexity and critical nature of the illness in intensive care, only patients of a high dependency level were included.

The inclusion criteria were:

- More than 24 h following any intravenous sedation.
- Length of stay greater than 24 h.
- More than 24 h since a general anaesthetic.
- A judgement made by the nurse caring for the patient that the patient was sufficiently lucid to understand the nature of the study and indicate a decision as to whether or not they wish to participate.
- High dependency level of care.
- Patient able to apply and remove the interventions themselves.

All the patients fulfilled the inclusion criteria before entering the study. Table 1 displays the demographic information about study participants.

Table 1 Demographic data

Demographic variable	Number of participants (%)
Gender	Male – 44 (69)
	Female – 20 (31)
Age	18–64 years – 23 (36)
	65–84 years – 38 (59)
	85 years and over – 2 (3)
	Missing – 1 (2)
Nature of airway	Extubated – 47 (73)
	Tracheostomy – 16 (25)
	Missing – 1 (2)
Length of stay in the unit	1–3 days – 35 (55)
	4–8 days – 13 (20)
	9–13 days – 5 (8)
	14 days and over – 11 (17)
Patient location	Cubicle – 6 (9)
	Open bed area – 58 (91)

Data collection

Data were collected in 2005 based upon participant-aided completion of a questionnaire consisting of closed and open questions. The closed questions provided demographic data, including location in the unit, reason for and length of stay in the unit, pain management, blood pressure monitoring and night sedation as well as ratings of sleep experiences and comfort of the interventions. The open questions obtained participants' views on the factors aided and prevented sleep.

The critical care unit nurse allocated to care for the patient throughout the night was informed of the study so that patients could be aided with placement and comfort of the interventions. Two different sleep assessment tools were employed to assist patients to assess their sleep (Figure 1). These were previously tested non-invasive approaches for sleep assessment, which provide critical care patients with quick and easy tools to complete (Richardson *et al.*, in press). Despite the known effectiveness of polysomongraphy physiological assessment tools to measure sleep (Chuman, 1983; Tamburri *et al.*, 2004), because of expense and intrusiveness of use of invasive techniques these were not seen as feasible for application in this critical care study.

Easy to visualize large clocks were placed at each patients' bed area to assist the patients to judge their sleep. Enlarged versions of the sleep assessment tools were printed and laminated for verbal completion or so participants could point to the scales.

All participants were asked to identify factors that disturbed and promoted their sleep, while those that wore them were also asked to rate the comfort of both eye mask and earplugs using a rating scale (Figure 2).

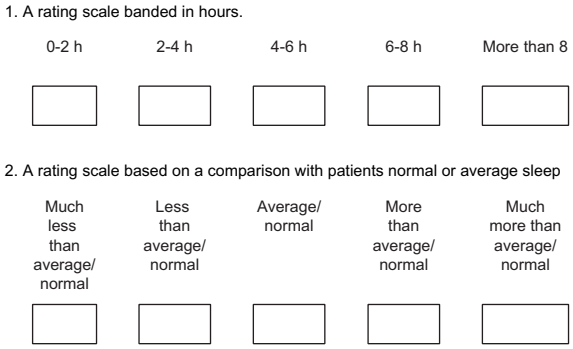

Figure 1 Sleep assessment tools.

Two members of the research team collected the demographic data and the critical care nurse who was caring for the patient collected the answers to the open-ended questions and patient-rating scales. The research nurses involved in the design of the project were not involved in the patient data collection to prevent any potential influencing of the patients' assessment.

A bid to obtain funding to support the purchase of earplugs and eye masks was submitted and successfully granted by a local charitable fund. Each set of earplugs and eye masks cost £2·50 (€ 3·7).

Data analysis

The collected quantitative data were, using SPSS version 12.0.2, subjected to descriptive statistical analysis, e.g. frequency counts and percentages. Evaluation of impact of the intervention, eye masks and earplugs, upon participants' sleep was made by use of the appropriate inferential statistical test, χ^2 analysis. The statistical significance of these data was set at 0·001. Unfortunately, sample size precluded valid testing of statistical significance.

Qualitative data were analysed using the content analysis method, whereby central words were identified and tabulated in a numeric way. Morse and Field (1996) stated that the numeric objectivity of content analysis increases the reliability of the procedure.

RESULTS

Sixty-four patients participated in the study, 34 patients in the intervention group and 28 patients in the non-intervention group. The population was

Figure 2 Comfort rating scale.

Table 2 Patients' reported sleep in hours

	0–2 h (%)	2–4 h (%)	4–6 h (%)	6–8 h (%)	More than 8 h (%)	Total
Intervention	8 (24)	11 (32)	9 (26)	4 (12)	2 (6)	34
Non-intervention	8 (29)	10 (36)	5 (18)	3 (11)	2 (7)	28

obtained from high-dependency planned and emergency admissions to a cardiothoracic intensive care.

Patients' reported sleep experiences

Thirty-four participants consented to use the interventions earplugs and eye masks, 28 participated in the study but did not use the interventions and there were two missing data sets.

Patients rated their sleep in two ways:

- Based on their perceived number of hours slept.
- As a comparison to how they normally slept.

Tables 2 and 3 display the sleep ratings in numbers and percentages. Overall, a majority of patients, 51 (82%) slept for 6 h or less and 44 (71%) patients slept less or much less than their average.

Study numbers prevented valid statistical analysis of the impact of the interventions upon reported sleep experiences. However, patients using the interventions earplugs and eye masks perceived they slept for longer hours in comparison with the non-intervention group. In the two low ranges of hours slept (0–2 h and 2–4 h), a greater percentage of patients were in the non-intervention group (65%) than the intervention group (56%). Similarly with reports on sleep in comparison with normal sleep, a higher percentage of patients in the intervention group (18%) rated their sleep in the two positive bands ('more than average' or 'much more than average') in comparison with the non-intervention group (7%).

Factors influencing sleep

Patients who did and did not use the interventions mentioned a variety of factors that helped and prevented them to sleep. The frequencies of citations are listed in Tables 4 and 5. The most common factor that helped the intervention group to sleep was eye mask and with the non-intervention group it was tiredness. The main factor in both groups preventing patients from sleeping was noise.

Comfort of the interventions

Twenty-nine patients rated the comfort of earplugs and 31 patients rated the comfort of the eye masks on a scale from very uncomfortable to very comfortable. The ratings uncovered a wide range of experiences (Table 6). Comments on the comfort of each intervention was recorded and the three key issues with earplugs were could still hear, would not stay in and sore ears. Again only three key issues were identified with the eye masks and these were, a feeling of hot and sweaty, too tight and claustrophobia.

DISCUSSION

Unsurprisingly, this study identified that most critical care patients rated their sleep 'less than' or 'much less than' average and '6 h or less'. These findings are supported by previous work highlighting patient sleep is commonly disturbed in acute care settings (Redeker, 2000).

When patients were asked what helped or prevented sleep in critical care, noise and light were highlighted as issues that kept them awake, and conversely reducing noise and light levels improved sleep. This is in keeping with the research suggesting that noise levels are too high at night and disrupt sleep (Topf, 1992; Topf and Davis, 1993; Wallace *et al*., 1999; Gabor *et al*., 2003). Specific noises were highlighted, such as staff talking, the telephone, monitor noise and alarms. Again these findings are supported by other research, which cites critical care unit alarms and staff conversation as the most disruptive sources of noise (Gabor *et al*., 2003). Ways to help patients sleep are therefore important.

A noteworthy finding was that there were more patients sleeping for shorter periods in the non-intervention group in comparison with the intervention group. The differences were small but the same theme was found with the open-ended questions, as most patients using eye masks rated them as a factor helping sleep. No previous research supports the use of eye masks, but links with previous research (Campbell

Table 3 Patients' reports of sleep in comparison with 'normal' sleep

	Much less than average (%)	Less than average (%)	Average (%)	More than average (%)	Much more than average (%)	Total
Intervention	12 (35)	13 (38)	3 (9)	4 (12)	2 (6)	34
Non-intervention	11 (39)	8 (29)	7 (25)	2 (7)	0 (0)	28

Table 4 What factors helped you go to sleep?

Key theme	Intervention group frequency	Non intervention group frequency	Example of theme
Eye mask	8		'Eye mask helped me not look at the monitors'
Tiredness	6	4	'Feeling tired'
Earplugs	5		
Lack of noise	4	1	'lack of noise' 'quiet in cubicle'
Sleeping tablet	4	3	
No sleep night before	1		
Lack of light	1		'lack of light'
Analgesia	1		

et al., 1993; Shochat *et al*., 2000; Wakamura and Tokura, 2001) suggests that finding ways to dim lighting at appropriate times could be used to strengthen circadian rhythms and improve quality of sleep.

Whether or not patients used the earplugs as a way of minimizing noise, noise remained the highest reported factor preventing sleep. Of the 34 in the intervention group, 20 found noise to be a factor preventing sleep. It may be that earplugs do not adequately block out the high noise levels recorded in critical care settings (Monsen and Edell-Gustafsson, 2005), or it could have been because of raised consciousness of earplugs being used to reduce noise, which resulted in heightened patient awareness of environmental noise. The small numbers of patients reporting that earplugs did help sleep, is aligned with previous small scale research suggesting a reduction of noise using eye plugs improves sleep within critical care (Haddock, 1994; Wallace *et al*., 1999). It is difficult to separate the impact of the two variables used in this study because of the small sample size, but it may be that the interventions work both ways. Patients reporting disturbed quantity and quality of sleep could be disturbed more by the interventions or they may have had no effect.

Table 5 What factors prevented you from sleeping?

Key theme	Intervention group frequency	Non Intervention group frequency	Example of theme
Noise	20	7	'Too much going on at night', 'Noise of staff on unit', 'staff talking' 'telephone and nurses', 'alarms' 'monitor noise'
Too hot/sweaty/ clammy	5	1	'Too hot'
General discomfort	4	2	'general discomfort' 'Kept sliding down the bed' 'being turned'
Pain	2	3	'pain from surgery'
Bed pan	2		
Light	2	1	
Nurse taking blood	1	1	
Previous sleep problem	1	1	
Anxiety	1	3	
Breathing difficulties		3	'CPAP machine', 'coughing'
General environment		1	'strange environment'

Other factors in critical care found to prevent sleep included staff practices, which could be changed to improve patients' sleep experiences. For example, patients reported 'a nurse taking blood' had prevented sleep. As arterial/venous blood sample could be obtained by collecting blood from a port away from the patient, this may reduce disturbance to patients when sleeping. Another factor identified was excessively high temperatures, probably because of data collection taking place during late June and July and problems with the efficiency of the air conditioning. Ensuring critical care units are air conditioned to appropriate temperatures could address this contributing factor.

Interestingly, patients who used the interventions named more factors that both prevented and helped them sleep. Again this could have been because of the fact that patients using the interventions were more aware of the environment as a whole, as well as sleep needs. Overall, patients were able to specify more factors that prevented them from sleeping rather than those that promoted sleep. This possibly reflects the nature of critical care, with more factors disturbing sleep rather than aiding sleep. In addition, neither earplugs nor eye masks were mentioned as factors preventing sleep.

Previous research has found predominately positive comments in relation to the comfort and use of earplugs (Haddock, 1994). This was not the case in this study. Patients' experiences were very mixed, the rating of earplugs ranged from 'very comfortable' to 'very uncomfortable'. This mixed experience was the same for the comfort and use of eye masks. It was noted that many patients requested cooling fans because of high temperatures during the period of the study, as

Table 6 Comfort of earplugs and eye masks

	Very uncomfortable	Uncomfortable	Satisfactory	Comfortable	Very comfortable
Earplugs	8	4	5	9	3
Eye masks	8	8	4	9	2

the air-conditioning system was not functioning to an appropriate level of comfort. Furthermore, the eye masks were made of nylon and in combination with the high environmental temperature appeared to cause tolerance difficulties. A small problem with earplugs was that they 'wouldn't stay in' and 'kept falling out' or ears were 'too sore'. The actual design of eye masks and earplugs may be an important consideration, to promote comfort and tolerance of these interventions.

The cost of funding a new intervention to improve the quality of care is a very important consideration in the NHS today. Nonetheless, knowing that sleep disturbance is one of the most stressful components of patients' critical care experience (Novaes *et al.*, 1997), the cost of £2·50 is a very small investment if it improves patients' sleep experiences.

Finally, within a critical care unit, both noise levels are excessive (Topf, 1992; Monsen and Edell-Gustafsson, 2005) and some light, albeit at a reduced level, is necessary to support patient observations. Therefore, interventions to minimize noise and reduce light levels to improve the patients' experience of sleep should be considered by all critical care staff. This pilot study has indicated that earplugs and eye masks can help some patients' sleep in a noisy and light critical care environment; however, not all find them easy to use or comfortable to wear. An important function for the critical care nurse is to consider all patients for this intervention as long as inclusion criteria are met. Then the nurse's role should involve discussing these interventions with the patient, including an opportunity for patients to try them for comfort, and then provide to those consenting to their use.

Limitations of the study

Polysomnography was not used in this study because of the cost and training time involved and the invasive nature of its application. Objective polysomnography data may have complimented the patients' reports of their sleep experiences. However, as the aims of the research were to capture patients' views on factors that influence sleep and the usefulness of two sleep interventions, assessment rating scales and open-ended questions were considered to be valid data collection methods.

An important consideration for maximizing reliability and validity in research is sample selection (Morse and Field, 1996). A convenience sample was selected using inclusion criteria intended to obtain the most appropriate sample to enable data to be meaningful and relevant. Unfortunately, the sample size was not large enough (n = 64) to enable inferential statistical analysis to be carried out. Originally the aim had been to achieve a sample of 100, unfortunately the length of time required to obtain suitable patients who fulfilled all the inclusion criteria exceeded the time available for conducting the study. Consequently, only 64 patients fulfilled the criteria, limiting the study's internal validity, as it was not possible to assess significance of the results.

In addition, external validity of the sample may have been compromised, as it may have been only patients who believed they had sleeping problems who opted to use the interventions. Other factors affecting the group patients went into included, their prior use of the interventions, previous experience of their effectiveness and comfort during consenting. Further studies may wish to consider a more robust method for allocating patients into either an intervention or a non-intervention group, such as a Randomised Control Trial to enhance both internal and external validity.

To limit interview bias, the critical care unit nurses caring for the patients asked the patients to assess their sleep using the rating scales and also obtained answers to the open questions. None of the research team took part in this process. The qualitative data may have been limited, as the bedside nurse (the interviewer) was typically inexperienced in recording research data and may not have gained the richest data when asking patients the open questions. Patients may have been subject to inconsistent interview techniques, which might limit the reliability of data collected, particularly from the open-ended questions.

When patients were asked to rate sleep in terms of 'much less than average', 'average' and so on, no reference was made to whether this referred to average at home or in hospital. If the question had been more specific, and referred to in hospital or in fact in critical care, the results could have been more relevant to the critical care environment.

Patients in this study were within a cardiothoracic critical care unit, therefore the findings may not be generalizable to level 3 and/or general critical care patients.

Finally, some patients will be predisposed to sleep disturbances because of chronic illness (Bourne and Mills, 2004) and recording this level of past medical history was not included in the patient demographics. So this information may have been helpful when analysing the data.

CONCLUSIONS

The study aims were answered, as factors that influenced sleep were identified and the usefulness of the interventions evaluated. Lack of inferential statistical analysis prevented producing results of statistical significance on the likelihood that the interventions enhanced sleep. However, the descriptive data did suggest that some patients' sleep was improved using the interventions, so should be considered as a matter of routine with critical care patients, specifically with those fulfilling the inclusion criteria. In offering these interventions to patients, nurses should take the time to show patients how to use them and patients encouraged to try them.

Many patients' experience of night-time sleep in critical care is considered to be less than their average sleep and a number of factors disturb this sleep. Noise is a big contributing factor and interventions such as earplugs and eye masks appear to improve sleep for some patients. Other factors that prevented and helped sleep could be reinforced and adopted into clinical practice, e.g. other ways of reducing noise, minimizing interventions and care and ensuring the environmental temperature is comfortable.

Recommendations for future research would be to conduct an RCT and include a larger population size to enable inferential statistical analysis to be performed. The design of the interventions could be modified whereby the eye masks are made of cotton, and earplugs easier to insert, so increasing patients' tolerance of the interventions. Further research could study night sedation, patient location and the sleep interventions, as subgroups to determine if this improved sleep quality and quantity. In addition, examining both earplugs and eye masks separately could identify benefits or limitations when used alone and other methods could be used to evaluate sleep, using polysomnography, or asking more specific questions to obtain greater detail about patients' sleep behaviour.

WHAT IS KNOWN ABOUT THIS TOPIC

- Sleep disturbance is common for patients within critical care units.
- Excess noise and abnormal light/dark patterns disrupt patients sleep.
- Earplugs to reduce excess noise at night helps patients sleep within the ward environment.

WHAT THE PAPER ADDS

- Some patients in critical care using earplugs and eye masks report longer periods of sleep than those without.
- Patients' experiences of wearing of earplugs and eye masks varied greatly from very comfortable to very uncomfortable.
- Provides evidence on alternative cheap (£2·50) interventions to assist some patient's sleep.

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7.4.3 Paper 3

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CLINICAL ISSUES

Journal of Clinical Nursing

Development and implementation of a noise reduction intervention programme: a pre- and postaudit of three hospital wards

Annette Richardson, Abigail Thompson, Elaine Coghill, Iain Chambers and Chris Turnock

Aims. By developing, implementing and delivering a noise reduction intervention programme, we aimed to attempt to reduce the high noise levels on inpatient wards.

Background. Sleep is essential for human survival and sleep deprivation is detrimental to health and well being. Exposure to noise has been found to disrupt sleep in hospitalised patients which is to be expected as noise levels have been measured and reported as high.

Design. A primarily nursing focused, multi-method approach, involving development of clinical guidelines, ward environment review and a staff noise awareness and education programme, was used to target mainly nursing staff plus other healthcare staff on three wards within one hospital.

Methods. This practice development initiative was carried out in three key phases (1) Preaudit of ward noise levels, (2) The development, implementation and delivery of a noise reduction intervention programme, (3) Postaudit of ward noise levels.

Results. Preintervention average peak decibel levels over 24 hours were found to be 96·48 dB(A) and postintervention average peak decibel levels were measured at 77·52 dB(A), representing an overall significant reduction in noise levels ($p < 0{\cdot}001$).

Conclusions. This study describes one way to reduce peak noise levels on inpatient hospital wards.

Relevance to clinical practice. Sleep deprivation is detrimental to patients with acute illness, so any developments to improve patients' sleep are important. Nurses have a key role in leading, developing and implementing changes to reduce peak noise levels on inpatient wards in hospitals. This nurse-led practice development programme has demonstrated how improvements can be achieved by significantly reducing peak noise levels using simple multi-method change strategies.

Key words: noise, nurses, nursing, sleep

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Background

Sleep is an essential function to the human body and is a basic physiological need for all humans' survival (Honkus 2003). Therefore, it is not surprising to find that sleep deprivation is detrimental to health and well being (Synder-Halpern 1985, Culpepper-Richards 1988). The effects of sleep deprivation have far reaching physical, behavioural and psychological consequences for patients. It is acknowledged that sleep deprivation is detrimental to patients with acute illness (Aurell & Elmqvist 1985, Wilson 1987, Soehren 1995, Perez de Ciriza *et al.* 1996) and sleep disturbance may have long-term detrimental effects on health outcomes and patient morbidity (Tamburri *et al.* 2004). A study found behavioural changes

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occurring within 48 hours of sleep deprivation, people became irritable, restless, tired and disorientated (Dines-Kalinowski 2002). Ongoing sleep deprivation can lead to psychotic behaviour (Hobson 1995), confused reactions (Dogan *et al.* 2005) and decreased pain tolerance (Weitzman *et al.* 1974). Honkus (2003) states sleep deprivation negatively affects the immune system, leading to decreased ability to resist and fight infection, thus adversely affecting patient recovery.

Studies have examined the causes of sleep disturbance, with many of these studies within the critical care environment showing patient sleep is disrupted when exposed to noise (Topf *et al.* 1996, Wallace *et al.* 1999, Freedman *et al.* 2001, Christensen 2007). However, patients also frequently report excess noise as one of the most disturbing factors in other ward areas in hospital (Southwell & Wistow 1995, Aaron *et al.* 1996, Lee *et al.* 2007). Noise can be described as a disturbing sound (Treffry 2004). This is not a new problem in the hospital setting; Nightingale, in 1859, recognised the detrimental effect of noise for patients; highlighting it as a factor negatively affecting patient sleep in the hospital setting. A study into noise exposure found patients experienced poorer sleep, taking longer to fall asleep, spend less time sleeping and had more awakenings (Topf *et al.* 1996). It was, therefore, expected that patients had a greater tendency to sleep when noise levels were decreased (Olson *et al.* 2001).

Noise is measured in decibel (dB) with 'A-weighting' (dB(A)) as the standardised value enabling comparisons to be made to human hearing [Health and Safety Executive (HSE) 2006]. Humans can hear from 0 dB to a pain threshold of 120 dB(A). Table 1 shows examples of decibel levels of daily situations (Health and Safety Executive 2006). It has been suggested that noise can be classified as continuous or impulsive (Sommargren 1995), continuous noise at a constant pitch and intensity over an extended period and impulsive noise as brief and intense on a sporadic or regular basis.

Causes of noise disturbance

Many causes of noise have been reported throughout the hospital environment. Alarms (Gabor *et al.* 2003), equipment and monitors (Green 1996) are some of the causes of excessive high noise levels reported in intensive care areas. Sommargren (1995) reviewed 20 common sources of noise in the patient care environment and Table 2 shows the seven activities with the highest sound levels, all exceeding 80 dB(A).

Other sources of noise such as nurses attending to other patients, other patients making a noise, emergencies on the ward, nurses' shoes and telephones ringing were reported by patients from multispecialty acute care wards (Southwell & Wistow 1995). In addition, some variations in noise levels have been uncovered linking higher levels of noise in areas with more patients (Southwell & Wistow 1995). Design characteristics of hospitals such as absorbance of tiles and room size and geometrics, can influence noise levels (MacKenzie & Galbrun 2007).

Noise regulations

Controlling the risk to those affected by noise is a statutory requirement under Health and Safety Law. The Control of Noise at Work Regulations 2005 (Crown 2005) places a general duty on employers to prevent or reduce risks to health and safety from exposure to noise at work. They require risk assessment to be undertaken in the work place and action to be taken if employees are exposed to peak levels higher than 80 dB(A), including the identification and control of hazards. No NHS patient focussed standards are set. However, guidance for noise levels in the hospital setting is provided by the United States Environment Protection Agency (1974), which recommended levels of 45 dB(A) for day time noise and 35 dB(A) for night time noise. The World Health Organisation (WHO) have recommended that noise levels should not exceed 35 dB(A) in rooms where patients are treated or observed (Berglund *et al.* 1999).

Measurements of noise levels in hospital settings

Many studies have investigated noise levels in critical care settings. An early study by McLaughlin *et al.* (1996) on a

Table 1 Examples of noise levels

Sound	Decibel level (dB(A))
Jumbo jet taking off 100 m away	140
Jackhammer	120
Nearby car horn/Chainsaw	100
Heavy traffic	80
Conversation	60
Office	40
Library	20

Table 2 Noise sources in the patient care environment

Activity	Decibel level (dB(A))
Dropping a stainless steel bowl	108
Raising/lowering bed rail	90
Conversations (staff, patients, family)	59–90
Pneumatic tube carrier thud	88
Opening a packet of rubber gloves	86
Scraping of chairs and stools across floor	46–86
Dropping refuse into rubbish bin	53–82

Cardiac Surgical Intensive Care Unit found the maximum recorded sound level was 100·9 dB(A), continuous background noise was 57·5 dB(A) at its lowest, with peaks averaging 77·3 dB(A). Further studies have found night time noise to be over 50 dB(A) (Petterson 2000) with peaks up to 80–86 dB(A) (Aaron *et al.* 1996, Topf *et al.* 1996). Day time levels have been measured at over 59 dB(A) (Petterson 2000) with peaks of 70–80 dB(A) (Aaron *et al.* 1996, Gabor *et al.* 2003). A recent study measuring noise levels on three critical care units found the equivalent noise levels between 55–60 dB(A) for a 24-hour period and varied between 56–59 dB(A) for daytime and 51–54 dB(A) for night time (MacKenzie & Galbrun 2007). Despite the many critical care investigations only one study has been conducted in a ward setting (Christensen 2005a). Noise levels were measured on a 28 bedded, general surgical ward in a UK hospital with a mean noise level of 42·28 dB(A) and acute spikes of 70 dB(A).

Strategies to reduce noise levels

Although noise pollution has been recognised for years, efforts to correct it are minimal. This might be due to a nursing knowledge deficit concerning both current legislation on noise control and the impact of noise exposure on those in the hospital environment (Christensen 2005b).

The majority of studies into noise reduction strategies to improve sleep have been based in critical care. Olson *et al.* (2001) found that in their comparison of pre/posttest noise measurements in a 10 bedded neurocritical care unit that patients were more likely to sleep when light and sound levels were decreased. This led to the introduction of a two hour quiet time policy for periods during the day and night. Lower *et al.* (2003), after measuring noise levels in a critical care unit, also introduced a two hour quiet time and reduced unit noise. They found that patient satisfaction scores increased and staff benefited from the quiet time. Similarly in a Swedish neurointensive care unit, a behaviour modification programme was tested involving the implementation of day and night non-disturbance periods. Nurses changed and co-ordinated care routines to reduce key activities such as suctioning, neurological observations and administering drugs, during the non-disturbance periods. This study minimised some activities that cause sleep disturbance and noise levels were reduced (Monsen & Edell-Gustafsson 2005).

A quality improvement approach to reduce noise levels was taken by Petterson (2000), where noise levels in a medical critical care unit were measured. They exchanged metal bins for plastic, divided the main nurses' station into four mini ones and merged three separate telephone lines into one main one. Their follow-up evaluation found reduced decibel levels and staff felt there was reduced noise on the unit. Elander and Hellstrom (1995) devised a nursing intervention program and undertook pre/postnoise measurements on a paediatric intensive care unit. They demonstrated that through simple low-cost methods involving nurse education, training and awareness raising sessions significantly reduced noise levels. All nurses undertook a one-hour intervention program that involved watching a video of a child's postoperative phase, a presentation on decibel values for care activities and participated in a discussion about the session. They found significant reduction in noise levels after the intervention program.

Further ways to reduce noise to improve patient sleep have been suggested but not tested. Scott (2004) emphasised the need for nurses to be more proactive in sleep promotion by highlighting the fact that sleep deprivation for patients could ultimately lead to longer hospital stays. Christensen (2005b) suggests provision of education to promote sleep awareness by providing staff information on the decibel levels of care activities. Most attention has been given to reducing the specific causes of high noise levels such as reducing equipment noise (Southwell & Wistow 1995, MacKenzie & Galbrun 2007), sound proofing patient areas (Southwell & Wistow 1995) and reducing the telephone ringing volume (Southwell & Wistow 1995, MacKenzie & Galbrun 2007). Other recommended methods include damping of bin lids (Petterson 2000, MacKenzie & Galbrun 2007), eliminating chair scraping by applying material to the bottom of chair legs and the use of lever arch files rather than ring binders (MacKenzie & Galbrun 2007), having quiet closing/oil free doors which are kept closed (Lower *et al.* 2003, MacKenzie & Galbrun 2007), minimising staff conversations (Kahn *et al.* 1998, Reid 2001, MacKenzie & Galbrun 2007) and an approach used by the prison service (BBC 2007) involves staff wearing soft-soled shoes at night (Reid 2001).

No studies examining ward based inpatient noise reduction strategies could be found. However, the emphasis on reducing the patients perception of noise disturbances, with the use of earplugs, within the ward setting (Haddock 1994) and the critical care environment (Richardson *et al.* 2007) have found this intervention can be an effective practical method to promote patient sleep.

Despite clear guidance on acceptable levels of noise within patient care areas the measurement of noise on wards is limited to one surgical ward (Christensen 2005a). This suggested a need to measure noise levels on other types of wards. Evidence exists showing improvements can be made to reduce noise in critical care areas; however, no ward based studies have been reported that assess the impact of a noise reduction programme in ward areas. Therefore, a noise

reduction educational programme was designed for ward staff with the aim of reducing ward noise levels.

Design

In a large, UK Teaching NHS Hospitals Foundation Trust a noise reduction intervention programme was designed as a nursing practice development initiative to reduce noise levels on three different inpatient wards. The practice development initiative was carried out in three key phases.

Phase 1. Preaudit of ward noise levels

Noise levels were measured using a Norsonic NOR-116 sound meter that was calibrated before each measurement period to ensure collection of reliable data. Data were transferred to a laptop computer for data storage. Measurements were made according to the manufacturer's specification. The sound meter was situated in the corner of a six-bedded bay, 1 m from the ground and 1 m from the wall, standing on its own tripod and plugged into the mains electricity supply. Noise levels were measured continuously over 24 hours.

The key levels measured were:

1 The equivalent continuous A-weighted sound pressure level defined as the constant value having the same amount of acoustic energy as a given noise event (Aleq).
2 The peak sound pressure defined as the maximum absolute value of instantaneous sound pressure (Apeak).

Three different speciality wards were chosen to assess variations in noise levels on wards with different activities associated with elective and non-elective patients.

Ward selection and description

Ward 1: Acute surgical inpatient ward – 30 beds (six single cubicles, four bays of six beds) specialising in vascular surgery. Total number of ward staff 29 (qualified nurses and support staff).

Ward 2: Acute medical inpatient ward – 30 beds (six single cubicles, four bays of six beds) specialising in gastrointestinal/liver medicine. Total number of ward staff 31 (qualified nurses and support staff).

Ward 3: Acute orthopaedic inpatient ward – 32 beds (eight single cubicles, four bays of six beds) specialising in orthopaedics. Total number of ward staff 30 (qualified nurses and support staff).

Noise levels were measured in February/March 2007. Ward staff were informed of the noise measurements in advance and during the measurements. The standards used to assess the noise levels against were:

- World Health Organisation (WHO) – noise pressure levels should not exceed 35 dB(A)
- The Control of Noise at Work Regulations 2005 (Crown 2005) requiring a risk assessment to be performed and action taken if employees are exposed to peak levels higher than 80 dB(A).

Phase 2: The development, implementation and delivery of a noise reduction intervention programme

First stage: Development of a sleep promotion clinical guideline

After the pre-audit of ward noise levels, a working group was set up involving ward sisters, staff nurses and modern matrons from different specialist areas, led by a nurse consultant. A guideline was developed and written based on best available research and best practice shared amongst the group. The guideline was agreed in May 2007 by the Trust Senior Nurse Management Team. This was a trust wide guideline for sleep promotion for ward-based patients.

Second stage: Review of ward environment

Key parts of the ward's environment were reviewed against the agreed clinical guideline. This included the door entry system, telephone positions, quantity and ringing volume, patientline system, nurse call system and the physical make up of the ward.

The review showed all three wards had hard lino flooring and external windows that could open. Each ward had blinds or curtains attached to all windows. Patient equipment in use included non-invasive blood pressure and heart rate monitoring, oxygen saturation measuring machines, syringe drivers and infusion pumps, all of which had acoustic alarms. Each bed space had piped oxygen and suction available. A patientline set was at each bed providing television, radio, internet and telephone. It automatically turned on at approximately 07·30. Entry/exit to one ward (Ward 2) was staff controlled by audible buzzer. Staff telephones were at a central nurse's station, with some telephones having volume adjust controls and all doctors' hospital mobile dect phones could be switched to vibrate.

One ward had been recently refurbished (Ward 1) and had a light panel for the nurse call system (as well as audible alarm). All the nurse call noises were projected at the nurse's station and although there was a panel to adjust noise levels (including a night mode option) it was rarely used on any of the three wards. The nurse call system had two different sounds, one for attention and the other for emergency. No rubbish bins or drawers were quiet closing although all doors were quiet closing. All wards had an afternoon quiet time/

restricted visiting time. Two of the wards (2 and 3) kept eye masks and earplugs for patient use, which were offered to patients by nurses or could be requested by patients.

Third Stage: Development and delivery of a staff noise awareness and education programme

A staff noise awareness and education programme to reduce noise and promote sleep was designed and agreed by the project lead (nurse consultant), a university lecturer and a staff nurse. No member of the team was directly involved in the care of patients on the target wards. The staff nurse was seconded for one day per week to deliver the staff intervention programme and was the only person delivering it to maintain consistency of the programme's content.

The staff nurse wore a uniform (the same as the ward staff nurses) and wore a trust-issued identification badge. Equal numbers of visits were made to the wards over a five-week period, at different times during the day and on different days on the week. Each ward was visited on seven separate occasions with visits lasting from 15 minutes–one hour. It had been planned to use one on one sessions and group sessions; however, all staff received a one on one session from the staff nurse. A five-minute training session was delivered on:

- current noise levels (from preaudit data), causes of high noise levels, a summary of noise level regulations
- impact of high noise on patients
- ways to reduce ward noise using examples such as telephones turned down at night or switched to vibrate and carried by a member of staff, thus reducing ringing volume, wearing soft soled shoes, alteration of nature of nurse call alarm at night
- encouraging use of earplugs and eyemasks by patients at night.

Staff were conveniently selected from the three participating wards, this was undertaken by asking any of the staff on duty at the time of ward visits if they were able to free up time to attend the training and those who could make themselves available participated. Staff were given the opportunity to ask questions and a PowerPoint handout was distributed reiterating the key points covered by the training. A total of 90 nursing and support workers worked permanently on these wards, including sisters/charge nurses, staff nurses and health care assistants. In addition, other staff groups involved in the many activities on the ward included porters, physiotherapists, occupational therapists, dieticians and different levels of medical staff. As many ward nursing staff as possible were targeted as well as medical staff and members of the multidisciplinary team who had regular contact with patients on the ward. Initially the charge nurse/sisters on the ward were approached before the involvement of all staff. Table 3 shows numbers of staff receiving the staff intervention programme on each of the wards.

Table 3 Number of ward staff and members of the multidisciplinary team the intervention programme

Ward	Number of ward staff on each ward	Number of ward staff (%) Received the Intervention Programme	MDT Received the Intervention programme
1	29	15 (51·7)	Physiotherapist F1 Doctor (x2)
2	31	16 (51 6)	F1 Doctor student Nurse
3	30	15 (50)	None

Fourth Stage: Staff follow up after awareness raising and education

Not all staff on the participating three wards had their own trust email address but those that did were sent an email at the end of the five-week education programme. They were emailed with strategies for noise reduction. Staff not receiving the education programme, but who had a trust email account received the PowerPoint handout electronically and noise reduction strategies. The quantity of email sent to staff varied by ward (see Table 4). Some emails sent back with a refused delivery notice and some email accounts were not accessed. Although an alert was set to be received when the email was opened, this did not mean the email was read nor did not receiving an alert mean the email was not read, users may have declined to send the message read reply and/or read the email in preview mode.

Fifth Stage: Display of sleep promotion posters

On the last day of stage four 'the staff awareness and education programme', a poster was displayed on each ward in a prominent position at the nurse's station. This was an A4 sized, colour, laminated poster displaying pictures and text. It tabulated current noise levels and their equivalents, a bullet point section of noise level regulations, the impact on patients and a summary of the sleep promotion guidelines. The poster was displayed for three weeks at the end of the staff training sessions before the postnoise level audits were undertaken.

Phase 3. Postaudit of ward noise levels

Three weeks following the development, implementation and delivery of a noise reduction intervention programme noise levels were measured on the same three inpatient wards using the same methods as in Phase 1 of the audit.

Table 4 Emails sent to staff postintervention programme

Ward	Number of staff received Intervention Programme	Staff receiving the intervention programme		Staff not receiving the intervention programme	
		Number (%) emailed	Number (%) opened email	Number (%) emailed	Number (%) opened email
1	15	5 (33 3%)	2 (40%)	0	N/A
2	16	7 (43 75%)	1 (14·3%)	5 (33·3%)	1 (20%)
3	15	12 (80%)	6 (50%)	2 (13·3%)	0

Table 5 Aleq results

Ward	Preintervention Aleq (*M*)	Preintervention Aleq SD	Postintervention Aleq (*M*)	Postintervention Aleq (SD)	Significance
1	50·60	2·86	49·93	8·84	0·64
2	44·24	5·36	48·58	7·61	< 0·01
3	45·76	6·25	50·57	7·49	< 0·01
All wards	46·87	5·67	49·69	7·93	< 0·01

Table 6 Apeak results

Ward	Preintervention Apeak (*M*)	Preintervention Apeak (SD)	Postintervention Apeak (*M*)	Postintervention Apeak (SD)	Significance
1	95·13	14·82	77·65	10·56	< 0·01
2	97·04	10·95	77·70	10·95	< 0·01
3	97·27	8·19	77·23	7·63	< 0·01
All wards	96·48	11·51	7752	8·75	< 0·01

The pre and postnoise levels data were compared. The sound measurements were subjected to descriptive (mean noise levels) and inferential (paired sample *t*-test) statistical analysis. To evaluate the significance of any difference in preintervention and postintervention noise measurements, significance was set at $p < 0{\cdot}05$.

Pre/postnoise levels

The results are presented in two tables. Table 5 contains the mean ± SD of all the 24 individual hourly Aleq preintervention and postintervention readings for each participating ward, plus overall mean and standard deviation for the data from all three wards. The table indicates that the slight decrease in postintervention Aleq findings for Ward 1 was not significant, but that the increases in postintervention Aleq means for Ward 2, 3 and the collated ward data were significant.

Table 6 contains the mean ± SD of all the 24 individual hourly Apeak preintervention and postintervention readings for each participating ward, as well as the findings for the collated ward data. The table indicates that the decreases in postintervention Apeak findings in each of the three participating wards and collated ward data were significant.

Discussion

Patients have reported noise as one of the most disturbing factors affecting sleep. This could be due to higher than recommended noise levels found in this audit and previous studies. Christensen (2005a) found a mean sound pressure level of 42·28 dB(A), similarly this audit's pre and postintervention average noise levels were pre 46·87 dB(A) and post 49·67 dB(A), both in excess of the WHO recommendation of 35 dB(A) in patient rooms (Berglund *et al.* 1999). The maximum values for average peak noise across three wards was 96·48 dB(A) pre and postintervention 77·52 dB(A), both high but postintervention noise was reduced to comply with the recommended lower exposure action value of 80 dB(A) (Crown 2005).

The main significant finding was the reduction in average peak noise levels on all three wards ($p = < 0{\cdot}001$). The reduction in average peak noise levels is important as Christensen (2007) explained how patients who are continually exposed to low-level white noise could become accustomed to the noise but they can be more aware of the high pitched, irregular sounds. Therefore, if the high levels (peak) are the most disturbing to patients, action to reduce this must be beneficial. The improvements found

following this noise reduction intervention programme are highly likely to be attributed to the development and implementation of a multi-method intervention approach to change practice.

Although a significant reduction in peak noise levels was achieved on all three wards, no significant reduction in average noise levels were found in this audit. Ward 1 noise levels were unchanged and Wards 2 and 3 had an increase in average noise levels. It is difficult to explain the increase in average noise but one suggestion is that general background noise in acute hospital wards is inevitable and it is hard to achieve a reduction with this type of noise, when so many of the patient care activities produce some levels of noise. Another reason could have been due to staffs' concentration of efforts and activities to reducing the peak high noise levels, with the other activities associated with background or lower noise levels being unchanged.

Whilst this development examined noise levels on three different specialist wards, there were no marked differences in the average noise levels and the average peak noise levels between the three wards. These similarities occurred despite differences in causes of noise identified in a review of the ward environment (Phase 2 second stage). For example, Ward 2 was a locked ward, resulting in visitors, staff and patients having to use the audible buzzer to gain entry. However, this may have been offset by other practices as Ward 2 routinely turned down telephones during the night to reduce ringer volume. Other ward differences included a recent refurbishment programme on Ward 1 with the use of a new nurse call system that had a visual panel at the nurse's station as well as an audible alarm, to enable the alarm volume to be easily turned down. Ward 3 reported that they occasionally turned down the nurse call system, although it was not known if these practices were undertaken during the noise measurements in Phase 3.

It is highly likely that the multi-method noise reduction intervention programme was successful due to the selection of several key stages to change practice. The first stage involved development of evidence based clinical guidelines, acknowledged as a strategy to assist clinicians to make better decisions about appropriate health care in specific circumstances (Jackson & Feder 1998). Adherence to guidelines by staff is often low (Ockene & Zapka 2000) but increased adherence and successful implementation can be improved when guidelines are introduced in response to a specific problem identified by practitioners (Cheater & Closs 1997). Once the preaudit data identified the problem, the establishment of a ward based nursing group to develop the guidelines would have been an effective way of assisting in the adherence to the guideline in practice.

Another key stage was the development and delivery of a staff noise awareness and education programme. Improving awareness of guidelines amongst those on whom the innovation will have an impact is important (Duff *et al.* 1996, Ockene & Zapka 2000, Johnson 2003). Initially the ward charge nurses or sisters approached were very supportive of the need for change. This leadership commitment is likely to have had an increase in the success of the guideline's implementation (Duff *et al.* 1996, Ockene & Zapka 2000). Cheater and Closs (1997) emphasise dissemination of guidelines alone is not enough to ensure change of practice, however it is prerequisite to their implementation. For successful implementation, they argue active educational intervention is the most effective method of communicating guidelines. Due to staffing levels and to ensure nurses stayed within the patient environment, one to one sessions were delivered to ward staff at convenient times.

When limited time is available for staff education, the education needs require a creative approach tailored to the setting (Ockene & Zapka 2000). To deliver important messages to ward staff, the staff nurse delivering the programme often discussed noise reduction practices whilst ward staff were undertaking nursing care activities, often helping with these activities, for example, making beds and emptying laundry bags. Despite only 50% of key ward staff gaining access to the training programme, changes in noise levels were achieved. This could be due to further cascading or spreading of information between staff which influenced and changed practice on an ongoing basis.

The final two stages involved email distribution of follow-up information to ward staff with email accounts and displaying sleep promotion posters. The use of email as a communication method has limitations as it relies on staff having trust accounts and for them to actually read the message in the email, as this could not be guaranteed posters were displayed in prominent positions on the wards. These methods were chosen as a way to promote implementation of clinical practice guidelines (Ockene & Zapka 2000), especially as it is acknowledged that educational interventions (including training sessions) can have only a short term effect (Grol & Grimshaw 2003). Others have advocated the use of reminders for staff (Duff *et al.* 1996).

Limitations

Limitations of this practice development need to be acknowledged. Firstly, we only chose three hospital wards to measure noise levels on two separate 24-hour periods (pre and postintervention) so the generalisability of results is limited. No attempts were made to hide or withhold recording of

noise levels measurements with the ward staff. This may have led to a change in staff behaviour that influenced noise levels when recordings were made. Plus, it was not possible to deliver the staff intervention programme to all relevant staff due to ward workload and activities, as well as staffing and shift pattern differences.

Conclusion

By developing, implementing and delivering a noise reduction intervention programme, along with the measurement of pre and postintervention noise levels we were able to demonstrate a significant reduction in peak noise levels on three hospital wards.

This ability to reduce peak noise levels appears to be due to the success of the devised mulitmethod approach. This programme targeted both nursing staff as well as other health care ward staff. No one factor could be claimed to have had the most impact, so future studies could assess the crucial or most influential aspect to changing practice when attempting to reduce ward noise. Evidence already existed showing improvements can be made to reduce noise levels in critical care areas. This practice development demonstrated similar achievements to reduce noise levels in hospital ward areas are attainable. In conclusion, reducing peak noise levels as a way to promote better sleep for patients is important and relevant to all nurses working clinically in inpatient wards.

Relevance to clinical practice

Sleep deprivation is detrimental to patients with acute illness, so any developments to improve patients' sleep are important. Nurses have a key role in leading, developing and implementing changes to reduce peak noise levels on inpatient wards in hospitals. This nurse-led practice development programme has demonstrated how improvements can be achieved by significantly reducing peak noise levels using simple multimethod change strategies.

Contributions

Study design: AR, EC, data collection and analysis: AR, EC, AT, IC, CT and manuscript preparation: AR, AT.

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7.4.4 Paper 4

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'Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England

THE MATCHING MICHIGAN COLLABORATION & WRITING COMMITTEE

▶ Additional data are published online only. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjqs-2012-001325)

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ABSTRACT

Background Bloodstream infections from central venous catheters (CVC-BSIs) increase morbidity and costs in intensive care units (ICUs). Substantial reductions in CVC-BSI rates have been reported using a combination of technical and non-technical interventions.

Methods We conducted a 2-year, four-cluster, stepped non-randomised study of technical and non-technical (behavioural) interventions to prevent CVC-BSIs in adult and paediatric ICUs in England. Random-effects Poisson regression modelling was used to compare infection rates. A sample of ICUs participated in data verification.

Results Of 223 ICUs in England, 215 (196 adult, 19 paediatric) submitted data on 2479 of 2787 possible months and 147 (66%) provided complete data. The exposure rate was 438 887 (404 252 adult and 34 635 paediatric) CVC-patient days. Over 20 months, 1092 CVC-BSIs were reported. Of these, 884 (81%) were ICU acquired. For adult ICUs, the mean CVC-BSI rate decreased over 20 months from 3.7 in the first cluster to 1.48 CVC-BSIs/1000 CVC-patient days ($p<0.0001$) for all clusters combined, and for paediatric ICUs from 5.65 to 2.89 ($p=0.625$). The trend for infection rate reduction did not accelerate following interventions training. CVC utilisation rates remained stable. Pre-ICU infections declined in parallel with ICU-acquired infections. Criterion-referenced case note review showed high agreement between adjudicators (κ 0.706) but wide variation in blood culture sampling rates and CVC utilisation. Generic infection control practices varied widely.

Conclusions The marked reduction in CVC-BSI rates in English ICUs found in this study is likely part of a wider secular trend for a system-wide improvement in healthcare-associated infections. Opportunities exist for greater harmonisation of infection control practices. Future studies should investigate causal mechanisms and contextual factors influencing the impact of interventions directed at improving patient care.

INTRODUCTION

Blood stream infections (BSIs) from central venous catheters (CVCs) increase morbidity and are estimated to increase mortality risk by 25% and costs of care in the USA by US $16 550 on average per patient[1 2] (box 1). A substantial body of evidence suggests that rates of CVC-BSIs are modifiable.[3–13] The Michigan-Keystone project[13] in 103 intensive care units (ICUs) in the USA reported a major reduction in CVC-BSIs from 7.7 to 1.4 CVC-BSIs per 1000 CVC-patient days using a complex intervention targeting specific technical practices (box 2), combined with support for cultural, behavioural and systemic change.[14] A 3-year follow-up study reported sustained improvement[15] and accelerated the trend for a reduction in case mix-adjusted mortality rates.[16]

The NHS Next Stage Review in 2008[17] announced that the National Patient Safety Agency (NPSA) would run a 'national patient safety initiative to tackle central line catheter-related blood stream infections, drawing lessons from a remarkably successful Michigan initiative'. This 2-year programme, known as *Matching Michigan*, ran in England from April 2009 to the end of March 2011. It aimed to minimise CVC-BSI rates in adult and paediatric ICUs in England to at least the mean level (1.4 per 1000 CVC-patient days) seen in the Michigan-Keystone project. It involved three components: technical interventions, which sought to ensure consistent use of evidence-based measures for reducing risks

Box 1 Background

- Central venous catheters (CVCs) are widely used in patients in intensive care units (ICUs) and other hospital locations for monitoring, drug delivery, and dialysis
- CVCs increase the risk of blood stream infections (BSIs) which increase mortality and costs of care
- CVC-BSIs can substantially be prevented when clinicians use best practice guidance during catheter insertion and subsequent maintenance
- CVC-BSI rates in the NHS in England are unknown
- This study examined the impact of benchmarking and best practice guidance on minimising CVC-BSIs in English ICUs

of CVC-BSIs; non-technical interventions, which sought to intervene in culture and systems; and establishment of a standardised national reporting system for CVC-BSIs. All participating sites were invited to take part in two training sessions, the first focused on data collection and the second focused on the technical and non-technical interventions.

Matching Michigan followed, and took place during, heightened media interest and policy initiatives focused on healthcare-associated infections and BSIs (table 1) including the introduction by the Department of Health (DoH) in 2007 of best practice guidance on CVC insertion and management[18] through its multicomponent 'Saving Lives' programme.[19] Other improvement activities relevant to CVC-BSIs included the Health Foundation's Safer Patients Initiative, which ran in two phases from 2004 to 2008,[20] and the Patient Safety First campaign, which began in 2008.[21] However, in the absence of a national reporting system, it was not possible to assess the impact of any of these or any other efforts on CVC-BSI rates.

In this article, we report an analysis of the impact of *Matching Michigan* on rates of reported CVC-BSIs in adult and paediatric ICUs in England.

METHODS

Design

This was a prospective, interventional, non-randomised, stepped, four-cluster, 2-year quality improvement project with continuous feedback of results to participating ICUs. The National Research Ethics Committee waived the requirement for informed patient consent on the basis that the intent was to improve uptake of established best practice care, and no patient-identifiable information would be collected centrally.

Box 2 Technical interventions to reduce central venous catheters (CVC)-blood stream infections

- Hand hygiene, gown, gloves, hat, mask. Eye protection when indicated
- Skin antisepsis: 2% chlorhexidine gluconate in 70% isopropyl alcohol
- Maximal sterile precautions including full barrier drapes
- Site of insertion: avoid the femoral route
- CVC maintenance: aseptic access technique, daily site review, and remove CVCs at earliest opportunity

Table 1 The context: national infection control initiatives in England before and during *Matching Michigan*

2001	Mandatory reporting to the Health Protection Agency (HPA) of MRSA bacteraemia. //www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1244763936373
2003	Report of the Chief Medical Officer: Winning ways: guidance to reduce healthcare associated infection in England. //www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4064682
2004	Mandatory reporting of *Clostridium difficile* infection (HPA website)
2004	Hospital in Europe Link for Infection Control through Surveillance of Nosocomial Infections in ICUs protocol. http://helics.univ-lyon1.fr/helicshome.htm
2004 to 2008	Health Foundation's Safer Patients Initiative (24 hospitals): includes CVC bundle. http://www.health.org.uk/areas-of-work/programmes/safer-patients-initiative/
2005	DoH Saving Lives programme—NHS High Impact Interventions (NHS-HII), modelled on Institute for Healthcare Improvement bundles. http://webarchive.nationalarchives.gov.uk/20120118164404/hcai.dh.gov.uk/whatdoido/high-impact-interventions/
2006	Health Act 2006: Department of Health Code of Practice gives new powers of inspection to the Healthcare Commission. Superseded by the Health & Social Care Act 2008
2008	Health and Social Care Act 2008: required registration with the Care Quality Commission: duty to protect patients against HCAIs. New code of practice. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081927
2008	Patient Safety First sponsored by National Patient Safety Agency (NPSA), NHS HII, and Health Foundation, includes interventions to reduce CVC-BSIs http://www.patientsafetyfirst.nhs.uk/content.aspx?path=/
2008	*High Quality Care For All: NHS Next Stage Review* (Darzi report) states that the NPSA will run an 'initiative to tackle central line catheter-related bloodstream infections'. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825
04/2009 to 03/2011	Matching Michigan project. http://www.patientsafetyfirst.nhs.uk/Content.aspx?path=/interventions/relatedprogrammes/matchingmichigan/
2011	Mandatory reporting of MRSA and *Escherichia coli* bacteraemia (HPA website)

BSI, blood stream infections; CVC, central venous catheter; HPA, Health Protection Agency; ICU, intensive care unit; MRSA, methicillin-resistant *Staphylococcus aureus*.

Delivery and recruitment

The NPSA established a national project team and an External Reference Group representing professional and governmental organisations. The scientific leads from the original Michigan-Keystone project acted as

advisors and provided their improvement tools. Chief executive officers (CEOs) of all acute hospitals in England with ICUs were invited to participate in the programme. Participating hospitals agreed to appoint a local project team comprising an ICU physician, an ICU nurse, a microbiologist or infection control specialist and an executive or non-executive director.

Clusters

ICUs were grouped into four clusters with stepped implementation (table 2). Cluster 1 (North-Eastern Strategic Health Authority) allowed piloting of data collection, training and interventions. Clusters 2 and 3 comprised ICUs in southern and northern England respectively. Cluster 4 consisted of ICUs unable to join the project in the earlier phases.

Definitions

Definitions of CVC, BSI, catheter-related (CRBSI) and catheter-associated BSI (CABSI) and measures of exposure are not straightforward. There is considerable evidence of variability in these definitions or a lack of clarity in their application in prior publications.[22–25] The definitions we used, which were current in 2009, were from the Hospital In Europe Link for Infection Control through Surveillance programme,[26] and the US National Nosocomial Infection Surveillance System from the Centre for Disease Control & Prevention,[27 28] and were piloted and refined to ensure applicability and ease of understanding for an English context (see electronic supplementary material 1 (ESM 1)). The definitions distinguish between the surveillance definition of CRBSI and the clinical definition of CABSI. The key distinction between these definitions lies in the type of microbiological analysis undertaken to determine whether the source of any individual BSI can be attributed to a CVC.

ICUs were asked to submit data monthly to a specially created web-based system and to identify which definition they used for each infection at the time of reporting. Infections reported as either CRBSI or CABSI were summed to calculate infection rates. Measures of *exposure* were recorded through a daily census in each ICU involving a count of the number of CVCs in situ at a set time each day. ICUs were asked to complete a survey on generic infection control practices (table 3). Infection data could be submitted until 31 March 2011. However, to permit data cleaning before project closure, analysis was limited to the 20-month period from May 2009 to December 2010.

Training and support

Each cluster was invited to attend two training days, the first on the data definitions developed for the programme (ESM 1) and the second some months later on the technical and non-technical interventions (table 4) adapted from the Michigan-Keystone

Table 2 ICU clusters, duration in project, training day attendance and reliability of submission of infection data

Cluster	Adult ICUs	Paediatric ICUs	Duration in project (months)	Training day dates and no. (%) of total ICUs attending				Attended both	Maximum opportunity to submit data and ICU-months submitted			No. ICUs submitting data			No. (%) ICUs with 100% submission
				Data collection		Interventions			Max ICU-months	All	Adult	Paediatric	All	Adult	Paediatric	
				Date	No. (%) attended	Date	No. (%) attended									
1	15	4	20	30/3/09	17 (8)	18/09/09	19 (9)	17 (8)	380	350	273	77	19	15	4	13 (68%)
2	73	7	12	20/10/09	70 (31)	16/03/10	57 (23)	54 (24)	2015	1776	1642	134	150	139	11	103 (66%)
3	70	5	12	3/11/09	71 (32)	18/03/10	72 (32)	69 (31)								
4	44	5	9	29/4/10	46 (21)	15/07/10	41 (18)	39 (17)	392	353	319	34	46	42	4	31 (63%)
Total	202	21	53		204 (91)		183 (82)	179 (80.3)	2787	2479	2234	245	215	196	19	147 (66%)

ICU, intensive care unit.

Table 3 ICU infection control practices (127 respondents of 223 ICUs, response rate 57%)

	No. (%) of respondents
Joint ward round with microbiology/infection control	
Daily weekday round	56 (44%)
Less frequent	54 (43%)
Never	17 (13%)
Chlorhexidine bed baths	
Routine	19 (15%)
If MRSA positive	63 (50%)
Never	27 (21%)
Information not given	18 (14%)
Oral hygiene	
Chlorhexidine mouthwash	25 (20%)
Corsodyl gel	31 (24%)
Corsodyl mouthwash	10 (8%)
Toothpaste	41 (32%)
None of above	2 (2%)
Information not given	18 (14%)
Antimicrobial-coated CVCs	35 (28%)
Antiseptic-coated CVCs	37 (29%)
Bionnector valve use	
Yes	86 (68%)
No	26 (20%)
Information not given	15 (12%)
Three-way tap use	
Routine	55 (43%)
Sometimes or rare	34 (27%)
Never	23 (18%)
Information not given	15 (12%)
Chlorhexidine-impregnated patch at CVC insertion site	
Yes	21 (17%)
No	90 (71%)
Information not given	16 (13%)

CVC, central venous catheter; ICU, intensive care unit; MRSA, methicillin-resistant *Staphylococcus aureus*.

project.[14] Training was held in a centralised location and involved plenary and small group interactive sessions. ICUs started baseline data collection as soon as possible after the first training day.

Teleconference calls and internet-based teaching sessions were offered over the course of the programme. Guidance was provided by telephone and email and, if appropriate, on-site visits by two quality improvement facilitators (ICU nurses). The Patient Safety First website was used to host information on the interventions and on the programme more generally.[21] The project clinical leads provided additional ad hoc support and guidance when required.

Data verification

Data limits and rules programmed into the software allowed erroneously entered data to be detected and corrected through the web-based tool. Extreme values were examined by clinical members of the project team, and discussed with local project leads. We also undertook verification of consistency between ICUs in identifying and reporting CVC-BSIs in a purposive sample of ICUs. To conduct the verification, we used on-site criterion-referenced case note review and contemporaneous telephone discussion with a second remote and blinded reviewer. Following institutional approval, each ICU in the verification sample provided a list of all blood cultures (BCs) performed over 3 months, and the case records of 5–20 patients with positive BCs. The number of BCs performed and the number of CVC-patient days were compared with the number of patient days to determine the frequency of sampling for BCs, and the CVC-utilisation ratio. Local adjudication and reporting of each CVC-BSI was compared with external review. Inter-observer agreement was determined using the κ statistic. ICUs were not asked to provide self-reported data on compliance or implementation of the technical and non-technical interventions because there was no method of assuring data reliability or completeness.

Statistical analysis

Random-effects Poisson regression modelling was used for the primary outcome, based on mean monthly CVC-BSIs related to CVC-patient days, anchored by time since the second training day for each cluster (zero pre-intervention, number of months from month of intervention onwards), and using as covariates the time trend (months from May 2009), teaching status, size of unit, random effect of unit, and cluster. This tests the hypothesis that the intervention (the second training day) will change the slope of an underlying secular trend. To explore whether changes in ICU infection rates were independent of, or potentially part of, a whole-hospital trend, and in the absence of a measure of pre-ICU exposure rates, we compared quarterly pre-ICU with ICU-acquired infection rates expressed as the proportion of all CVC-BSIs which were ICU acquired (ICU-acquired CVC-BSIs divided by the sum of ICU-acquired and pre-ICU CVC-BSIs). A stable ratio over time would suggest ICU trends were part of a wider whole-hospital effect. A χ^2 test for trend was performed to evaluate changes in this ratio. All p values are two sided, with $p \leq 0.05$ considered statistically significant. Stata (V.9) was used for all analyses.

RESULTS

Participant characteristics

Chief executives of all (139) acute hospitals in England with ICUs agreed that their organisations would participate. Of these, 32 (23%) were university hospitals. The study sample represented 223 ICUs, of which 176 (79%) were general adult ICUs, 21 (9%) paediatric, and 26 (11.6%) subspeciality. The mean (range) number of ICU beds per unit was 12 (3–43); the mean (range)

Table 4 Technical and non-technical interventions

Resource or tool	Content, format
Technical	
Evidence based	
Effective hand hygiene 2% chlorhexidine skin antiseptic Full-barrier precautions Avoidance of the femoral route Review and prompt removal	▶ CVC insertion checklist ▶ DoH high-impact interventions ▶ Technical interventions to prevent CVC-BSIs evidence summary ▶ Frequently asked questions
Facilitators	
CVC insertion checklist	▶ Printable example
Colocated materials	▶ CVC insertion trolley or pack
Non-technical	
Science of safety	
Guidance and teaching resources on safety	▶ PowerPoint presentation ▶ WebEx sessions
Clinical stories and safety incidents	▶ Videos
Attendance at training sessions	▶ Document
Identifying and learning from incidents	
Identifying hazards, learning from safety incidents	▶ Guidance for identifying and learning from incidents ▶ Assessment of potential patient safety incident
LFD framework/root cause analysis	▶ Web tools (National Patient Safety Agency)
Staff safety assessment	▶ Short survey
Executive–clinician partnerships	
Senior executive/shadowing partnership	▶ Guidance note ▶ Executive Leadership Webex
Safety issues worksheet for executive partnership	▶ 'How to' guide for leadership walk-rounds ▶ Video
Teamwork and communication	
Establishing a unit safety team	▶ Guidance note
Safety 'climate' and teamworking	▶ Guide and framework for observing patient rounds and handovers ▶ Shadowing another professional
Safety culture survey	▶ AHRQ
Daily goals checklist	▶ Three examples of daily goals charts offered

Also available via: http://www.patientsafetyfirst.nhs.uk/content.aspx?path=/
AHRQ, Agency for Healthcare Research and Quality; BSI, blood stream infections; CVC, central venous catheter; DoH, Department of Health; LFD, Learning from Defects.

annual admissions was 685 (166–2423). More than 80% of ICUs attended both training days (table 2), though the size of the team attending training ranged from single individuals (doctor or nurse) to large groups including executive leads.

Most (96.4%, 215) ICUs submitted at least some infection data to *Matching Michigan*. Responses (57%) to the survey of generic infection control practices demonstrated wide variation between ICUs (table 3).

Infection rates

Infection data were submitted on 2479 ICU-months of a maximum 2787, giving a reliability rate of 0.89. Complete data were submitted for every possible month by 147 (66%) ICUs (range between clusters 63–68%) (table 2). The first cluster of 19 ICUs (15 adult, 4 paediatric) provided baseline comparator infection data for subsequent clusters. Clusters 2 and 3 received their training a few weeks apart and their infection data were merged into a single cluster for analysis.

Of 1092 CVC-BSIs reported over 20 months, 884 (81%) were ICU acquired. A majority (66.7%) were diagnosed using the catheter-associated definition (table 5). Paediatric CVC-BSIs accounted for 14.6% of total declared infections, but only 7.89% of CVC-patient days. A total of 438 887 (404 252 adult

and 34 635 paediatric) CVC-patient days were reported, giving a mean ICU-acquired infection rate for the entire project of 2.01 CVC-BSIs per 1000 CVC-patient days (adult ICUs 1.88, paediatric ICUs 3.58). Detailed monthly infection and CVC utilisation rates are given in ESM 2.

Changes in infection rates

Aggregated adult and paediatric ICU infection rates diminished with time from a first month rate of 4.4 CVC-BSIs/1000 CVC-patient days for cluster 1, to 1.7 CVC-BSIs in December 2010 (all clusters) (ESM 2 monthly, figure 1A quarterly). The ratio between ICU-acquired CVC-BSIs and all CVC-BSIs remained stable during the project (test of homogeneity $\chi^2=16.11$, $p=0.6497$; test for trend of odds $\chi^2=0.12$, $p=0.7237$), suggesting a possible common cause for the reduction in infection rates in ICU and non-ICU locations (figure 1B).

Mean adult ICU CVC-BSIs diminished from 3.7 CVC-BSIs/1000 CVC-patient days in the first quarter (inception of cluster 1), to 1.48 in the last quarter (figure 1C), and for paediatric ICUs from 5.65 (four paediatric ICUs) to 2.89 (18 paediatric ICUs) (figure 1E). The progressive reduction in infection rates was statistically highly significant for adult ICUs (Z statistic −4.45, χ^2 $p<0.0001$), but not paediatric ICUs (Z statistic −0.79, χ^2 $p=0.625$).

The rate of change in reduction in infection rates did not accelerate following the second training day. For adult ICUs, each successive cluster to join the project had an entry-level infection rate close to the post-intervention level of the preceding cluster (figure 1D) (Z statistic 1.29 and 0.87, χ^2 probability 0.19 and 0.38 for clusters 2 and 3 and cluster 4 respectively). Late engagement (cluster 4) was not associated with poorer performance in any metric. Numbers were too small, and the variation in infection rates too great, to draw secure conclusions from the paediatric data (figure 1F).

Associations

The trend for reduction in infection rates was not associated with hospital type or the number of CVC-patient days for either adult or paediatric ICUs. CVC utilisation ratios could only be determined from December 2009; utilisation rates remained stable (66.3/100 patient days for December 2009–February 2010, 64.6/100 for October–December 2010) (ESM 2 and figure 1A,C,E), despite the continuing fall in pre-ICU and ICU-acquired CVC-BSI rates for this period.

Attendance at both training days was achieved by 179 ICUs (80.3%), 127 of which also provided 100% complete infection data (of 147 ICUs achieving this). Training day attendance was strongly associated with more reliable data submission (χ^2 10.2187, $p<0.005$), but not with infection rates (Z statistic −0.29, $p=0.773$).

Data verification

Twenty-eight of 45 ICUs responded to an invitation to participate in data verification and 17 actually participated (one paediatric ICU, two university, 14 adult general). Reasons for non-participation included no response to further contacts (10), clinical workload (3), inadequate administrative support (4), absence of timely authority to access medical records (7), and inadequate project team resources (4).

The 17 ICUs participating in the verification substudy performed 2357 BCs during 17 020 patient-days and 10 601 CVC-patient days, of which 328 (13.9%) BCs were positive (ICU range 5.7–23%). Frequency of sampling and CVC use varied widely: the BC:patient-days ratio was 2357/17 020=13.8 BCs/100 patient-days (range 4.8–39.6) and the CVC utilisation ratio was 0.62 (range 0.42–0.78).

Criterion-referenced case note review was conducted in 177 patients with 187 positive BCs; in 54 patients (30.5%) no CVC was in situ within 48 hours of the positive BC, which excluded potential CVC-BSIs. Of the 177 patients with positive BCs, 17 had been declared as CVC-BSIs and 160 as non-attributable. External adjudication agreed with local adjudication in 167 instances (seven reclassified as attributable, three as non-attributable, overall correct classification 94.3%). The kappa for agreement between local and external adjudicators was 0.706 (SE of kappa=0.088; 95% CI 0.534 to 0.877). The method did not permit determination of CVC infection in the absence of a blood culture.

DISCUSSION

On initial examination, and using the metrics employed by the majority of studies in this area,

Table 5 1092 CVC-BSIs by infection classification and location

	Pre-ICU acquired			ICU acquired				
Infection classification	CVC associated	CVC related	Total pre-ICU	CVC associated	CVC related	Total in ICU	CVC-patient days	ICU CVC-BSI rate/1000 CVC-patient days
Adult	114	57	171	503	258	761	404252	1.88
Paediatric	28	9	37	84	39	123	34635	3.55
Total	142	66	208	587	297	884	438887	2.01

BSI, blood stream infection; CVC, central venous catheter; ICU, intensive care unit.

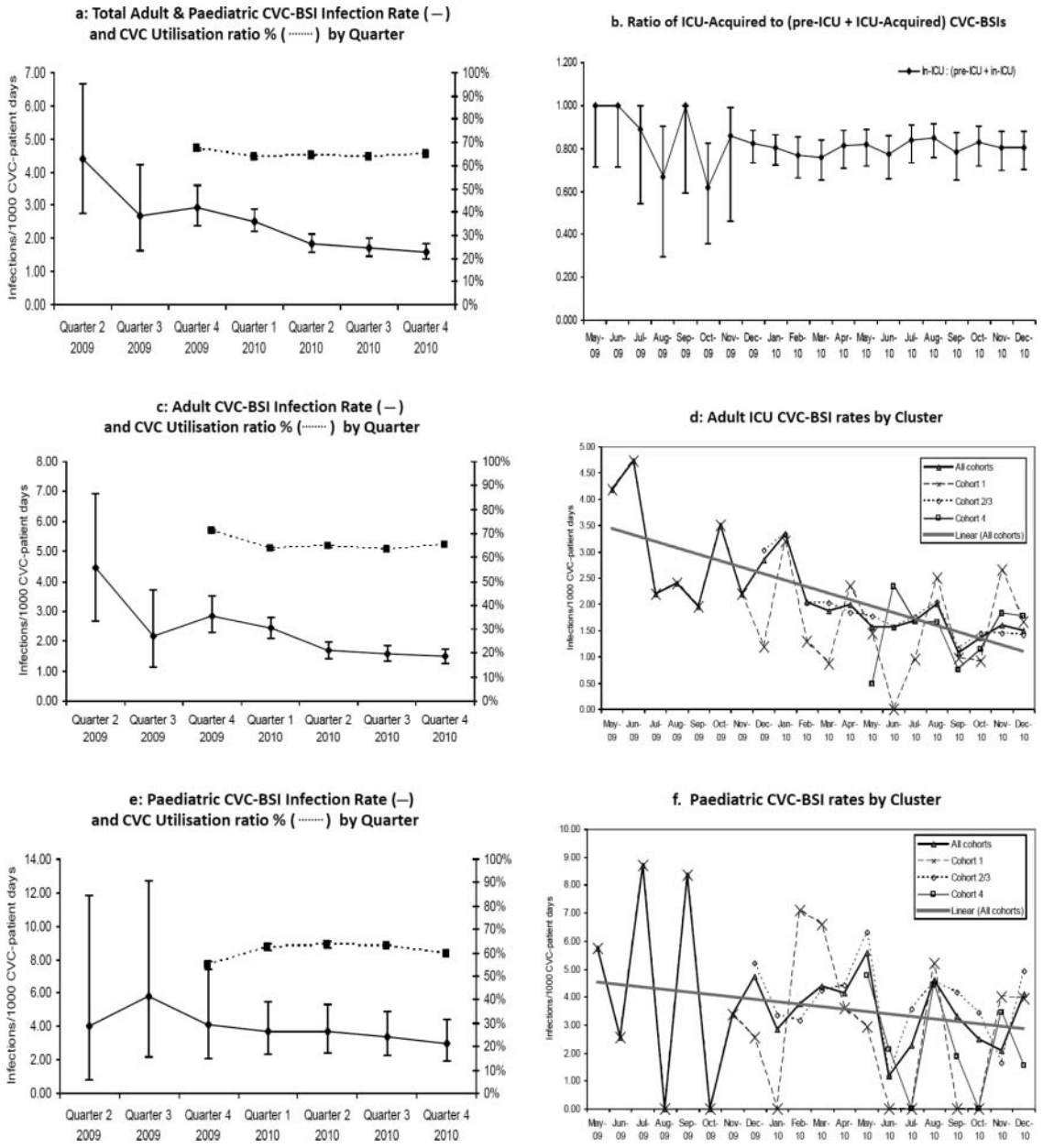

Figure 1 Central venous catheter (CVC)-blood stream infection (BSI) rates. (A) Total adult and paediatric CVC-BSI infection rate (——) and CVC utilisation ratio % (……) by quarter. (B) Ratio of intensive care unit (ICU)-acquired to (pre-ICU+ICU-acquired) CVC-BSIs. (C) Adult CVC-BSI infection rate (——) and CVC utilisation ratio % (……) by quarter. (D) Adult ICU CVC-BSI rates by cluster. (E) Paediatric CVC-BSI infection rate (——) and CVC utilisation ratio % (……) by quarter. (F) Paediatric CVC-BSI rates by cluster.

Matching Michigan was a success. The programme demonstrated a 60% reduction in reported CVC-BSIs in adult ICUs in England, despite starting with less headroom for improvement than the original Keystone-Michigan project[13] (baseline 4.4 CVC-BSIs per 1000 patient catheter days in the first *Matching Michigan* cluster compared with 7.7 at baseline in Michigan). For paediatric ICUs the 48% reduction did not achieve statistical significance; the difficulty of reducing CVC-BSIs in paediatric intensive care is well recognised.[29–32] A conventional narrative might run thus: training in technical and non-technical interventions to improve patient safety combined with measurement and performance feedback stimulated a change in behaviour which resulted in a reduction in BSIs from CVCs.

Closer examination of the data reveals a more complex picture requiring a nuanced interpretation. Attributing the impressive reduction in adult ICU CVC-BSIs rates solely to programme participation is complicated by two novel insights. First, each successive cluster joined the project on the trend line for the post-intervention level of the preceding cluster, thus indicating a strong secular trend. Second, pre-ICU infections (which were not targeted by *Matching Michigan*) diminished in line with ICU-acquired

infections, indicating that the secular trend was not limited to the ICU. These findings suggest the possibility that the reduction in infection rates could be attributable as much to concurrent and preceding improvement efforts and to the consciousness-raising effect of a nationwide programme as to any specific component of the *Matching Michigan* programme itself.

This study is an example of the challenges of conducting field evaluations of complex interventions to improve care in real time in rapidly moving fields. It illustrates in particular the challenges of identifying causal mechanisms during 'rising tides' when multiple policy pressures and the emergence of professional and scientific consensus combine to produce improvements across the board.[33–35] Falling rates of CVC-BSIs have been reported in a number of studies worldwide[36 37] and our study was undertaken during a period of intense national activity in England directed towards reducing hospital-acquired infections, including methicillin-resistant *Staphylococcus aureus* BSI rates (which fell by 22% between April 2009 and March 2011, and by 50% since 2008).[38] For example, many hospitals had already introduced 2% alcoholic chlorhexidine skin disinfectant, full-barrier drapes were becoming more widely available, and alcohol hand rub had become universally available.

Our stepped before and after design reduces the risk of bias,[39] and the analysis therefore emphasises the need for caution in attributing the reduction in infection rates to specific elements in the programme. Lack of a specific causative link between complex behavioural interventions and improved outcomes has been reported for end-of-life care,[40] stroke care,[33] coronary balloon angioplasty[34] and multifaceted safety programmes,[35] while others have reported strong secular trends for improvement in CVC-BSI rates in conjunction with national reporting but in the absence of specific targeted interventions.[36] Financial penalties as a further stimulus for improvement do not appear to have had an additional impact on the adoption of self-reported CVC-BSI prevention measures in the USA.[41]

Study designs involving randomisation, which could help to determine quality improvement programme effects more precisely, are challenged by ethical considerations when best practice is already well established, and practical considerations of isolating intervention from controls. Cluster-randomised designs are particularly important for interventions involving behavioural change,[40 42] since the component elements may be rooted in specific cultures, locations and periods, and require testing in the same way as a pharmaceutical intervention in a new population.[43 44]

A design such as that used in our study—involving clusters joining in a pre-determined sequence, with each successive cluster acting as a de facto control for the preceding cluster—although not formally randomised is one of the more robust approaches that can feasibly be deployed. However, it is subject to a number of threats to internal validity. The 'waiting' clusters were exposed to diffusion of treatment effects, as the interventions were widely publicised on the *Patient Safety First* website from the beginning of the study, and the original Michigan-Keystone project had received widespread attention. ICUs in 'waiting' clusters may also have engaged in 'compensatory rivalry',[45] and increased their efforts to reduce CVC-BSIs while waiting to join the programme. It is also possible that the reduction in reported rates of infections may to some extent have been an artefact of reporting behaviours, since data were collected and reported by ICUs themselves and may have been influenced by perceptions of external scrutiny and performance management.[46] How far any trend in reported infection rates may reflect changes in reporting behaviour over time is not easy to establish. A further limitation of our study was the absence of measures of adoption of the interventions and compliance with best practice. Several studies have reported an association between higher compliance and lower infection rates,[47–49] but data completeness and the methods chosen for compliance monitoring are rarely described in detail, and the literature on hand hygiene demonstrates poor correlation between self-reported and observed compliance.[50–52]

The data verification sub-study provides some reassurance of validity in relation to reporting behaviours, but also demonstrates considerable variability in local practices in relation to CVC use and intensity of sampling blood for culture. Variability in surveillance techniques is well recognised and substantially alters reported infection rates.[25] The survey of generic infection control practices (not compliance with the technical interventions) demonstrates wide variation, including the level of interaction between intensive care physicians and microbiologists. These factors make direct comparison between ICUs challenging. Harmonisation of practice would reduce the risk of confounding, and could bring additional benefits in reducing nosocomial infection rates.

Despite the difficulties of identifying specific programme effects, it is unlikely that the contribution of large-scale programmes such as *Matching Michigan* to the 'rising tide' is trivial. Such programmes may have a particular role in raising awareness, increasing the intensity of focus and stimulating managerial support for professional activities. Feedback of infection rates may have promoted more reliable provision of and adherence to the well known technical aspects of infection prevention for CVCs. Understanding more precisely how such programmes work remains an important task, since such understanding is likely to avoid inappropriate and ineffective interventions, optimise delivery and improve effectiveness.[53] This is

especially important when elements of programme design vary from the original: *Matching Michigan* was not exactly the same as the original Michigan-Keystone project. Differences included amendments to some of the programme materials to ensure contextual relevance; definitions of CVC-BSIs were specified more precisely; and the programme was directed by a government agency with advisory clinician input, not as a clinician-led collaborative. Contextual variability was also evident: *Matching Michigan* was, unlike Michigan-Keystone, implemented following extensive prior national efforts to improve practice, in a national health system in which intensive care specialists direct infection management with input from microbiology, as opposed to this being the domain of independent infection control practitioners.

It is encouraging that reported rates of pre-ICU and ICU-acquired CVC-BSIs showed reductions over the course of *Matching Michigan*. Reduced rates of infection will deliver health gains for patients and benefits for health systems. The apparent trend for a reduction in CVC-BSIs acquired before ICU admission should not encourage complacency, however,[54] since in the absence of a denominator, conclusions cannot be drawn about rates of infection and quality of care. CVC use in non-ICU locations requires the same intensity of focus as it has received in the ICU.[55–60] A national clinician-directed system for sustained continuous CVC-BSI benchmarking, such as those in Scotland[61] and Wales,[62] would ensure continued attention to CVC-BSIs, and could provide a platform for monitoring other healthcare-associated infections with linkage to patient outcomes.

This study adds to the science of improvement by using a quasi-experimental design that reveals the significance of underlying secular trends but does not rule out the possibility that the programme itself was implicated in that trend. Future studies should use robust mixed-methods research methodologies to clarify causal mechanisms underpinning quality improvement interventions, and to identify those most likely to promote more reliable delivery of best practice throughout the healthcare system, as well as promoting clinician ownership.[63] To this end, a separate, independent ethnographic study of culture and behaviour in relation to CVC-BSIs in England was conducted at the same time as *Matching Michigan* and may provide insights that will promote such understanding.

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Competing interests None.

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7.4.5 Paper 5

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Central venous catheter dressing durability: an evaluation

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Abstract

Background: Skin organisms at the insertion site are frequently implicated in central venous catheter blood stream infections (CVC BSIs) yet few studies have compared the durability of CVC dressings in critically ill patients.

Aims: To undertake an evaluation of the durability and associated costs of different CVC dressings.

Methods: Dressing duration was captured prospectively using a pro forma on four different dressings on five critical care units over a 12-month period. Staff received training on CVC dressing evidence-based practices and a 'how to guide' was implemented.

Findings: A total of 1229 CVC dressings were observed from 590 CVCs. One dressing had a median (IQR) duration of 68.5 h (range, 32–105 h) compared to a median duration of 43.5, 46.0 and 40.5 h for the other dressings (P <0.001). The mean time to change a CVC dressing was 13.5 min and the cost of a dressing change was in the range of £1.97–4.97. During the 12-month study period we observed a downward trend in CVC BSIs.

Discussion: Despite few dressings remaining adherent for 7 days, the low rates of CVC BSI observed suggests good dressing practices.

Conclusions: One dressing appeared more durable than the others, although it was still below the recommended standard and more expensive.

Keywords

Blood stream infections, central venous catheters, dressing techniques

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Background

Preventing central venous catheter blood stream infections (CVC BSIs) is an important patient safety issue and a number of initiatives aimed at decreasing CVC BSIs have been implemented at an international, national and local level. The DOH Saving Lives Campaign focused on CVC insertion and ongoing care to reduce CVC-BSIs through the use of high impact interventions (DOH, 2007). Between 2009 and 2011 the National Patient Safety Agency (NPSA) led the 'Matching Michigan' patient safety initiative (Bion et al., 2013). This introduced technical and non-technical

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interventions which had previously been shown to reduce ICU CVC-BSIs (Pronovost et al., 2006). Since the Matching Michigan initiative, we have maintained a system to continuously monitor CVC BSIs in adult and paediatric critical care, allowing ongoing evaluation of our practice.

One unresolved issue identified locally and supported by audit data from 151 CVCs in a study in Birmingham (Shapey, 2009) is that of CVC dressing durability. Audit work in our Trust had shown that CVC dressings remained in place for an average of 2 days. Non-adherence seemed a particular problem when patients were febrile, had clammy skin, or when more than one CVC was used in the same insertion site.

Current national guidelines (Loveday et al., 2014) recommend that 'Transparent, semi-permeable polyurethane dressings should be changed every 7 days, or sooner, if they are no longer intact or if moisture collects under the dressing'. In our experience, it was rare for dressings to last 7 days and many were changed much more frequently. As skin organisms at the insertion site are frequently implicated in CVC BISs (Mermell, 2011), decreasing bacterial colonisation at the insertion site by improving dressing adherence may decrease the risk of CVC BSIs.

At a local level CVC usage was high, each year approximately 2800–3000 CVCs were inserted within the five critical care units and operating departments. The local approach to CVC dressing use was very variable, with wide practice variation in both the type of dressing and method of application. We therefore set out to prospectively evaluate the durability of various commercially available dressings and the optimum dressing technique, including an evaluation of costs.

CVC dressing literature review

We searched the published literature for studies evaluating the optimum CVC dressing or application technique in critically ill patients and found few to guide practice. Vokurka et al. (2009) compared once-weekly versus twice-weekly dressing change on non-tunnelled CVCs in oncology patients. The once-weekly group achieved a mean duration of 5.4 days due to problems with soiled dressings or bleeding. Keene et al. (2009) tested CVC dressings and techniques on Hickman lines, including different types of semi-permeable dressings and various fixation techniques (described as loop-line, sandwich loop-line and a bridge technique). The study was undertaken in a laboratory setting with dressings applied to a hairless part of an arm and weights added until the dressing peeled off. The greatest skin adherence was with a combination of a semi-permeable dressing (Tegaderm®) and a non-woven polyester adhesive fabric strip (Mefix®) using a bridge technique. We tried the bridge technique in clinical practice and modified it to a 'window' technique with four strips of a similar adherent fabric strip (Hypafix®) applied like a window frame around the dressing.

Aims

To undertake an evaluation of the durability of CVC dressings and the associated costs. The specific objectives were to evaluate:

- Four different commercially available, sterile, transparent, semi-permeable polyurethane dressings against the 7-day standard (Loveday et al., 2014).
- A 'window' technique to improve durability of a CVC dressing.
- Costs of the various CVC dressings and techniques.

Methods

A small central strategy team was set up to direct and facilitate the evaluation. This strategy team consisted of a nursing project lead and a medical consultant in critical care. The proposal to undertake a CVC dressing durability evaluation was highlighted to the critical care units in the local healthcare organisation and five critical care units agreed to participate. This included one paediatric and four adult units, each unit identified one or two experienced project nurses to participate in the evaluation. This approach was to support local responsibility and ownership of the evaluation within their clinical area.

Data were collected prospectively using a pro forma which had been designed and tested to ensure it was simple, clear and unambiguous. The data collection form captured the following items:

1. Name of unit
2. Type of dressing
3. Date and time this dressing was applied
4. CVC insertion date
5. CVC insertion site (e.g. internal jugular, sub-clavian, femoral)
6. CVC type (e.g. 4-lumen CVC, Vas-Cath, pulmonary artery catheter sheath, other)
7. Date and time this dressing was removed
8. Reason for why this dressing removed: line removed; routine dressing change at 7 days; dressing no longer adhering to skin; clammy skin; bleeding under dressing; and other
9. Any general comments about the dressing or technique used

We undertook the CVC dressing evaluation in five critical care units (4 adult and 1 paediatric) between December 2012 and December 2013. Data were collected on dressings applied to CVCs while in critical care. We did not

Table 1. Phases of the continuous evaluation of CVC dressing durability.

Phase	Months	CVC dressing evaluated	Other securement techniques
One	1–4	Standard dressings: sterile, transparent, semi-permeable polyurethane dressings (Opsite IV 3000 and 3M Tegaderm®)	None
Two	5–8	3M Tegaderm® IV Advanced: sterile, transparent, semi-permeable polyurethane dressings	Dressing with an integrated border around the dressing. Separate Hyperfix® border applied to create a further secure 'window' around the edge of the dressing
Three	9–12	Sorbaview®: sterile, transparent, semi-permeable polyurethane dressings	Integrated two piece dressing, one part for the site with a wide border and second part with a wide supporting bridge

include dressings applied to CVCs inserted outside of the ICU, for example those inserted in theatre or the radiology department. As this evaluation was of routine clinical practice we evaluated the new dressings and techniques in three phases (Table 1).

Evaluation of time and costs associated with CVC dressings

In a subset of dressing changes in this study (n = 20), the project nurses from each critical care unit recorded the time it took for them to change a CVC dressing as part of their routine CVC care. Four steps in the procedure were timed: assembling the trolley; preparing self and patient; dressing change; and disposal of waste and equipment. The dressing and material costs were obtained from the hospital supplies department.

Staff training

As this evaluation took place within routine clinical practice it was important that the clinical team were trained in the various dressing techniques and shown how to accurately complete the data collection forms. Training was provided to the clinical teams at the beginning of each phase of the evaluation including unit-based and one-to-one teaching sessions, 'how to guide' posters, and discussion at critical care nursing meetings. The educational content included: current clinical evidence and guidelines for CVC dressings; dressing design (permeability, adhesiveness); dressing technique; and how and when to change a CVC dressing.

Analysis

The primary outcome measure was the average duration in hours that a CVC dressing remained in place, this included dressings which were removed because the CVC was removed. We also performed a secondary analysis excluding CVC dressings which had been changed because the CVC was removed or because the dressing had been in place for 7 days, or 'other'. This sub group then included dressings which had been changed because of non-adherence, clammy skin or bleeding under dressing. We excluded from the analysis any pro forma returned without the type of dressing being recorded. As the distribution of the data for dressing duration was not normally distributed these data are presented as median (interquartile range). We compared median duration of CVC dressing using the Kruskal-Wallis test, a nonparametric alternative to the one-way analysis of variance. Descriptive statistics are used to present the results of the evaluation of time and costs.

Ethics

This service evaluation was primarily intended to improve local care, not provide generalizable knowledge in a field of inquiry, and as such did not require review by a research ethics committee. Confidentiality was maintained as no patient identifiable data was shared outwith the clinical team.

Findings

During the 12 month period, 1229 dressing changes were recorded from 590 CVCs The numbers of CVCs and the numbers of CVC dressing changes observed for each unit are shown in Table 2. The durability of the three CVC dressings evaluated during the three phases of the study is shown in Table 3. Of the 1229 dressing changes 304 (24.7%) did not have the type of dressing recorded so were excluded from the analysis. One dressing (Sorbaview) had a median [IQR] duration of 68.5 [32-105] hours compared to 43.5, 46.0 and 40.5 hours for the other three dressings ($P<0.001$). There was no significant difference in the median dressing duration between the other three dressings ($p=0.74$).

The reasons for removal of the CVC dressings are shown in Figure 1. The most common reason for removal of the

Table 2. Numbers of CVCs and dressing changes by unit.

Unit number (type)	CVCs Observed, n	Dressing changes recorded, n (%)
1 (adult general)	191	387 (31%)
2 (adult cardiothoracic)	107	206 (17%)
3 (adult general)	88	183 (15%)
4 (adult general)	126	252 (21%)
5 (paediatric cardiothoracic)	78	201 (16%)
Total	590	1229

dressing was that the CVC was also being removed (34%). The second most common reason was non-adherence. Only 3% of CVC dressing removals was due to the dressing remaining intact for 7 days.

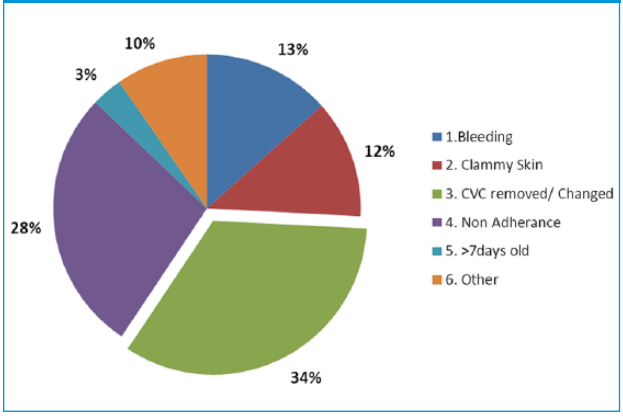
A secondary analysis identified 630 dressing changes for non-adherence, clammy skin or bleeding under dressing; of these 163 (25.8%) had no dressing type recorded and were excluded from the analysis. Findings were similar with one dressing (Sorbaview) having a longer durability than the other dressings, median [IQR] 53 [30-95] hours compared to 36.0, 45.5 and 32.0 hours for the other dressings (P=0.002).

CVC-BSI rates were monitored routinely during the 12 months before and the 12 months during the dressing evaluation project (Figure 2).

Associated time and costs

Twenty individual dressing changes were timed by nurses on the ICU. The mean (range) time taken for all dressings was 13.5 (10 to 19) minutes. The CVC dressing and material costs were calculated and varied from £1.97 to £4.97 (Table 4).

Figure 1. Reasons for dressing removal, all CVC (n=590).



Staff Feedback on CVC dressing preferences

Throughout the evaluation period the critical care project nurses collected feedback from ICU nurses on the practicalities of each CVC dressing. The consensus was that cutting separate borders of Hyperfix® for the "window" was not practical and too time consuming. Some reported that the "window" looked messy and they didn't like this look when providing caring for their patients.

The Sorbaview® Integrated two piece dressing was viewed as easy to apply and was seen as a supportive dressing, adding strength with the weight of the CVC lumens on internal jugular insertion sites, as this was part of the CVC dressing which could drag the dressing off the skin.

Heightened awareness with the importance of CVC dressing durability was observed by the project nurses on their critical care units. Particular awareness was noted with the important aspect of saving nursing time with the number of CVC dressing changes, ensuring a cost effective use of CVC dressings and the importance of thorough ongoing care with the CVC site.

Table 3. CVC dressing duration in the 4 dressing types.

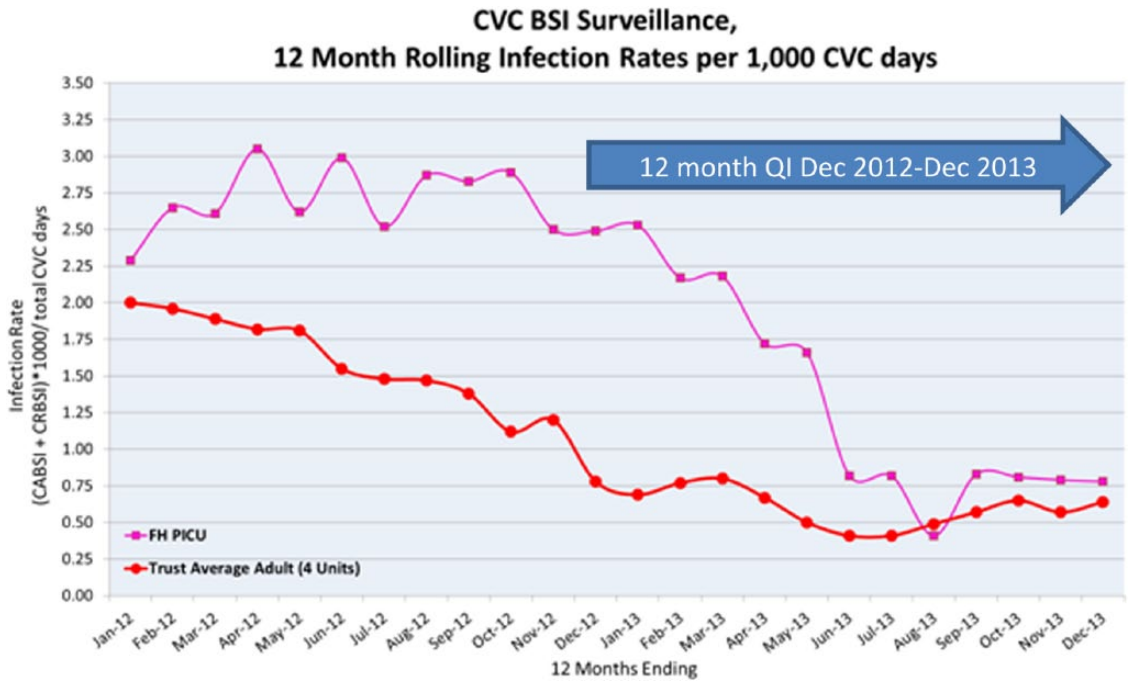
	Dressings removed for any reason, n=1229			Dressings removed for non-adherence, clammy skin, or bleeding under dressing n=630		
Dressing Type	Number of dressings observed	Dressing duration (hrs) median [IQR]	z value*	Number of dressings observed	Dressing duration (hrs) median [IQR]	z value**
Opsite IV 3000	310	43.5 [21–78]	–1.79	160	36.0 [15-67.5]	–1.21
Tegaderm	237	46.0 [22–85]	–0.33	122	45.5 [22-73.8]	1.17
IV Advanced	262	40.5 [20–85]	–1.12	143	32.0 [14-69.5]	–1.98
Sorbaview	116	68.5 [32–105]	4.51	42	53.0 [30-95]	3.39
Unrecorded	304			163		

IQR, inter quartile range; *P < 0.001 and ** P = 0.002 for at least one difference between dressings.

Table 4. CVC Dressing and Material Costs.

	Opsite IV 3000	Tegaderm	IV Advanced with Hypafix window	Sorbaview
Sterile dressing pack including sterile gloves, clinell wipes, apron and non-sterile gloves	£0.53	£0.53	£0.53	£0.53
CVC Dressing	£1.44	£1.67	£1.48	£4.44
Total costs	£1.97	£2.20	£2.01	£4.97

Figure 2. CVC BSI Surveillance across all five critical care units.



Discussion

This evaluation found that few CVC dressings remained adherent to 7 days. One dressing (Sorbaview®) appeared to be significantly more durable, lasting on average a day longer than the other dressings. The "window" technique was not popular with nursing staff who preferred the two-piece CVC dressings. The Sorbaview dressing tended to perform better compared to other dressings. We identified the costs associated with a CVC dressing change and found that the CVC dressing was the most expensive part, with some variation in costs between dressings.

Our findings are in keeping with those of (Shapey, 2009) who found that CVC dressings were not kept intact on 158 of 1000 catheter days. These findings are also in line with the study by Timsit et al (2012) who found CVC dressings became detached in 64% to 72% of cases. Taken together it would appear that CVC dressing adherence in an unresolved issue worthy of further development.

Despite poor dressing adherence and frequent need for dressing changes the rates of CVC BSIs observed during the study period were low. Although the rates of CVC BSIs were falling in the months prior to the study period, this project may have contributed to the on-going fall in infection rates. The education and awareness programme regarding CVC dressing care which ran alongside this evaluation emphasised to staff the importance of meticulous care of the CVC insertion site with early identification and replacement of a displaced dressing. This would be in keeping with previous studies which have shown that staff education, used in conjunction with audit and feedback, are an effective way of reducing CVC-BSIs (Loveday et al, 2014).

The act of monitoring CVC dressing duration may also have influenced practice (Hawthorne effect) and improved the overall standard of CVC care.

This project evaluated prospective data from a continuous period of 12 months including a large numbers of CVC dressings from four adult ICUs and a paediatric ICU meaning the findings should be generalizable to other units. Despite these strengths, some limitations require acknowledgement. Firstly the CVC dressings were allocated in phases of four months rather than randomly and nurses were still able to use standard dressings throughout all three phases; raising the possibility of allocation bias. Secondly, the data collection was patchy at times and required regular motivation of staff to continue data collection. Lastly, the reason why dressings were removed required a judgement by the nurse and some variability between nurses is likely.

Conclusions

In conclusion, our evaluation found that the commercially available CVC dressings performed similarly with few dressings remaining adherent for 7 days. One dressing (Sorbaview) appeared to last longer than the other dressings but was still below the recommended standard and at increased cost. Staff tended to prefer the two-piece design over other dressings. Despite frequent dressing changes low rates of CVC BSI infection were possible in this context, reinforcing the importance of meticulous care of the CVC insertion site through staff education and awareness-raising.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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7.4.6 Paper 6

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Falls in critical care: a local review to identify incidence and risk

Annette Richardson and Rachel Carter

ABSTRACT

Background: Patient falls are the most common adverse event in hospitals, resulting in devastating physical, psychological and financial consequences. Therefore the emphasis on falls assessment and prevention is a key priority. Within hospitals those reported at greatest risk of falls are older patients with little known about the factors within critical care. At a local level, a practice development project was identified to review risk factors contributing to falls in critical care.

Aims: To identify the incidence of falls within adult critical care and the risk factors most likely to contribute to a fall.

Methods: Reported falls incidents were reviewed retrospectively using a local incident reporting system, over a 2-year period from four critical care units.

Findings: Forty-two incidents were reviewed indicating a low rate of injury and low rate of occurrence (0·99 falls/1000 bed days). The median age of fallers was 58 years and the most common risk factor for falls was confusion or agitation, followed by patients attempting to mobilize against advice.

Discussion: Critically ill patients were less likely to fall and were more likely to be younger than patients falling on an acute care ward. Neuroscience/trauma critically ill patients were more likely to fall than general critically ill patients; this was expected to be because of the increased presence of confusion or agitation in this group. The local system used to report falls produced difficulties in identifying risk factors in a consistent way. Although limitations exist, this review has enabled the development of more suitable local critical care falls risk factor assessment and interventions to minimize the risk of falling.

Conclusions: Fall rates, related injuries and circumstances of falls vary considerably among acute care and critical care specialities. Future work should concentrate on better falls reporting systems and further research should include validating risk factors for critical care falls.

Key words: Critical care • Falls assessment • Falls risk factors • Quality improvement

BACKGROUND

In the hospital setting, patient falls are often reported as the most common adverse event (Halm and Quigley, 2011; Patman *et al.*, 2011). In 2006, the National Patient Safety Agency (NPSA) reported over 1260 falls in one average size acute hospital every year in England and Wales (NPSA, 2007). More recently this number was calculated to be over 250,000 per annum in English hospitals alone (Royal College of Physicians, 2012), resulting in a median incidence of 6·8/1000 bed days.

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Other reports of falls incidence within acute hospitals has fluctuated between 2 and 18 falls/1000 bed days (Patman *et al.*, 2011), with rates varying significantly depending on the patient mix (Enloe *et al.*, 2006). Higher rates of falls have been found in patients with medical, neuroscience, psychiatric or rehabilitation disorders, and in critical care rates have been lower with an incidence of 0·78/1000 bed days (Enloe *et al.*, 2006). Despite the lower rate of falling whilst in critical care, the risk of falling in critical care unit survivors on hospital wards is greater, with an incidence of 3·8–4·1/1000 bed days (Patman *et al.*, 2011).

Despite the varying frequency of falls in acute and critical care settings, prevention of falls is an important patient safety requirement as they result in many devastating physical, psychological and financial consequences. Injuries from falls are often associated with morbidity and mortality (Flanders *et al.*, 2009; Boushon et al., 2012), and falls can cause severe or moderate

injury, such as bruising, lacerations, fractures and head injuries (NPSA, 2007). The reported psychological consequences include loss of confidence and loss of independence (NICE, 2013) and the financial burden is an additional major consequence of falls. They have been estimated to cost the National Health Service (NHS) more than £2·3 billion per year (NICE, 2013) with an estimated cost of inpatient falls, in a typical acute hospital, ranging from £80 K to £500 K annually (Royal College of Physicians, 2012).

Owing to the serious untoward outcomes associated with falls, the emphasis on prevention is a key UK national and local priority. Two key NHS publications have set out information to assist hospitals with the implementation of falls prevention strategies. The first was published by the NPSA and focussed on a national review of falls over 12 months (NPSA, 2007) and identified recommendations to reduce the risk of falling. The second was published by the National Institute of Clinical Excellence (NICE) providing recommendations aimed at preventing falls in older people (NICE, 2013). More recently a further NHS strategy was launched called the NHS Safety Thermometer (Department of Health, 2012). This was aimed at reducing patient harm and included falls as one of the 'harm free care' indicators for improvement. The NHS Safety Thermometer was designed as a monthly prevalence tool made available locally to measure, monitor and analyse patient harms. It involves the entire acute hospital setting including critical care.

This review aims to summarize what is currently known about the risk factors associated with patient falls and patient assessment predominately within critical care. It also includes a review of local falls incidence data, as part of a quality improvement programme, to provide a better understanding of falls risk factors in the critically ill.

FALLS RISK FACTORS

For many years the prevention of falls has focussed on older people as those at highest risk; however patients of all ages fall. Generally within a hospital setting those reported at greater risk of falls are older patients (NPSA, 2007) and are much more likely to experience serious injury (NPSA, 2007). The proportion of patients falling above the age of 80 years old has been high and for patients below 65 years old the proportion has been lower (Schwendimann *et al.*, 2008). A variation was noted in one study where the majority (84%) of falls amongst intensive care unit (ICU) survivors on hospital wards was found to be less than 65 years old (Patman *et al.*, 2011), with a median age of 44 years old (age range 15–78 years). Little is known about the age of fallers within critical care.

Other than age, a number of physiological risk factors have been identified as common causes of falls including mental deficiencies, sensory deficits (impaired hearing and vision) and altered mobility (Flanders et al., 2009). Another less likely cause, but often reported, is the association with environmental factors such as trip hazards or slips. The least common unanticipated causes of falls include faints, fits and an acute illness (Flanders *et al.*, 2009), such as a fall during recovery from an anaesthetic (NPSA, 2007). Patients who have a history of falling are more at risk of falling (Flanders *et al.*, 2009; Halm and Quigley, 2011) and risk factors such as medications and delirium have been identified as specific critical care risk factors (Halm and Quigley, 2011). Critical care patients have been viewed as at risk of a falls, unless the patient is in a coma (Halm and Quigley, 2011).

The recently published NICE guidelines (NICE, 2013) sets out recommendations on the assessment and prevention of falls concentrating on older people above 65 years old, and includes additional recommendations for people admitted to hospital as inpatients above 50 years old (NICE, 2013). One of the recommendations is for a multifactorial assessment of risk to be carried out on patients at risk of falling. This is to ensure that the patient's individual risk factors for falling are identified, and then interventions to eliminate or reduce these risks implemented (NICE 2013). Despite this falls assessment recommendation no multifactorial tool or risk factors exist with a focus on critically ill patients.

At a local level within a large teaching acute hospital organization in the UK, a multifactorial falls risk assessment process was used in practice in line with NICE (2013) and NPSA (2007) guidelines for adult hospital in-patients. However on informal review of the assessment process within critical care the suitability was questioned. The reason for the lack of suitability was due to the inability to adequately identify patients at risk of falls using the local assessment criteria. An example was with the identification of the risk factor called 'on medication's', this factor would trigger with almost all patients as this did not focus on the types of medications which could increase the risk of falling. Another example was with the ability to appropriately assess the risk factors 'balance, transfer and walking', this assessment was viewed by some staff as limited due to the critical nature of the patient's illnesses and the majority of time spent lying in bed. Consequently, at a local level a practice development project was identified to review risk factors contributing to falls in critical care, in order to provide a more suitable falls

risk assessment for the critically ill. Therefore a retrospective local review was undertaken into the types of patients falling in critical care, as part of a local quality improvement project.

LOCAL FALLS REVIEW

Aims of the review

The aims of the review were to:

- To identify the incidence of patient falls within adult critical care
- To identify types of patients and risk factors most likely to contribute to a fall in critical care

Incident data review

A search of all reported falls incidents was conducted using the hospital online incident reporting system 'DATIX' (DatixWeb 12.3.1). Reported falls incidents were reviewed over a 2-year period (1 January 2011 to 31 December 2012) from four critical care units. The four critical care units admitted both intensive care and high dependency patients as defined in Comprehensive Critical Care (Department of Health 2000).

The four units included:

1. Unit A – a 22 bedded general surgical/medical critical care unit specialising in hepatobiliary surgery and liver transplantation.
2. Unit B – a 23 bedded cardiothoracic critical care unit.
3. Unit C – a 22 bedded neuroscience/trauma critical care unit.
4. Unit D – a 20 bedded general medical/surgical critical care unit specializing in Burns.

Falls incidences were then closely analysed to identify age, common themes, location of the fall, injuries and risk factors.

Table 1 Number and Incidence of falls

Unit	Total number of falls reported	Number of bed days (2011–2012)	Incidence/ 1000 bed days
Unit A	4	10,350	0·38
Unit B	1	9300	0·11
Unit C	25	12,650	1·97
Unit D	12	10,250	1·17
Total	**42**	**42,550**	**0·99**

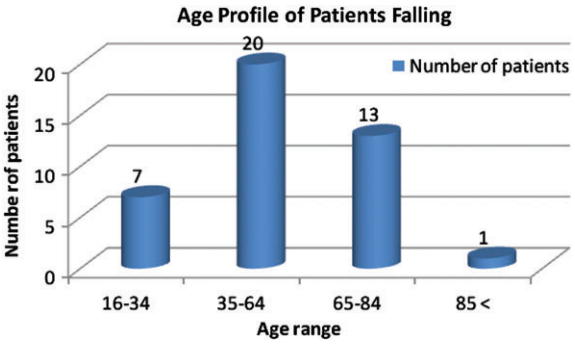

Figure 1 Age profile of patients falling.

Table 2 Factors contribution to falls

			Description of contributing falls factor		
Unit	Number of falls	Median age (years)	Patient agitated/ confused	Patient mobilizing against advice	Environmental
Unit A	4	73	2	1	1
Unit B	1	54	0	1	0
Unit C	25	44	18	7	0
Unit D	12	60	5	7	0
Total	**42**		**25**	**16**	**1**

Incident data findings

Over the 2-year period the total number of falls within the four critical care areas was 42. Of the 42 reported falls this involved 41 patients as one patient experienced two falls; 29 patients were male (71%) and 12 were female (29%), and the numbers are broken down by unit in Table 1. The number of bed days was calculated to provide a falls incidence per 1000 bed days (Table 1).

The critical care patient incidence was found to be 0·99 falls/1000 bed days. Unit C the neuro/trauma critical care unit had the highest incidence of 1·97/1000 patient bed days.

The age profile of patients falling in critical care ranged from 16 to 86 years old and the median was 58 years old. Figure 1 shows a wide age profile of patients falling in critical care. The largest group of patients were those between 35 and 64 years old (49%). Table 2 identifies the median age range for each of the four critical care units and the neuro-trauma critical care unit (unit C) has the lowest median of 44 years old.

Common themes and factors contributing to falls were identified from the review process and shown in Table 2. The most common risk factor for patient falls on all four units was confusion or agitation (60%), followed by patients attempting to mobilize against advice (38%).The least common cause of falls was environmental, the one case identified involved a patient

Table 3 Locations where patients fall

Locations	Number of falls (%)
Fall from bed	14 (33%)
Fall from chair	18 (43%)
Fall on level ground/walking/slip	3 (7%)
Fall from commode/toilet	5 (12%)
Not recorded	2 (5%)
Total	**42**

Table 4 Number of reported falls injuries

Injuries	Number of falls	Grading (using local grading of incident matrix)
No injury	35	Insignificant
Bruising	2	Minor
Abrasion/graze	4	Minor
Head laceration and wrist fracture	1	Moderate
Total	**42**	

leaning on a bedside table which then moved, resulting in the fall.

A number of locations were identified where the patient was reported to have originated, prior to the fall. Falling from a chair (43%) and a bed (33%) were the two most common in critical care (Table 3).

Most falls (83%) did not cause any reportable injury. However six (14%) incidents resulted in minor injuries including bruising or abrasions/grazing and one fall resulted in the patient sustaining moderate harm with a right wrist fracture and laceration of the head (Table 4).

DISCUSSION

Over a 2-year period, we found the incidence of patient falls within critical care to be lower than the incidence reported for acute hospitals as a whole. This incidence, an average rate of 0·99 falls/1000 bed days in critical care, resembled previously reported critical care rates (Enloe et al., 2006). Schwendimann *et al.* (2008) discovered inpatient fall rates to vary significantly among clinical departments and that this was likely to be due to differences in patient characteristics. In our local review related variations were found within the different unit case mixes. Double the average rate of falls was identified within the neuroscience/trauma critical care when compared to the average for critical care. Therefore, although in general terms critical care patients seem less likely to fall than patients on an acute care ward, patients within a neuroscience/trauma critical care unit are more likely to fall than other critically ill patients.

One of the explanations for the higher rate of falls in the neuroscience/trauma critical care unit is because of the increased presence of confused or agitated patients. This risk factor contributed to 60% of the 42 reported critical care falls and has been recognized as a falls risk factor in many other hospital settings (George *et al.*, 1997; Hitcho *et al.*, 2004; NPSA, 2007). Another frequently reported falls risk factor was patients who mobilized against advice. This risk factor can be linked to the confused and/or agitated patient, again associated with neurologically injured patients. Consequently these risk factors provide some explanation for the increased falls incidence within the neuroscience/trauma critical care unit.

Many other patient characteristics and causes of falls have been reported within the literature with older age as one of the most common characteristic (Schwendimann et al., 2008; NICE, 2013). Within critical care we did not find this feature as the median age of all fallers was 58 years and the largest group of patients were in the age range of 35–64 years. Consequently recognizing other important risk factors other than age is crucial within the critical care setting.

We attempted to identify other factors contributing to patient falls such as the location from where the patient fell. Falls from bed and from a chair were the most commonly identified (76%) in the four critical care units. However in a review of national incidents, the NPSA (2007) identified falls occurred whilst walking as the most common, followed by falls from bed; and falls from a chair as least common within acute hospitals. Within the critical care environment differences exist in comparison to the acute ward setting and reasons for these differences can be explained due to the increased dependency of the patients in critical care, resulting in patients spending more time in bed and less likely to be walking by themselves when they fall.

Within the 2-year review period, the majority of falls resulted in minimal physical injury and only one incident resulted in a serious fracture injury. This low injury rate within critical care was consistent with nationally reported data (NPSA, 2007). Nonetheless the psychological consequences were not captured and the likelihood of psychological patient outcomes such as loss of confidence and loss of independence could well have been experienced by the patients. Consequently the avoidance of all patient falls, even if rates

are low, is an important agenda for all healthcare professionals.

A difficulty we identified from our local review of 42 falls incidents was with the subjective reporting of the nature and cause of each fall, from the incident reporting system DATIX. The reporting of the cause of the fall was required using an open text box and this allowed nurses to report on the fall with as much or as little information as they felt individually appropriate. This open text box system produced difficulties in pulling out the risk factors in a consistent way, which consequently provides limitations for the data presented.

Uncovering important issues such as whether the patient was receiving an intensive care or high dependency level of care; and if the patient was in a single cubicle or on an open bay, would have been informative. This as well as providing a better understanding of the critical care nurse to patient staffing ratio at the time of the fall, may have uncovered nurse staffing difficulties contributing to the fall. Plus information on whether or not the patient fell in the presence of a nurse would have been valuable. Issues with a patient's mobility were revealed and often referred to as 'mobilizing against advice'; however, identifying any previous mobility difficulties such as requiring assistance by one or two staff with mobility would have been helpful or whether early mobilization had contributed to the fall. Other factors such as whether interventions to help with the prevention of falls, for instance, wearing appropriate footwear when mobilizing high dependency patients and the use of bed rails when patients are in bed, would be informative for future reporting. Patients with a history of falls are known to be at an elevated risk of falling again (Flanders *et al.*, 2009; Halm and Quigley, 2011); however, this risk factor was not identified from the local incident reporting system along with other risk factors specific to critical care such as medications and delirium (Halm and Quigley, 2011). This reporting deficit signifies risk factors associated with a fall in critical care, may not have been identified, limiting the data shown.

The findings from this review identified areas for practice development at a local level. Owing to the unsuitability of the existing falls risk assessment tool, a more suitable assessment has been developed for the critically ill. The critical care assessment includes risk factors highlighted from the incident data and the review of evidence on falls risk factors. The critical care assessment identifies falls risk by assessing the following three factors: (1) if the patient is receiving sedation or is on hypnotics; (2) if the patient is confused and/or delirious and/or has dementia and (3) if the patient has a history of falls. A further practice change has been the development of a set of critical care interventions to minimize the risk of falling and has been included within the local nursing care plan documentation. These critical care interventions include: ensuring the patient is in safe position and observed closely; while the patient is in bed, use bed rails appropriately; while mobilizing the patient use appropriate mobility aids and number of staff as per moving and handling assessment; while the patient is in a chair ensure appropriate footwear worn; and communicate with the patient their risk of falls and provide advice on how they should mobilize to avoid falling. It is hoped that these practice developments will help critical care nurses to identify patients at risk of falling and also inform nurses on the interventions to assist in the prevention of falls within critical care.

CONCLUSION

Despite limitations with the local reporting system, this review offers a focussed analysis of 42 falls in critical care. In summary, fall rates, related injuries and circumstances of inpatient falls varied considerably among different clinical departments in acute care hospitals and within different critical care specialities. Despite the variations, unless the patient is in a coma, critical care patients are at risk of falls, therefore a high priority should be assigned to the identification of patients at an elevated risk. A number of critical care risk factors appear to identify patients at an elevated risk of falling and include the presence of agitation and confusion and mobilizing against advice. Therefore the importance of assessing these risk factors is vital in critical care so that subsequently fall prevention strategies and interventions can be implemented in help prevent.

Future work should concentrate on ensuring the reporting systems to record falls captures the causes and risk factors in a more reliable and systematic way. The incident reporting systems for critical care falls should capture the following fields: patients' mobility needs and mobility assistance provided when the fall occurred, the location of the patient fall, the level of critical care being provided and the nurse to patient staff ratio at the time of the incident.

Further research should include critically ill patients and of all ages with a focus on validating an assessment tool to confirm suitable risk factors for critical care falls.

WHAT IS KNOWN ABOUT THIS TOPIC?

- Patient falls are the most common adverse event in hospitals, resulting in many devastating physical, psychological and financial consequences.
- Prevention of falls has focussed on older people as those at highest risk.
- Adult hospital in-patient falls assessment processes are unsuitable to adequately identify patients at risk of falls in critical care.

WHAT THIS PAPER ADDS

- A low rate of injury as a result of a fall and a low rate of occurrence (0·99 falls/1000 bed days) in critical care.
- Patients within the neuroscience/trauma critical care unit are more likely to fall compared with other types of critical care specialities.
- The median age of critical care fallers was 58 years and the largest group of patients were in the age range of 35–64 years.

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7.4.7 Paper 7

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Part 1: Pressure ulcer assessment – the development of Critical Care Pressure Ulcer Assessment Tool made Easy (CALCULATE)

Annette Richardson and Isabel Barrow

ABSTRACT

Introduction: Critically ill patients are at high risk of developing pressure ulcers resulting in serious untoward patient and health care system outcomes. Pressure ulcer prevention is therefore an important patient safety priority and establishing a structured approach to pressure ulcer risk assessment to identify patients at risk is a critical first step.

Methods: The literature was searched using three electronic databases from 2000 to 2011 to identify papers reporting on pressure ulcer risk factors and assessment in adult critical care. The review and appraisal of papers were conducted by two critical care nurses. Papers underwent detailed review if they met inclusion criteria where they identified pressure ulcer assessment scores, scales or risk factors and related to adult critical care patients

Findings: Seven papers were reviewed. No single assessment tool was sufficiently validated for critically ill patients and seven key critical care risk factors were identified. These risk factors were: mechanical ventilation, impaired circulation, dialysis, long surgery, low protein and too unstable to turn.

Tool development: The tool Critical Care Pressure Ulcer Assessment Tool made Easy (CALCULATE) was developed utilizing the risk factors from the literature and expert critical care nursing consensus decision-making.

Discussion: In the absence of current consensus, valid assessment scales and limited evidence for the most appropriate pressure ulcer assessment for critically ill patients, this assessment tool offers an easy, appropriate alternative for critically ill patients than existing tools primarily validated for acute care wards.

Conclusions: 'CALCULATE' offers an important contribution towards the advancement and development of critical care pressure ulcer risk assessment. Future research is needed to further enhance and inform pressure ulcer risk assessment of the critically ill patients.

Implications for practice: The identification of critical care risk factors may be an indicative method of assessing pressure ulcer risk in the critically ill patients.

Key words: Pressure ulcer risk assessment • Pressure ulcer risk factors • Quality improvement

INTRODUCTION

The National Institute of Clinical Excellence (NICE) calls attention to the fact that pressure ulcer prevention is an important patient safety priority and often preventable (NICE, 2014). An important priority as pressure ulcers cause patients to experience embarrassment, suffer unnecessary pain and scarring (Alderden *et al.*, 2011) and infection (Reddy *et al.*, 2006). Pressure ulcers also result in increased hospital length of stay (Alderden *et al.*, 2011), increased nursing workload (Kaitani *et al.*, 2010) and cost the tax payer high sums of money to treat (Bennett *et al.*, 2004). The additional consequences of pressure ulcers occurring in the critically ill patients include increased mortality and morbidity rates and longer intensive care unit (ICU)

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stay (Tayyib *et al.*, 2013). Considering these serious untoward patient and health care system outcomes, it is fortunate that the prevention of pressure ulcers has become a key National Health Service (NHS) quality target, increasing the drive to avoid pressure ulcers in the future (Department of Health, 2012).

This is the first of two papers highlighting techniques used to develop a critical care pressure ulcer assessment tool to be considered for use by nurses caring for the critically ill patients. Part 2 will describe the implementation of the tool across four adult critical care units and provide an overview of risk factors associated with pressure ulcers development in adult critical care.

BACKGROUND

At a local level within a large health care provider organization, pressure ulcer prevention was identified as a key quality improvement priority. Within this organization the four adult critical care units were identified as having higher incidence of pressure ulcers when compared to other acute ward areas. This increased incidence in critical care is frequently reported in the international literature (Brindle, 2010; Alderden *et al.*, 2011; Lahmann *et al.*, 2011; Cox, 2013; Tayyib *et al.*, 2013).

Because of the increased incidence in the four local critical care units, nursing leaders from the units agreed to establish a pressure ulcer prevention task group. This task group was set up to direct, facilitate and review all aspects of critical care pressure ulcer prevention as part of a quality improvement programme. The group was tasked with reviewing the ways in which pressure ulcers could be reduced and prevented. The multiple pressure ulcer prevention strategies focused on interventions to address impaired mobility such as repositioning and support surfaces, as well as the use of skin products for impaired skin health. However, the assessment of patients at risk was seen as an important first step in the quest to tackle pressure ulcer prevention with critically ill patients.

The European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP and NPUAP (2009) recommend establishing a structured approach to risk assessment to identify individuals at risk of developing pressure ulcers. More recently the NICE (2014) published guidelines for pressure ulcer prevention and management and recommend carrying out and documenting pressure ulcer risk assessment for adults being admitted to secondary care. Assessment scales in general are recommended for raising the awareness of risk factors in the clinical setting and for providing a minimum standard for risk assessment and documentation (Kottner and Dassen, 2010).

In the past, assessment tools to calculate pressure ulcer risk had mainly concentrated on patients in the acute hospital ward setting and included Braden, Waterlow and Norton scores (Smith *et al.*, 1995). At the start of this project, the Braden score (Braden and Bergstrom, 1989) was the tool used in practice within the local organization for all patients including those in critical care; however, when applied to the critically ill most patients had a very low Braden score so it was identified that Braden was unable to adequately highlight elevated risk with critical care patients. Cho and Hoh (2009) uncovered similarities in a study with surgical ICU patients, where they found the Braden score to have a low usability and utility. Owning to the apparent current lack of appropriate pressure ulcer assessment tools for the critically ill patients, an initial objective of the local pressure ulcer prevention task group was to undertake a more detailed review of the evidence with the aim of identifying a valid and reliable pressure ulcer risk assessment tool. Then in the absence of a valid and reliable tool, to identify critical care risk factors and develop a more suitable pressure ulcer risk assessment tool.

AIMS OF THE LITERATURE REVIEW

This literature review aimed to identify a valid and reliable pressure ulcer risk assessment tool for critical care. In the absence of a suitably valid and reliable tool, to identify critical care risk factors to inform the development of a pressure ulcer risk assessment tool for critical care patients.

Literature review

At the start of the local pressure ulcer quality improvement programme a search of the literature was conducted. The time period for the search was from 2000 to 2011. The literature search was set up to identify papers and articles relating to pressure ulcer risk factors and assessment in adult critical care. Three electronic databases (Cinahl, Medline and BNI) were searched. Only English language articles that published since 2000 were included. The following key words, acronyms and combination of terms were used: intensive care or critical care; and pressure ulcer(s), or pressure sores(s) or pressure ulcer scales, and risk factor(s), or risk assessment. Two members of the pressure ulcer prevention task group were involved in the review and appraisal. The papers were selected for detailed review if they meet the following inclusion criteria:

1 studies identifying pressure ulcer assessment scores, scales or risk factors
2 studies relating to adult critical care patients

Findings

The literature review uncovered an extensive number of papers' of which seven were reviewed in detail as they met the inclusion criteria. Data were extracted from the papers, tabulated and analysed into critical care risk factors. A summary of the seven papers reviewed is provided in Table 1.

One paper assessed the interrater reliability and validity of Braden and Waterlow scores and subjective pressure ulcer risk assessment, in two ICUs (Kottner and Dassen, 2010). They found a high degree of measurement error inherent in the scores and concluded that the use of Braden or Waterlow for pressure ulcer risk assessment in ICU patients was not recommended. Of the remaining six papers only one paper identified a local development of two pressure ulcer assessment tools (Brindle, 2010). One tool was developed to select patients for inclusion into a trial of a new pressure ulcer prevention product. This pressure ulcer assessment tool included four criteria for automatic selection and a list of 15 factors of which 5 or more should apply to qualify for the trial. The second tool identified 9 controllable and 20 uncontrollable risk factors for the critically ill and was developed to identify 'the sickest of the sick' in a trauma population. These tools were developed based on a local consensus group and neither had been tested. In both tools the high number of risk factors was considered to be too large for application into practice, every shift within critical care. An important outcome from the review of the seven papers was that no pressure ulcer assessment tool was sufficiently validated for use locally for critically ill patients.

Despite the lack of sufficiently validated pressure ulcer assessment tools for critically ill patients, many critical care risk factors emerged from the seven papers reviewed. Four papers used logistical regression to identify the level of positive association of variables on the development of pressure ulcers. This level of evidence was utilised to identify the most indicative risk factors for pressure ulcer development (Eachempati *et al.*, 2001; Nejs *et al.*, 2008; Frankel *et al.*, 2007; Kaitani *et al.*, 2010).

There was an intention to create less than 10 risk factors so that an assessment tool could be developed for easy and regular use in practice every shift; therefore with an awareness of this intention the findings were themed into seven key critical care risk factors.

Impaired circulation

'Impaired circulation' was identified as a risk factor from a number of identified conditions and treatments. This was described directly as impaired circulation as this has a direct result in reduced tissue oxygenation (Keller *et al.*, 2002), but other associated medical treatments and diagnosis impacting on circulation included diabetes (Frankel *et al.*, 2007, Keller *et al.*, 2002, Brindle, 2010); history of vascular disease (Frankel *et al.*, 2007; Nejs *et al.*, 2008, Brindle, 2010); smoking (Brindle, 2010) and 'on inotropes' (Keller *et al.*, 2002; Frankel *et al.*, 2007; Nejs *et al.*, 2008; Brindle, 2010).

Too unstable to turn

The risk factor 'too unstable to turn' was identified from a number of connected findings. Described directly as 'too unstable to turn' (Keller *et al.*, 2002) and also the inability to turn or mobilize placing the patient at the highest risk (Eachempati *et al.*, 2001). Issues also associated with pressure ulcer development and linked to this risk factor was infrequent turning particularly with emergency admissions where patients are likely to have laid on a stretcher resulting in many hours of immobility (Kaitani *et al.*, 2010).

Low protein

Poor nutrition is known to lead to muscle wasting and soft tissue loss allowing the impact of bony prominences on external skin surfaces. Therefore prolonged periods without any nutrition pose an increased risk for pressure ulcers (Eachempati *et al.*, 2001). Malnutrition was also identified as a risk factor by Brindle (2010) and similarly Kaitani *et al.* (2010) found a link between low nutrition scores and increased incidence of pressure ulcer damage. Low serum albumin from whatever cause was seen as a risk factor increasing the likelihood of pressure ulcer development (Keller *et al.*, 2002).

Dialysis

Patients who required treatments for renal failure such as intermittent haemodialysis or continuous veno-venous dialysis were found to be positively associated with patients with pressure ulcers and 48 h prior to the occurrence of the damage (Nejs *et al.*, 2008). This may well be due to how this type of support limits patient mobility.

Feacal incontinence

Keller *et al.* (2002) found feacal incontinence and/or diarrheoa as a risk factor for pressure ulcer development. The consequence of moist skin caused by feacal incontinence was identified as the main problem leading to the increased risk of pressure damage.

Table 1 A summary of critical care pressure ulcer risk factor papers reviewed

Author(s)/Year/country	Population/ clinical setting	Aim(s)	Design/intervention	Results/risk factors associated with pressure ulcers
Eachempati *et al.* (2001) USA	Surgical ICU	To determine patient factors contributing to the formation of decubitus ulcers	Prospective. Phase one 2615 patients (4 years 6 months) Phase two (8 months) 412 patients	Phase one ICU incidence 3·8%. Phase two ICU Incidence 8%. Emergency admissions, age, days in bed, inability to turn or mobilise and days without nutrition.
Frankel *et al.* (2007) USA	Surgical ICU	To assess risk Factors	Retrospective over 12 months 820 patients (25 with grade 2 or greater pressure ulcer)	ICU incidence 3%. Increased risk associated with diabetes, vascular disease, age >60 years old, creatitine >3 mg/dL, on pressors and spinal cord injury.
Brindle (2010) USA	Surgical trauma ICU	To identify high risk ICU patients and trial a prophylactic dressing	Improvement study: 3 months 93 patients assessed (41 patients identified at risk)+ Creation of risk factors based on known research and staff experiences. Implemented a sacral dressing	9 controllable risk factors: immobility, friction, shear, moisture, nutrition, activity, faecal incontinence, urinary incontinence, knowledge deficits 20 uncontrollable risk factors: multiple OR procedures, mechanical ventilation, sedation/paralysis, traction, spinal cord injury weeping anasarca, morbid obesity, shock, cardiac arrest, vasopressors, drive lines, nitric, oscillating ventilation, malnutrition, peripheral vascular disease, heart disease, diabetes, advanced age, liver failure, smoking.
Keller *et al.* (2002) Netherlands	ICU papers	To review risks and prevention of pressure ulcers in ICU	Literature review 1980–1999	No conclusive studies to identify pressure ulcer risk factors. Existing risk assessment scales not developed for ICU patients. Risk factors linked to pressure ulcer development included: duration of surgery and number of operations, faecal incontinence, low protein/albumin, disturbed sensory perceptions, moisture, impaired circulation, use of isotropic drugs, diabetes, too unstable to turn, decreased mobility, high APACHE II score, poor nutritional state.
Nejs *et al.* (2008) Belgium	Long-stay surgical ICU	To determine the incidence of pressure ulcers occurring at least 48 h after admission and risk factors for pressure ulcer grades 2-4	Prospective descriptive design with multivariate logistic regression analysis 520 patients (>24 h stay)	Incidence 20%. Risk factors identified included: on dopamine, history of vascular disease, IHD or CVVH.
Kaitani *et al.* (2010) Japan	ICU and HDU	To identify risk factors for pressure ulcer development early in the critical care admission and interventions to decrease the risk	Prospective cohort study: 3 months. 98 patients, 11 with pressure ulcers	Incidence 11·2%. Mean age 62 years. Emergency admission patients and infrequent turning.
Kottner and Dassen (2010) Germany	Two ICUs	To assess interrater reliability and validity of Braden and Waterlow scores and subjective pressure ulcer risk assessment	Observational study of two interrater reliability studies. Patients assessed by 53 nurses.	High degree of measurement error inherent in the two scores. The use of Braden or Waterlow for pressure ulcer risk on ICU patients not recommended.

Mechanical ventilation

Patients on mechanical ventilation were identified as at risk of pressure damage (Brindle, 2010). Likewise Nejs *et al.* (2008) found mechanical ventilation as a variable with positive association with patients developing a pressure ulcer 48 h prior to the occurrence.

Long surgery

Duration of surgery was seen to increase the incidence of pressure ulcer development (Keller *et al.*, 2002). Brindle (2010) identified an extended time in the operating department as a risk factor with the risk increasing after 4 h and then representing extreme risk at an 8-h duration.

Some risk factors identified in the review of the seven papers were not highlighted as key factors. This included variations found with age, as over 60 years old was identified as a risk factor by Frankel *et al.* (2007). However, Kaitani *et al.* (2010) found no relationship between age and pressure ulcer development, therefore age was excluded due to the differences. Also, spinal cord injury was not included as this was a very small group of patients who were generally picked up as very high risk of pressure ulcer damage using the other seven risk factors.

Development of the critical care assessment tool

International and national guidelines on pressure ulcer prevention identify the importance of having an assessment using a structured approach relevant to the health care setting and the assessment should to be targeted with timings and should allow for documentation (EPUAP and NPUAP, 2009; NICE, 2014). Considering these recommendations an assessment tool was developed.

Important parts of the assessment tool development were the tests of face validity and content validity. This was undertaken using an expert nursing consensus group which included: the nurse consultant in critical care, senior nurses and staff nurses from four critical care units with experiences in the following critical care specialities: cardiothoracic, liver, neuro-trauma, burns, medical and surgical; along with tissue viability nursing expertise. The high level of knowledge and experience of the subject matter 'critically ill patients at risk of pressure ulcer development' was present in this group, therefore all the identified risk factors were shared with this group and their agreement with the seven key risk factors provided an effective way to evaluate the tools' content validity. Face validity was tested as a way of ensuring the risk factors were appropriate and relevant, i.e. identify applicable patients at risk of pressure ulcer development. The expert consensus group viewed the seven risk factors as highly likely to identify what they were meant to identify, patients at risk of pressure ulcer damage.

As the intention was for the assessment tool to be easily applied on a 12 hourly shift basis and accepted as an appropriate tool by critical care nurses. The tool was designed with a definition for each risk factor to help understanding and application in a consistent way every 12 h. The tool was developed so that each patient would be assessed for each risk factor and then the number of factors added together to calculate a score. Each risk factor and the total score would be recorded in the nursing care plan documentation. The tool was developed with the intention that the higher the score, the higher the risk. The seven point pressure ulcer assessment tool was called Critical Care Pressure Ulcer Assessment Tool made Easy (CALCULATE) (Figure 1).

All critically ill patients were considered to be at a high risk due to the nature of their illness; however an important consideration was to calculate and identify those patients at an elevated risk (very high risk). Therefore two groups were created those at 'high' risk and those at 'very high' risk. Patients with four or more risk factors were classed as 'very high' risk and patients with three or less risk factors as 'high' risk. The cut of level of four risk factors was decided by testing the tool on a small number of patients and through discussion at the critical care expert nursing consensus group.

The risk factor tool CALCULATE and the plans for recording and frequency of assessments were presented to the critical care senior nurses for the four critical care units and accepted for implementation.

DISCUSSION

In the past, critically ill patients have been assessed for pressure ulcer risk using tools validated for acute care wards, but invalid for critical care departments so not necessarily the most useful (Cho and Hoh, 2009). This needs to change if critical care nurses are serious about achieving pressure ulcer reduction targets and more importantly preventing the associated severe consequences of pressure ulcer damage.

In the absence of current consensus, valid assessment scales and limited evidence for the most appropriate pressure ulcer assessment for critically patients, this literature review has systematically identified critical care risk factors to help assess critical care

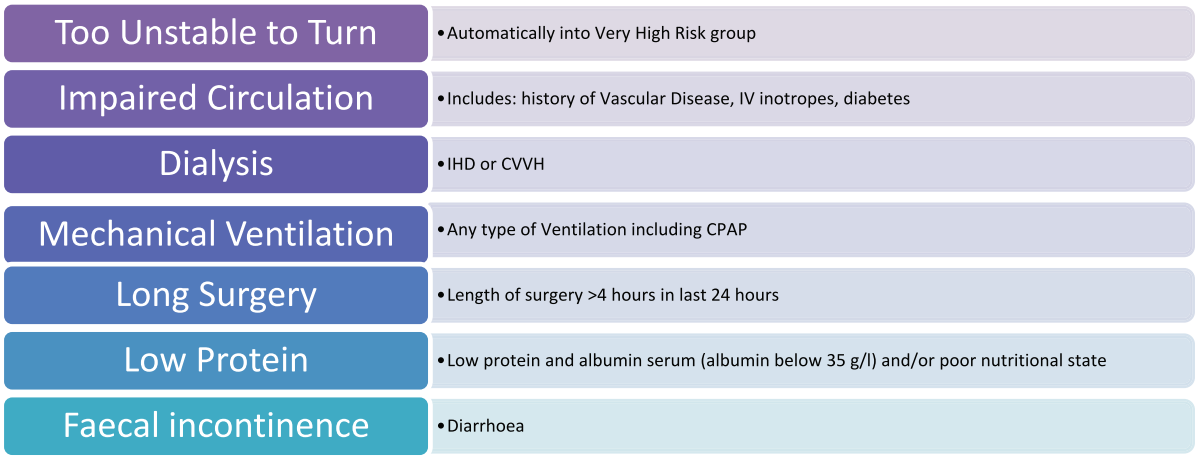

Figure 1 Seven point pressure ulcer assessment tool

patients at risk of developing pressure ulcers. 'CALCULATE' a locally developed assessment tool is certainly not seen as the definitive guide to pressure ulcer risk assessment in the critically ill patients. Nonetheless it has identified seven critical care risk factors drawn from the evidence and subsequently gained face validity by consensus agreement by a panel of expert critical care and tissue viability nurses. Therefore, it provides an important move forward and contribution towards the advancement and development of a more appropriate critical care pressure ulcer risk assessment tool for the future. In addition it helps to fulfil the recent NICE recommendations for nurses to carry out and document an assessment of pressure ulcer risk (NICE, 2014).

A real challenge in the development of assessment tools for critically ill patients is the need to develop a tool for easy and quick application. This quick and easy assessment needs to be balanced against the importance of providing valid comprehensive assessments. We chose seven risk factors and a simple count of each risk factor, with the view that the higher the score the higher the risk. This approach was reported by nurses in the four critical care units to be easy to use.

Some limitations exist with this literature review and the development of the pressure ulcer assessment tool. The literature review was not undertaken systemically therefore it is possible other evidence relating to critical care pressure ulcer assessment tools could be in existence. Also the identification of the most reliable risk factors may not have been appropriately acknowledged as the appraisal of each paper wasn't formally assessed using a recognized quality appraisal tool. The strength of each risk factor identified in the four papers using logistical regression analysis was not formally reviewed systematically and compared; these approaches would have provided a more robust indication of the likelihood of each risk factor influencing pressure ulcer development. However, the two reviewers were experienced critical care nurses and familiar with appraisal of evidence, plus the four papers utilizing logistical regression analysis were carefully considered to identify the most valid risk factors; these together reinforce the reliability of the identified risk factors.

Further limitations include the fact that the tool development did not allow for any weighting of each risk factor, and it is likely that some factors indicate a higher risk than others.

A specific weighting was applied to the risk factor 'too unstable to turn'. The expert nursing consensus group considered this factor to carry the highest level of risk in comparison to the others. This opinion on this highest level of risk was based on the likelihood of these patients having circulatory and or oxygenation difficulties producing impaired circulation and the limited ability to relieve pressure through turning due to instability. In order to deal with this opinion, patients identified as 'too unstable to turn' were automatically placed into the 'very high' risk group and interventions such as higher level of bed mattresses were suggested as part of a bundle of prevention interventions.

It is suggested that further research should be conducted to refine CALCULATE in the future, particularly to evaluate the application of appropriate weightings, for all the risk factors and to assess the reliability in practice.

CONCLUSIONS

In the absence of available valid critical care pressure ulcer assessment tools the development of 'CALCULATE', as part of a local quality improvement project to reduce pressure ulcers, should provide an informed approach using appropriate risk factors to assess critically ill patients. In the future, studies should concentrate on work to further validate critical care risk factors including 'CALCULATE' and to test the reliability and weighting of each factor as a predictor of risk.

WHAT IS KNOWN ABOUT THIS TOPIC

- Pressure ulcers cause serious patient and health care system outcomes.
- Critically ill patients have an increased incidence of pressure ulcers when compared with other acute care areas.

WHAT THIS PAPER ADDS

- Seven key pressure ulcer critical care risk factors indicating an elevated risk of pressure ulcer development.
- An easy, appropriate pressure ulcer risk assessment tool called 'CALCULATE'.

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7.4.8 Paper 8

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Part 2: pressure ulcer assessment: implementation and revision of CALCULATE

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ABSTRACT

Introduction: Critically ill patients are a vulnerable group at very high risk of developing pressure ulcers, and the incidence varies within critical care.

Methods: A number of strategies were used to implement the pressure ulcer assessment tool CALCULATE across four adult critical care units. Strategies included, nursing leadership, the provision of definitions for each risk factor, information laid out on posters at each patient's bedside, changes to pre-printed nursing documentation and a 30-min focused training package. Two local audits were conducted to measure the number and types of risk factors occurring in patients with pressure ulcers, and to assess the frequency of assessments and gain feedback on the usability of the tool in practice.

Findings: Critical care acquired pressure ulcer incidence was 3.4%. The two most commonly occurring risk factors were impaired circulation (82%) and mechanical ventilation (75%). Patients had a mean score of 4, and 65% had 4 or more reported risk factors. Feedback on the usability of the tool was mainly positive.

Discussion: The tool CALCULATE was relatively straightforward to implement and was likely to be due to the design and the various change strategies used to implement the new approach. The seven point tool was revised to an eight point score based on nurses' clinical feedback.

Conclusions: Research is required to further enhance and develop pressure ulcer assessment. Meanwhile CALCULATE offers an easy to use and appropriate tool to assist in the identification of patients at an elevated risk of pressure ulcer damage.

Implications for Practice: Careful choice of change management strategies are needed when implementing a new assessment tool. CALCULATE should be considered for use in critical care for pressure ulcer assessment, but used alongside nurses' clinical judgement and observations of skin.

Key words: pressure ulcer risk assessment • pressure ulcer risk factors • quality improvement

In the first part of this two part series of papers focussing on pressure ulcer assessment, we described techniques used to identify critical care risk factors and the development of a critical care pressure ulcer assessment tool called CACLCULATE. In this second part, the three aims were to highlight the incidence of pressure ulcers in critical care, to describe the implementation of the critical care pressure ulcer assessment tool CALCULATE and to provide a review of how CALCULATE was modified.

Critically ill patients have an increased incidence of pressure ulcers when compared to other acute care areas (Brindle, 2010; Alderden *et al.*, 2011; Lahmann *et al.*, 2011; Cox, 2013; Tayyib *et al.*, 2013) and within critical care variation exists in the reported incidence. Recently, pressure ulcer incidence was calculated in an intensive and high dependency unit in Finland and was found to be 11.1% (Ahtiala *et al.*, 2014). A similar incidence of 11.2% was reported from a Japanese critical care unit (Kaitani *et al.*, 2010). A higher incidence of 20% was found in Belgium on a surgical intensive care unit (ICU) (Nejs *et al.*, 2008), and another study quantified pressure ulcer incidence much lower at 3% (Frankel *et al.*, 2007). There are a few likely reasons to help explain the incidence rate variations. First, the probable case mix differences and the critical care levels included, such as whether or not the patients studied included ICU patients and/or high dependency patients. Another reason for the disparities is likely to have been due to the categories included to count pressure ulcer incidence; sometimes, the lowest level of skin damage 'category 1' is excluded in incidence reporting. In addition, moisture lesions are often

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excluded as not caused directly by pressure. Despite the pressure ulcer incidence reporting variations, the incidence rates at a local level within critical care were unknown and measurement was seen as a requirement by the local critical care nursing task force group.

Changing how we deliver care to make patient care safer is not straightforward. Therefore, careful choice of change management strategies to enable successful implementation of new nursing practices is an important step in improving patient safety. There are multiple models and theories to facilitate and hinder successful organisational change, but relatively few have been developed specifically for improving the patient safety agenda (Noble *et al.*, 2011). Notwithstanding the general limited evidence, a successful patient safety improvement approach was applied to a number of critical care units in the USA and achieved substantial reductions in central venous catheter infections (Pronovost *et al.*, 2006). Key to their success was senior leadership in each critical care unit, standardisation of available evidence procedures, communication improvements, training tools to improve safety culture and measurement of infections. The choices of implementation strategies to introduce a new pressure ulcer assessment tool were, therefore, carefully considered. They included some of the approaches identified by Pronovost (2006) as well as critical care nursing experience, from the expert consensus group, on techniques used to facilitate and support successful change within critical care.

IMPLEMENTATION OF THE LOCAL CRITICAL CARE ASSESSMENT TOOL

Nursing leadership

The critical care pressure ulcer prevention expert group which was set up to direct, facilitate and review all aspects of critical care pressure ulcer prevention as part of a quality improvement program, provided the overall leadership for the implementation of the pressure ulcer assessment tool. This expert group included the nurse consultant in critical care, a consultant in intensive care, senior nurses and staff nurses from four critical care units and had experience in the following critical care specialities: cardiothoracic, liver, neuro-trauma, burns, medical and surgical, along with tissue viability nursing expertise. The implementation plans were presented to the critical care senior nurses/matrons for the four critical care units, and their approval provided a further level of nursing support and leadership.

Staff training

To assist with the practice change, a short training session was designed using a set of power point slides to cascade information to all staff working in the four critical care units. It was designed as a 30-min focused session on the essential aspects of critical care pressure ulcer prevention. This included evidence about the impact of pressure ulcers, the incidence and assessment using the risk factor tool CALCULATE and prevention strategies. The session focused on the pressure ulcer risk factor assessment and how the score should be determined and documented. The training was delivered to nursing staff on each critical care unit by a range of staff including clinical nurse educators, a critical care nurse consultant and the expert nursing group which included senior nurses and staff nurses from four critical care units. These approaches were in line with the European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP and NPUAP) recommendations that pressure ulcer assessment should allow for documentation and should include time for educating professionals on accurate and reliable assessment (EPUAP & NPUAP, 2009).

Nursing guidance

CALCULATE was designed and laid out on an A4 document, laminated and placed at every bedside to enable the tool to be available for quick reference and guidance. Previous pressure ulcer assessment guidance of assessments was 'on admission' and 'every week' and had not been measured so the exact frequency was not known. However, the feeling was that assessments were generally completed every 4–5 days or on discovery of a pressure ulcer. Therefore, in order to capture any sudden changes in the patient's risk factors and help identify actions to be taken more quickly, the expert nursing consensus group recommended that a patient should be assessed using 'CALCULATE' every 12 h. This was specified as 'on admission' within the first 12 h, and then '12 hourly'. To enable the nursing assessments to be recorded on a 12-h basis, the risk factors were laid out within the pre-printed nursing care plan documentation.

The nursing assessment using CALCULATE involved three key steps. First, the nurse reviewed the patient and assessed how many of the risk factors the patient was affected by. The second step was to count the number of affected risk factors to establish a total score. Lastly, this total score was used to predict the level of risk, a total score of 0 risk factors was the lowest level of risk and a total score of 7 risk factors was the highest level of risk. In the development stage of CALCULATE (Richardson and Barrow, 2015), all critically ill patients were considered to be at a high level of risk due to the nature of their illness; however, patients with four or more risk factors were classed as 'very high' risk and patients with three or less risk

factors as 'high' risk. This level was decided by testing the tool on a small number of patients on the critical care units and through discussion with the critical care expert nursing consensus group.

Measurement of the tool

The pressure ulcer risk factor tool was implemented in May 2013, and 1 month after implementation, the task force group identified a requirement to audit two elements of the application in practice. This measurement was seen as an important part of the continuous process for quality improvement. Brandrud *et al.* (2011) identified measurement of practice as a key success factor of a continual improvement system. They particularly identified the importance of knowing how well the improvement work is going and measurements to understand why aims may not have been reached. Therefore, two parts of the practice change were audited and included:

- A review of the number and types of risk factors (using CALCULATE) occurring in patients with pressure ulcers.
- An audit of the frequency of the assessments against the 12-h standard and to gain feedback on the usability in practice.

A review of the risk factor tool 'CALCULATE'

A local audit was conducted on the four adult critical care units over a 4-month period (June–September 2013). The audit was designed to establish the type and number of risk factors identified on all patients presenting with pressure ulcers.

The risk factor data were collected retrospectively by the critical care nurse responsible for pressure ulcer prevention and tissue viability on each unit. This nurse was experienced and knowledgeable about the risk factors and had been involved in training of others on the risk factors. Secondary data were obtained from the local DATIX incident reporting system and from the nursing records of all patients presenting with pressure ulcers consecutively in the 4-month period. Patients with pressure ulcers of all categories 1–4, uncategorised and moisture lesions were included from the DATIX system and provided the information to calculate the incident rate. The critical care risk factor information was taken directly from the nursing records. There were no exclusion criteria.

A total of 110 patients with pressure ulcers were reported (Category 1–4, uncategorised and moisture lesions) on the DATIX reporting system. Of the 110 patients, 48 were admitted with an existing pressure ulcer and 62 developed a pressure ulcer in critical care. The total number of patients admitted in the 4-month period was 1820, providing a pressure ulcer incidence of 6% for all patients and 3.4% for patients developing a pressure ulcer whilst in critical care.

Table 1 Frequency of the reported risk factors

Risk factor	Ninety-two patients with reported pressure ulcer (%)	Thirty-five patients with PU on admission to critical care (%)	Fifty-seven patients with ICU acquired reported pressure ulcer (%)
Too unstable to turn	16 (17)	3 (9)	11 (19)
Low protein	53 (58)	27 (77)	26 (46)
Dialysis	36 (39)	8 (23)	28 (49)
Faecal incontinence	55 (60)	19 (54)	36 (63)
Mechanical ventilation	62 (67)	19 (54)	43 (75)
Long surgery	38 (41)	8 (23)	30 (53)
Impaired circulation	73 (79)	26 (74)	47 (82)

ICU, intensive care unit; PU, pressure ulcer.

Of the 110 patients reported with pressure ulcers, we were able to obtain 92 patients (84%) risk factor data which was collected from the nursing records. There were 18 missing patient data. Of the 92 patients with risk factor information, the location of pressure ulcers were reported as sacrum/buttocks 78% ($n=72$), heals 18% ($n=17$), head 1% (1), back 1% ($n=1$) and elbow 1% ($n=1$). Thirty-four percentage of patients were female and 66% were male. The age range was 18–97 years old, with a mean of 61 years old and median 63 years old. Thirty-five patients were admitted with an existing pressure ulcers and 57 developed a pressure ulcer in critical care.

Table 1 identifies the frequency each individual risk factors was identified on the 92 critically ill patients. This information is also split to provide detail on the 35 patients identified with pressure ulcers on admission to critical care, as well as the 57 patients who developed a pressure ulcer whilst in critical care. The two most commonly occurring risk factors with patients developing pressure ulcers whilst in critical care were impaired circulation (82%) and mechanical ventilation (75%). A slight difference was noted in the patients admitted to critical care with a pressure ulcer as the two most commonly occurring risk factors were low protein (74%) and impaired circulation (77%). In both groups, the least commonly occurring risk factor was too unstable to turn.

The overall scores calculated from the individual risk factors at the time the pressure ulcer was reported are displayed in Table 2. A wide spread in the total score for each patient was uncovered from 0 to 7 risk factors. Patients acquiring a pressure ulcer whilst in critical care had a mean score of 4 and 65% of these patients had

Table 2 Reported risk factor score

Total risk factor score	Ninety-two patients with reported PU (%)	Thirty-five patients with PU on admission to critical care (%)	Fifty-seven patients with ICU acquired reported PU (%)
0	1 (1)	0	1 (2)
1	4 (4)	2 (6)	2 (4)
2	17 (18)	8 (23)	9 (16)
3	21 (23)	13 (37)	8 (14)
4	25 (27)	7 (20)	18 (32)
5	13 (14)	2 (6)	11 (19)
6	7 (7)	3 (9)	4 (7)
7	4 (4)	0	4 (7)
	Mean 4	Mean 3	Mean 4

ICU, intensive care unit; PU, pressure ulcer.

4 or more reported risk factors. A focused review of the 35% of patients (n = 20) with a total score of 3 or less found the most common risk factor to be impaired circulation ($n = 13$) followed by mechanical ventilation ($n = 10$). The location of the pressure ulcers in the group of patients with a score of less than 3 was found to be sacrum/buttocks 65% ($n = 13$) and heal 35% (n-7).

Audit of the frequency and usability of CALCULATE

An audit was conducted throughout December 2013 and January 2014 to assess how often CALCULATE was documented and this was audited against the standard which was, within 12 h of admission and every 12 h. The audit also set out to obtain feedback on the usability and acceptability of the tool from critical care nurses using the tool in practice.

Data were collected retrospectively by the critical care nurse responsible for pressure ulcer prevention and tissue viability on each unit. A convenient sample of four patients' pressure ulcer risk assessments were reviewed from each of the four critical care units nursing records, providing a total of 16 individual pressure ulcer assessments. Twenty-five nurses from the four critical care units were asked their opinion on the use of the tool in practice

Seventy-five percent of pressure ulcer assessments were completed meeting the standard of within 12 h since admission. With the subsequent assessments, all patients were assessed every 2 days, although only 25% were undertaken every 12 h. A further 58% were undertaken every 24 h and 17% were assessed every 2 days.

A rating scale of 1–5 (1 = difficult and 5 = easy) was used to establish how easy the tool was to use in practice by staff nurses on the four units. All nurses rated the tool 3, 4 or 5, and the majority (65%) rated the tool with the highest score of 5 (easy). The nurses individual comments included 'good and less paper work', 'need a date on the documentation so know when assessments due' and 'need to include a factor to capture patients on sedation and with mobility problems'. A further observation was the need to improve definitions used, to guide nurses on the assessment of each risk factor, as often this was reported as subjective and could be more objective.

FURTHER MODIFICATIONS TO CALCULATE

Following the audit and staff feedback on CALCULATE, the findings were reviewed by the critical care expert consensus group. This review resulted in adding an extra risk factor to capture patients with impaired mobility. This factor was viewed by the expert group to be a very important risk factor and not explicit enough within the tool. Each of the risk factor definitions were reviewed and enhanced to help nurses with a more objective assessment of each risk factor (Figure 1). CALCULATE was revised from a seven point score to an eight point score. The nursing documentation was also reviewed and changed to include a date, so it was clearer when the 12-h assessments were due to be completed.

DISCUSSION

Pressure ulcer incidence varies widely in critical care; we uncovered an incidence of 3.4% which was similar to the low incidence reported by Frankel *et al.* (2007). The incidence rate of 3.4% included all categories of pressure ulcers and moisture lesions. Others have reported much higher rates of critical care pressure ulcer incidence (Nejs *et al.*, 2008; Kaitani *et al.*, 2010; Ahtiala *et al.*, 2014). Explanations for the varying rates are likely to be with the various methods used to calculate incidence, particularly with the varying categories of pressure ulcers included in the calculations, plus whether those pressure ulcers included were truly critical care acquired. Despite the varying incidence, pressure ulcers are often preventable (NICE, 2014) and pressure ulcer assessment is an important first step in the prevention of serious consequences such as pain, scaring and increased likelihood of survival (Alderden *et al.*, 2011; Tayyib *et al.*, 2013).

The implementation of CALCULATE, a new pressure ulcer risk assessment tool, was relatively straightforward to implement. A reason for this may well have been due to the lack of confidence in the use of Braden as an appropriate valid tool for the critically ill, plus the varied approaches used to facilitate the changes in practice. Strong nursing leadership with credible critical care nursing expertise from each of the four units

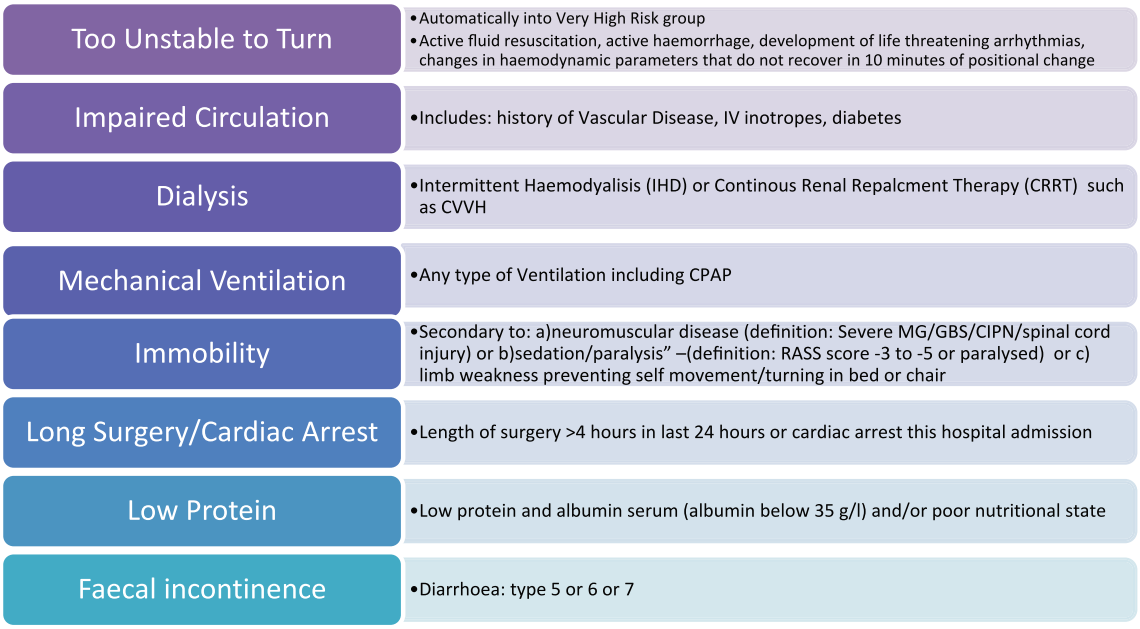

Figure 1 Eight point pressure ulcer assessment tool (CALCULATE). CIPN, Chemotheraphy Induced Peripheral Neuropathy; CPAP, Continuous Positive Airway Pressure; CVVH, Continuous Veno Venous Hemofiltration; GBS, Guillain-Barre Syndrome; MG, Myasthenia Gravis; RASS, Richmond Agitation Sedation Score.

was seen as a key success factor, as highly influential in convincing the staff of the need for change.

The audit data measuring how well the tool was used in practice uncovered most nursing assessments of pressure ulcer risk documented as a minimum of every 2 days and the majority of assessments every 24 h. Prior to the implementation of CALCULATE, the standard for assessments were, on admission and then every week, and although this had not been measured, the feeling was that the assessments were generally completed every 4–5 days. Therefore, since the introduction of CALCULATE, the frequency of pressure ulcer assessments was likely to have increased. Despite this likely improvement, further attention to improve compliance and meet the 12-h standard was indicated, such as providing space for timings to be recorded within the nursing assessment records to clearly identify when the last assessment occurred.

The pressure ulcer incidence data and the associated risk factors have identified the types of risk factors occurring in patients with pressure ulcers. The most frequently occurring risk factor on patients who developed a pressure ulcer whilst in critical care was impaired circulation (82%). This factor was a comparable to previous critical care finding (Keller *et al.*, 2002; Frankel *et al.*, 2007; Nejs *et al.*, 2008; Brindle, 2010). Likewise, the second most frequently occurring risk factor was mechanical ventilation (75%), and again this factor was identified in other studies (Nejs *et al.*, 2008; Brindle, 2010). Together this supports the importance of identifying patients with impaired circulation and mechanical ventilation as critical risk factors, indicating an elevated risk of developing pressure ulcers.

Even though all critically ill patients can be considered to be at a high risk due to the nature of their illness, in this quality improvement project, patients with 4 or more factors were classed as 'very high' risk and patients with 3 or less risk factors classed as 'high' risk. This grouping may not be the most reliable or indicative of risk, nonetheless the groupings provided a start to base future developments. A wide range of scores (0–7) were uncovered in patients with pressure ulcers. Even though the highest number of patients had a total score of 4 and 5 risk factors, it is important to acknowledge that this tool does not replace nurses' clinical judgement and observations of skin, as others worthwhile methods to assess patient risk. The other nursing observations and judgements should complement assessment tools such as CALCULATE. Consequently, the refined eight point risk factor tool 'CALCULATE' should be seen as an 'aide memoire' to assist nurses in their assessment of critically ill patients.

Despite only 16 nurses expressing their perceptions on CALCULATE, it was viewed by all as easy to use in practice. Factors viewed to have contributed to this positive perception were the support of a laminated bedside tool which included definitions for each risk factor. In addition, a relatively short but focused training delivered to staff to support the implementation.

Limitations exist with the implementation and evaluations undertaken with this quality improvement programme. Many change strategies exist and those chosen were not necessarily the best or most successful as no measurement of these approaches were undertaken. The evaluation of the risk factors identified in patients with pressure ulcers was not compared to data from patients without pressure ulcer occurrence; therefore, no comparisons can be made to identify risk factors in the two different groups. In addition, only small amounts of data were collected over a 4-month period from four critical care units limiting the generalizability of the findings. As nurses opinions on the tool were established from a small sample, the finding may have been biassed, and similarly only 16 individual pressure ulcer assessments were reviewed, so these small evaluations may have missed important issues therefore placing a query over the accuracy of the feedback.

CONCLUSIONS

It is hoped that the development, implementation, evaluation and refinement of the pressure ulcer risk assessment tool 'CALCULATE' provides valuable progress in the pursuit to assess and prevent pressure ulcers in the critically ill. 'CALCULATE' may well be an easier and more appropriate assessment tool to assist in the accurate identification of patients at an elevated risk of pressure ulcers.

Further work should concentrate on larger sample sizes, and consideration should be given to investigating an ideal threshold for patients at the highest level of risk. This could be done by comparing the scores from a group of patients with pressure ulcers against patients without pressure ulcers. This will hopefully more accurately signal patients at a 'very high' risk or whether a more graduated risk is more reliable. The overall aim of future research should be to provide critical care nurses with stronger evidence to guide pressure ulcer risk assessment.

WHAT IS ALREADY KNOWN?

- International data reports varying levels of critical care pressure ulcers incidence.
- Multiple models and theories to facilitate and hinder successful organisational change are well known.
- Relatively few change models have been developed specifically for improving patient safety.

WHAT THIS PAPER ADDS

- A multi-method approach to implement a new critical care assessment tool.
- Information on risk factors associated with critical care patients with pressure ulcers.
- A revised eight point risk factor tool to assess pressure ulcer assessment in the critically ill.

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7.4.9 Paper 9

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A critical care network pressure ulcer prevention quality improvement project

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ABSTRACT

Background: Pressure ulcer prevention is an important safety issue, often underrated and an extremely painful event harming patients. Critically ill patients are one of the highest risk groups in hospital. The impact of pressure ulcers are wide ranging, and they can result in increased critical care and the hospital length of stay, significant interference with functional recovery and rehabilitation and increase cost.

Aims: This quality improvement project had four aims: (1) to establish a critical care network pressure ulcer prevention group; (2) to establish baseline pressure ulcer prevention practices; (3) to measure, compare and monitor pressure ulcers prevalence; (4) to develop network pressure ulcer prevention standards.

Methods: The approach used to improve quality included strong critical care nursing leadership to develop a cross-organisational pressure ulcer prevention group and a benchmarking exercise of current practices across a well-established critical care Network in the North of England. The National Safety Thermometer tool was used to measure pressure ulcer prevalence in 23 critical care units, and best available evidence, local consensus and another Critical Care Networks' bundle of interventions were used to develop a local pressure ulcer prevention standards document.

Results: The aims of the quality improvement project were achieved. This project was driven by successful leadership and had an agreed common goal. The National Safety Thermometer tool was an innovative approach to measure and compare pressure ulcer prevalence rates at a regional level. A limitation was the exclusion of moisture lesions.

Conclusion: The project showed excellent engagement and collaborate working in the quest to prevent pressure ulcers from many critical care nurses with the North of England Critical Care Network.

Relevance to clinical practice: A concise set of Network standards was developed for use in conjunction with local guidelines to enhance pressure ulcer prevention.

Key words: collaborative working • critical care network • NHS Safety Thermometer • pressure ulcers • quality improvement

Pressure ulcer prevention is an important safety issue, often underrated and an extremely painful event harming patients. Pressure ulcers can result in a number of adverse health outcomes such as increased morbidity and mortality, reduced quality of life and they constitute a significant financial burden to the National Health Service (NHS) (Reddy *et al.*, 2006). The impact of pressure ulcers for critical care patients are wide ranging, and they can result in increased critical care and the hospital length of stay; significant interference with functional recovery and rehabilitation; and pain (Theaker *et al.*, 2000; Reddy *et al.*, 2006; Elliot *et al.*, 2008). The financial implications associated with pressure ulcers are substantial. In 2004, the estimated annual cost of pressure ulcer care in the UK was between £1.4 billion and £2.1 billion per year, and the mean cost of treatment per patient for a grade IV pressure ulcer was calculated to be £10 551 (Bennett *et al.*, 2004). A more recent estimate was that the cost of treating a pressure ulcer highlighted as £1214 for a category 1 and £14 108 for a category IV [National Institute Clinical Excellence (NICE), November 2014].

All patients in hospital are potentially at risk of developing a pressure ulcers, but critically ill patients are at a higher risk (Elliot *et al.*, 2008; Brindle, 2010; Tayyib *et al.*, 2013). Despite the higher risk, it is difficult

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to estimate the true incidence and prevalence rates of pressure ulcers due to wide variation in methods of classifying and reporting. This variation includes the different definitions for pressure ulcer categories, the denominator or population studied and the identified care setting. Nevertheless, reported prevalence rates have ranged widely from 3% to 48% for hospital populations (Bours *et al.*, 2001; Elliot *et al.*, 2008; Vermette *et al.*, 2012). A survey of 25 hospitals in five European countries identified a pressure ulcer prevalence (grade 1–4) of 18.1%, and if grade 1 ulcers were excluded, it dropped to 10.5% (Vanderwee *et al.*, 2007).

Evidence has shown that pressure ulcer development is more prevalent in specific populations such as those patients receiving mechanical ventilation and with multiple comorbid states (Theaker *et al.*, 2000; Pender and Frazier, 2005; Alderden *et al.*, 2011), also patients with a neurological condition, and those who have impaired mobility and impaired nutrition (Alderden *et al.*, 2011). Other factors putting critical care patients at increased risk include use of vasopressors, mechanical devices and invasive catheters (dialysis, central venous catheters and drains) (Cox, 2011; Cooper, 2013).

Recently, from a national UK perspective, the importance of pressure ulcer prevention has been raised as a high patient safety priority. The Chief Nursing Officer and the NHS Medical Director (DH, 2012) identified pressure ulcers as a key quality policy issue for improvement in care. The status of pressure ulcer prevention has been raised further within the Department of Health's NHS Outcomes Framework 2014/2015 (DH, 2013), it includes pressure ulcer prevention within domain 5 'Treating and caring for people in a safe environment and protecting them from avoidable harm'. Further emphasis has been placed on pressure ulcer prevention through the introduction of a national Commissioning for Quality and Innovation (CQUIN) target to measure pressure ulcer prevalence through the NHS Safety Thermometer, as a way of obtaining more systematic and robust data available in an open and transparent format (DH, 2012).

The NHS Safety Thermometer is a quick and simple point of care survey instrument, used as an improvement tool for measuring, monitoring and analysing patient harm and harm free care. It can be used to measure local and system progress in providing a care environment free of harm for our patients. The original programme had four key areas for measurement and improvement; one of four areas was to reduce pressure ulcers (NHS Safety Thermometer, 2013).

Critical Care Networks are well placed to facilitate quality improvement across a number of critical care departments. One of their key functions is to develop common standards across critical care specialities within a geographical area (DH, 2000). Within the North of England Critical Care Network (NoECCN), there are well established communication channels between all critical care units within acute hospitals and systems set up to share and collaborate within the North of England region. Therefore, a Network pressure ulcer prevention quality improvement project was initiated, as an ideal opportunity for nurses within critical care units to work in a cohesive and collaborative manner and to tackle this patient safety problem. The national focus on pressure ulcer prevention provided an increased awareness of strong desire by nursing leaders from critical care units to work together to maximise sharing and learning, and to prevent pressure ulcer damage. Nursing leaders were keen to understand and compare pressure ulcer prevalence rates within the NoECCN and to set region wide standards to help prevent pressure ulcers.

AIMS OF THE NETWORK QUALITY IMPROVEMENT PROGRAMME

This quality improvement project had four key aims. These were:

- To establish a critical care network pressure ulcer prevention group
- To perform a benchmark exercise to establish a baseline of pressure ulcer prevention practices
- To measure, compare and monitor pressure ulcers prevalence rates across a critical care Network
- To develop NoECCN pressure ulcer prevention standards for critically ill patients

THE NETWORK QUALITY IMPROVEMENT PROGRAMME

Development of a Critical Care Network pressure ulcer prevention group

Initially, within the NoECCN, a scoping exercise was undertaken by the project leadership to develop a pressure ulcer prevention group. The project leadership included a nurse consultant in critical care and two lead nurses from the NoECCN. The lead nurses from each unit were contacted by the project leadership via email and asked to identify a representative from their critical care unit to participate in the project. Nursing representation from all critical care units within the region was established. The NoECCN supported and coordinated the group. A consensus group methodology was chosen to engage expert clinicians and encourage maximum participation (Rycroft-Malone, 2001; NICE, 2004)

The pressure ulcer prevention group met on a quarterly basis for a 12-month period with timetabled

meetings arranged throughout the programme. At the first meeting, a common goal 'to improve pressure ulcer damage' was agreed. Group objectives were discussed, and consensus agreement was reached on the following:

- To undertake a benchmarking exercise to review current pressure ulcer prevention practices within units
- To share, compare and monitor pressure ulcer prevalence rates through a Network telephone survey and NHS Safety Thermometer
- To develop NoECCN pressure ulcer prevention standards for critically ill patients

Benchmarking exercise

A proforma was designed to capture benchmarking practices from each critical care unit. Then one of the NoECCN lead nurses telephoned the identified pressure ulcer prevention nurse from each critical care unit to obtain information on key areas of practice within their critical care unit. The key areas of practice explored were a review of the pressure ulcer risk assessment, prevalence/incidence monitoring, bed mattresses, seating equipment, skin cleaning products and any successful pressure ulcer prevention strategies adopted on their critical care unit.

The data were analysed using Microsft Excel® an electronic spreadsheet to store, organise and analyse data. This was presented back to the Network Critical Care pressure ulcer prevention group.

Measurement and monitoring of pressure ulcer prevalence

Evidence supports the use of nursing directed prevalence audits as a way of decreasing the development of pressure ulcers (Cooper, 2013). Pressure ulcer prevalence data were one of the NHS Safety Thermometer data requirements for each organisation, and data submission involved data collection in a consistent way on a monthly basis. Using this information prevented duplication of data capture and submission, plus it was designed as a quick and simple improvement tool for local measuring, monitoring and analysing patient harm and harm free care (NHS Safety Thermometer, 2012). Therefore, using the pressure ulcer prevalence data from NHS Safety Thermometer was agreed as the tool to be used to ascertain the current level of pressure ulcer prevalence across the Network by the NoECCN pressure ulcer prevention group.

Not all critical care units were submitting their pressure ulcer prevalence data into the NHS Safety Thermometer tool; however, compliance with data submission increased overtime. Chart 1 shows the percentage of critical care units from the NoECCN submitting data to the NHS Safety Thermometer, overtime. In April 2012, there were eight critical care units (33%) submitting data, this increased to 20 units (83%) by August 2012 and 23 units (100%) by August 2013, when all units within the NoECCN were submitting data. From April 2014, there have been 21 units submitting data (95%), the reduction in the number of units was due to a unit closure and reconfiguring of a unit; and one unit not submitting any data.

In order to monitor and compare the pressure ulcer prevalence rates across the NoECCN critical care units, the data were presented using a series of run charts. Run charts were chosen as a method to plot data, in an ordered sequence, over a period of time and allows for visual appreciation of the data and identification of trends, shift and stability (Gershengorn *et al.*, 2014b). Data were collected and submitted to the NHS Safety Thermometer on a monthly basis; however, the pressure ulcer prevention group agreed to monitor and compare the data presented in quarterly time plots on the run charts. On review of first 3 months of data, peaks (high rates) and troughs (low rates) in the prevalence rates were noticeable across the units resulting in trends not quickly visible. Therefore, a quarterly frequency was chosen to enable the data to be viewed in a more stable format.

A further data monitoring strategy was to compare units against each other. It was agreed to present and compare the data using the three main critical care specialities, these were:

- General critical care
- Cardiothoracic critical care
- Spinal and neurocritical care

An example of the run chart used for the cardiothoracic critical care units within the NoECCN is provided in Chart 2.

During the 2 year and 9 month period, pressure ulcer prevalence data were collected and ranged from a quarterly rate of 5.0–8.9%. Table 1 displays the quarterly pressure ulcer numbers, patients surveyed and average prevalence rates across the NoECCN. Chart 3 shows the average pressure ulcer prevalence rates on a quarterly basis.

Development of NoECCN pressure ulcer prevention standards

The benchmarking exercise was shared within the pressure ulcer prevention group, and it identified that there were differences in the clinical practices used to prevent pressure ulcers in critical care. For example, the frequency of pressure ulcer risk assessments

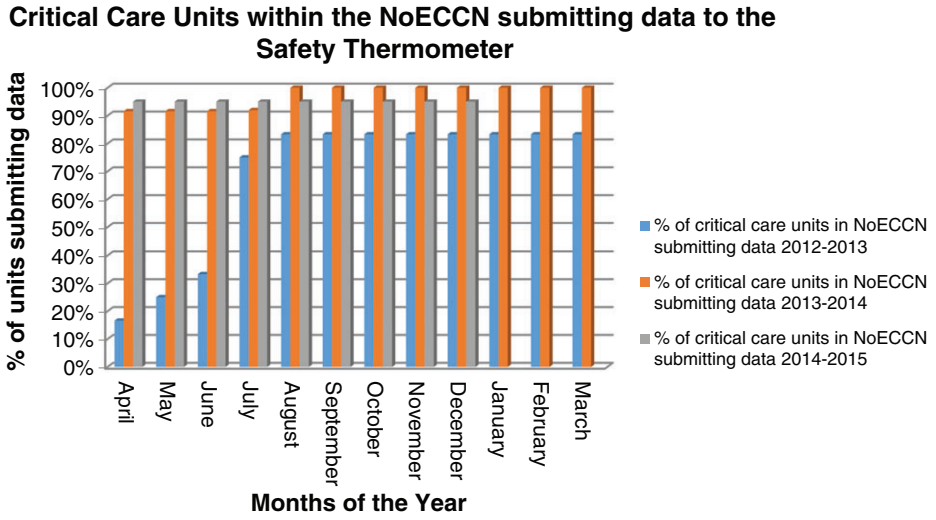

Chart 1 Critical care units submitting data from April 2012–March 2014. NoECCN, North of England Critical Care Network.

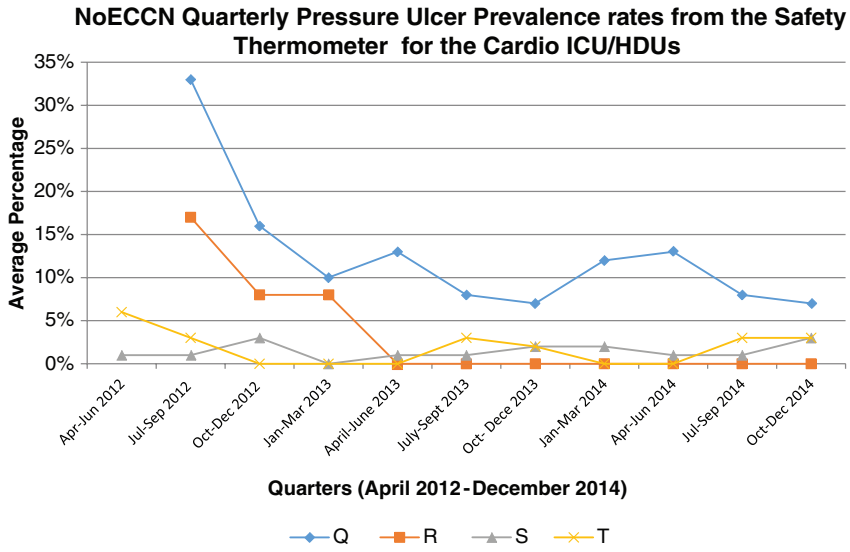

Chart 2 Data submission per quarter for the cardiothoracic intensive care unit (ICU)/high dependency units (HDUs) within the North of England Critical Care Network (NoECCN).

undertaken varied from every shift to weekly. Plus the types of pressure relieving mattresses used for critically ill patients involved standard foam, gel-filled and a number of dynamic systems such as alternating pressure devices (sequentially inflating and deflating) and low airloss devices (support on air filled sacs inflated at constant pressure, through which air can pass). Therefore, the NoECCN pressure ulcer prevention group developed a set of minimum standards based on best available evidence, local consensus and another Critical Care Networks' bundle of high impact interventions to reduce pressure ulcers (Baldwin and Berry, 2012). A document was produced called 'Reducing pressure ulcers for critically ill patients' (NoECCN, 2013) with the following key parts: aims, objectives, pressure ulcer risk assessment, prevention strategies categorised into four key elements known as a 'SKIN' bundle. The 'SKIN' bundle represented the following; **S**urface, **K**eep moving, **I**ncontinence and **N**utrition (Chart 4). The standard document was launched at the NoECCN Lead Nurse clinical forum meeting in February 2013.

DISCUSSION

This quality improvement programme achieved its aims. First, a critical care network pressure ulcer prevention group was established and involved a nurse

Table 1 NoECCN quarterly pressure ulcer prevalence numbers and rates

	April–June 2012	July–September 2012	October–December 2012	January–March 2013	April–June 2013	July–September 2013	October–December 2013	January–March 2014	April–June 2014	July–September 2014	October–December 2014
Total number of pressures ulcers reported	18	51	49	47	50	51	44	69	42	51	40
Total number of patients monitored	302	656	696	717	757	698	768	775	662	782	803
NoECCN mean	6%	7.8%	7.0%	6.6%	6.6%	7.4%	5.7%	8.9%	6.3%	6.5%	5.0%

NoECCN, North of England Critical Care Network.

from each critical care unit who then played a key role in the development and agreement of the minimum standards. Key success factors with this group were with the project leadership, an agreed common goal, consensus agreement and regular timetabled meetings. The meetings allowed for the sharing of expert knowledge, constructive discussion and consensus decision making to inform good practice standards. Overall, it enabled learning and sharing across organisational boundaries.

Benchmarking is a useful tool as part of a quality improvement initiative, as it allows for peer comparison and this identifies strengths and weaknesses (Gershengorn *et al.*, 2014a). We found the benchmarking exercise and feedback on practices associated with pressure ulcer prevention, uncovered wide variations in standard practices and reinforced the need for the development of a core set of NoECCN pressure ulcer prevention standards. The process of agreeing the NoECCN standards took several months which allowed for all critical care units to participate, discuss and agree with the core set of standards. The challenge with maintaining the group overtime included difficulties for staff gaining the required time to be away from the critical care units to attend meetings, this was sometimes due to staffing pressures within the clinical areas, and resulted in limited attendance at some meetings. This provided challenges with communication, so information on progress was emailed to supplement the discussion and communication at meetings. A key success of this part of the improvement programme was the drive and motivation of the project leadership, and the determination by all involved to improve pressure ulcers within the region. A key output was a concise, user friendly document to be used in conjunction with local guidelines for each critical care unit.

This improvement project also produced regular pressure ulcer prevalence rates for comparisons across a Network using the NHS Safety Thermometer tool (NHS Safety Thermometer, 2013). Utilising the existing NHS Safety Thermometer data avoided data being collected twice, making a more efficient use of resources.

Initially, all critical care units within the Network were not involved in the submission of data into the NHS Safety Thermometer (NHS Safety Thermometer, 2013); however, all critical care units were engaged in the quality improvement programme. The engagement in this quality improvement programme focussing on pressure ulcer prevention was likely to have encouraged those not submitting, to submit data, as they were easily identifiable by their peers as not compliant with data submission and subsequent comparisons.

Obtaining the data from the NHS Safety Thermometer tool was not straightforward, each unit had a

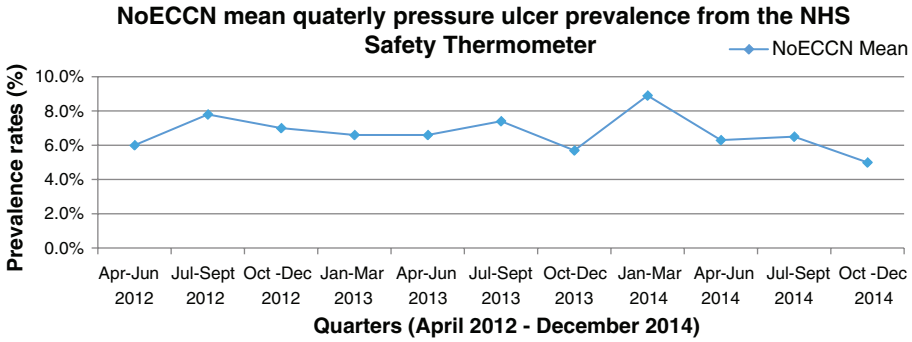

Chart 3 Mean prevalence for all units submitting data within the North of England Critical Care Network (NoECCN).

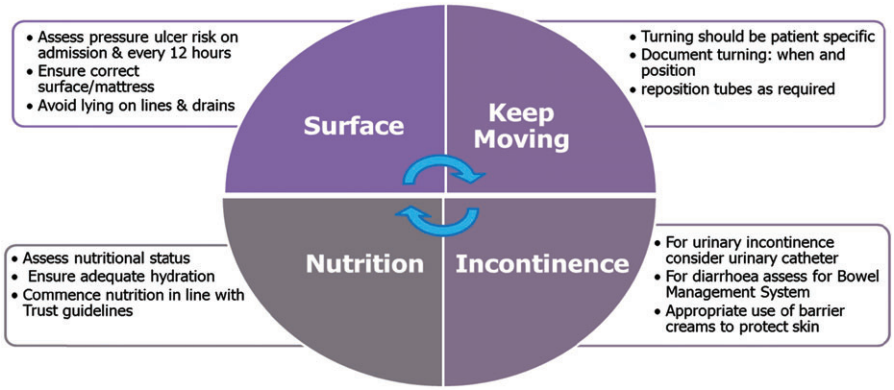

Chart 4 North of England Critical Care Network (NoECCN) SKIN bundle.

specific unit identifier used to submit data and the NoECCN staff extracting the information from the tool did not know the code for each unit. This required a contact with each unit to find out the unique code so the relevant data were utilised on the run charts. In addition, the NHS Safety Thermometer recommended prevalence survey data to be submitted each month within a specific 10-day period, to allow the data to be released on a specific date each month. In reality, the NoECCN found a delay in this data being released and so gaining access to the information. The NoECCN were required to adjust their timescales in response to this delay. Also compiling the data from the NHS Safety Thermometer was time consuming initially, so care and attention were required to ensure that the data were obtained correctly from each critical care unit within the region, and then transcribed onto the run charts for the comparisons.

Some limitations with this programme existed. First, the data used from the NHS Safety Thermometer were monthly prevalence data, so provided a snap-shot of the percentage of patients with pressure ulcers on 1 day each month. The data were not validated by the network as the numbers were simply transferred directly from the Safety Thermometer into the NoECCN data monitoring system. In addition, each critical care units' level of compliance with the NoECCN core standards was not measured; therefore, how well they were applied in practice was not identified. A future work stream for the NoECCN is to audit the unit compliance with the pressure ulcer prevention standards. This future work stream should further reduce pressure ulcers, as measuring process compliance as part of a quality improvement programme, serves to isolate which parts of the process fall short of current standards and can then be targeted for quality improvement (Gershengorn *et al.*, 2014a).

Another limitation is with what is included within the NHS Safety Thermometer data for reporting pressure ulcers. It requires data to be submitted to include pressure ulcer damage of categories 2–4 and those unable to be categorised. Therefore, data on patient harm including moisture lesions and category 1 pressure ulcers are excluded from the rates. The NoECCN plans to undertake a separate piece of work to monitor moisture lesions within critical care units as these lesions cause similar serious outcomes such as pain, discomfort, increased risk of wound infection and sepsis to patients (Reilly *et al.*, 2007).

Future plans for the NoECCN are to continue to collect the monthly pressure ulcer prevalence rates from the NHS Safety Thermometer for each critical care unit and to share and compare the data on a quarterly basis with the NoECCN using the run charts. It is hoped that this will provide further opportunities to review trends and identify improvement.

CONCLUSIONS

This pressure ulcer prevention quality improvement project has provided a high level of critical care nursing engagement from units within the NoECCN. It has shown collaborative working with a common goal to tackle a major patient safety problem through sharing expert knowledge and the development of NoECCN pressure ulcer prevention standards. This quality improvement programme has demonstrated an innovative approach to using the NHS Safety Thermometer data to monitor and compare pressure ulcers prevalence within a large geographical area with many critical care specialities.

It is hoped that overtime improvements in pressure ulcer prevalence will be realised across the NoECCN, and the data reporting will be ideally placed to evidence these improvements across the North East of England.

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WHAT IS KNOWN ABOUT THIS TOPIC?

- Pressure ulcers result in adverse health outcomes; they cause pain, interfere with functional recovery and rehabilitation and increase morbidity and mortality.
- Pressure ulcers constitute a significant financial burden for the NHS.
- Pressure ulcers are often preventable.

WHAT THIS PAPER CONTRIBUTES

- Pressure ulcer prevalence rates from 23 critical care units over a 2-year and 9-month period.
- A quality improvement programme utilising the NHS Safety Thermometer tool to monitor and compare critical care pressure ulcer prevalence.
- A concise set of critical care pressure ulcer prevention standards agreed by a wide consensus group of critical care nurses.

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7.4.10 Paper 10

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Quality in Practice

Quality in Practice

Reducing the incidence of pressure ulcers in critical care units: a 4-year quality improvement

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Abstract

Quality problem: Critical care patients often have several risk factors for pressure ulceration and implementing prevention interventions have been shown to decrease risk.
Initial assessment: We identified a high incidence of pressure ulcers in the four adult critical care units in our organization. Therefore, avoiding pressure ulceration was an important quality priority.
Choice of solution: We undertook a quality improvement programme aimed at reducing the incidence of pressure ulceration using an evidence-based bundle approach.
Implementation: A bundle of technical and non-technical interventions were implemented supported by clinical leadership on each unit. Important components were evidence appraisals; changes to mattresses; focussed risk assessment alongside mandating patients at very high risk to be repositioned two hourly; and staff training to increase awareness of how to prevent pressure ulcers.
Evaluation: Pressure ulcer numbers, incidence and categories were collected continuously and monitored monthly by unit staff. Pressure ulcer rates reduced significantly from 8.08/100 patient admissions to 2.97/100 patient admissions, an overall relative rate reduction of 63% over 4 years. The greatest reduction was seen in the most severe category of pressure ulceration. The average estimated cost saving was £2.6 million (range £2.1–£3.1).
Lessons learned: A quality improvement programme including technical and non-technical interventions, data feedback to staff and clinical leadership was associated with a sustained reduction in the incidence of pressure ulceration in the critically ill. Strategies used in this programme may be transferable to other critical care units to bring more widespread patient benefit.

Key words: quality improvement, patient safety, pressure ulcers, intensive care

Quality problem

Prevention of pressure ulcers is of great importance due to serious patient consequences including pain and scarring, increased length of hospital stay and mortality [1]. For healthcare organizations, there are also significant cost pressures totalling £1.4bn–£2.1bn per annum in the UK [2] and reputational implications associated with pressure ulcers. Reported incidence of pressure ulcers in critical care varies from 3% [3] to 20% [4] suggesting a potential opportunity to reduce avoidable harm. Critical care patients have numerous risk factors for pressure ulceration including incontinence, immobility, impaired nutrition, mechanical ventilation and inotropes [5, 6]. In addition, poor oxygenation and tissue perfusion associated with one or more organ failures also make the critically ill vulnerable to

pressure ulcers [7]. A large percentage of critically ill patients demonstrate some or all of these risk factors and are a high-risk group for developing pressure ulcers [8]. Staff attitudes present a further challenge, since pressure ulcers may be viewed as being inevitable in the critically ill, due to the complexity of patient conditions and associated risk factors [9].

Initial assessment

In 2012, the National Health Service (NHS) identified pressure ulcer prevention as a quality improvement target [10]. At the same time, we identified a high incidence of pressure ulcers in the four adult critical care units in our organization and therefore aimed to prevent pressure ulcers using a quality improvement methodology. A numerical target for improvement was not set at the beginning of the programme.

The setting for the improvement programme was four adult critical care units (intensive care and high dependency beds) within a NHS organization on two acute hospital sites. The units had the following number of beds and case-mix:

1. Cardiothoracic critical care unit: following urgent and routine major cardiac and thoracic surgery, including heart and lung transplantation, 24 beds
2. General critical care unit specializing in transplantation of the liver, pancreas and kidneys, vascular surgery, hepatobiliary surgery, severe pancreatitis and advanced cancer care, 22 beds
3. General critical care unit specializing in complex gastric and plastic surgery, burns and long-term ventilation and medical emergencies, 20 beds
4. Neuro/trauma critical care unit specializing in major neurosurgery and traumatic injury, 22 beds

Choice of solution

At the beginning of the improvement programme, a review of the literature revealed a number of studies focussing on single interventions to prevent occurrence, such as those addressing mobility, nutrition or skin health [11]. Implementation of a number of pressure ulcer improvement interventions together in critical care, as a bundle approach, was not well reported. A recent publication from one intensive care unit introduced a bundle of interventions using a Plan, Do, Study, Act (PDSA) approach but was limited to 12 months [12]. Aside from pressure ulcers, other quality improvement programmes in critical care have demonstrated impressive patient safety improvements when a bundle approach was implemented, such as with central venous catheter infections [13, 14]. Given the evidence pointed towards multiple small interventions being important we chose a bundled approach to try to reduce this important source of harm.

Implementation

Programme leadership

Overall programme leadership was provided by the nurse consultant in critical care. A pressure ulcer task group was established to lead, direct and facilitate the implementation of the improvement programme. The task group included the nurse consultant in critical care at least one charge nurse or staff nurses from each of the four units, a consultant in critical care medicine, a critical care data monitoring specialist and a tissue viability nurse specialist. The task group met every 1–2 months to discuss the strategy, share evidence reviews and to develop guidance.

Pressure ulcer prevention interventions

Careful consideration was given to the choice of pressure ulcer prevention interventions. Parallels were noted between infection prevention and pressure ulcer prevention, as both were seen as opportunities for the reduction of avoidable harms and both were key patient safety priorities for critical care. A combination of technical and non-technical interventions, process measures plus a measurement of improvement were utilized throughout the 4-year period (Table 1).

In the first 12 months (January–December 2012), we appraised the published evidence to identify the parts of the bundle for implementation. National and European clinical guidelines were reviewed [15, 16] and re-reviewed when updated when published guidance published [17] to ensure the interventions to be implemented were in line with best practices. We focussed our appraisal on key areas such as valid pressure ulcer assessment [18], turning regimes, seating regimes, mattress choice, skin care and incontinence management. The topics were shared out within the task group and each member of the group reported back on their appraisal of important aspects of pressure ulcer prevention at the monthly task group meetings. The other interventions undertaken by the task group included revising the existing nursing care plan and nursing documentation, developing a new pressure ulcer risk assessment tool, updating the pressure ulcer prevention guidance and introducing the new pressure relieving mattresses for the highest risk patients. In addition, after analysis of early results, which highlighted a significant proportion of moisture lesions a greater focus was given to the use of bowel management systems and skin care. When process measures later identified a delay in the use of bowel management systems a critical care Bowel Management Assessment Tool was developed. The ability to continuously measure the impact of implementing the interventions was an important component of the improvement programme. The local incident reporting system (DATIX®) was used to measure the incidence of pressure ulcers as its use for reporting pressure ulcers was well established at the start of the programme.

During the second 12 months of the programme (January–December 2013), we prepared for implementation of the interventions by building awareness for planned changes and anticipating potential problems. Prior to implementation, a 30-min training session aimed at new and existing staff was delivered and the numbers of staff trained were recorded for each unit.

The third 12 months (January–December 2014) was a period of refinement of the interventions and of refocussing on the original aims of the project. The pressure ulcer risk assessment tool was revised to include a better understanding of the factors. Because of difficulties releasing staff for a 30-min group training session 'flash training' was delivered at the bedside using five pre-printed and laminated slides with key messages delivered by one member of staff in a short 5-min time period. As well as the continuous measurement of pressure ulcer incidence, the number of days without pressure ulcers was recorded and displayed on each of the four critical care units. When 30 'harm-free days' were achieved, cookies were presented as a reward to staff. Process measures included an audit of compliance with the 12 hourly pressure ulcer assessment standards, compliance against the bowel management assessment tool guidelines and numbers of staff trained.

From April to September 2015, we continued to collect and report on pressure ulcer incidence with data feedback to the units on

Table 1 Pressure ulcer prevention improvement interventions

	Date	Interventions Technical [T]/Non-Technical [NT]/ Measurement [M]	Content, format
0–12 months	Dec 2011	• Established Task Group [NT]	Multidisciplinary: nurses, doctors varying levels At least one representative/unit
	Jan–Mar 2012	• Review of evidence base and benchmarking [T] o Literature review o Guideline development o National benchmark of practices o Network benchmark of practices • Established a continuous measurement plan [M]	Pressure ulcer interventions: assessment, turning regimes, seating regimes, mattress choice, skin care 6 national units, 15 local units in a network Number of pressure ulcers from local DATIX reporting system
	Mar 2012	• Case series audit [M]	Five Fulminant Liver Transplant patients on one unit
	Jun–Jul 2012	• Reviewed use of bowel management system [M & T]	Audit of four units Shared audit results
	Aug 2012	• Developed Prevention Strategy [T] • Implemented guidelines for pressure ulcer prevention [T]	Pressure ulcer assessment, learning from incidences, turning regimes, seating regimes, mattress choice, skin care
	Aug 2012	• Trial of new mattresses [T]	12 dynamic support surface mattress (low continuous pressure and alternating low pressure systems)
	Nov 2012	• PU incidence data shared at key meetings [M] • BMS assessment tool introduced [T]	2006–2011 data from once a year snap shot Assessment of tissue integrity, continence and mobility
12–24 months	Apr 2013	• 50% Foam & Gel mattress replacement [T]	New dynamic support surface mattresses (low continuous pressure and alternating low pressure systems)
	May 2013	• Introduced new risk assessment tool called CALCULATE [T & NT] • New care plan guidance introduced and documentation changed [T] • Training: [NT] o pressure ulcer prevention training o new mattresses o Preventing ulcer prevention on nurse induction programme	CALCULATE tool—7 risk factors and an overall score to indicate level of risk Guidance on turning frequencies, mattress choice, skin care guidance and a seating in a chair plan of care All staff or new staff, 30 min session
	Jun–Sep 2013	• An audit of assessment tool 'CALCULATE' [T]	92 patients assessments and 16 nurses' views obtained
24–36 months	Mar 2014	• Measurement added to Critical Care unit based dashboard [M]	Monthly number of PUs using a run chart over time
	Apr 2014	• Training 'preventing moisture lesions' nurse induction programme [NT]	30 min training session
	Apr 2014	• Remaining 50% of Foam & Gel mattresses replaced providing 100% [T] • Case presentations from one unit following route cause analysis (RCA) and shared learning at senior nursing group [NT]	New dynamic support surface mattresses (alternating low pressure systems). Case presentations included: timeline of risk assessments and skin observations, factors contribution to damage, avoidable and unavoidable factors, lessons learned, photos of the pressure ulcers
	Aug 2014	• Flash training on Pressure Ulcer prevention [NT] • Dedicated Tissue Viability nurse to focus on prevention [NT] • 30 day counts for Harm-free care [NT]	5 min training session using laminated flash cards at the bedside 0.6WTE expert tissue viability nurse Staff rewarded with cookies at achievement of 30 days harm free
	Sep 2014	• Revision of assessment tool—CALCULATE [T]	Increased from 7 to 8 factor assessment tool Changes to care plan documentation
	Nov 2014	• Evidence reviewed for spinal injury patients [T]	Guideline developed and introduced for spinal patients

BMS, bowel management system; PU, pressure ulcer.

a monthly basis. Work continued towards reducing the incidence of pressure ulcers and aiming for harm-free care.

Evaluation

A hospital standard was to report all pressure ulcers using the local DATIX® reporting system; this was reinforced at a unit level through staff meetings and training sessions and backed up by the regular presence of tissue viability nurses in the clinical areas. Great efforts were taken to train nursing staff on reporting and categorization of pressure ulcers. All the assessments and categorizations were based on the National Pressure Ulcer Advisory Panel definitions [16] and were checked and verified by a Tissue Viability Nurse Specialist. If a patient had more than one pressure ulcer in the same month then only the worst category ulcer was recorded, if the patient developed another pressure ulcer on a different month this was recorded as another pressure ulcer.

The number of pressure ulcers was taken from the local DATIX® reporting system, the information was collated by our organization's Quality and Governance department and reported

back to the critical care units ~3–4 weeks after the end of each month. The number and category of pressure ulcers on each unit was displayed on run charts over time. This timely feedback ensured clinical staff could monitor the effects of changes in their practice over time. On 1 day of each month, an audit was undertaken to record the prevalence of pressure ulcers on a given day. These point-prevalence audits confirmed the precision of the reporting system by showing that all identified pressure ulcers had already been reported in the DATIX system. The method of data collection and reporting remained the same throughout the programme.

Before undertaking the analysis for this report, all data recorded in DATIX since September 2012 were checked by a Tissue Viability Nurse Specialist to ensure the final grade of pressure ulcer was correctly attributed to each patient, increasing the reliability of the data. Data prior to September 2012 had been archived so was not easily accessible.

Data in this report are presented using descriptive statistics and a statistical process control chart to show the change in incidence over time [19]. A 6-month baseline period is defined as the 3 months prior to the quality improvement project starting and the first 3 months of project. The incidence of pressure ulceration was calculated using the number of admissions to critical care as the denominator, if a patient was re-admitted to the unit this was counted as another admission.

This pressure ulcer prevention quality improvement programme was deemed exempt from ethics review according to local policy. It met the criteria of service development as the programme introduced changes in practice based upon evidence derived from research in other healthcare settings, where changes had already been introduced and evaluated.

The provision, activity or case-mix of the four adult critical care units in our organization did not change significantly over the four years of the quality improvement programme (Table 2). During the 4-year study period, the incidence of pressure ulcers reduced significantly from 8.08/100 patient admissions (baseline) to 2.97/100 patient admissions (April 15 to September 2015) (Table 3), a relative rate reduction of 63% over the 4 years. The greatest reduction was seen in the most severe types of pressure ulcer damage (categories IV and Black Necrosis depth undetermined) and also the least severe type (category I). The proportion of admissions to critical care that developed pressure ulcers across all four critical care units are presented in a statistical process control chart (Fig. 1). This chart shows that the reduction in pressure ulceration observed meets the commonly accepted criteria for special cause variation of eight or more successive points on one side of the centre line [19].

During the project, we presented a run chart showing data from all four units to allow comparisons to be made between units (Fig. 2). Three of the four units showed a similar downward trend as interventions were implemented, unit four observed a low and consistent rate of pressure ulcers throughout the 4 years.

Lessons learned

In response to a high baseline incidence of pressure ulcers in our organization, we developed and delivered a quality improvement programme, including a bundle of interventions, aimed at reducing the incidence of pressure ulcers in the critically ill. Over the 4-year study period, we observed a significant and sustained reduction in pressure ulceration, in particular in the more severe grade of pressure ulcers.

The reduction in pressure ulcers was noted in some but not all grades of pressure ulcers, the incidence of category III ulcers did not appear to change. While one would expect a consistent reduction across all grades of pressure ulcer it is possible that the interventions were most effective at reducing the development of the more severe grades of pressure ulcers but did not prevent them developing to grade III.

This quality improvement programme has some limitations. Firstly, the before and after study design is prone to confounding from temporal changes which might influence the results. We are

Table 2 Activity and outcome data for adult critical care services (four critical care units) in our organization

	Total number of beds	ICU beds, *n*	HDU beds, *n*	Total admissions, *n*	Admissions, planned, *n*	Admissions, unplanned, *n*	ICU stay (days), mean	ICU mortality, %
2011/2	81	45	36	5003	2911	2092	4.1	9.3
2012/3	81	45	36	5287	3029	2256	4.3	9.4
2013/4	83	46	37	5468	2957	2510	4.4	9.0
2014/5	83	46	37	5424	3039	2385	4.5	9.0

ICU, intensive care unit; HDU, high dependency unit.

Table 3 Incidence of pressure ulcers in critical care per 100 admissions by pressure ulcer category

	ML	Cat I	Cat II	Cat III	Cat IV	BN[a]	Overall rate
Oct 11–Mar 12 (baseline)	1.42 ($n = 36$)	2.56 ($n = 65$)	3.47 ($n = 88$)	0.04 ($n = 1$)	0.08 ($n = 2$)	0.51 ($n = 13$)	8.08 ($n = 205$)
Apr 12–Sept 12	2.42 ($n = 62$)	0.78 ($n = 20$)	2.46 ($n = 63$)	0.20 ($n = 5$)	0.04 ($n = 1$)	0.66 ($n = 17$)	6.56 ($n = 168$)
Oct 12–Mar 13	2.04 ($n = 55$)	0.59 ($n = 16$)	2.56 ($n = 69$)	0.11 ($n = 3$)	0.07 ($n = 2$)	0.11 ($n = 3$)	5.49 ($n = 148$)
Apr 13–Sept 13	1.90 ($n = 52$)	0.58 ($n = 19$)	2.22 ($n = 61$)	0.04 ($n = 1$)	0.11 ($n = 3$)	0.00 ($n = 0$)	4.96 ($n = 136$)
Oct 13–Mar 14	1.25 ($n = 34$)	0.44 ($n = 12$)	1.94 ($n = 53$)	0.15 ($n = 4$)	0.00 ($n = 0$)	0.00 ($n = 0$)	3.78 ($n = 103$)
Apr 14–Sept 14	1.41 ($n = 38$)	0.33 ($n = 9$)	1.49 ($n = 40$)	0.11 ($n = 3$)	0.00 ($n = 0$)	0.00 ($n = 0$)	3.34 ($n = 90$)
Oct 14–Mar 15	0.82 ($n = 22$)	0.22 ($n = 6$)	1.65 ($n = 46$)	0.17 ($n = 4$)	0.00 ($n = 0$)	0.00 ($n = 0$)	3.05 ($n = 82$)
Apr 15–Sept 15	1.00 ($n = 28$)	0.21 ($n = 6$)	1.68 ($n = 47$)	0.07 ($n = 2$)	0.00 ($n = 0$)	0.00 ($n = 0$)	2.97 ($n = 83$)
Total	$n = 327$	$n = 157$	$n = 467$	$n = 23$	$n = 8$	$n = 33$	$n = 1015$

ML, moisture lesion.

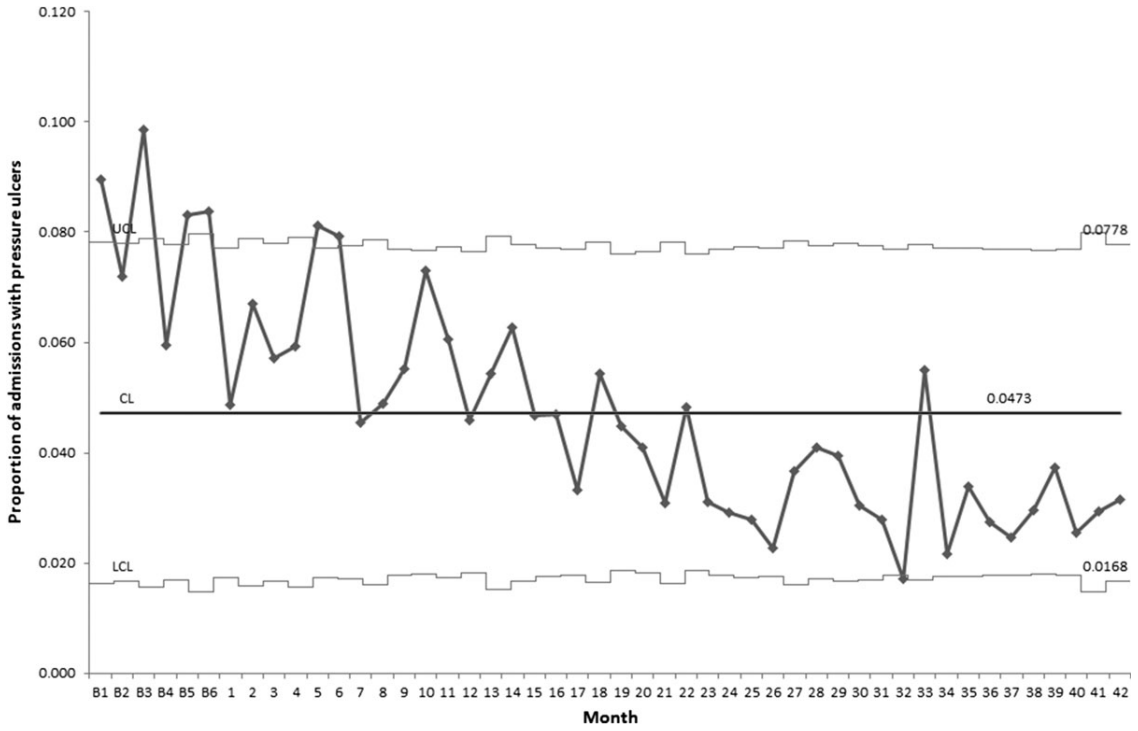

Figure 1 Proportion of admissions to critical care developing pressure ulcers over the time frame of the quality improvement project. B denotes the baseline period during the first 6 months of the project.

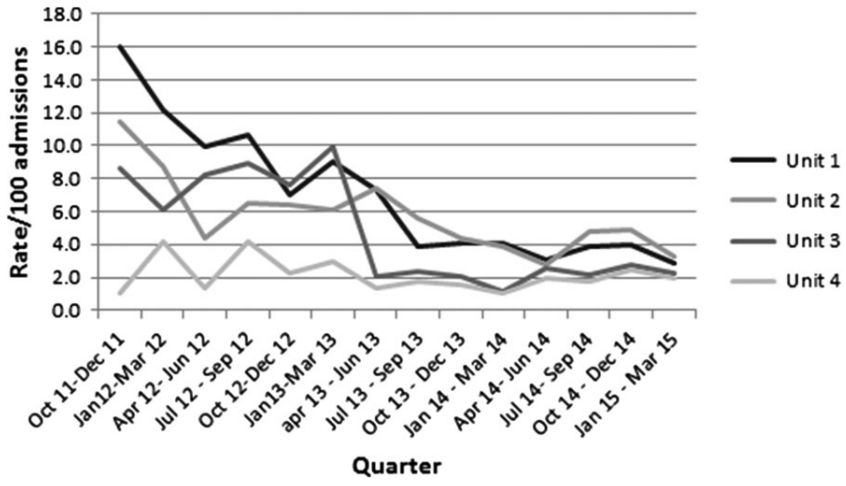

Figure 2 Quarterly pressure ulcer rate/100 admissions by unit.

not aware of any significant changes in capacity (bed numbers), activity (admissions) or case-mix, but these and other confounding factors cannot be excluded. Secondly, our efforts to reduce pressure ulcer prevention came at a similar time to national policy directives focussing on and aiming to reduce pressure ulcers, such as the NHS Safety Thermometer monthly monitoring of pressure ulcer prevalence in all acute hospitals in England [20]. Thirdly, there may have been some data categorization inaccuracies before September 2012 as we were not able to retrospectively check the data from this period to ensure the grade of pressure ulcer was correct. Finally, not all units had a similar high incidence of pressure ulcers at baseline—unit 4 had low rates of pressure ulcers throughout the 4-year period, which we believe was due to the unique case-mix of neuro/trauma patients, who tend to be younger with fewer co-morbidities. This unit's case-mix had a lower risk of pressure ulcer damage and hence less opportunity for improvement, they were not already using the interventions.

A recent systematic review of interventions to change behaviour in healthcare identified a bundle of interventions packaged together as an effective approach [21]. It is difficult to say which components of the bundle of interventions used were most important but we believe a number of key components were critical to the success of

the programme. Firstly, setting up a multidisciplinary, pressure ulcer task group is seen as an important component of quality improvement initiatives [22]. The task group comprised motivated clinical staff who contributed to the development of the interventions. Clinical leadership is known to be challenging in improving quality in healthcare and is necessary at different levels [23]. Our task group members, all experienced clinical staff, successfully influenced and encouraged the application of the changes on each of the critical care units.

Another key component thought to be successful was the data feedback to critical care staff. Johnson and May found audit and feedback relating to any summary of clinical performance, to be one of the most successful interventions to change professional behaviour [21]. The DATIX reporting system is extremely detailed and time consuming. It was vital, therefore, to regularly relay information from this system to maintain staff commitment to this part of the process. Feedback took the form of a poster in each unit, updated monthly using a run chart allowing staff to assess and monitor the impact of the changes they had implemented. This feedback was supplemented with more descriptive case presentations summarizing detailed incident investigations including photographs.

A further successful intervention was the change from foam and gel mattresses to alternating low pressure mattresses. Early nurse feedback suggested a high level of confidence that the new mattresses were effective, particularly in the highest risk patients. This positivity helped to increase confidence in the overall project.

The Braden Scale [24] was used to assess pressure ulcer risk prior to the improvement programme, and the group agreed that risk factors specific to the critically ill were not addressed using this assessment tool. As a result, the subset of 'very high risk' patients was not identified. The under recognition of risk meant that patients were often being repositioned three to four hourly, rather than two hourly. As part of the quality improvement programme, we developed a new pressure ulcer risk assessment tool, CALCULATE, which comprises a list of risk factors specific to critical care patients, including impaired circulation, mechanical ventilation, dialysis and cardiac instability. CALCULATE was viewed as good and easy to use by critical care nurses [8]. The focus on turning regimes, with a drive to increase frequency of turning to two hourly for patients in the new 'very high risk' category was the most challenging change to institute, since nurses had significant workload concerns. Gradually, however, it was recognized by nursing staff that the risks associated with not achieving this two hourly standard were significant, and towards the end of the improvement programme, this intervention was regarded as mostly achievable with no increase in nursing resource. Patient instability was identified as the reason why this turning intervention could not always be achieved.

The final key component thought to be important for our results was our emphasis on staff training and increased awareness of pressure ulcer prevention. A large amount of time was invested to provide staff with an increased understanding of the importance of pressure ulcer damage in critical care and interventions to prevent the harm. This emphasis helped to challenge the belief that pressure ulcers were in any way an inevitable consequence of critical illness.

Similarities are noted with our experiences with these key components, with other recently published quality improvement projects in this topic area. In one hospital in Canada, they reduced hospital acquired pressure ulcers by 80% and identified the following key corresponding components; involvement of inter-professional teams and senior leadership, replacement of support surfaces and a pressure ulcer prevention education bundle [25]. Likewise in the USA in one critical care unit a collaborative approach using a combination of staff education and a focus on assessment scores, skin care protocol, fluidized repositioners and dressings achieved a 69% reduction in pressure ulcers over 3 years [26]. The common approaches such as clinical leadership, staff education and pressure ulcer assessment suggest that these are likely to be the successful interventions for reducing pressure ulcers in critical care.

Reductions in pressure ulcer incidence observed during our project have potentially significant implications for healthcare organizations. We have demonstrated that this harm is not inevitable even in the highest risk patients. Widespread application of similar methods has the potential to bring significant patient and financial benefit. We calculated the number of pressure ulcers prevented over 4 years and inserted these numbers into the NHS National pressure ulcer productivity calculator [27] and the average estimated cost saving was £2.6 million (range £2.1–£3.1).

We plan to formally validate the CALCULATE tool to encourage and enable its use in other organizations in future.

In conclusion, this 4-year quality improvement programme including technical and non-technical interventions, data feedback to staff and clinical leadership was associated with a sustained reduction the incidence of pressure ulceration in the critically ill. Consequently, many serious effects of pressure ulcer damage have been avoided. The strategies used in this programme may be transferable to other critical care units faced with a similar high incidence of pressure ulceration. Future work could assess whether a similar bundle of interventions aimed at preventing pressure ulceration reproduced the same benefits in other healthcare settings.

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7.5 Appendix 5 - Declarations of co-authorship of published work

northumbria UNIVERSITY NEWCASTLE

northumbria UNIVERSITY NEWCASTLE

northumbria UNIVERSITY NEWCASTLE

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A

Name of candidate: Annette Richardson

Name of co-author: Chrs Turnock

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A. Crow, W. Coghill, E. Turnock, C (2007) A comparison of sleep assessment tools by nurses and patients in critical care. Journal of Clinical Nursing. 16, 1660–1668.

Section B

DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(i) principal author

My specific contribution to the publication was (*maximum 50 words*):

Project lead, conception and design of the work, data analysis and interpretation, drafted paper

Signed: .....Annette Richardson.....(candidate) **.....09/05/2017.....**(date)

Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i)** **I agree with the above declaration by the candidate**

or **(ii)** **I do not agree with the above declaration by the candidate for the following reason(s):**

Signed: Chris Turnock (co-author) **17/05/17** (date)

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A

Name of candidate: Annette Richardson

Name of co-author: Elaine Coghill

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A. Crow, W. Coghill, E. Turnock, C (2007) A comparison of sleep assessment tools by nurses and patients in critical care. Journal of Clinical Nursing. 16, 1660–1668.

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My specific contribution to the publication was (*maximum 50 words*):

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Signed: .....Annette Richardson.....(candidate) **.....09/05/2017.....**(date)

Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i) I agree with the above declaration by the candidate**

or **(ii)** ~~**I do not agree with the above declaration by the candidate for the following reason(s):**~~

Signed: .....E Coghill**.....**(co-author) **.....**31/05/17**.....** (date)

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A

Name of candidate: Annette Richardson

Name of co-author: Michaela Allsop

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A. Coghill, E. Allsop, M (2007) Ear Plugs and Eye Masks: Do they improve Critical Care patients' sleep? Nursing in Critical Care. 12 (6) 278-286.

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Signed: .....(co-author) **16/05/17** (date)

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Name of co-author: Elaine Coghill

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Signed: .....(co-author) 31/5/17 (date)

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A

Name of candidate: Annette Richardson

Name of co-author: Elaine Coghill

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A; Thompson, A; Coghill, E; Chambers I; Turnock, C (2009) Development and implementation of a noise reduction intervention programme: a pre and post audit of three hospital wards. Journal of Clinical Nursing, 18, 3316–332.

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Section C

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or **(ii)** ~~**I do not agree with the above declaration by the candidate for the following reason(s):**~~

Signed: .....E Coghill.....(co-author) .....31/05/17..... (date)

northumbria UNIVERSITY NEWCASTLE

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Section A

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Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i)** **I agree with the above declaration by the candidate**

or **(ii)** **I do not agree with the above declaration by the candidate for the following reason(s):**

Signed: Chris Turnock (co-author) **17/05/17** (date)

Richardson, Annette

From: Julian Bion <J.F.BION@bham.ac.uk>
Sent: 17 May 2017 10:30
To: Amelia Murray
Cc: Paul Agnew; Claire Price (College of Medical and Dental Sciences); Richardson, Annette
Subject: Re: Annette Richardson Co-authorship request for information
Attachments: Matching Michigan Editorial on-line first BMJQ&S Oct 2012.pdf; Matching Michigan on-line first version BMJQ&S Sept 20th 2012.pdf; Prof Bion statement of contribution re Annette Richardson May 17th 2017.doc

Dear Ms Murray,

I am delighted to confirm that Mrs Annette Richardson contributed equally to the research outputs from the Matching Michigan project (most notably the attached publication, which was the highest cited publication in BMJQS to date). Annette and I were co-primary first authors.

I have tried adding my signature electronically to the document you sent, but it will not accept images. I do not have access to a printer at present, and do not wish to print, sign, pdf and return electronically. Can you tell me how I can sign this document and then pdf it to return to you?

I have copied in my PA Mrs Claire Price.

Yours sincerely

Professor Julian Bion FRCP FRCA FFICM MD

Professor of Intensive Care Medicine,

University of Birmingham

PA: Mrs Claire Price: c.s.price@bham.ac.uk

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A
Name of candidate: Annette Richardson

Name of co-author: Julion Bion

Full bibliographical details of the publication (*including authors*)**:**

Bion, J; Richardson, A; Hibbert, P Beer J, Abrusci T, McCutcheon M, Cassidy J, Eddleston J, Gunning K, Bellingan G, Patten M, Harrison D,I (2012) Matching Michigan': a two-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England. BMJ Quality & Safety. Feb:22(2):110-23.

Section B
DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(ii)joint author

My specific contribution to the publication was (*maximum 50 words*):

Nursing lead and with the co-authors conception, design and execution of the work, interpretation of the data, and writing the manuscript

.(co-author) **August 15th 2017**

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A
Name of candidate: Annette Richardson

Name of co-author: Geoff Bellingan

Full bibliographical details of the publication (*including authors*)**:**

Bion, J; Richardson, A; Hibbert, P Beer J, Abrusci T, McCutcheon M, Cassidy J, Eddleston J, Gunning K, Bellingan G, Patten M, Harrison D,I (2012) Matching Michigan': a two-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England. BMJ Quality & Safety. Feb:22(2):110-23.

Section B
DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(ii) joint author

My specific contribution to the publication was (*maximum 50 words*):

Nursing lead and with the co-authors conception, design and execution of the work, interpretation of the data, and writing the manuscript

Signed: .....Annette Richardson.....(candidate) **.....09/05/2017.....**(date)

Section C
STATEMENT BY CO-AUTHOR (*delete as appropriate*

I agree with the above declaration by the candidate

Signed: Geoff Bellingan (co-author) **26 May 2017** (date)

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A
Name of candidate: Annette Richardson

Name of co-author: David Harrison

Full bibliographical details of the publication (*including authors*)**:**

Bion, J; Richardson, A; Hibbert, P Beer J, Abrusci T, McCutcheon M, Cassidy J, Eddleston J, Gunning K, Bellingan G, Patten M, Harrison D,I (2012) Matching Michigan': a two-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England. BMJ Quality & Safety. Feb:22(2):110-23.

Section B
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(ii) joint author

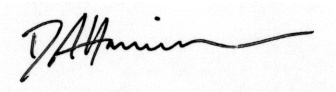
My specific contribution to the publication was (*maximum 50 words*):

Nursing lead and with the co-authors conception, design and execution of the work, interpretation of the data, and writing the manuscript

Signed: .....Annette Richardson.....(candidate) **.....09/05/2017.....**(date)

Section C
STATEMENT BY CO-AUTHOR (*delete as appropriate*)

(i) I agree with the above declaration by the candidate



Signed: .....David Harrison.....(co-author) **....16/05/2017.....** (date)

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A
Name of candidate: Annette Richardson

Name of co-author: Jane Eddleston

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Bion, J; Richardson, A; Hibbert, P Beer J, Abrusci T, McCutcheon M, Cassidy J, Eddleston J, Gunning K, Bellingan G, Patten M, Harrison D,I (2012) Matching Michigan': a two-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England. BMJ Quality & Safety. Feb:22(2):110-23.

Section B
DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(ii) joint author

My specific contribution to the publication was (*maximum 50 words*):

Nursing lead and with the co-authors conception, design and execution of the work, interpretation of the data, and writing the manuscript

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Section B
DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(i) principal author

My specific contribution to the publication was (*maximum 50 words*):

Project lead, conception and design of the work, data analysis and interpretation, drafted paper

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or ~~**(ii) I do not agree with the above declaration by the candidate for the following reason(s):**~~

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Name of co-author: Catherine Coulter

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A Melling, A, Straughan, C, Simms, L, Coulter, C, Elliot, Y, Reji, R, Wilson, N, Byrne, R, Desmond, C, Wright, SE. (2015). Central Venous catheter dressing durability: an evaluation. Journal of Infection Prevention. 16 (6): 256-261.

Section B
DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(i) principal author

My specific contribution to the publication was (*maximum 50 words*):

Project lead, conception and design of the work, data analysis and interpretation, drafted paper

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Section A

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Richardson, A Melling, A, Straughan, C, Simms, L, Coulter, C, Elliot, Y, Reji, R, Wilson, N, Byrne, R, Desmond, C, Wright, SE. (2015). Central Venous catheter dressing durability: an evaluation. Journal of Infection Prevention. 16 (6): 256-261.

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My specific contribution to the publication was (*maximum 50 words*):

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Section C

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Section A

Name of candidate: Annette Richardson

Name of co-author: Natalie Wilson

Full bibliographical details of the publication (*including authors*)**:**

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Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

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Section B

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STATEMENT BY CO-AUTHOR (*delete as appropriate*)

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Signed: RACHAEL BYRNE (co-author) 02/09/17 (date)

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Section A

Name of candidate: Annette Richardson

Name of co-author: Stephen Wright

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A Melling, A, Straughan, C, Simms, L, Coulter, C, Elliot, Y, Reji, R, Wilson, N, Byrne, R, Desmond, C, Wright, SE. (2015). Central Venous catheter dressing durability: an evaluation. Journal of Infection Prevention. 16 (6): 256-261.

Section B

DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(i) principal author

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Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i) I agree with the above declaration by the candidate**

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Section A
Name of candidate: Annette Richardson

Name of co-author: Rachel Carter

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A and Carter R (2015) Falls in critical care: a local review to identify incidence and risk. Nursing in Critical Care. DOI: 10.1111/nicc.12151

Section B
DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(ii) joint author

My specific contribution to the publication was (*maximum 50 words*):

Conception and design of the work, data analysis and interpretation, drafted paper

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Section C
STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i) I agree with the above declaration by the candidate**

Signed: .....Rachel Carter.....(co-author) **....30/05/2017.....** (date)

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A

Name of candidate: Annette Richardson

Name of co-author: Isabel Barrow

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A and Barrow, I (2015) Part 1: Pressure ulcer assessment - the development of Critical Care Pressure Ulcer Assessment Tool made Easy (CALCULATE). Nursing in Critical Care. 20:6 308-314.

Section B

DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(i) principal author

My specific contribution to the publication was (*maximum 50 words*):

Project lead, conception and design of the work, data analysis and interpretation, drafted paper

Signed: .....Annette Richardson.....(candidate) **.....09/05/2017.....**(date)

Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i)** **I agree with the above declaration by the candidate**

or **(ii)** **I do not agree with the above declaration by the candidate for the following reason(s):**

Signed: .....Isabel Barrow.....(co-author) **.....06/06/2017.....** (date)

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

(Please use one form per co-author per publication)

Section A

Name of candidate: Annette Richardson

Name of co-author: Christine Straughan

Full bibliographical details of the publication (*including authors*)**:**

Richardson, A and Straughan, C (2015) Part 2: pressure ulcer assessment: implementation and revision of CALCULATE. Nursing in Critical Care. 20: 6 315-321

Section B

DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

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My specific contribution to the publication was (*maximum 50 words*):

Project lead, conception and design of the work, data analysis and interpretation, drafted paper

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Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i) I agree with the above declaration by the candidate**

or ~~**(ii) I do not agree with the above declaration by the candidate for the following reason(s):**~~

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C. STRAUGHAN

DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Section A
Name of candidate: Annette Richardson

Name of co-author: Joanna McBride

Full bibliographical details of the publication (*including authors*)**:**

McBride, J and Richardson, A (2015) A critical care network pressure ulcer prevention quality improvement project. Nursing in Critical Care. Mar 30. doi: 10.1111/nicc.12174.

Section B
DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

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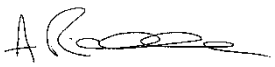
My specific contribution to the publication was (*maximum 50 words*):

Project lead, conception and design of the work, data analysis and interpretation, drafted paper

Signed: .....Annette Richardson.....(candidate) **.....11/05/2017.....**(date)



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STATEMENT BY CO-AUTHOR (*delete as appropriate*)

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Section A

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Name of co-author: Iain McCullagh

Full bibliographical details of the publication (*including authors*)**:**

***Richardson, A; Peart, J; Wright, SE; McCullagh, I J (2017) Reducing the incidence of pressure ulcers in critical care units: a 4-year quality improvement programme. International Journal of Quality in Healthcare.* 1–7doi: 10.1093/intqhc/mzx040**

Section B

DECLARATION BY CANDIDATE (*delete as appropriate*)

I declare that my contribution to the above publication was as:

(i) principal author

My specific contribution to the publication was (*maximum 50 words*):

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Section C

STATEMENT BY CO-AUTHOR (*delete as appropriate*)

Either **(i) I agree with the above declaration by the candidate**

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DECLARATION OF CO-AUTHORSHIP OF PUBLISHED WORK

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Section A

Name of candidate: Annette Richardson

Name of co-author: Stephen Wright

Full bibliographical details of the publication (*including authors*)**:**

***Richardson, A; Peart, J; Wright, SE; McCulloch, I J (2017) Reducing the incidence of pressure ulcers in critical care units: a 4-year quality improvement programme. International Journal of Quality in Healthcare.* 1–7doi: 10.1093/intqhc/mzx040**

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8. Glossary of Terms

BN	Black Necrosis
CALCULATE	Critical Care Pressure Ulcer Assessment Tool made Easy
CC	critical care
CVC-BSI	central venous catheter - blood stream infections
CQC	Care Quality Commission
EBP	Evidence Based Practice
IHI	Institute for Health Improvement
MRC	Medical Research Council
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NPSA	National Patient Safety Agency
PDSA	Plan Do Study Act
PU	pressure ulcers
QI-MQCS	Quality Improvement Minimum Quality Criteria Set
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

9. References

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