# Designing Out Medical Error in surgical wards

By

Oliver Anderson BSc MSc MRCS

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Imperial College London

Department of Surgery & Cancer

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## Declaration of originality

I carried out the research described in this thesis entirely during a period of study for a PhD at Imperial College London. I composed this thesis, which is a record of work that I have not previously submitted for a higher degree. All work contained in this thesis that is not my own is appropriately referenced.

Oliver Anderson
October 2015

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# Abstract

## Designing Out Medical Error in surgical wards

Background

One in ten hospital patients are unintentionally harmed by their healthcare management. Healthcare professionals are often blamed for making mistakes that could be prevented if all the factors influencing human performance were addressed by designing the system to be safer.

Hypothesis

This thesis is part of the Designing Out Medical Error (DOME) project, which tested the hypothesis that a multidisciplinary team of designers, clinicians, psychologists and business analysts working collaboratively could design interventions to improve patient safety in surgical wards.

Methods & Results

We used a combination of observational techniques including Healthcare Failure Mode and Effects Analysis to proactively assess risk in surgical wards. We focused on five high-risk processes: hand hygiene, isolation of healthcare-associated infection, vital signs monitoring, handover communication and medication delivery. Patients and healthcare professionals were involved at every stage and helped co-design a suite of concepts to address risk in these processes. We progressed two prototypes: the Respiratory Rate Recorder and the CareCentre® (a bedside work table containing equipment including alcohol hand-rub) to simulated and clinical trials. The trials demonstrated that the accuracy of manual respiratory rate measurement and the adherence of healthcare workers to hand hygiene guidelines was significantly improved respectively, thus supporting the hypothesis.

Conclusion

Multidisciplinary collaborations that engage with the teams, processes and equipment of the healthcare system can co-design safer interventions. Better design can influence behaviour and improve the performance of healthcare professionals. The DOME project demonstrates a successful method for others to follow.

## Preface

The DOME project was set up to improve design and benefit patient safety through a multidisciplinary team. I was a surgical trainee employed as a member of the DOME team to give clinical input. We addressed patient safety in the surgical ward, our chosen environment, functioning as a microcosm of the NHS. I was the only clinician amongst the junior members of the DOME team. The other junior DOME team members included two designers, one business analyst and one psychologist. This innovative and exploratory work brought together qualitative and quantitative disciplines. While design brought empathy and intuition and I brought clinical experience and expertise plus scientific rigour. Different approaches are not surprising in a multidisciplinary team, but they did create tensions. These were resolved by focusing on our shared goals and by speaking a common language. At times the designers took the leadership role and sometimes the clinicians took the leadership role supported by the rest of the team. It is therefore not possible to delineate a single person who was responsible or who can take sole credit for any particular aspect of the work, it was a team effort. However, it would be reasonable to say that in design issues the work was led by Jonathan West and Grace Davey and their supervisors and in clinical and scientific research the work was led by my supervisors and myself.

Part one of this thesis discusses the DOME project. This recounts the collaborative work done by the DOME team including how patient safety in surgical wards was analysed, targets were identified, design briefs developed, ideas and concepts generated and translated into working prototypes, which were tested in the clinical environment. Part two contains detailed reports of the scientific studies described in part one.

## My interest in the DOME project

I chose to be involved in the DOME project, because I was working as a trainee surgeon in an NHS hospital and I became frustrated with the obstacles posed by a poorly designed system. Much of a doctor's time and energy is spent on the non-clinical work required to convey the patient down the diagnostic and treatment pathway when it could be spent on patient care. I felt disempowered to influence the system. I wanted to know how a healthcare professional like myself could learn to investigate a more effective way of working and put it into practice.

In the past, I had made my own attempts to make things better. For example, I had designed a hand over form to be used by on call surgical teams at shift changeovers, which focused on the most important aspects including the identity of the patient, where the patient was, the working diagnosis and key investigation results. This worked well but only while I was promoting it, which is typical of the elastic nature of the NHS that returns to baseline once the stimulus has been removed. I did not know how to make the improvements longer lasting.

At the cutting edge of surgery, advancements have been made. The old days of general surgery where operating was likened to butchery with knives and haemorrhage are still occasionally seen in emergencies, but planned operations are more likely to be keyhole or even performed with robots. It seemed odd to me that while inside the operating room there was hi-tech equipment, in the rest of the hospital the technology and integration could not rival that in the local supermarket, bank or even the smartphone in your pocket.

I met Prof Hanna at a deanery teaching session at St Mary's hospital. I was assisting him perform a simulated gastrojejunostomy and he asked me if I would like to do some research with him. When he told me there was a vacancy to be the clinical research fellow in a project working with industrial designers that aimed to improve the surgical health care system I could not believe my luck and jumped at the opportunity.

I hoped that I would get the chance to take novel interventions all the way from concept through research trials and finally release them into the Market. This would give me the knowledge, experience and confidence to do the same again in my future career and also show others how to do it.

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# Dissemination

## *Book*

Anderson O, Davey G, West. J. Myerson J (Ed.). (2011) Make it better: Designing out medical error. Helen Hamlyn Centre for Design, Royal College of Art. ISBN: 978-1-907342-40-0

## *Website*

domeproject.org.uk

## *Twitter*

@domeproject

## *Peer reviewed publications*

Anderson O, Brodie A, Vincent CA, Hanna GB. (2012) A systematic proactive risk assessment of hazards in surgical wards: a quantitative study. ***Annals of Surgery.*** 255:1086-92.

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Norris B, West J, Anderson O, Davey G, Brodie A. (2014) Taking ergonomics to the bedside – a multi-disciplinary approach to designing safer healthcare. ***Applied Ergonomics.*** 45:629-38.

## *Awards*

**Double first prizes for best research proposal,** Translational Research Skills & Development Course, Imperial College London. 18 June 2010.

**Prize for best research poster**, 3rd North British Patient Safety Research Symposium. 19 November 2010.

**Prize for most innovative patient safety research project**, Health Innovation & Education Cluster for Patient Safety. 19 November 2010.

**Finalist for Respiratory Innovation Award**, Medical Futures Innovation Awards. 6 April 2011.

**Research paper prize**, Design for Health. Sheffield Hallam University. 14 July 2011.

**Most Popular: A Systematic Proactive Risk Assessment of Hazards in Surgical Wards: A Quantitative Study**, Annals of Surgery. 15 June 2012.

**Academy Award**, 8th Design & Health World Congress. 30 June 2012.

**Pro Runner Up in the Strategy & Research category**, Core77 Design Awards. 2012.

**Shortlisted for 2 Building Better Healthcare Awards**, Hospital Development. 7 November 2012.

**Finalist at Patient Safety Awards 2013**, Patient Safety Awards. 24 May 2013.

**Best paper 2014**, Applied Ergonomics. 15 April 2015.

## *Oral presentations*

Anderson O, West J, Davey G, Brodie A, Kapsali M, Aggarwal R, Norris B, Matthews E, Myerson J, Vincent CA, Hanna GB. Designing out preventable patient harm on general surgery wards **(winner of prize for most innovative patient safety research project).** ***3rd North British Patient Safety Research Symposium.*** Bradford, UK. 19 November 2010.

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West J, Davey G, Anderson O, Matthews E, Myerson J. Designing Out Medical Error **(winner of research paper prize).** ***Design for Health.*** Sheffield Hallam University, UK. 14 July 2011.

Anderson O. Improving the accuracy of respiratory rate documentation. ***Swiss Patient Safety Foundation International Congress.*** Basel, Switzerland. 29 November 2011.

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Anderson O, West J, Davey G, Briggs M, Vincent CA, Hanna GB. The CareCentre™: a cluster-randomised crossover clinical trial. ***Association of Surgeons of Great Britain and Ireland.*** Liverpool, UK. 9 May 2012.

## *Invited oral presentations*

Anderson O, Aggarwal R, Myerson J. Design for patient safety. ***International Society of Quality and Safety in Healthcare.*** Paris, France. 10 October 2010.

Anderson O, Hanna GB. Evaluating innovation. ***Showcase Hospitals: Innovation and technology for combating healthcare associated infection.*** Imperial College London, UK. 16 November 2010.

Aggarwal R, Anderson O, West J, Davey G, Brodie A. Surgical ward care - how to enhance clinical safety. ***International Society of Quality and Safety in Healthcare.*** Hong Kong, China. 16 September 2011.

Anderson O, West J, Walker S. Design is everything! Work-environment design and how it matters. ***Swiss Patient Safety Foundation International Congress.*** Basel, Switzerland. 30 November 2011.

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## *Exhibitions*

West J, Davey G, Anderson O, Norris B. Designing Out Medical Error. ***Include.*** Royal College of Art, London, UK. 18 April 2011.

Anderson O. Designing Out Medical Error/The Care Station. ***Clinical Human Factors Group Seminar.*** Imperial College London, UK. 19 April 2011.

Anderson O, West J, Davey G, Brodie A, Kapsali M, Norris B, Aggarwal R, Matthews E, Vincent CA, Hanna GB, Myerson J. Make it better: Designing Out Medical Error. ***The problem comes first.*** Royal College of Art, London, UK. 22 September 2011.

Anderson O, West J, Davey G, Brodie A, Kapsali M, Aggarwal R, Matthews E, Myerson J, Vincent CA, Hanna GB. Designing Out Medical Error. ***Royal College of Surgeons of England.*** Hunterian Museum. London, UK. 31 January 2012.

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## *Poster presentations*

Anderson O, Brodie A, Vincent CA, Hanna GB. Identifying and prioritizing high-risk processes in elective general surgery wards. ***Centre for Patient Safety and Service Quality winter symposium.*** Imperial College London, UK. 21 January 2010.

Anderson O, Brodie A, Vincent CA, Hanna GB. An analysis of risk on general surgery wards: failure mode and effects analysis of six high-risk processes. ***Centre for Patient Safety and Service Quality winter symposium.*** Imperial College London, UK. 21 January 2010.

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# Part one: the DOME project

# Introduction

## Why is patient safety important?

The Institute of Medicine Report *To err is human* concluded that 44000-98000 patients died annually in American hospitals due to medical error. (Kohn, Corrigan et al. 1999) Approximately 1 in 10 hospital in-patients suffered *an "unintended injury or complication resulting in prolonged length of hospital stay, disability at the time of discharge or death that was caused by healthcare management and not by the patients' underlying disease."* It was estimated that the application of expected standards of care could have prevented approximately half of these adverse events. (de Vries, Ramrattan et al. 2008) In addition to these statistics, patients might also have suffered from psychological harm including depression and post-traumatic stress disorder after medical injury. (Vincent and Coulter 2002)

Healthcare workers believed that they should not make mistakes and when they did, they suffered from feelings of guilt, anxiety, anger, shame, embarrassment, loss of confidence, sleeplessness, self-blame, a damaged reputation, reduced job satisfaction and a fear of litigation or disciplinary proceedings. (Christensen, Levinson et al. 1992, Wolf, Serembus et al. 2000, Penson, Svendsen et al. 2001, Gallagher, Waterman et al. 2003, Waterman, Garbutt et al. 2007, Scott, Hirschinger et al. 2009) These effects could be long lasting and even permanent and resulted in career-threatening burnout and depression. (Christensen, Levinson et al. 1992, Penson, Svendsen et al. 2001, Schwappach and Boluarte 2009, Scott, Hirschinger et al. 2009) These negative consequences of acknowledging medical error meant that healthcare workers might not report incidents. Hiding mistakes is associated with subsequent suboptimal care and further errors, because insufficient reflection, learning and recovery have taken place. (Schwappach and Boluarte 2009)

Preventable death, disability and prolonged hospital stay increased healthcare costs; partly through the direct cost of additional healthcare requirements and partly through healthcare litigation, which has been increasing. (Fenn, Diacon et al. 2000) In the UK, medical error was estimated to cost an additional £2 billion per year in increased length of stay alone. (DoH 2000) In the USA, the estimate included the cost of additional healthcare and loss of work income and was valued at between $17 and $29 billion annually. (Kohn, Corrigan et al. 1999) In addition to the financial implications, inadequate patient safety can result in public loss of trust and confidence in a healthcare system and a reduced perception of quality. (Kohn, Corrigan et al. 1999) Spending on patient safety innovation can result in overall cost savings. (Hwang and Herndon 2007)

## The person approach to patient safety

Traditionally, the 'aberrant mental processes' of people, such as 'forgetfulness, inattention, poor motivation, carelessness, negligence and recklessness' were considered to be the causes of medical error. (Reason 2000) The main goal was to identify the person responsible. The individual involved is blamed, named, shamed and re-trained, but the error happens again, maybe not by the same individual, but by someone else in another location. This was the blame culture, which subscribed to the person approach to medical error. Culture is the set of assumptions that are shared by a group of people. These assumptions might include ways of interpreting and responding to challenges that function to help individuals and the groups cope. (Weick and Sutcliffe 2001) The safety culture within an organisation is how people interpret and respond to patient safety incidents and risk. The blame culture may more fully satisfy the immediate desire for justice in other workers, consumers, the law, media and public, but it suppresses the openness and honesty required to design a safe system. (Reason 2000) Many doctors were reluctant to be completely open with their patients about medical errors (Gallagher, Waterman et al. 2003) especially if they were preventable. (Lamb, Studdert et al. 2003) Half of medical professionals said they found it difficult to discuss mistakes with anyone and a third did not acknowledge that they made any errors at all. Within the medical profession, medical error was considered embarrassing and unacceptable. Error was considered to be a personal failing. (Sexton, Thomas et al. 2000) However, some of the most experienced and competent individuals make the biggest mistakes. (Gawande 2002)

## The system approach to patient safety

Human Factors is synonymous with the term ergonomics. It is a scientific discipline concerned with any factor that can influence performance including the interaction between teams, products and processes. In contrast to the person approach to medical error, the theory of ergonomics considers medical errors to be caused not only by the humans in the system, but also by all the other components and their interactions with one another. This means that humans were not solely to blame for medical error, and that other components of the system could be targets for improvement.

Reason's system approach to accidents crystallised the key messages. He illustrated the principles with the Swiss cheese model. The Swiss cheese model shows hazards originating on one side of a series of barriers, represented by slices of Swiss cheese. Hazards have a straight trajectory that is usually blocked by the cheese slices, which represents safety mechanisms. However, some hazards happen to have a trajectory that passes through holes in every slice of cheese and then impact on the other side and might result in losses. Losses are harm to patients, healthcare workers and healthcare organisations. What the Swiss cheese model illustrates is that safety barriers exist throughout the organisation and deficiencies in these barriers might allow an error to result in harm. Management and design of the healthcare system represent barriers and can *err* just like the healthcare workers involved, but management and design are more distant from the manifestation of losses and therefore their weaknesses are more obscure and less readily identified. Slips, lapses and violations are traditional types of medical errors. They are proximal to the impact and committed by individual healthcare workers. The management and design decisions that make those slips, lapses and violations more likely, such as a stressful and rushed working environment, are increasingly recognised as suitable patient safety intervention targets. An expanded version of the Swiss cheese model more clearly illustrates that, although high-level management decisions cannot directly cause accidents, they change the likelihood of accidents occurring at the coalface. (Vincent, Taylor-Adams et al. 1998) The risk of a management decision resulting in harm is modified by factors in the workplace and decisions made by front line staff. Defensive barriers might block the ‘latent error’ in the majority of cases. However, when the failure does result in harm the organisational model shows that causality and therefore responsibility is shared throughout the organisation. (Reason and Vincent 2001)

## Design for patient safety

*'Human beings make mistakes because the systems, tasks and processes they work in are poorly designed.'* Professor Lucian Leape, (DoH 2003) This insight came from other industries which had improved their safety, such as aviation, rail, nuclear, etc. *"...mistakes can best be prevented by designing the health system at all levels to make it safer--to make it harder for people to do something wrong and easier for them to do it right."* To Err is Human (Kohn, Corrigan et al. 1999)

The Design for Patient Safety report was based on a scoping study. (DoH 2003) It found that the NHS had not kept up to date with design, as had other industries with improved safety records. The deficit was not only superficial and relating to products, packaging and information, but was deep within the system of healthcare itself. *"Health care is a decade or more behind many other high-risk industries in its attention to ensuring basic safety."* To Err is Human (Kohn, Corrigan et al. 1999)

The report said, *"Design is a structured process for identifying problems and developing, testing and evaluating user-focused solutions."* For a system to work successfully, feedback from all key stakeholders must be obtained. (Buckle, Clarkson et al. 2006) Poor design in healthcare has partly been due to lack of user engagement in the design process and a lack of intuitive understanding by designers of the teams, equipment and processes in the system of healthcare. The design for patient safety report promoted the multidisciplinary collaboration of healthcare workers, designers and manufacturers throughout the product design and development process. (DoH 2003) This is similar to the methods used by some multinational companies with large resources in high-risk industries, but has not yet been applied in the NHS.

## A multidisciplinary approach to patient safety

The Design for Patient Safety report proposed projects to implement its recommendations. The Designing Out Medical Error (DOME) project successfully won funding from the Engineering and Physical Sciences Research Council. The aim of the DOME project was to test the hypothesis that a systems-based, user-centred, design-led multidisciplinary approach involving key stakeholders including clinicians and manufacturers could substantially benefit patient safety and ideally “design out” medical errors before they occur.

Being systems-based means appreciating the broader context and the human factors that influence performance. Three of those factors include the people, the processes and the products that they use. Each influences the other. Designing better equipment can influence behaviour and practices and improve the performance of teams of healthcare professionals. Being user-centred means starting by analysing the needs of the user and not by proceeding to merely iteratively improve existing designs. Design-led means conducting the project as a design process. The design process has been described in various ways including: starting with the problem, exploring and understanding the problem and factors contributing to it and focusing the challenge as a design brief. Ideas are created to solve the challenge without restriction in order to explore every avenue. Ideas are filtered and the most effective, acceptable and viable concepts are selected. (Design Council 2007) Being multidisciplinary means involving key stakeholders at all stages from the start, including designers, clinicians and manufacturers.

## We chose the surgical ward environment

Among hospital departments, surgical services are associated with the highest frequency of adverse events and therefore, it is a priority to address the causes of surgical adverse events. (Wilson, Runciman et al. 1995, Thomas, Studdert et al. 2000, Vincent, Neale et al. 2001, Davis, Lay-Yee et al. 2003, Baker, Norton et al. 2004, de Vries, Ramrattan et al. 2008) Approximately half of these adverse events are preventable. (Gawande, Thomas et al. 1999, Calland, Adams et al. 2002, Healey, Shackford et al. 2002) The majority of adverse events in surgical patients are not associated with errors in the technical aspects of performing an operation, (Gawande, Thomas et al. 1999, Andres, Remon et al. 2005) but are instead associated with the non-operative management including avoidable delays in treatment, inadequate monitoring and supervision, personnel practicing outside their expertise and inappropriate treatment. (Briant, Morton et al. 2005) There is limited evidence regarding the location of the root causes, but what evidence exists suggests that an important source of preventable surgical adverse events is the surgical ward. (Brennan, Leape et al. 1991, Wilson, Runciman et al. 1995, Davis, Lay-Yee et al. 2003, de Vries, Ramrattan et al. 2008) Most studies of surgical safety have focused on the operating theatre, neglecting the critical role of ward care. The general surgery ward is ubiquitous to in-patient general surgery care. It is on the general surgery wards where patients spend the majority of their time in the hospital and where the most junior doctors manage the greatest number of patients with the least supervision. Detecting and reacting to patients that are developing a complication at the earliest opportunity is the purpose of keeping patients monitored on the ward. In the ward, timely detection and management of complications may prevent unfavorable consequences. In addition, errors in pre- and postoperative ward care can undermine the outcome of technically sound operations. For example, one study found that 42% of general surgical patients did not receive their long-term cardiac medication, as they should have done before their operation. (Corfield, Trivedi et al. 2006) This could lead to arrhythmias, uncontrolled blood pressure and increase morbidity and mortality. Venous thromboembolism, a common postoperative risk, could potentially have been prevented in two-thirds of cases if indicated prophylaxis had not been omitted. (Arnold, Kahn et al. 2001) Surgical site infection is the most common healthcare associated infection. The correct implementation of current evidence-based guidelines including preoperative skin cleansing and antibiotics may only prevent 55% of cases. (Umscheid, Mitchell et al. 2011) Other measures to break the transmission of germs are required to prevent the rest. The earlier detection of deterioration through increased vigilance and more rapid response might improve outcome of critically ill surgical patients. (Subbe, Williams et al. 2005) The NCEPOD report, knowing the risk 2011 has called for better surgical ward care. (NCEPOD 2011)

# The DOME project

## Plan

### *Challenge*

To create interventions that are welcomed by end-users and work by influencing human factors to improve patient safety.

### *Hypothesis*

We believe that healthcare can be safer if we consider all three elements of the healthcare system together (team, process and equipment) with a multidisciplinary team in a way that empowers patients and healthcare professionals through the process of co-design.

### *Aim*

Bring together a multidisciplinary team of hospital staff, safety experts and process analysts from St. Mary's Hospital and Imperial College London together with designer-researchers from the Royal College of Art. Analyse the system of ward processes, prioritise errors, generate ideas and concepts, co-design prototype interventions and measure their impact.

### *Output*

- An example of a collaborative multidisciplinary healthcare co-design process
- A suite of concept designs
- Trials of prototypes

# The DOME project overview

## *The multidisciplinary team*

The Design for Patient safety report hypothesised that patient safety could be improved with better design. (DoH 2003) The DOME hypothesis was better design required designers, clinicians, psychologists and business experts to work collaboratively.

## *Involving patients and healthcare staff in co-design*

The team immersed themselves in the surgical ward environment and engaged with patients and hospital staff, gained their trust and encouraged open conversation and shared insights. This rapport allowed valuable user input and feedback at all stages.

## *Setting the design challenges*

Through systematically reviewing the literature, making observations and risk assessments, the five most problematic processes and their components were revealed. We addressed these by first making design briefs, which defined targets for the next phase.

## *Generating ideas and concepts*

We used brainstorms, focus groups, workshops and site visits to analogous industries and continuous consultation with patients and healthcare staff to create a broad range of ideas, which we narrowed down to a selection of concepts.

## *Prototype trials*

Allowing end-users to try out the new designs in a simulated ward environment enabled their safety and usability to be checked. This also permitted the designs to be refined for the clinical prototypes, which underwent clinical trials on the wards.

# The multidisciplinary team

## *Designers*

### Helen Hamlyn Centre for Design

Professor Jeremy Myerson Principal Investigator

Ed Matthews Project Manager

Dr Beverly Norris Co-Investigator

Jonathan West Senior Research Associate

Grace Davey Senior Research Associate

## *Clinicians*

### Imperial College London - St Mary's Hospital

Professor George B Hanna Co-Investigator, Clinical practice and Imperial College lead

Mr Rajesh Aggarwal Co-Investigator

Mr Oliver Anderson Clinical Research Fellow

## *Psychologists*

### Imperial College London - Centre for Patient Safety and Service Quality

Professor Charles Vincent Co-Investigator

Andrea Brodie Research Associate

## *Business analysts*

### Imperial College London Business School

Professor John Bessant Co-Investigator

Dr Maria Kapsali Research Associate

Dr Emma Stanton Research Associate

## Advisory board

Professor Roger Coleman Professor Emeritus Royal College of Art

Andrew Worthington Principal Nurse Barnet and Chase Farm NHS Hospitals

Dr Sally Curtis Consultant Microbiologist Imperial College Healthcare NHS Trust

Colin Matthews Chief Operating Officer Team Consulting

Colum Lowe Partner Being Design

Professor John Wilson Professor of Human Factors University of Nottingham and Principal Ergonomist Network Rail

Professor Nick Cheshire Professor of Vascular Surgery Imperial College Healthcare NHS Trust

Shahana Buchanan Health, Safety, Environment and Community Director, North America, Ausenco

Professor Barrie Mintz Professor Emeritus School of Engineering and Mathematical Sciences City University London

John Warrington Deputy Director Procurement Policy and Research Department of Health

Steve Graham Partner Hadley Graham

## The DOME project timeline

The original plan for the DOME project was divided into seven work packages over three years.

### Work package 1 (0-6 months)

Ethical permission for the DOME project was obtained. Exploratory observations and a literature review were conducted.

### Work package 2 (6-12 months)

User risk assessment surveys, process mapping and Failure Mode and Effects Analyses were conducted.

### Work package 3 (12-18 months)

Representatives from analogous high-risk industries were interviewed and site visits were made.

### Work package 4 (12-18 months)

Design briefs were defined.

### Work package 5 (18-30 months)

Ideas were generated and concepts were designed

### Work package 6 (24-30 months)

Working prototypes were made, further ethical approvals granted, simulation and clinical trials were conducted.

### Work package 7 (30-36 months)

Conference presentations, exhibitions, the DOME Website and published papers were used to disseminate the results.

The progress of the project adhered to this timeline very closely.

## Exploring the problem

In order to explore the subject of medical error in surgical wards, we conducted a systematic review of the literature on surgical adverse events. An adverse event is defined as 'an unintended injury or complication resulting in harm that is caused by healthcare management and not by the patients' underlying disease.' (Brennan, Leape et al. 1991) This definition is the most widely accepted measure of patient safety in the literature. The detailed report of this study is in part two of this thesis; a systematic review of surgical adverse events, which is published in the American Journal of Surgery. (Anderson, Davis et al. 2013) We included 19 studies reporting the frequency of unintended injuries or complications resulting in harm caused by the healthcare management of at least 93224 surgical patients. We wanted to investigate surgical adverse events so that we could target patient safety improvement efforts and gain insights into how design could improve patient safety.

We determined the frequency, severity and preventability of the consequences and causes of surgical adverse events and quantified preventable patient harm. We demonstrated that errors in non-operative management caused more frequent and severe adverse events than errors in surgical technique. Non-operative management errors consisted of incorrect or delayed diagnosis and treatment associated with monitoring, medication, anaesthesia and judgement. Wound problems were the most frequent and the most frequent preventable consequence of surgical adverse events. This category included wound infections, a healthcare associated infection. Cardiovascular and gastrointestinal complications of surgical adverse events were the types of surgical adverse event consequences associated with the most fatalities and severe harm. We confirmed that patient safety improvement efforts should include the surgical ward and not only the operating room and justified our focus on this environment.

What this study did not give us was insight into how design could be improved to benefit patient safety. The original articles associated each error with one cause. This does not subscribe to the system-based approach that suggests many factors throughout the organisation contribute to errors. We needed to conduct our own study to get this crucial information.

## Observations, mapping, risks prioritisation & cause analysis

In order to design interventions to improve patient safety in surgical wards we required more information than detailed in the published literature on surgical adverse events. The system of healthcare is composed of teams, processes and equipment. We needed to understand the system in order to adopt a system-based approach. Therefore, we conducted a series of observational studies on surgical wards. Firstly, we spent time in and observed the surgical ward environment. Imperial College Healthcare NHS Trust has three hospitals: St. Mary's, Charing Cross and Hammersmith Hospitals. The multidisciplinary design team experienced all of the surgical wards and spoke to patients, carers and healthcare professionals. What was instantly recognised was the great complexity of the surgical ward environment and overwhelming multitude of opportunities for design interventions. The DOME project needed a structure that would limit the scope of the work to make it manageable and a systematic method for achieving this that could be repeated. The detailed report of this study is in part two of this thesis; a systematic proactive risk assessment of hazards in surgical wards, which is published in the Annals of Surgery. (Anderson, Brodie et al. 2012) We used observations, surveys and modified Healthcare Failure Mode and Effects Analysis to prioritise the highest risk medical errors in surgical wards. Firstly we observed all activities to determine the processes of healthcare that teams of healthcare professionals engaged in and the equipment involved. Then we asked patients and healthcare professionals to rate how risky they felt the processes were. We took the five highest-risk processes, which was a manageable number, and then subjected them to modified Healthcare Failure Mode and Effects Analysis. This process mapped out the steps in each process, rated each step for risk by a group of stakeholders including patients and healthcare professionals, and gave insights into the causes of the high-risk steps. This not only allowed us to focus the DOME project, but also gave us a shared experience and understanding of the system of healthcare in our chosen environment. The process maps gave us a platform, which we called the common language that was essential for our multidisciplinary team to function effectively and also allowed efficient communication with patients and healthcare professionals.

The five most hazardous healthcare processes on surgical wards were:

1. hand hygiene,
2. information hand-over,
3. vital signs monitoring,
4. isolation of infection and
5. medication delivery.

## Generating ideas

Ideas were generated by visiting hospitals and talking to patients and staff, brainstorming sessions, liaising with experts, workshops and gaining advice from safety representatives from analogous industries.

The DOME team considered how other industries have improved safety. Emma Stanton, completed an MBA entitled *What can patient safety learn from analogous high hazard industries?* (Stanton 2009) She investigated how the chemical, mining, oil and rail industries managed safety and drew analogies with healthcare. This learning was incorporated into the DOME project and the DOME team also consulted safety representatives from the chemical and rail industries directly and also visited a chemical plant and a construction site to search for more ways that patient safety could benefit from design in these industries. The design of tasks, reminders, equipment and space were identified as important generic components that influenced our solutions.

We presented ideas as words on posters to patients and healthcare staff to gather their opinions. These are shown in the subsequent figures along with how the ideas were filtered down to concepts under the heading of each healthcare process. Members of the DOME team described, explained and discussed the ideas with the participants. Participants gave their feedback and opinions. We selected ideas that showed potential to turn into a suite of concepts that addressed each of the five healthcare processes.

The ideas were developed into concepts by making sketches, creating computer models and physical prototypes. Patients and healthcare staff provided continuous critical feedback at every stage and were actively engaged in the process of co-design.

# A suite of concepts

## Hand hygiene

### *Design brief*

Improve hand hygiene by designing a way of effectively reminding and educating staff to clean their hands at the right time, when entering and exiting the bed space.

### *The Problem*

The role of hand hygiene in preventing the spread of infection is well known, but the lack of effective reminders means people still do not wash their hands at the right time. There is a plethora of hand hygiene reminders on the ward, mainly positioned at the entrance to wards or bays, but there is a lack of focus at the point of care – in the bed space.

### *Insights*

The team visited a construction site where there was a different approach to signage. Instead of posters or homemade laminated signs, every sign was official, clear, and instantly recognisable. This insight inspired the development of a single hand hygiene symbol for use on hospital wards.

### *The Solution*

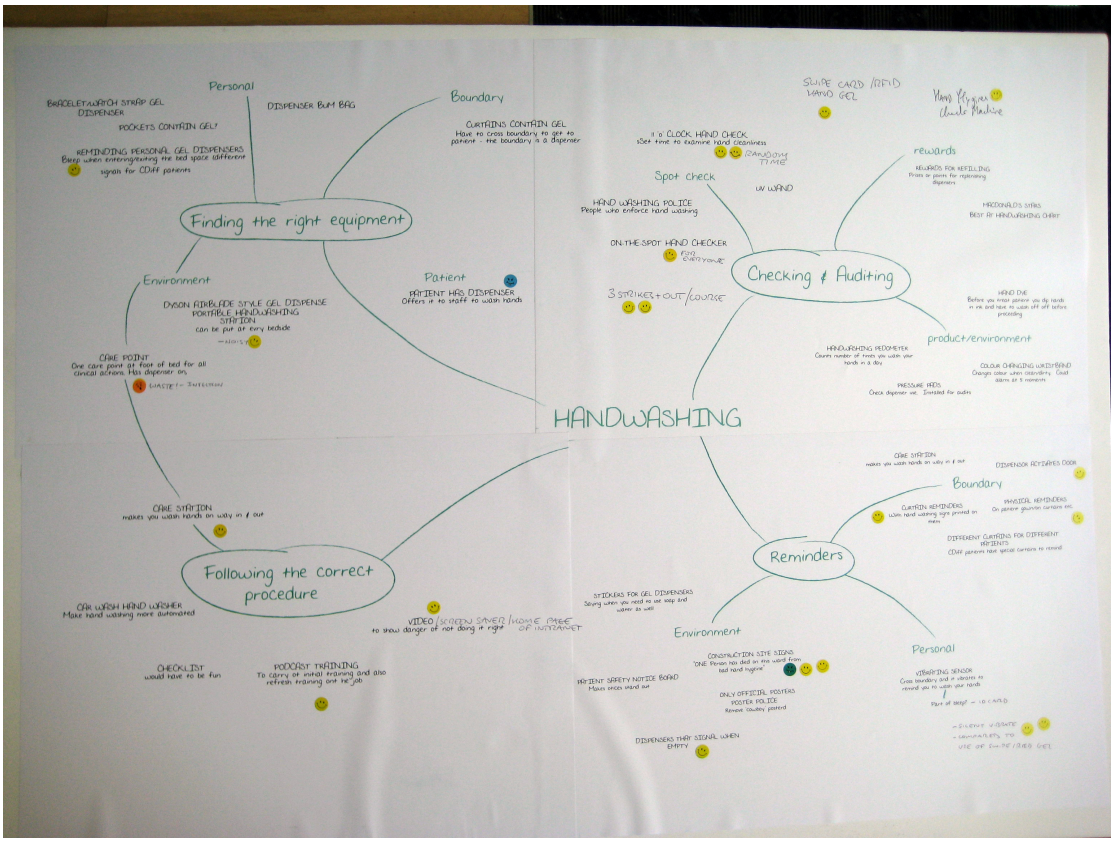
The hand hygiene symbol was developed to standardise the visual reminders on the ward; the communications campaign raises awareness and educates staff about the new initiative.

### *How It Works*

The mirrored signs catch people's attention as it emphasises movement in the bed space. The supporting campaign uses novel ways to raise awareness, and educate staff about the new initiative.

(Anderson, Davey et al. 2011)

Figure 1.1. Hand hygiene ideas & concepts




| INITIAL IDEAS | | MOST POPULAR IDEAS | IDEAS TO BE TAKEN FORWARD |
|---|---|---|---|
| **Finding the right equipment** | | | |
| Personal | Dispenser bum bag | | |
| | Bracelet/watch strap gel dispenser | | |
| | Pockets contain gel? | | |
| | Reminding personal gel dispensers | | |
| Environment | Care station | Care Station | |
| | Mobile Sink | Mobile Sink | |
| | Dyson airblade style gel dispense | | |
| Patient | Patient has dispenser | | |
| Boundary | Curtains contain gel | | |
| **Checking & Auditing** | | | |
| Spot Check | Hand washing police | | |
| | On-the-spot hand checker | On-the-spot hand checker | |
| | UV wand | | |
| | 11 'O' clock hand check | 11 'O' clock hand check | |
| Rewards | Rewards for refilling | Dispenser Indicates when empty | |
| | Macdonald's stars | | |
| | Hand dye | | |
| | Best at handwashing chart | | |
| Facilitate | Colour changing wristband | | |
| | Pressure pads | | |
| | Wireless id badge | Wireless handwashing reminder | |
| | Handwashing pedometer | | |
| **Following correct procedure** | | | |
| Facilitate | Care station | Care Station | |
| | Car wash hand washer | | |
| Training | Checklist | | |
| | Podcast training | | |
| | Video | | |
| **Reminders** | | | |
| Boundary | Care station | Care Station | |
| | Dispenser activates door | | |
| | Physical reminders | | |
| | Curtain reminders | | |
| | Different curtains for different | | |
| Personal | Wireless reminder | Wireless reminder | |
| Environment | Construction site signs | Construction site signs | |
| | Only official posters | | |
| | Patient safety notice board | | |
| | Lights sensors on gel dispensers | | |

**Care Station**

A product that enables staff to comply with hand hygiene and infection control protocols by positioning all the necessary equipment in one convenient place. Furthermore it could support the other three processes: medication delivery, vital signs and handover; A central hub for bed space activity.

**Wireless Handwashing Reminder**

A wireless system which could track staff movement on the ward and subtly remind them when they should wash their hands in line with the WHO five moments. It would 'learn' so as to only remind non-compliers.

This system could also incorporate equipment reminders.

**Universal Signage**

The design of universal signs for hand washing and infection control, to provide clear visual reminders to take the necessary precautions.







# Isolation of healthcare-associated infection

## *Design brief*

Design a way to improve staff use of the apron and gloves for patients with a known infection, and encourage the use of alcohol hand gel.

## *The Problem*

Staff do not always adhere to infection control rules, because the apron and gloves are not always handy, and the alcohol hand gel is easy to forget.

## *Insights*

From spending time shadowing nurses and immersing themselves in the ward environment, the team observed that most equipment needed for patient care at the bedside was scattered all around the ward. This not only meant that common tasks took longer to complete, it also made it difficult for staff to stick to procedure as the equipment they needed was not easily accessible.

## *The Solution*

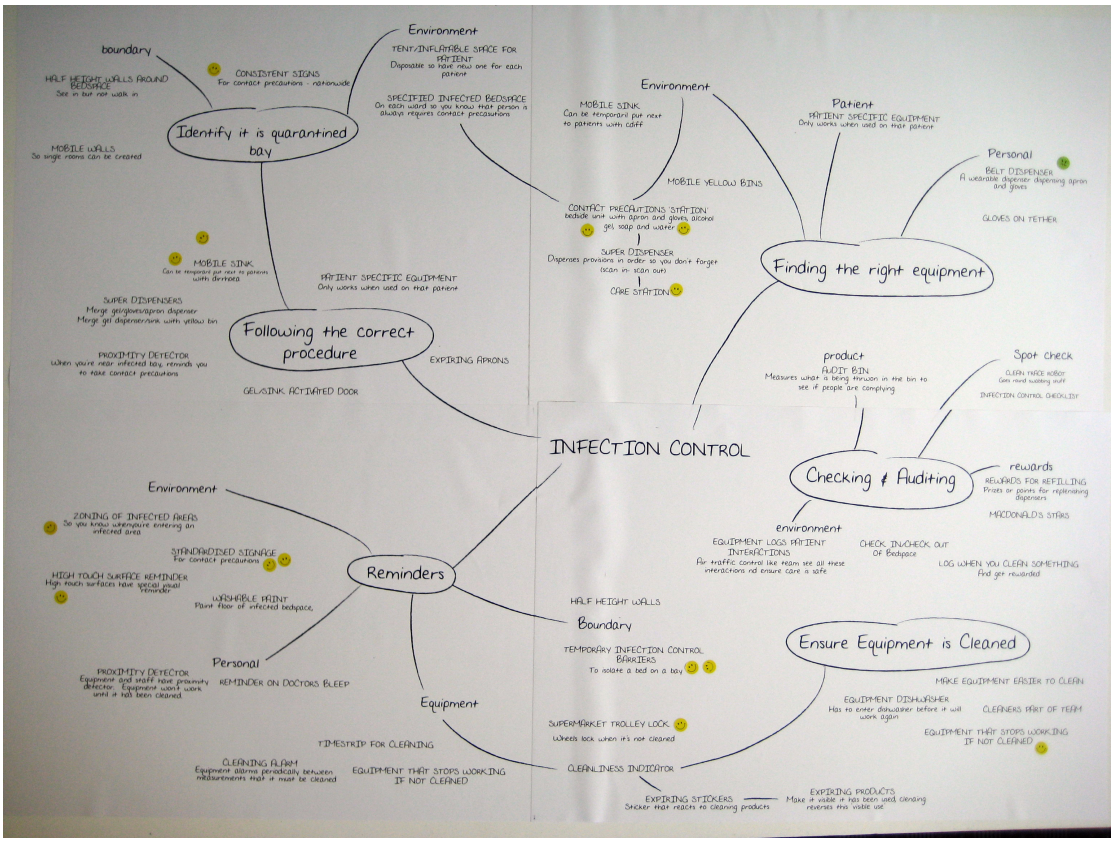
The Care Station houses all the equipment needed to care for a patient in the bed space. It contains gloves, aprons, hand gel, a medication locker, a bin, and has a flat surface for reading and writing documents.

## *How It Works*

The Care Station is located at the end of every bed. The staff workflow is channelled past it, and the gloves, apron and gel become much more readily accessible. It also contains other items such as medication, streamlining the work and improving efficiency and compliance.

(Anderson, Davey et al. 2011)

Figure 1.2. Isolation of infection ideas & concepts




| INITIAL IDEAS | | MOST POPULAR IDEAS |
|---|---|---|
| **Finding the right equipment** | | |
| Personal | Belt dispenser | |
| | Gloves on tether | |
| Environment | Contact precautions 'station' | Contact precautions 'station' |
| | Super dispenser | Super dispenser |
| | Care station | Care Station |
| | Mobile sink | Mobile Sink |
| | Mobile yellow bins | |
| Patient | Patient specific equipment | |
| **Checking & Auditing** | | |
| Facilitate | Audit bin | |
| Spot check | Clean trace robot | |
| | Infection control checklist | |
| Rewards | Rewards for refilling | Dispenser Indicates when empty |
| | Macdonald's stars | |
| Environment | Check in/check out | |
| | Log when you clean something | |
| | Equipment log patient interaction | |
| | Wireless id badge track staff | Wireless id badge tracks staff |
| **Ensure Equipment is Cleaned** | | |
| | Make equipment easier to clean | |
| | Cleaners part of team | Wireless handwashing Badge |
| | Equipment doesn't work if not cleaned | |
| **Following correct procedure** | | |
| Facilitate | Care station | Care Station |
| | Mobile sink | Mobile sink |
| | Super dispensers | Super dispensers |
| Enforce | Patient specific equipment | |
| | Expiring aprons | |
| | Gel/sink activated door | |
| | Proximity detector | |
| **Reminders** | | |
| Boundary | Temporary infection control barriers | |
| Equipment | Supermarket trolley lock | |
| | Cleanliness indicator | Cleanliness indicator |
| Personal | Wireless reminder | Wireless reminder |
| | Proximity detector | |
| Environment | Zoning of infected areas | Zoning of infected areas |
| | Construction site signs | Construction site signs |
| | High touch surface reminder | High touch surface reminder |

**Care Station**

A product that enables staff to comply with hand hygiene and infection control protocols by positioning all the necessary equipment in one convenient place. Furthermore it could support the other three processes; medication delivery, vital signs and handover; A central hub for bed space activity.

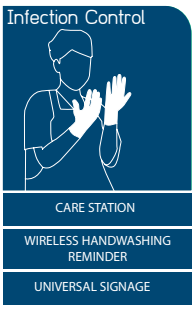
**Wireless Handwashing Reminder**

A wireless system which could track staff movement on the ward and subtly remind them when they should wash their hands in line with the WHO five moments. It would 'learn' so as to only remind non-compliers.

This system could also incorporate equipment reminders.

**Universal Signage**

The design of universal signs for hand washing and infection control, to provide clear visual reminders to take the necessary precautions.





# Vital signs monitoring

## *Design brief*

Redesign the way vital signs such as blood pressure and temperature are measured, making the recording of results and the cleaning of the equipment easier.

## *The Problem*

A patient's deterioration may be missed if vital signs are not measured at the right time, if they are not documented properly, and if they are not correctly interpreted. One of the most important indicators – respiratory rate – is often not measured at all. The vital signs equipment has the potential to spread infection as it is wheeled from patient to patient; the cables are often tangled and it is difficult to clean.

## *Insights*

From carrying out an audit of the charts the team saw that plotting was inconsistent and it was not surprising that the results were not correctly interpreted. It was clear that an electronic system would remove transcription errors. A simple redesign of the trolley introducing easy clean surfaces and a cable management solution was also necessary.

## *The Solution*

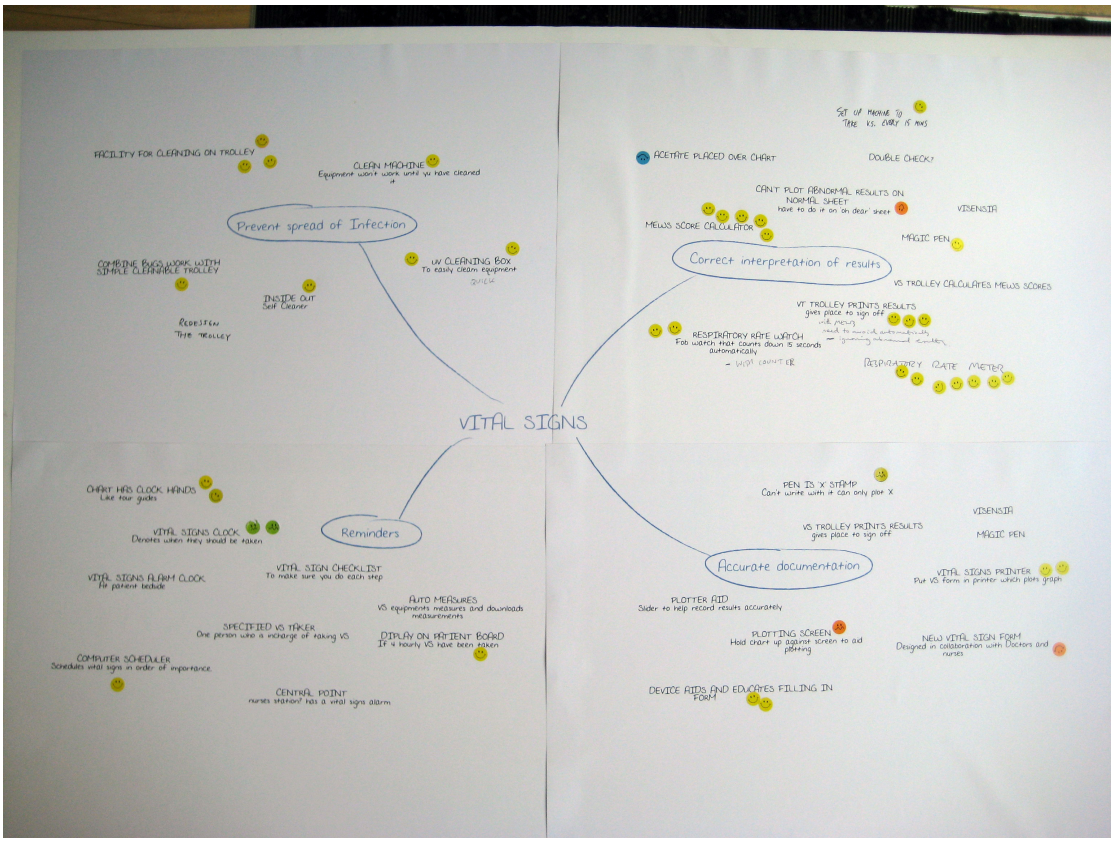
The easy-clean design and improved cable management system of the trolley reduces the risk of infection. The new interface facilitates easy collection of results including respiratory rate, which is often overlooked, whilst the automatic plotting removes transcription errors. The trolley can dock with a larger computer on wheels.

## *How It Works*

The screen guides the nurse through the correct procedure, captures all the data and automatically displays the figures on a chart. The screen also helps nurses to accurately measure respiratory rate, which is a crucial but often neglected vital sign. When finished, the cables are retracted back into the trolley, keeping it tidy and making it easier to clean.

(Anderson, Davey et al. 2011)

Figure 1.3. Vital signs ideas & concepts




| INITIAL IDEAS | | MOST POPULAR IDEAS |
|---|---|---|
| **Prevent spread of Infection** | | |
| **Facilitate** | Facility for cleaning on trolley | **Facility for cleaning on trolley** |
| | Clean machine | **Clean machine** |
| | UV cleaning box | |
| | Inside out | |
| | Combine with bugs work | |
| | Easy clean trolley | **Easy clean trolley** |
| **Reminders** | Supermarket trolley lock | |
| | Cleaning alarm | |
| **Interpretation of results** | | |
| Recording | Acetate placed over chart | |
| | Double check? | |
| | Can't plot abnormal results | |
| | Re-design of chart | **Re-design of chart** |
| | Respiratory rate meter | **Respiratory rate meter** |
| **Interpretation** | Mews score calculator | **Mews score calculator** |
| | VS trolley calculates mews scores | **VS trolley calculates mews scores** |
| | VS trolley prints results | **VS trolley prints results** |
| | Wireless uploading of data for analysis | **Wireless uploading of data for analysis** |
| **Reminders** | | |
| | Chart has clock hands | |
| | Vital signs clock | |
| | Vital sign checklist | |
| | Auto measures | **Auto measures** |
| | Display on patient board | |
| | Specified VS taker | |
| | Vital signs alarm clock | |
| | Computer scheduler | **Computer scheduler** |
| | Central point | **Central point** |
| **Accurate documentation** | | |
| | Pen is 'x' stamp | |
| | VS trolley prints results | **VS trolley prints results** |
| | Magic pen | |
| | Plotter aid | |
| | New VS form | |
| | Device aids and educates filling in | |

IDEAS TO BE TAKEN FORWARD

**Easy Clean Vital Signs Trolley**

Re-design the Vital Signs trolley so it is easier to clean as well as combining with the 'Design Bugs Out ' blood pressure cuff and pulse oximeter.. The issue of documentation and interpretation of results must also be addresses as part of the design.

**Respiratory Rate Meter**

The design of a device to measure respiratory rate to ensure it is measured more frequently and accurately.

**Wireless Cleaning Reminder and Data Transfer**

A wireless way of tracking equipment in the bedspace (part of the wireless handwashing reminders system), to ensure equipment is cleaned between patients. The network could also transmit data to avoid transcription errors.

**Care Station**

A product that enables staff to comply with hand hygiene and infection control protocols by positioning all the necessary equipment in one convenient place. Furthermore it could support the other three processes; medication delivery, vital signs and handover; A central hub for bed space activity.




EASY CLEAN TROLLEY

RESPIRATORY RATE METER

WIRELESS CLEANING REMINDER AND DATA TRANSFER

CARE STATION




37
120
80
62
98
16

# Handover communication

## *Design brief*

Design a way to improve the accuracy and reliability of handover of information between shifts.

## *The Problem*

Handover is vital to the continuity of patient care. A successful handover needs to be supported by a well-designed environment with all the necessary information at hand. It usually takes place in a room, which is ill- equipped, too small and prone to interruption.

## *Insights*

The team surveyed 50 ‘handover rooms’ in three hospitals. This revealed that there was actually no such thing as a ‘dedicated handover room’ and handover usually took place in a staff room, nurses station or office.

## *The Solution*

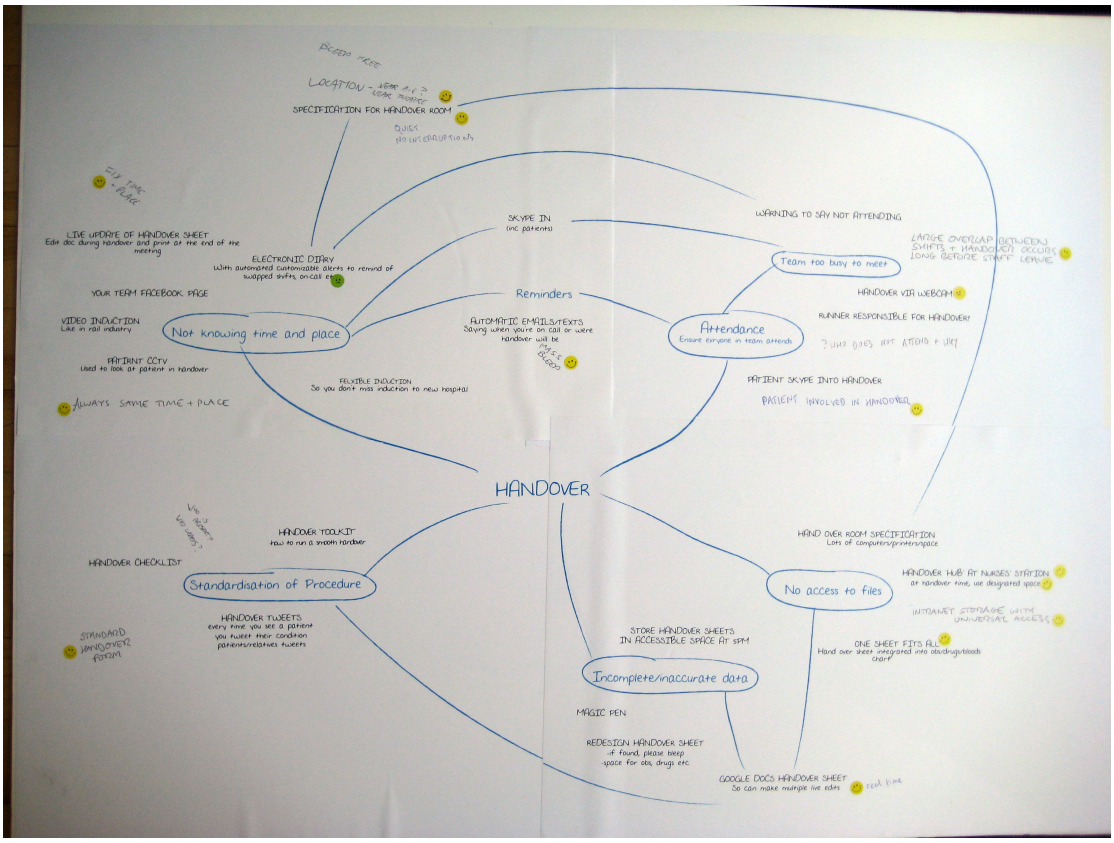
The design of an exemplar environment to support a safer handover. This multi-purpose room incorporates all the necessary equipment needed for an effective handover, as well as flexible seating for up to ten nurses. When not being used for handover it provides a relaxing staff room environment.

## *How it works*

Because space is at a premium it is not possible to have a room solely for handover. Therefore the room is designed to be flexible and has two modes: when in handover mode there is bright lighting, formal seating, writing surfaces and signage to reduce interruptions; when in staff room mode there is relaxing lighting, comfortable seating and a kitchenette for staff to take their breaks.

(Anderson, Davey et al. 2011)

Figure 1.4. Handover ideas & concepts




| INITIAL IDEAS | | MOST POPULAR IDEAS |
|---|---|---|
| **Not knowing time and place** | | |
| Reminders | Automatic reminders - emails/texts | Handover software |
| | Mass bleep | |
| | Electronic diary | |
| | Your team facebook page | |
| Informing | Flexible induction | Handover toolkit |
| | Video induction | |
| Make it easier to attend | Patient cctv | |
| | Always same time and place | Design of new handover room |
| | Specified handover room/place | |
| | Skype In | |
| **Attendance** | | |
| Reminders | Automatic reminders - emails/texts | Handover software |
| | Mass bleep | |
| | Electronic diary | |
| | Your team facebook page | |
| Informing | Warning to say not attending | |
| Make it easier to attend | Specified handover room/place | Design of new handover room |
| | Always same time and place | |
| | Runner responsible for handover Skype | |
| | Skype in | |
| | Patient skype into handover | |
| | Bigger overlap between shifts | |
| | Handover via webcam | |
| **Standardisation of procedure** | | |
| Streamline process | Handover checklist | |
| | Handover 'toolkit | Handover toolkit |
| | Handover tweets | |
| Form | Standard handover form | Handover toolkit |
| | Live update of handover sheet | Handover software |
| **Incomplete/inaccurate data** | | |
| Accessibility | Store handover sheets in accessible | |
| | Magic pen | |
| Real time updates | Live update of handover sheet | Handover software |
| | Internet storage with universal access | |
| Completeness of data | Redesign handover sheet | |
| **No access to files** | | |
| Specific space | Hand over room specification | Design of a new handover room |
| | Handover 'hub' at nurses' station | Specification for ideal handover room |
| Form | One sheet fits all (inc bloods, obs, etc.) | Handover software |
| | Google docs handover sheet | Handover software |

**IDEAS TO BE TAKEN FORWARDS**

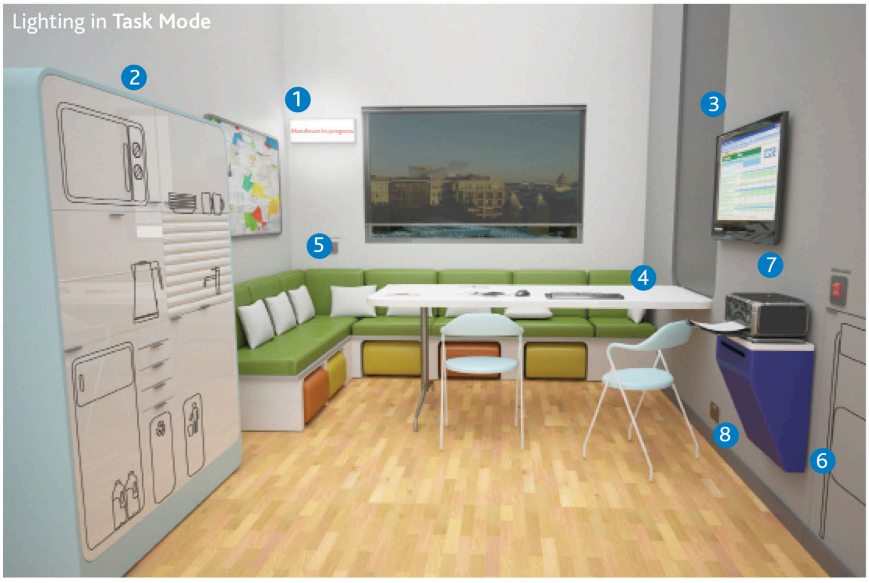
**Handover Toolkit**

Providing tools to facilitate efficient handover, including; a specification for what should be included in an ideal handover room, how to encourage less interruptions, and software with template handover sheets and a server to store sheets and facilitate live editing.

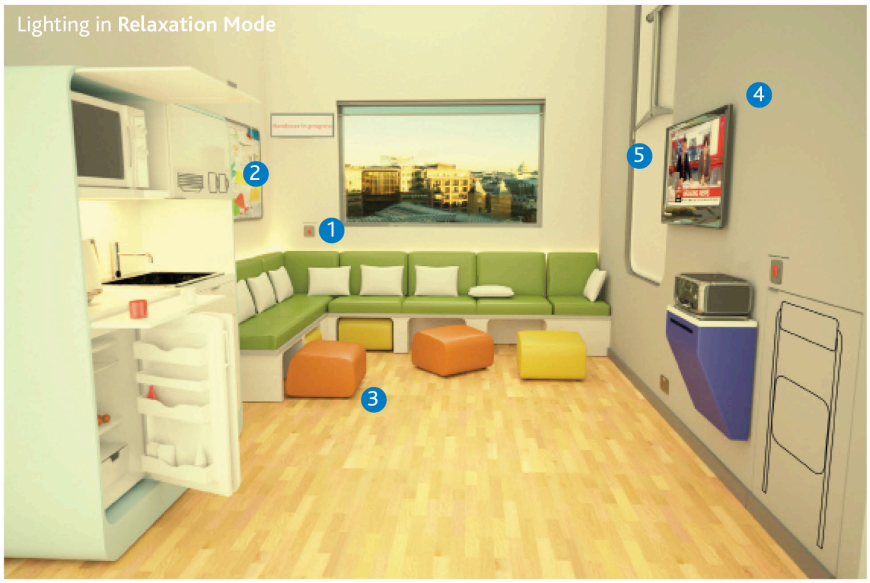
**Care Station**

A product that enables staff to comply with hand hygiene and infection control protocols by positioning all the necessary equipment in one convenient place. Furthermore it could support the other three processes; medication delivery, vital signs and handover; A central hub for bed space activity.






1 'Handover in Progress' sign
2 Kitchenette tidied away
3 Integrated software and screen
4 Fold down table for writing
5 Formal seating for 8 nurses
6 Addition folding chairs
7 Printer
8 Confidential waste bin




1 Comfortable fexible seating
2 Kitchenette
3 Additional stolls/foot rest
4 Television
5 Table stowed away

# Medication delivery

## *Design brief*

Design a way of improving the safety of the drugs round on a ward by reducing omissions (nurses missing a drug off a patient's round) and interruptions.

## *Insights*

The team observed medication rounds and were surprised at how many times the nurses were interrupted whilst performing such an important task. When they did get interrupted there was no safety net in place to catch an error if one occurred. If the patient was given more information and was more involved in their medication regime, it could act as a 'double check' to reduce errors. The current pill pot is lost amid bedside clutter

## *The Problem*

Failure to administer medication can have severe consequences; missed doses, repeated doses, wrong drug or wrong strength are particular errors. It is not only the staff who are responsible – some patients refuse to take their own medication. The process is badly supported by equipment with many different systems evident, depending on the ward. Often the information about a drug becomes separated from the tablet, increasing the opportunities for error.

## *The Solution*

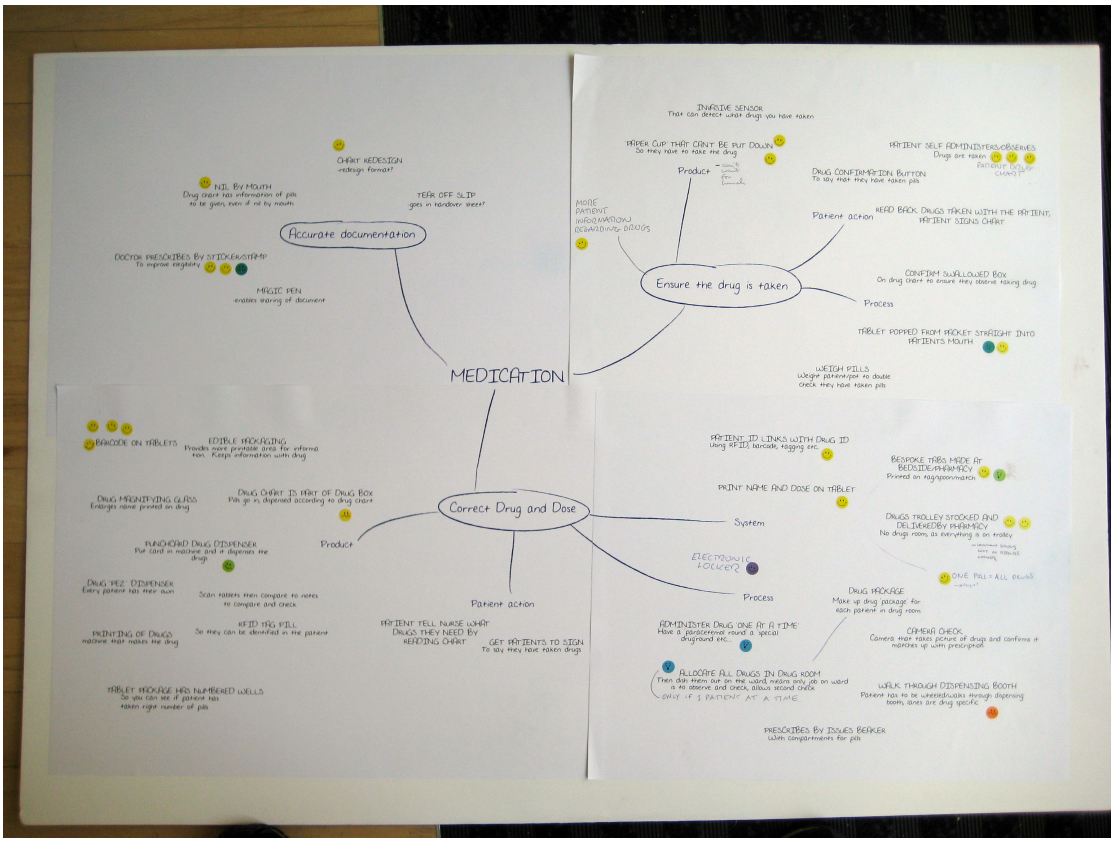
The medication pack has been redesigned in the shape of a spoon with patient-friendly information printed on the handle and the tablet contained in the end. Each patient has a dedicated tray to contain and display the new spoon-shaped packs. This keeps the information with the tablet right up to the point of ingestion.

## *How It Works*

During a drugs round, the nurse tears off a blister 'spoon' from each pack. The various spoons are placed on the patient's tray which displays all their drugs and information for that drugs round. If a drug needs to be ordered from pharmacy, a reminder 'spoon' is placed on the tray, reminding both patient and nurse that the order still needs to be completed.

(Anderson, Davey et al. 2011)

Figure 1.5. Medication ideas & concepts




| INITIAL IDEAS | | MOST POPULAR IDEAS | IDEAS TO BE TAKEN FORWARD |
|---|---|---|---|
| **Accurate documentation** | | | |
| **Legibility** | Doctor prescribes by sticker/stamp | **Doctor prescribes by sticker/stamp** | |
| | Tear off slip | | |
| **Recording** | Chart redesign | **Chart redesign** | |
| | Provide more info for nil by mouth | **Provide more info for nil by mouth** | |
| | Magic pen | | |
| **Ensure drug is taken** | | | |
| **Products** | 'Paper cup' that can't be put down | **'Paper cup' that can't be put down** | |
| | Invasive sensor detects swallowed | | |
| | More patient information about drugs | **More patient information about drugs** | |
| **Patient Action** | Drug confirmation button | | |
| | Patient self administers/observes | **Patient self administers/observes** | |
| | Patient signs chart | | |
| **Process** | Confirm swallowed box | | |
| | Tablet popped straight into mouth | | |
| | Weigh pills to confirm correct | | |
| **Correct Drug and Dose** | | | |
| **Products** | Barcode on tablets | **Barcode on tablets** | |
| | Edible packaging | | |
| | Drug magnifying glass | | |
| | Drug chart is part of drug box | | |
| | Punch card drug dispenser | | |
| | Drug 'pez' dispenser | | |
| | Printing of drugs | | |
| | Rfid tag pill | | |
| | Tablet package has numbered wells | | |
| | Re-design of patient locker | | |
| **Patient Action** | Patient tell nurse what drug they need | | |
| | Get patients to sign | | |
| | Patients self administer | **Patients self administer** | |
| **Process** | Administer drug 'one at a time' | | |
| | Allocate all drugs in drug room | | |
| | Prescribes by issues beaker | | |
| | Walk through dispensing booth | | |
| | Camera check | | |
| | Drug package | | |
| **System** | Print name and dose on tablet | **Print name and dose on tablet** | |
| | Bespoke pill made for each patient | **Bespoke pill made for each patient** | |
| | Patient id links with drug id | **Patient id links with drug id** | |
| | Drugs trolley stocked by pharmacy | **Drugs trolley stocked by pharmacy** | |

**The Multi-pill**

A pill which would be produced uniquely for each patient for each occasion they needed to take medication. It would combine all the drugs they needed in one bespoke pill, removing the chance for wrong drug/ wrong dose errors.

**Patient Information Sheet**

An information sheet design specifically for patients which provides them with information about the drugs they are taking, why are taking them, possibly side effects etc.to encourage them to actively take their drugs. There could also be provision for the patients to complete their own drigs chart.

**Care Station**

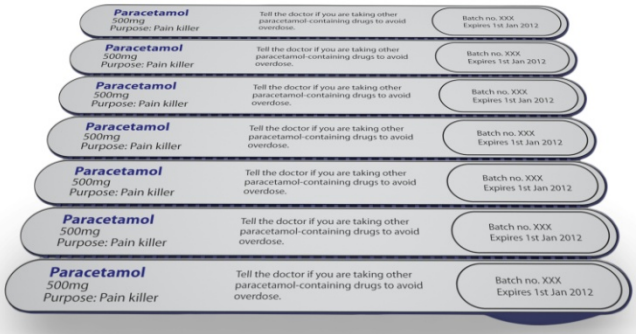
A product that enables staff to comply with hand hygiene and infection control protocols by positioning all the necessary equipment in one convenient place. Furthermore it could support the other three processes; medication delivery, vital signs and handover; A central hub for bed space activity.




THE MULTI-PILL

PATIENT INFORMATION SHEET

CARE STATION


Paracetamol
500mg
Purpose: Pain killer
Tell the doctor if you are taking other paracetamol-containing drugs to avoid overdose.
Batch no. XXX
Expires 1st Jan 2012


Please ask your doctor or nurse if you are unsure about your medication.
Mr J Smith
DOB 17/08/1975
Hosp no. 1234567
Paracetamol
Co-Amoxiclav
Omeprazole
medication on order

## Selection of concepts to be prototyped

The DOME project team weighed up the viability of progressing each of the concepts to the prototype stage. The factors we took into consideration included the potential benefit to patient safety, feasibility of manufacture and suitability for trial. We piloted the hand hygiene concept signs and they did not demonstrate a beneficial effect. They were easy to manufacture, but to demonstrate a convincing significant benefit would require a large study that was beyond our resources. We pursued development of the Care Station, because it addressed both hand hygiene and isolation of infection briefs, was novel and potentially effective and the DOME project team already had a relationship with a potential manufacturer, Bristol Maid, which could deliver a working prototype within the time scale and could be trialed. The DOME team worked with HumanScale to develop the Vital Signs trolley concept. Unfortunately, no working prototype was produced for trial, partly because HumanScale mainly sell to the American Market that do not purchase vital signs trolleys, because their patients are mostly in single rooms with a fixed monitor at the bedside. Therefore, we pursued development of the Respiratory Rate Recorder that required no manufacturing to make into a working prototype that could be trialed. We liaised with the hospital regarding the handover room concept, which was a collection of multiple interventions. Testing the effectiveness of each component would require a complicated large trial. We were unable to gain permission to alter one of the handover rooms and conduct the trial within the time scale of the project. The medication-packaging concept also required a complex large-scale trial to test and the cooperation of the pharmaceutical industry that was beyond the scope and the time scale remaining in the DOME project.

## The Respiratory Rate Recorder

Respiratory rate is frequently inaccurately recorded in the wards. It is measured by a nurse or healthcare assistant by manually counting how many breaths the patient takes over a period of time. Inaccurate recordings might partly be due to the absence of a well-designed medical device to facilitate the manual measurement of respiratory rate. A timing device is required for accurate respiratory rate measurement. However, healthcare workers are not provided with such a device by the healthcare organisation. The most accessible device is a wristwatch, but due to the *bare below the elbows* policy, healthcare workers are not supposed to wear one. (Henderson and McCracken 2008) The *bare below the elbows* policy intends to reduce the risk of healthcare-acquired infection through the increased efficacy of hand hygiene whilst no clothing or jewellery other than a wedding ring is worn below the elbows. Lapel-worn fob watches are not freely available and must be purchased by healthcare workers at their own expense. Wall clocks might be present in the wards. However, wall clocks might not have a second hand or might not be visible from the bedside. The use of wall clocks is particularly unsuitable if healthcare workers wish to maintain the dignity of their patient whilst monitoring vital signs by closing the privacy curtain around them and thus obscuring the wall clock from view. Furthermore, the vital signs trolley, which is a mobile stand with blood pressure, pulse, oxygen saturation and temperature measurement equipment, has no timing device that can be used to measure respiratory rate. Even with a suitable timing device, the currently recommended method of respiratory rate measurement requires the operator to focus on counting breaths and measuring time simultaneously, which is difficult, because two objects must be observed (patient and timing device) as well as two simultaneous counting tasks (number of breaths and time remaining). Additional difficulties may occur during the process, particularly interruptions, because whilst recording respiratory rate, the healthcare worker might appear to be unoccupied and available for ad hoc requests from patients, visitors and other healthcare workers.

Medical devices that continuously monitor the respiratory rate of patients are already implemented in healthcare. Most commonly, these consist of electrocardiogram electrodes, which work by passing a small alternating current through the chest and across the lungs, thus measuring changes in electrical impedance as the patient breathes. The continuous use of these devices is usually limited to intensive care (level 3) or high dependency units (level 2) as the limited length of the electrical leads restricts the patient's mobility out of bed. Restricting the mobility of the patient is inappropriate for the majority of ward patients (level 0 or 1) who are ambulatory. Mobile continuous respiratory rate measurement devices that work by measuring electrical impedance are being developed for ambulatory patients, which include wireless stick-on chest patches. Another device, the RespiR8™ has an air flow meter built into an oxygen mask. This is useful for monitoring patients' respiratory rate during operations and postoperatively whilst recovering from the anaesthetic, but can only be used if the patient requires mask-delivered oxygen therapy. These patients are already well attended

and monitored by healthcare workers and are not the same as the group of patients who require routine postoperative vital sign observations to detect complications after they have recovered from the anaesthetic. (Smith, Mackay et al. 2011) These are alternatives to continuous monitoring devices rather than intermittent vital sign spot-checks. Alternatives to manual vital sign spot-checks include a non-invasive Radar gun, which has been used to measure respiratory rate, but its usability, accuracy and safety have not been fully evaluated in the clinical environment. (Droitcour, Seto et al. 2009) Another worn device that can be used intermittently is the respiratory belt. This has been shown to improve upon the prognostic value of manual respiratory rate recordings, but the authors admit that it is totally unsuitable for generalised clinical use and is limited to research. (Kellett, Li et al. 2011)

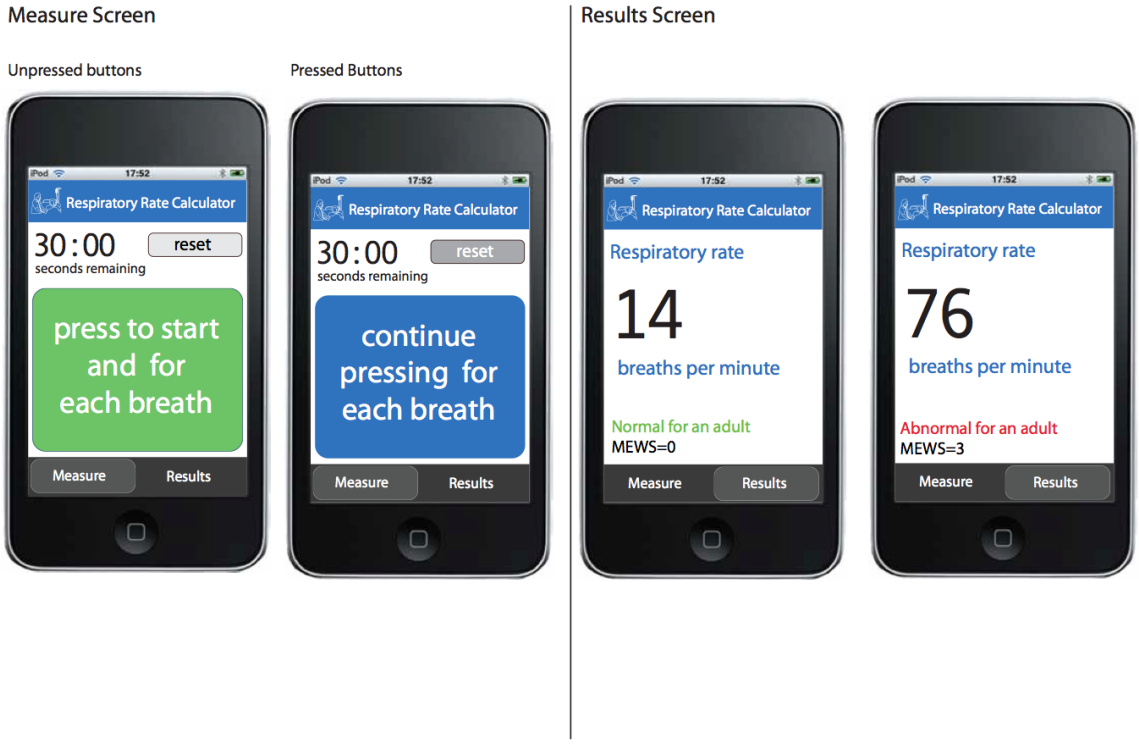
Existing innovations in this area have iteratively improved current continuous vital signs monitoring devices that are applied to patients who are already known to be unwell. Deficiencies in monitoring the respiratory rate of patients who are thought to be well may cause delay in the detection of deterioration and outcome. Therefore innovation is needed that addresses monitoring the accuracy of respiratory rate recording of patients who were initially thought to be well and have their vital signs monitored through intermittent vital signs spot-checks. The design brief we set included facilitation of the current practice of manual respiratory rate recording in the majority of patients in wards who are receiving intermittent vital signs monitoring to detect the earliest signs of deterioration to determine whether escalation of care is required. We also intended to enhance clinical skills and patient - healthcare worker contact, rather than replace them with technology. This may enhance the tacit and intangible healthcare worker skills of spotting sick patients as a secondary benefit, or at least help prevent the erosion of clinical skills.

The idea was simple. Instead of healthcare workers using an analogue watch, the Respiratory Rate Recorder concept is a replacement timing and counting device. The healthcare worker manually logs each breath by pressing and the device times 60 seconds and counts how many breaths are taken.

Ideally, we would have made a purpose built handheld device with either an electronic or mechanical mechanism. However, we did not have the in-house expertise to do this and outsourcing would have been too expensive. Therefore we explored the option of using an existing programmable hand-held electronic device. Smart phones had recently become programmable with applications (or 'apps' for short). Apple® allow anyone to build programs for iPhone® apps and use them on their own phone or a limited number of other phones. If the application meets Apple's® criteria, it can be released on the App Store and is then available to all iPhone® users either for a fee or for free. An advantage of using a phone is that it already belongs to the healthcare worker and not the healthcare organisation. It is also usually kept nearby where it is readily available. However, there are restrictions on using

mobile phones in the hospital due to disturbance to other people and electromagnetic interference with medical devices, such as implanted defibrillators and pacemakers. iPhones® can be electromagnetically isolated in "Airplane Mode" which is an option in the phone's settings. A disadvantage is that not all healthcare workers own iPhones®. However, the principal was worth testing, because the Respiratory Rate Recorder program could easily be incorporated into any suitable electronic device of a similar nature including a vital signs trolley.

Figure 1.6. Respiratory Rate Recorder



## The CareCentre®

The primary purpose of the CareCentre® was to increase healthcare worker adherence to the World Health Organisation's *my 5 moments for hand* hygiene guidelines at the bedside. The CareCentre® is a table that houses alcohol-based hand rub, aprons and gloves at a convenient location at the foot of the patient's bed. Surveys of both nurses in the intensive care unit and paediatric ward have shown that one of the factors in the environment that hampers delivery of good clinical care is lack of space to write charts. (Gurses and Carayon 2007, Gurses and Carayon 2009) By providing the additional facility of a writing surface at the end of the bed, we imagined that healthcare workers would intuitively place their documents down, thus freeing their hands to use the conveniently positioned alcohol-based hand rub. While using the alcohol-based hand rub, healthcare workers can view their documents or the patient's chart, thus wasting no time. The feeling that hand hygiene takes too much time is thought to be a factor that detrimentally affects adherence. (Weeks 1999) The raised position of the alcohol-based hand gel in the CareCentre® compared with the standard location, hung from the end of the bed, increases accessibility of the gel to healthcare workers who are standing beside the patient, where they are most in need of it. The presence of the CareCentre® might also give the impression of a threshold, which the healthcare worker must cross. We know that hand hygiene is improved by single patient rooms and in operating theatres that have walls between patients or a large, bespoke set of hand hygiene facilities between the healthcare worker and patient. (Ulrich, Zimring et al. 2008) The CareCentre® might emulate these circumstances.

The CareCentre® also housed aprons and gloves to help improve adherence of healthcare workers to isolation of infection guidelines. We imagined that this would make it more likely that healthcare workers would don and remove aprons and gloves at the bedside and not elsewhere. If aprons and gloves are worn while moving from one area to another, contact-borne healthcare-associated infections are more likely to be spread either to or from the patient. (Mangini, Segal-Maurer et al. 2007)

At this point in the development of the CareCentre®, the DOME project team decided to engage with a manufacturer. The aim of the DOME project was to work collaboratively with clinicians, designers and industry in order to increase the speed and success of translating the benefits of patient safety research and innovations into clinical practice. Therefore, we took the decision to engage industry early in the design pathway. Members of the DOME project (Jonathan West and Ed Matthews) already had a working relationship with Bristol Maid Hospital Metal Craft Limited though collaboration in the Resus:Station project since 2007. Therefore, we approached the board with the Care Station concept and the results of a user feedback survey and they agreed to collaborate and make a working prototype that could be trialed and developed into a commercial product.

## Prototype trials

The detailed reports of the Respiratory Rate Recorder and CareCentre® studies are in part two of this thesis. We began by gathering user opinions and used their feedback to make improvements to the designs. We tested the working prototypes in a simulated ward environment for safety and in order to control the variables in the environment. The simulated ward studies demonstrated a potential benefit to patient safety and raised no safety concerns. Therefore, we subsequently tested the prototypes in the hospital wards. These field trials showed that the Respiratory Rate Recorder significantly improved the accuracy of the manual measurement of respiratory rate and the CareCentre® was associated with significantly improved adherence of healthcare workers to hand hygiene guidelines.

# Discussion

## Principal findings

### *Overview*

The DOME project implemented the advice in the Design for Patient Safety Report and hypothesised that a multidisciplinary approach would be beneficial to patient safety. The DOME project team consisted of designers, clinicians, psychologists and business experts. Patients and healthcare staff were involved at every stage. We applied a systems-approach to design by analysing healthcare processes and assessing risk within them. We generated numerous ideas and concepts and these resulted in the production of two prototypes. The fact that the prototypes were efficacious in simulated and clinical trials proved the initial hypothesis. We also developed a clearly described, novel and repeatable methodology to identify and address patient safety that can be applied in other environments.

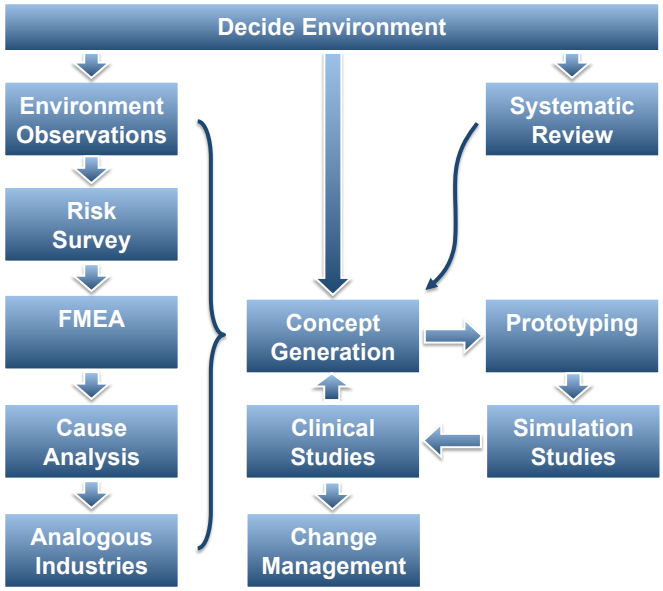
### *Summary of the DOME project journey*

The systematic review of surgical adverse events is detailed in chapter 2.1. This demonstrated what insights could be gleaned from published studies, including the frequency, severity and preventability of adverse events categorised by consequence and cause. This helped to confirm that considerable preventable patient harm might originate from the ward outside the operating theatre. We were interested in using the parameters of adverse events to prioritise where patient safety interventions could be targeted most effectively and also trace their causes back to the latent errors, particularly causes of preventable harm that might be suitable for intervention. This was not possible as the level of detail reported was limited. The results did identify that the non-operative management of surgical patients was associated with a significant quantity of preventable patient harm and worthy of further investigation. However, despite systematic literature review of surgical adverse events, little evidence-based patient safety information could be gained that might be useful to guide new design for patient safety interventions.

## *The DOME method*

We dubbed the combination of methods we used in this project as the '*DOME method,'* which is illustrated in the figure below. In order to reproduce the DOME project, the first step is to decide on the clinical environment to address. The next steps are to perform a review of the relevant literature and observe the chosen environment to determine the processes that compose the system, which are performed within it. The processes are then subjected to risk assessments to determine hazards for intervention. The causes of prioritised targets can then be explored and analogies sought in other industries that might have already found a solution. All this information feeds into the generation of ideas and concept solutions and through a process of selection, prototypes are created that can be subjected to simulation and clinical studies to prove their efficacy. End user and business involvement at every stage ensures that relevant and viable outputs are generated.

Figure 1.7. DOME method



## Strengths and weaknesses

The Design for Patient Safety report hypothesised that improved design could improve patient safety. The key strength of the DOME project was the multidisciplinary approach. By immersing designers in the healthcare environment they shared experience and collaborated with key stakeholders including patients and healthcare professionals. The support of business experts, allowed a rapid generation of ideas and concepts to be translated into working prototypes that were true to the needs of hospital staff. The design outputs are rooted in extensive clinical research, spanning the full three years of the project. This time span not only enabled an in-depth analysis of typical ward processes and errors, but also allowed for genuine co-design and co-research to take place. The DOME project delivered on every level and succeeded beyond its original goals. The five briefs were considered in parallel, in keeping with the research aim of looking at the broader context of use whenever a new design is developed. This ensured that the concepts would be fit for purpose in the complex system of a hospital ward. Using a systems approach rather than a person or product approach to human error and addressing several processes at once allowed interconnected, safer and more effective concepts to be designed. It was initially regarded as too ambitious for a 3-year project to design, develop, manufacture and distribute an evidence-based patient safety solution. In the DOME project, this was achieved twice. Firstly, with the CareCentre® which was commercialised by Bristol Maid in November 2011 and secondly with the Respiratory Rate Recorder, which was released on the App Store in November 2012. However, the most important output of the DOME project was not the physical entities, but the validation of a project methodology that can now be repeated in other environments.

## Comparison with the literature

Grout describes how the word design can be used to mean a myriad of different things. From activities as broad as simply planning and being creative to specifically changing the form of something to optimise its function. Design can be applied primarily to physical artefacts, processes and systems. Grout defines *mistake proofing*, primarily in the limited physical sense whilst acknowledging that all physical artefacts in hospitals are part of processes and the healthcare system. This includes a change to a tangible or visible part of a process, e.g. change to the connector on a syringe or appearance of tubing, rather than interventions that are limited only to changes to protocol or culture, e.g. prohibiting non-proprietary drug names. *'...if you cannot take a picture of the design change, it is probably not mistake proofing.'* (Grout 2006)

In the DOME project, we did not limit design to the definition of mistake proofing used by Grout 2006, but we took a broader approach. The executive summary of the design for patient safety report said that *'design is a structured process for identifying problems and developing, testing and evaluating user-focused solutions. It has been successfully used to transform products, services and even entire organisations.'* (DoH 2003)

The design of the healthcare environment can be categorised into a continuum based on its effect on process and outcome. (Schweitzer, Gilpin et al. 2004) At one end are the designs that are toxic and contribute to harm. Opposing these are the beneficial designs that help reduce error and harm. Both of these groups are primarily of interest to patient safety and usually exert at least part of their effect by either hindering or helping some aspect of human performance. Then there are the designs that are neutral and simply non-toxic. Finally, there are the designs that are actively healing or salutogenic and usually exert their effect directly upon the patient.

The DOME project built on these concepts and also progressed from previous design for patient safety projects that had been conducted locally. The first of these was Design Bugs Out. This project aimed to reduce the incidence of healthcare associated infections by using designers to improve the design of hospital ward furniture to make it easier to clean and more difficult to get dirty. The project produced several working prototypes that were successfully commercialised and tested during the time span of the DOME project. Unpublished reports suggest that these interventions did not improve contamination levels as hoped. The hypothesis is that the adequacy of cleaning and not the physical design might be more important, but because the project did not start with a broad remit and consider all processes that might influence healthcare associated infection, this potential factor was missed. In another project; Resus:Station, clinicians and designers worked on the design of the resuscitation trolley. They analysed the process of resuscitation and considered the physical artefact of the trolley as only part of the process and not in isolation. This led to a radical

redesign and improvement in process measures on subsequent trials of the working prototype. Unfortunately, the Market was too small to commercialise the Resus:Station. The DOME project built on the learning from these projects. The Design Bugs Out project was product-focused, the Resus:Station was process-focused, but the DOME project was system-focused and also had a multidisciplinary team with all key stakeholders from the start. The improved methodology of the DOME project was associated with faster translation of effective interventions.

## Implications

The implications of the DOME project reinforce the messages in the Design for Patient Safety report. These included statements that humans make mistakes because the healthcare system is poorly designed. A modern, systems-based, user-led, multi-disciplinary approach to healthcare design does benefit patient safety. The DOME project demonstrated the benefit of time and space for a true collaborative working methodology to emerge. It is by forging these methods of working together that the complex multidisciplinary problem of medical error can be tackled effectively. The question for clinicians and policy-makers is how to take these lessons forward. The Mayo clinic in America has an in-house design team, which can generate ideas and concepts and produce working prototypes in response to clinicians who raise concerns. These can be rapidly experimented with in the field. This is one example of a potential solution, but this is outside the NHS. A barrier to embedding designers in the NHS is funding. Research departments are rarely integrated closely into the NHS. At Imperial College London we were fortunate to have a World-class university that incorporates an NHS trust and is geographically neighbours with a World-class healthcare design centre at the Royal College of Art, but this alignment of resources is rare. Most hospitals are not close to universities or designers and the DOME project did not investigate how to implement the lessons learnt into the NHS. There is also a cultural barrier to learning the lessons from the DOME project. Healthcare research funding is focused on improving outcomes for patients and on projects that demonstrate how this will be directly achieved. The DOME project presents a strong argument for funding research that improves patient outcomes through a less direct route, by improving the hospital staff workflow. The success of the DOME project as detailed in the dissemination section helped to win funding for the Healthcare Innovation Exchange (HELIX) project (helixcentre.com).

## Unanswered questions and future research

The DOME project poses more questions than it answers. What is the ideal composition of a multidisciplinary healthcare design team or the ideal structure and methodology of a design for patient safety project? DOME more than achieved its objectives, but does not claim to be the definitive answer and it is more than likely that modified approaches are appropriate for different environments. Many of the concepts that were presented in the DOME project were not pursued to the working prototype stage and were not trialed. We remain interested in developing the vital signs trolley, handover room and medication packaging concepts further. In the DOME project we trialed two prototypes, but as detailed in part two of this thesis, we only measured process outcomes and did not measure hard patient safety measures, so the question remains whether the Respiratory Rate Recorder and the CareCentre® are associated with fewer patient deaths and shorter length of hospital stay. Leading on from this point is the fact that the cost effectiveness of the DOME project also cannot be estimated at this stage. The DOME project also did not investigate the factors involved in the implementation of new innovations (known as change management) that is crucial to the translation of new interventions into practice.

## Reflections

Teamwork was essential and each discipline worked together towards well-defined shared and individual goals. Clinical members required effective solutions to important problems, research members required scientific studies, designers required clever, creative and innovative concepts and industry required profit. As the DOME project progressed, different members of the team changed roles. At the beginning, the clinical members were crucial to allow the other disciplines access to the healthcare environment and help them develop their understanding and gain experience. In the creative phase, the designers took over the lead role and were crucial to engage stakeholders in a manner than generated and progressed ideas. In the latter stages, the business experts became crucial in assessing which concepts were commercially viable and worthy to progress to working prototypes. After working prototypes were obtained, scientific researchers were necessary to conduct robust trials to prove their effectiveness. Involving all disciplines throughout this process was novel and streamlined. There were challenges within the multidisciplinary team including communication and different ways of working and expectations. These were overcome by developing a common language, by being flexible and also by aligning the needs of each individual discipline with the overall aims of the project.

At the beginning of the project, many meetings were held between all members of the DOME team. The DOME project had been funded on the basis of the Design for Patient Safety report and the main premise was that a multidisciplinary approach to design in healthcare could improve patient safety. The DOME project needed to be focused in order to progress. Initial discussions were held regarding how to focus the project. We decided to focus it on the surgical ward. This limited the potential of the project in one way, but enabled it to work by making it manageable and there was no reason why lessons learnt from surgical wards, a microcosm of the NHS, could not potentially be generalised to other healthcare environments.

The DOME project was conducted and led through management meetings. These were of different types. Some were with all members of the DOME team including the professors with formal presentations from the junior DOME team members. More frequent meetings were held between the junior DOME team members. Objectives were set at each meeting and progress was monitored. Difficulties meeting objectives were flagged up early to senior colleagues to help resolve problems. Exhibitions and presentations acted as deadlines to hit targets such as the production of a suite of concepts that helped to progress the project as a whole. Each time data were analysed, the results of the study were fed back to the team to discuss and plan the next step forward. The initial work was exploratory.

Much of my time working on the DOME project was spent with the designers, Jonathan West and Grace Davey. Almost every day, I had contact with them. I helped them to get access to the hospitals, wards, patients and healthcare staff. I helped them get their ID badges and

planned visits and introduced them to people. As the DOME project progressed, I realised that the design profession did not give the same importance to the scientific rigour demanded in medicine. Designers valued empathy and insight and other intangible tacit knowledge and skills. I realised that it was down to me to generate the scientific rigour. In part two of the thesis, I have presented the output. I conducted the systematic review of surgical adverse events with Rachel Davis, who was not a member of the DOME team, because she had the expertise and time necessary. The Systematic proactive risk assessment of hazards in surgical wards was mainly carried out by myself and Andrea Brodie, who was the research psychologist in the DOME team. As I conducted observations and surveys and officially collected data, the designers joined me without formally collecting data for the study. A number of people who are acknowledged helped me conduct the simulation and clinical trials of the Respiratory Rate Recorder and the CareCentre® and I led those studies.

Relationships between representatives of the different disciplines were not always easy. There were communication problems with different professions using the same words to mean different things and also there was little understanding of the importance of the detailed methods used by one another's profession. This was resolved by using the failure mode and effect analysis to clearly represent processes as unambiguous flow diagrams. This allowed a level playing field. Each profession shared the goal of having a successful project, but the definition of success for each profession was different. The designers wanted to create a suite of concepts that received good feedback. As a clinician, I wanted to prove that I had improved patient safety by scientifically testing the interventions we created in trials. From a business point of view, the idea had to be commercially viable.

During my time working on the DOME project, I learnt that the process of designing in healthcare is usually fragmented. The designers are rarely the patients or healthcare staff who will use the product. They usually work for the manufacturer. These in-house designers make something that is more commercially viable for the manufacturer. Clinicians are usually only exposed to the new product when their healthcare organisation has purchased it, which is usually on the basis of cost saving. Feedback from the clinicians is usually minimal and from surgeons is likely to be negative if they were used to using the old product and have not been involved in the decision to try the new one especially if effort is required to adapt an established skill. The DOME approach of involving all stakeholders at all stages was clearly beneficial. The design process can be likened to Reason's Swiss cheese model of accidents. Many ideas can be generated, but layers of obstacles will block most. Those layers include clinical importance, user acceptance and commercial viability. By involving representatives from all stakeholder groups in co-design from the beginning of the process and by exposing designers to the environment of interest and allowing them to gain insight, more relevant ideas can be generated that can more rapidly be filtered out to select the successful ones that adequately meet all the multidisciplinary criteria.

A key to the success of this project was the involvement of patients and healthcare staff at every stage. We persuaded them to help us by explaining that the outputs of the DOME project were focused on important clinical issues that would be more successful with their participation. Prof Hanna was the lead clinician and his very good reputation facilitated the DOME project. I worked as a surgical registrar and negotiated with other clinicians, nurses and managers. I am familiar with the ward environment and I did not appear to be an outsider. An unaccompanied stranger might have been viewed with suspicion. I could take responsibility for the conduct of the other DOME team members in the clinical environment and the conduct of the research, which gave patients and healthcare staff confidence.

# Conclusion

The central hypothesis of this thesis was the question: can a collaboration of clinicians, designers and manufacturers design and develop effective, novel and viable patient safety interventions? The DOME project showed how we collaborated as a multi-disciplinary clinical, design and industrial team that involved the end-users of the product throughout its development. It demonstrated the journey of products throughout the entire design and development process, from exploring and defining the problem, generating concepts and delivering, evaluating and iteratively improving successful solutions. In order to improve patient safety, healthcare organisations should create an environment that allows greater communication and understanding between clinicians, designers and industry in which the shared and individual goals of each discipline can be achieved.

# Part two: study reports

1. Systematic review of surgical adverse events
2. A systematic proactive risk assessment of hazards in surgical wards
3. Respiratory Rate Recording
4. The CareCentre®

# Systematic review of surgical adverse events

## Overview

The aim of this study was to characterise surgical adverse events from the published literature to help us identify targets for design interventions. The steps were:

1. Identify studies for inclusion
2. Extract and process data from the studies to determine
    a. the most important surgical adverse events
    b. the causes of those adverse events

## Introduction

An adverse event is defined as 'an unintended injury or complication resulting in harm that is caused by healthcare management and not by the patients' underlying disease.' (Brennan, Leape et al. 1991) Adverse events cause preventable patient harm, lengthen hospital stay and increase healthcare costs. (Andrews, Stocking et al. 1997, Thomas, Studdert et al. 1999) The majority of adverse events in hospital are associated with surgical care. (de Vries, Ramrattan et al. 2008) Patient safety improvement efforts should target the leading causes of preventable patient harm, which can be identified from the frequency, severity and preventability of adverse events. (Aranaz-Andres, Aibar-Remon et al. 2009)

Sources of data on surgical adverse events include morbidity and mortality meetings, incident reports, retrospective note review studies, cross sectional surveys and prospective studies. I discuss the pros and cons of each surgical adverse event data source below.

### *Morbidity and mortality meetings*

Surgical teams in hospitals discuss in-patient deaths and complications at monthly morbidity and mortality (M&M) meetings. The purpose of these M&M meetings is to review the case and assess whether any improvements in process or outcome could have been achieved. Attendees can learn the suggested improvements and apply them in the future. Unfortunately, M&M meetings have several important limitations. The presentation of cases resulting in complications is incomplete. Their selection is open to bias. No attempt is made to present cases associated with near misses, medical errors or adverse events that did not result in complications or death. Only 74% of suitable events identified by screening for occurrences and 35% of suitable events identified through case record review were presented at surgical M&M meetings. (Thompson and Prior 1992) Also, the way in which the case is presented is open to bias. If improvements are to be made, suboptimal care must be identified. A punitive blame culture may inhibit the open reporting of suboptimal care. Other stakeholders including the nurses and patients do not contribute. The results of M&M meetings are usually not published or externally accessible. Therefore, data from M&M meetings is not sufficient for the overall frequency, severity and preventability of harm in surgical care to be analysed.

## *Incident reports*

Healthcare workers voluntarily submit incident reports when they wish to report a patient safety event. A patient safety event is not limited to adverse events, but may include near misses and medical errors that have not resulted in death or complications. Incident reports are collected locally and nationally. Locally, the line manager reviews the incident report and decides what action to take. If the incident report is serious, which the submitter or the line manager might identify, then the clinical director, a higher manager, reviews the incident report and decides what action to take. The National Learning and Reporting System (NRLS) collects incident reports nationally. Sir Liam Donaldson recommended the formation of the NRLS in his report *An Organisation with a memory.* The purpose of the NRLS was to learn from incident reports and disseminate that learning throughout the NHS so that individuals within the NHS did not have to experience every incident first-hand in order to learn from it. Unfortunately, incident reports have some important limitations. Healthcare workers submit them voluntarily and patients are unable to submit them. Therefore, they form an incomplete record of adverse events. Healthcare workers are also biased in their selection of which incidents to report. They tend to favour severe incidents that did not result in death and also neglect to submit the majority of more minor events. (Ej 2008) Therefore, incident report-based studies provide only tentative insights into the frequency, severity and preventability of patient harm.

## *Retrospective record review*

Retrospective record review was the method used by the landmark Harvard Medical Practice study that started the patient safety revolution and is regarded as the gold standard method that has subsequently been repeated. This is because the retrospective note review studies incorporated two methods of reducing bias. The first was by randomly sampling records from a large defined population. The second was by validating the classification of patient safety incidents as adverse events including their severity and preventability. This mechanism consisted of the inter-rater reliability between two independent ratings. This is reported as the kappa value, a measure of agreement, although it might not be clear how disagreements were resolved. The main drawback of retrospective record review studies is, if the adverse event was not detailed in the notes it cannot be detected. Overall, retrospective record review studies are able to give more reliable measures of the frequency, severity and preventability of surgical adverse events than incident reports.

## *Observational studies*

Observational methods include cross sectional surveys and prospective studies. These differ from incident reports and retrospective record review methods, because they collect data primarily for the purpose of determining the frequency and severity of adverse events. Their

samples are often smaller, because they are more intensive. They may sample the whole of a local population and therefore avoid selective sampling bias, but they often do not include a clearly defined method of determining the presence of an adverse event or inter-rater reliability like retrospective record review studies. Also, they might not follow up their participants long enough to detect all adverse outcomes. However, they are the only study design that collects primary evidence, which has not been collected from what healthcare workers have written down. Therefore, observational studies can add detail to the data used to determine the frequency, severity and preventability of surgical adverse events.

Published incident report-based, retrospective record review and observational studies have all been used to investigate surgical adverse events, but they have produced varied results. (Runciman, Webb et al. 2000, Michel, Quenon et al. 2004) In order to address this; I conducted this systematic review of the literature incorporating these study designs. This allowed comprehensive inclusion of relevant data. I compared the overall frequency, severity and preventability of surgical adverse event consequences and causes and I also analysed sub-groups corresponding to different methods to examine the influence of study design.

## *Aims*

The aim was to systematically review published evidence regarding surgical adverse events in order to establish the extent of existing knowledge, quantify harm and attempt to target patient safety improvement efforts in further research.

## *Hypotheses*

The hypothesis was that surgical adverse events have been studied in many countries using a variety of methods with similarities amongst common research design types. I predicted that adverse events occurred with an incidence rate of approximately 10% and with a preventability of approximately 50% based on an existing systematic review of in-hospital adverse events. (de Vries, Ramrattan et al. 2008) I hoped to link surgical adverse events back to their causes and prioritise which causes were most important.

## *Objectives*

The first objective was to systematically *search* and *identify* studies that quantified surgical adverse events. Therefore the primary inclusion criterion was that all studies demonstrated a measure of surgical adverse event incidence or frequency. The next objective was to *extract* data on frequency, severity and preventability related to the consequences and causation of the surgical adverse events and use this to prioritise targets for patient safety interventions.

# Methods

## *Literature search*

I conducted this research in accordance with the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines. (Stroup, Berlin et al. 2000) I systematically searched medical databases including: the Cochrane library (February 2011), MEDLINE (January 1980-February 2011), EMBASE (January 1980-February 2011), PsycINFO (1967-February 2011) and CINAHL (1982-February 2011). The full electronic medical literature database search strategy is in appendix 2.1.1. I identified clinical studies published in peer-reviewed journals in the English language. I performed a hand-search of reference lists from eligible papers to identify additional articles.

## *Selection of articles*

Two researchers (myself and Rachel Davis) independently reviewed the titles and abstracts and the full-text of potentially relevant articles identified by the electronic searches. We excluded articles that did not have full-text versions, e.g. abstracts only. A third researcher (Charles Vincent) would have independently resolved disagreements regarding the inclusion of studies if there had been any, but we had none. In order to include comprehensive data, we used a modified definition of adverse event: *an unintended injury or complication resulting in harm that is caused by healthcare management and not by the patients underlying disease*. All studies that allowed this modified definition of adverse events to be applied to surgical patients within a general surgery service (excluding studies incorporating single surgical sub-specialties) were eligible for inclusion. We excluded studies if it was not possible to extract numerators and denominators that allowed the frequency of surgical adverse events to be calculated.

## *Inclusion criteria:*

- Data regarding the frequency of adverse events in surgical patients;
- Empirical study;
- English language;
- Non-interventional;
- Acute care setting;
- Adult patients;
- Hospital patients;
- Full-text available.

## *Exclusion criteria:*

- No data regarding the frequency of adverse events in surgical patients;
- Non-empirical study;

- Non-English language;
- Interventional;
- Non-acute care setting;
- Paediatric or geriatric patients only;
- Non-hospital patients;
- No full-text available.

## *Validity assessment*

Two researchers (myself and Rachel Davis) independently assessed the selected studies for methodology and endpoints. We extracted information regarding the method of data collection, record selection and review, the time frame of included adverse events and inter-rater reliability. The primary endpoint was the frequency of surgical adverse events. The secondary endpoints were the severity of outcome, preventability, consequences and causation.

## *Data collection*

We extracted data on frequency, severity, preventability, consequence and causation of surgical adverse events. We used raw data wherever possible. We grouped data into common categories that the majority of the articles used, which is shown in table 2.1.1.

Table 2.1.1. Severity scale

| Study | Score | | | |
|---|---|---|---|---|
| | 1<br>Minor | 2<br>Moderate | 3<br>Severe | 4<br>Fatal |
| Adar, Bass et al. 1982 | Mild: 'Causing added discomfort but no disability or undue lengthening of hospitalization' | Moderate: 'Causing temporary disability or mild permanent disability, leading to an operation or causing considerable prolongation of hospitalization time' | Severe: 'A life threatening situation, major amputation, or moderate to severe permanent disability' | Death |
| Aranaz-Andres, Aibar-Remon et al. 2009 | Neither moderate or severe | Moderate: 'Caused re-admission or prolonged hospital stay' | Severe: 'Death or required surgery' | - |
| Bilimoria, Kmiecik et al. 2009 | Not life threatening, non-invasive treatment | Potentially life threatening, non-invasive or invasive treatment | Permanent disability | Death |
| Briant, Morton et al. 2005 | Disability <1 month | Disability 1-12 months | Permanent disability | Death |
| Forster, Asmis et al. 2004 | - | - | Permanent disability or death | - |
| Gawande, Thomas et al. 1999 | - | - | Permanent disability | Death |
| Griffin and Classen 2008 | Temporary harm | Temporary harm with prolonged hospitalisation | Permanent harm or intervention required to save life | Death |
| Kable, Gibberd et al. 2002 | Disability <1 month | Disability 1-12 months | Permanent disability | Death |
| Letaief, El Mhamdi et al. 2010 | Letaief, El Mhamdi et al. | Letaief, El Mhamdi et al. | Letaief, El Mhamdi et al. | Letaief, El Mhamdi et al. |
| Rebasa, Mora et al. 2009 | Ninguna/Minimal | Moderate | Permanents | Death |
| Wanzel, Jamieson et al. 2000 | Trivial | Moderate | Life threatening | Fatal |
| Wilson, Runciman et al. 1995 | Disability <1 month | Disability 1-12 months | Permanent disability | Death |

## *Sensitivity and subgroup analyses*

We identified studies for sensitivity analysis that used the *exact* definition of adverse event: 'an unintended injury or complication resulting in prolonged hospital stay, disability at the time of discharge or death that is caused by healthcare management and not by the patients underlying disease.' (Brennan, Leape et al. 1991) We compared the results of three study design subgroups including: record review, incident report-based and observational studies.

# Results

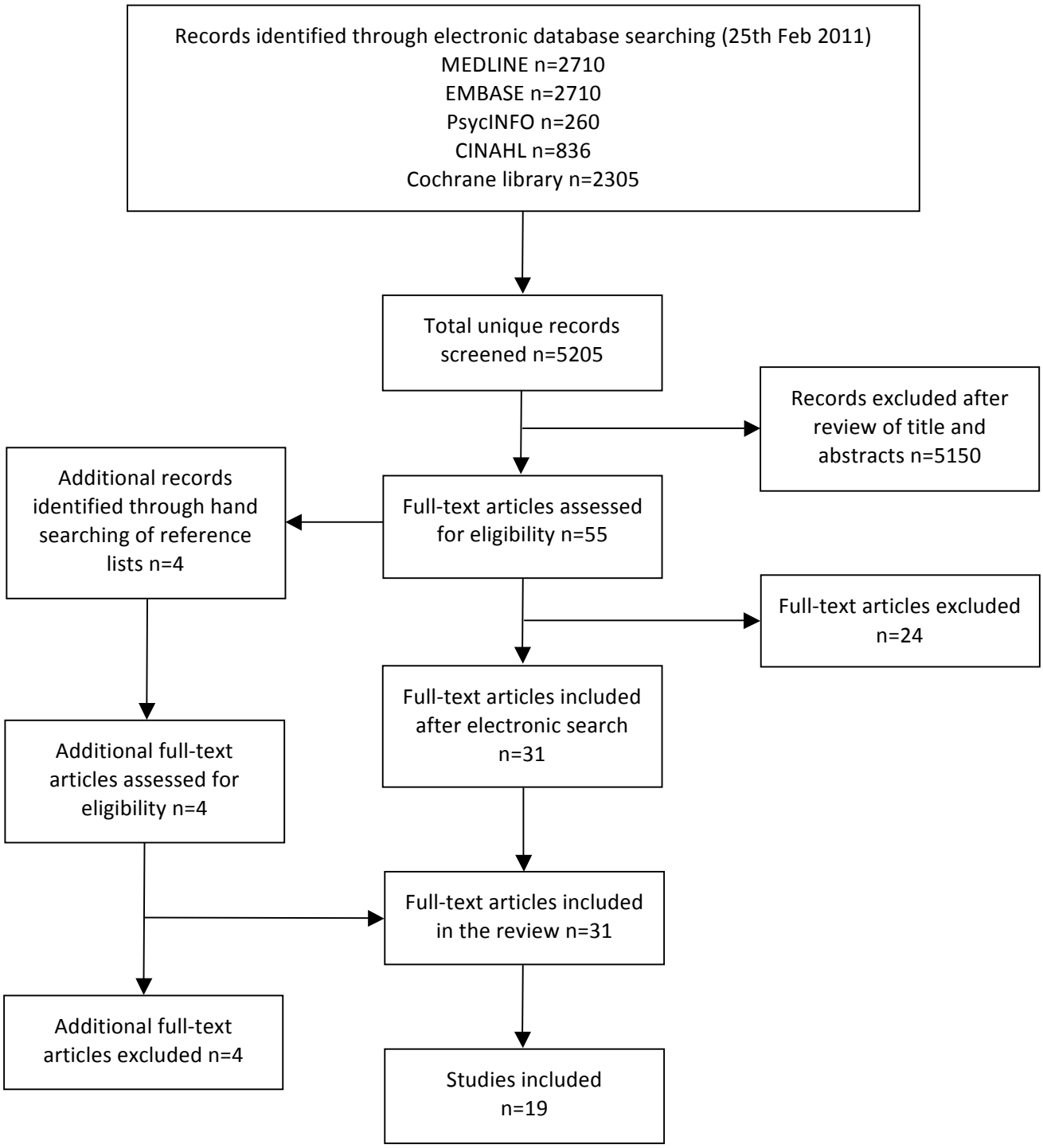
## *Article retrieval*

We conducted the electronic searches of the medical literature databases and identified 5205 unique records as shown in figure 2.1.1. We excluded 5150 records after reviewing the titles and abstracts and applying the inclusion and exclusion criteria. Foreign language records accounted for 340. Of the remaining 55 records, we excluded a further 24 records after reviewing the full-text article and applying the inclusion and exclusion criteria. This left us with 31 potentially relevant articles identified from searches of medical literature databases. I identified 4 additional records by hand-searching the reference lists of potentially relevant articles. We excluded all 4 additional records identified by hand-searching the reference lists of potentially relevant articles after reviewing the full-text articles and applying the inclusion and exclusion criteria. All of the articles that we excluded after reviewing their full-text are shown in appendix 2.1.2. Our inter-rater agreement was 100%.

## *Included studies*

In total, we included 31 articles in the review. Of these articles, 12 reported additional data from patient populations that were already reported in other included publications. In this review, these articles were considered as one study together with the article that was most relevant to this review. All of the included articles are shown in appendix 2.1.3. In total, this resulted in 19 included studies.

Figure 2.1.1. Study retrieval and selection process



## *Study characteristics and methods*

I report the characteristics and methods of included studies in Tables 2.1.2 and 2.1.3. I included data from a total of at least 93224 surgical patients' records. I don't know the exact number, because the full-text articles of 7 of the studies did not report the total number of surgical patients' records reviewed. I obtained the missing total number of surgical patients reviewed from the original report of 1 study. (HMPS 1990) The number of hospitals included in each study ranged from 1 to 51 and the median number of surgical patients' records reviewed per study was 2933 (Inter-quartile range [IQR] 263-5432). Eight record review studies documented the *exact* definition of adverse event and these formed a group of studies for the sensitivity analysis. We excluded two record review studies from the sensitivity analysis, because they used a definition of adverse event that did not document that disability was present on discharge. We excluded the remaining 9 studies, which represented study designs other than record review, because they reported the harmful consequences of medical management, but did not specify the requisite consequences specified in the definition of adverse events, i.e. prolonged length of hospital stay, disability at the time of discharge or death.

Table 2.1.2. Study characteristics

| Study | Year of publication | Country | No. of hospitals | No. of surgical records | Inclusion period | Study design | Exact adverse event definition |
|---|---|---|---|---|---|---|---|
| Adar, Bass et al. | 1982 | Israel | 1 | 3 736 | 1976-1980 | Incident reports | Incorrect outcome |
| Aranaz-Andres, Aibar-Remon et al. | 2009 | Spain | 24 | - | 2005 | Record review | Incorrect outcome |
| Baker, Norton et al. | 2004 | Canada | 20 | - | 2000 | Record review | Correct |
| Bilimoria, Kmiecik et al. | 2009 | USA | 1 | 15 524 | 2009 | Incident reports | Incorrect outcome |
| Brennan, Leape et al. | 1991 | USA | 51 | 2 933 | 1984 | Record review | Correct |
| Briant, Morton et al. | 2005 | New Zealand | 13 | - | 1998 | Record review | Incorrect outcome |
| Calland, Adams et al. | 2002 | USA | 1 | 6 296 | 1999 | Record review | Incorrect outcome |
| Forster, Asmis et al. | 2004 | Canada | 1 | 206 | - | Record review | Correct |
| Gawande, Thomas et al. | 1999 | USA | 28 | - | 1992 | Record review | Correct |
| Goldfarb and Baker | 2006 | USA | 1 | 53 541 | 1998-2005 | Incident reports | Incorrect outcome |
| Griffin and Classen | 2008 | USA | 11 | 854 | 2003-2004 | Record review | Incorrect outcome |
| Kable, Gibberd et al. | 2002 | Australia | 28 | 5 432 | 1992 | Record review | Disability not at discharge |
| Letaief, El Mhamdi et al. | 2010 | Tunisia | 1 | - | 2005 | Record review | Correct |
| Michel, Quenon et al. | 2004 | France | 7 | 263 | - | Record review & Observational | Correct |
| Rebasa, Mora et al. | 2009 | Spain | 1 | 3 807 | 2005-2006 | Incident reports | Incorrect outcome |
| Vincent, Neale et al. | 2001 | UK | 2 | 290 | 1999-2000 | Record review | Correct |
| Wanzel, Jamieson et al. | 2000 | Canada | 1 | 192 | 1996 | Observational | Incorrect outcome |
| Williams, Olsen et al. | 2008 | Scotland | 1 | 150 | 2004 | Record review | Correct |
| Wilson, Runciman et al. | 1995 | Australia | 28 | - | 1992 | Record review | Disability not at discharge |

Table 2.1.3. Study methods

| First author | Surgical specialties | Method of record selection | Method of review | More than one adverse event per patient? | Time frame of included adverse events | Kappa value for inter-rater reliability | Surgical endpoints |
|---|---|---|---|---|---|---|---|
| Adar | General & peripheral vascular | All postoperative patients | Voluntarily reported by surgical team | No | Occurred and detected postoperatively | - | Frequency, severity, preventability & causation |
| Aranaz-Andrés | All surgical specialties | All discharged patients staying >24 hours | Two-stage record review: first, screening for one of 19 criteria by trained nurses; second, review by physician | Yes | Occurred before or during and detected during index admission | 0.431 to 0.784 | Frequency, severity, preventability & causation |
| Baker | All surgery specialties | Random sample of adult patients admitted for >24 hours | Two-stage record review: first, screening for one of 18 criteria by nurses; second, review by physician | Yes | Occurred during the index admission and detected either during the index or subsequent hospital admission during the following 12 months. adverse events were also counted that related to previous hospital admissions within 12 months preceding the index admission, but were not detected until the index admission. | 1st stage review: 0.7<br>2nd stage review: 0.45 (adverse event), 0.47 (severity), 0.69 (preventability) | Frequency, preventability & causation |
| Bilmoria | General, transplant, vascular & thoracic | All patients admitted | Voluntarily reported by surgical team | Yes | Occurred before or during and detected during index admission | - | Frequency, severity, consequences, preventability & causation |
| Brennan | General | Random sample | Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by physician | No | Occurred before or during and detected during index admission and up to 30 days post-discharge | 0.61 (adverse event), 0.24 (preventability) | Frequency & preventability (negligence) |
| Briant | All surgery specialties | Random sample | Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by physician | Not specified | Occurred before or during and detected during index admission | 0.47 (adverse event) | Frequency, severity, consequences, preventability & causation |
| Calland | All surgery specialties | All postoperative patients | Two-stage review: first, screening by two trained reviewers; second, review by three physician reviewers | Yes | Occurred before or during and detected during index admission | 0.47 (injury), 0.45 (causation), 0.69 (preventability) | Frequency, severity, consequences, preventability & causation |
| Forster | All surgery specialties | Random sample | Two-stage record review: first, screening for one of 16 criteria by trained nurses; second, review by physician | Not specified | Occurred before or during and detected during index admission | - | Frequency, severity & preventability |
| Gawande | All surgery specialties | Random sample | Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by physician | Yes | Occurred and detected during index admission | 0.4 (adverse event), 0.81 (preventability) | Frequency, severity, consequences, preventability & causation |
| Goldfarb | General and vascular | All postoperative patients | Voluntarily reported by surgical team | Yes | Occurred and detected during index admission | - | Frequency, severity, consequences, preventability & causation |
| Griffin | All surgical specialties | Random sample | Single-stage record review: screening for one of 24 criteria by a team of physicians | Yes | Occurred and detected during index admission | - | Frequency, severity & consequences |
| Kable | All surgical specialties | Random sample | Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by physician | No | Occurred before or during and detected during index admission | 0.55 (severity & preventability) | Frequency, severity, consequences, preventability & causation |
| Letaief | All surgical specialties | Random sample | Two-stage record review: first, screening for one of 18 criteria by medical student; second, review by physician | Not specified | Occurred before or during and detected during index admission | First stage 0.67, second stage 0.82 | Frequency, severity & preventability |
| Michel | All surgical specialties | Random sample | Two-stage review: first, screening for one of 17 criteria by nurses; second, review by physician. Prospective method reviewed ward staff, retrospective method reviewed records. | Yes | Occurred before or during and detected during index admission | 0.83 (frequency), 0.31 (preventability) | Frequency & preventability |
| Rebasa | General | All patients | Voluntarily reported by | No | Occurred before or | 0.98 (adverse | Frequency, |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | admitted | surgical team with second review by surgeon/researcher | | during and detected during index admission or up to 30 days after patient discharge | event), 0.92 (consequences), 0.91 (error) | severity, consequences & preventability |
| Vincent | All surgical specialties | Random sample | Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by physician | Yes | Occurred before or during and detected during index admission | - | Frequency, severity, consequences & preventability |
| Wanzel | General | All patients admitted | Single observer daily review of charts, rounds, wards and operating suites | No | Occurred and detected during index admission | - | Frequency, severity, consequences, preventability & causation |
| Williams | All surgical specialties | All patients admitted | Two-stage record review: first, screening for one of 16 criteria by trained nurses; second, review by consensus group of physicians | Yes | Occurred before or during and detected during index admission | First stage = 1.0 | Frequency |
| Wilson | General | Random sample | Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by two physicians | Not specified | Occurred before or during index admission and detected during or after index admission | 0.55 (adverse event), 0.33 (preventability), 0.49 (severity) | Frequency, severity & preventability |

## *Frequency and severity of outcome*

I show data on frequency and severity of outcome in Tables 2.1.4 and 2.1.5. Overall, a median of 14.4% (IQR 11.7-28.3%) surgical patients had one or more adverse events. Of all surgical patients experiencing an adverse event, a median of 3.6% (IQR 3.0-11.6%) had fatal consequences, 18.3% (IQR 11.8-25.4%) were severe, 35.3% (IQR 34.5-44.3%) were moderate and 40.5% (IQR 28.6-42.4%) were minor. Overall, the median frequency of adverse events per surgical patient was 14.5% (IQR 6.4-36.6%). A median of 4.0% (IQR 2.9-5.7%) adverse events were fatal, 8.2% (IQR 4.7-11.8%) were severe, 37.4% (IQR 25.8-57.9%) were moderate and 48.9% (33.7-56.1%) were minor. Sensitivity and record review subgroup analyses demonstrated similar results. The incident reports subgroup demonstrated a lower frequency of adverse events, but a greater proportion with fatal consequences and the observations subgroup demonstrated a higher frequency of adverse events, but a lower proportion with fatal consequences.

Table 2.1.4. Patients with surgical adverse events

| First author | Number of surgical records | Number of surgical patients with at least one adverse event | Outcome severity | | | |
|---|---|---|---|---|---|---|
| | | | Fatal | Severe | Moderate | Minor |
| Adar | 3736 | 286 (7.7%) | 27 (9.4%) | - | - | - |
| Aranaz-Andrés | - | 343 | † | 83 (24.2%) | 121 (35.3%) | 139 (40.5%) |
| Baker | - | - | - | - | - | - |
| Bilmoria | 15524 | - | 89 | - | - | - |
| Brennan | 2933 | - | - | - | - | - |
| Briant | - | - | 13 | - | - | - |
| Calland | 6296 | - | 23 | - | - | - |
| Forster | 206 | 24 (11.7%) | - | 7 (29.2%) | - | - |
| Gawande | - | - | 23 | - | - | - |
| Goldfarb | 53541 | 621 (1.2%) | 86 (13.8%) | - | - | - |
| Griffin | 854 | 125 (14.6%) | 4 (3.2%) | - | - | - |
| Kable | 5432 | 1190 (21.9%) | 43 (3.6%) | 147 (12.4%) | 402 (33.8%) | 527 (44.3%) |
| Letaief | - | 30 | 6 (20.0%) | 3 (10.0%) | 16 (53.3%) | 5 (16.7%) |
| ‡Michel | 263 | 80 (30.4%) | - | - | - | - |
| Rebasa | 3807 | 1177 (30.9%) | 34 (2.9%) | - | - | - |
| Vincent | 290 | 41 (14.2%) | - | - | - | - |
| Wanzel | 192 | 75 (39.1%) | 2 (2.7%) | - | - | - |
| Williams | 150 | 18 (12.0) | - | - | - | - |
| Wilson | - | - | 10 | - | - | - |
| **Main analysis** | | | | | | |
| **Median (Interquartile range)** | **2933 (263-5432)** | **14.4% (11.7-28.3%)** | **3.6% (3.0-11.6%)** | **18.3% (11.8-25.4%)** | **35.3% (34.5-44.3%)** | **40.5% (28.6-42.4%)** |
| **Sensitivity analysis** | | | | | | |
| **Median (Interquartile range)** | **263 (206-290)** | **13.1% (11.9-18.2%)** | **20.0% (20.0-20.0%)** | **19.6% (14.8-24.4%)** | **53.3% (53.3-53.3%)** | **16.7% (16.7-16.7%)** |
| **Record review** | | | | | | |
| **Median (Interquartile range)** | **572 (249-3558)** | **14.4% (12.5-20.1%)** | **3.6% (3.4-11.8%)** | **18.3% (11.8-25.4%)** | **35.3% (34.5-44.3%)** | **40.5% (28.6-42.4%)** |
| **Incident report** | | | | | | |
| **Median (Interquartile range)** | **9666 (3789-25028)** | **7.7% (4.4-19.3%)** | **9.4% (6.2-11.6%)** | **-** | **-** | **-** |
| **Observational** | | | | | | |
| **Median (Interquartile range)** | **228 (210-245)** | **21.6% (12.9-30.3%)** | **2.7% (2.7-2.7%)** | **-** | **-** | **-** |

†Fatal adverse events were included in the severe category by the study authors
‡Cumulative results used in main and sensitivity analysis, sub-group results used in record review and observational analysis

Table 2.1.5. Frequency of surgical adverse events

| First author | Number of surgical records | Number of adverse events in surgical patients | Outcome severity | | | |
|---|---|---|---|---|---|---|
| | | | Fatal | Severe | Moderate | Minor |
| Adar | 3736 | 480 (12.8%) | 27 (5.6%) | 63 (13.1%) | 147 (30.6%) | 243 (50.6%) |
| Aranaz-Andrés | - | - | - | - | - | - |
| Baker | - | 185 | - | - | - | - |
| Bilmoria | 15524 | 957 (6.2%) | 89 (9.3%) | 12 (1.3%) | 638 (66.7%) | 218 (22.8%) |
| Brennan | 2933 | 205 (7.0%) | - | - | - | - |
| Briant | - | 326 | 13 (4.0%) | 37 (11.3%) | 79 (24.2%) | 189 (58.0%) |
| Calland | 6296 | - | 23 | - | - | - |
| Forster | 206 | - | - | - | - | - |
| Gawande | - | 402 | 23 (5.7%) | 38 (9.5%) | - | - |
| Goldfarb | 53541 | 1026 (1.9%) | 86 (8.4%) | - | - | - |
| Griffin | 854 | 138 (16.2%) | 4 (2.9%) | 8 (5.8%) | 61 (44.2%) | 65 (47.1%) |
| Kable | 5432 | - | 43 | - | - | - |
| Letaief | - | - | 6 | - | - | - |
| †Michel | 263 | 114 (43.3%) | - | - | - | - |
| Rebasa | 3807 | 2193 (57.6%) | 34 (1.6%) | 24 (1.1%) | 464 (21.2%) | 1671 (76.2%) |
| Vincent | 290 | 47 (16.2%) | - | - | - | - |
| Wanzel | 192 | 144 (75.0%) | 2 (1.4%) | 10 (6.9%) | 90 (62.5%) | 42 (29.2%) |
| Williams | 150 | 5 (3.3%) | - | - | - | - |
| Wilson | - | 317 | 10 (3.2%) | 48 (15.1%) | - | - |
| **Main analysis** | | | | | | |
| **Median (Interquartile range)** | **2933 (263-5432)** | **14.5% (6.4-36.6%)** | **4.0% (2.9-5.7%)** | **8.2% (4.7-11.8%)** | **37.4% (25.8-57.9%)** | **48.9% (33.7-56.1%)** |
| **Sensitivity analysis** | | | | | | |
| **Median (Interquartile range)** | **263 (206-290)** | **11.6% (6.1-23.0%)** | **5.7% (5.7-5.7%)** | **9.5% (9.5-9.5%)** | **-** | **-** |
| **Record review** | | | | | | |
| **Median (Interquartile range)** | **572 (249-3558)** | **11.6% (6.1-16.2%)** | **3.6% (3.1-4.4%)** | **10.4% (8.5-12.3%)** | **34.2% (29.2-39.2%)** | **52.5% (49.8-55.3%)** |
| **Incident report** | | | | | | |
| **Median (Interquartile range)** | **9666 (3789-25028)** | **9.5% (5.1-24.0%)** | **7.0% (4.6-8.6%)** | **1.3% (1.2-7.2%)** | **30.6% (25.9-48.6%** | **50.6% (36.7-63.4%)** |
| **Observational** | | | | | | |
| **Median (Interquartile range)** | **228 (210-245)** | **75.0% (75.0-75.0%)** | **1.4% (1.4-1.4%)** | **6.9% (6.9-6.9%)** | **62.5% (62.5-62.5%)** | **29.2% (29.2-29.2%)** |

† Cumulative results used in main and sensitivity analysis, sub-group results used in record review and observational analysis

## *Preventability*

I show the data on preventability in Tables 2.1.6 and 2.1.7. Overall, a median of 7.7% (IQR 5.9-9.9%) surgical patients had one or more preventable adverse events. Sensitivity and subgroup analyses demonstrated similar results. The median frequency of preventable adverse events per surgical patient was 7.8% (IQR 5.7-10.7%). Sensitivity and record review subgroup analyses demonstrated similar results. Again, the incident reports subgroup demonstrated a lower frequency of preventable adverse events, but a greater proportion with fatal consequences and the observations subgroup demonstrated a higher frequency of preventable adverse events, but a lower proportion with fatal consequences.

Table 2.1.6. Patients with preventable surgical adverse events

| First author | Number of surgical records | Number of surgical patients with at least one preventable adverse event | Outcome severity | | | |
|---|---|---|---|---|---|---|
| | | | Fatal | Severe | Moderate | Minor |
| Adar | 3736 | 286 | - | - | - | - |
| Aranaz-Andrés | - | 343 | - | - | - | - |
| Baker | - | - | - | - | - | - |
| Bilmoria | 15524 | - | - | - | - | - |
| Brennan | 2933 | - | - | - | - | - |
| Briant | - | - | - | - | - | - |
| Calland | 6296 | - | 15 | - | - | - |
| Forster | 206 | 6 (2.9%) | - | 3 (50.0%) | - | - |
| Gawande | - | - | - | - | - | - |
| Goldfarb | 53541 | - | - | - | - | - |
| Griffin | 854 | - | - | - | - | - |
| Kable | 5432 | 571 (10.5%) | - | - | - | - |
| Letaief | - | 15 | - | - | - | - |
| Michel | 263 | 26 (9.9%) | - | - | - | - |
| Rebasa | 3807 | - | 11 | - | - | - |
| Vincent | 290 | 17 (5.9%) | - | - | - | - |
| Wanzel | 192 | - | - | - | - | - |
| Williams | 150 | - | - | - | - | - |
| Wilson | - | - | - | - | - | - |
| **Main analysis Median (Interquartile range)** | **2933 (263-5432)** | **7.7% (5.9-9.9%)** | **-** | **50.0% (50.0-50.0%)** | **-** | **-** |
| **Sensitivity analysis Median (Interquartile range)** | **263 (206-290)** | **5.9% (4.4-7.9%)** | **-** | **50.0% (50.0-50.0%)** | **-** | **-** |
| **Record review Median (Interquartile range)** | **572 (249-3558)** | **5.2% (4.2-7.0%)** | **-** | **50.0% (50.0-50.0%)** | **-** | **-** |
| **Incident report Median (Interquartile range)** | **9666 (3789-25028)** | **7.7% (7.7-7.7%)** | **-** | **-** | **-** | **-** |
| **Observational Median (Interquartile range)** | **228 (210-245)** | **4.6% (4.6-4.6%)** | **-** | **-** | **-** | **-** |

Table 2.1.7. Frequency of preventable surgical adverse events

| First author | Number of surgical records | Number of preventable adverse events in surgical patients | Outcome severity | | | |
|---|---|---|---|---|---|---|
| | | | Fatal | Severe | Moderate | Minor |
| Adar | 3736 | - | - | - | - | - |
| Aranaz-Andrés | - | - | - | - | - | - |
| Baker | - | - | - | - | - | - |
| Bilmoria | 15524 | - | - | - | - | - |
| Brennan | 2933 | 57 (1.9%) | - | - | - | - |
| Briant | - | 81 | - | - | - | - |
| Calland | 6296 | - | 15 | - | - | - |
| Forster | 206 | - | - | - | - | - |
| Gawande | - | 217 | - | - | - | - |
| Goldfarb | 53541 | - | - | - | - | - |
| Griffin | 854 | - | - | - | - | - |
| Kable | 5432 | - | - | - | - | - |
| Letaief | - | 15 | - | - | - | - |
| Michel | 263 | - | - | - | - | - |
| Rebasa | 3807 | 330 (8.7%) | 11 (3.3%) | - | - | - |
| Vincent | 290 | 20 (6.9%) | - | - | - | - |
| Wanzel | 192 | 32 (16.7%) | 0 (0.0%) | 3 (9.4%) | 17 (53.1%) | 12 (37.5%) |
| Williams | 150 | - | - | - | - | - |
| Wilson | - | 168 | - | - | - | - |
| **Main analysis Median (Interquartile range)** | **2933 (263-5432)** | **7.8% (5.7-10.7%)** | **1.7% (0.8-2.5%)** | **9.4% (9.4-9.4%)** | **53.1% (53.1-53.1%)** | **37.5% (37.5-37.5%)** |
| **Sensitivity analysis Median (Interquartile range)** | **263 (206-290)** | **4.4% (3.2-5.7%)** | **-** | **-** | **-** | **-** |
| **Record review Median (Interquartile range)** | **572 (249-3558)** | **4.4% (3.2-5.7%)** | **-** | **-** | **-** | **-** |
| **Incident report Median (Interquartile range)** | **9666 (3789-25028)** | **8.7% (8.7-8.7%)** | **3.3% (3.3-3.3%)** | **-** | **-** | **-** |
| **Observational Median (Interquartile range)** | **228 (210-245)** | **16.7% (16.7-16.7%)** | **0.0% (0.0-0.0%)** | **9.4% (9.4-9.4%)** | **53.1% (53.1-53.1%)** | **37.5% (37.5-37.5%)** |

## *Consequences of surgical adverse events*

We sorted the consequences of surgical adverse events into categories common among included articles and determined their frequency as shown in table 2.1.8. Overall, the most frequent consequences were wound problems, genitourinary, gastrointestinal and medication related. Only one study (Vincent) was available for sensitivity analysis and only one study was available for the observational subgroup analysis (Wanzel). Remaining record review and incident report subgroup analyses demonstrated similar results.

Table 2.1.8. Frequency of surgical adverse event consequences

| First author | Bilmoria | Briant | Calland | Gawande | Griffin | Goldfarb | Rebasa | Vincent | Wanzel | **Main analysis Median (Interquartile range)** | **Record review Median (Interquartile range)** | **Incident report Median (Interquartile range)** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Number of surgical records | 15524 | - | 6296 | - | 854 | 53541 | 3807 | 290 | 192 | **3807 (572-10910)** | **854 (572-3575)** | **9666 (3069-25028)** |
| Wound problems | - | - | - | 16 | - | 58 (0.11%) | 206 (5.41%) | 11 (3.79%) | 17 (8.85%) | **4.60% (2.87-6.27%)** | **3.79% (3.79-3.79%)** | **2.76% (1.43-4.09%)** |
| Genitourinary | - | - | - | - | - | - | 50 (1.31%) | 5 (1.72%) | 16 (8.33%) | **1.72% (1.52-5.03%)** | **1.72% (1.72-1.72%)** | **0.04% (0.04-0.04%)** |
| Gastrointestinal | - | 17 | - | - | - | 21 (0.04%) | - | 4 (1.38%) | 14 (7.29%) | **1.38% (0.71-4.34%)** | **1.38% (1.38-1.38%)** | **0.04% (0.04-0.04%)** |
| Medication | - | - | - | 26 | - | 13 (0.02%) | 73 (1.92%) | 2 (0.69%) | 3 (1.56%) | **1.13% (0.52-1.65%)** | **0.69% (0.69-0.69%)** | **0.97% (0.50-1.44%)** |
| Fluid/Electrolytes/Renal | - | - | - | - | 9 (1.05%) | - | 91 (2.39%) | 2 (0.69%) | - | **1.05% (0.87-1.72%)** | **0.87% (0.78-0.96%)** | **1.72% (1.39-2.06%)** |
| Bleeding | 175 (1.13%) | 34 | 8 (0.13%) | 43 | 9 (1.05%) | 119 (0.22%) | 249 (6.54%) | 1 (0.34%) | 2 (1.04%) | **1.04% (0.28-1.09%)** | **0.34% (0.24-0.70%)** | **1.09% (0.85-2.48%)** |
| Sepsis (including abscess) | 160 (1.03%) | 88 | 5 (0.08%) | 73 | 17 (1.99%) | 40 (0.07%) | 63 (1.65%) | 1 (0.34%) | 5 (2.60%) | **1.03% (0.21-1.82%)** | **0.34% (0.21-1.17%)** | **1.34% (0.79-1.74%)** |
| Cardiovascular | - | 38 | 4 (0.06%) | 13 | 26 (3.04%) | 64 (0.12%) | 39 (1.02%) | - | 9 (4.69%) | **1.02% (0.12-3.04%)** | **1.55% (0.81-2.30%)** | **1.02% (0.57-2.03%)** |
| Respiratory | 88 (0.57%) | - | 1 (0.02%) | 4 | 15 (1.76%) | 42 (0.08%) | - | 4 (1.38%) | 23 (11.98%) | **0.97% (0.20-1.66%)** | **1.38% (0.70-1.57%)** | **0.57% (0.32-1.16%)** |
| Intra-operative | 217 (1.40%) | - | 1 (0.02%) | - | - | - | - | 2 (0.69%) | - | **0.69% (0.35-1.04%)** | **0.35% (0.18-0.52%)** | **1.40% (1.40-1.40%)** |
| Anastomotic leak | 76 (0.49%) | 9 | - | - | - | 55 (0.10%) | 66 (1.73%) | 2 (0.69%) | - | **0.59% (0.39-0.95%)** | **0.69% (0.69-0.69%)** | **0.49% (0.30-1.11%)** |
| Cerebrovascular | 36 (0.23%) | - | 4 (0.06%) | 5 | - | - | - | - | 9 (4.69%) | **0.23% (0.15-2.46%)** | **0.06% (0.06-0.06%)** | **0.23% (0.23-0.23%)** |
| Anesthesia | 10 (0.06%) | - | - | 6 | - | 24 (0.04%) | - | 4 (1.38%) | - | **0.06% (0.05-0.72%)** | **1.38% (1.38-1.38%)** | **0.05% (0.05-0.06%)** |
| Thromboembolic | 4 (0.03%) | - | - | 24 | - | 24 (0.04%) | - | 1 (0.34%) | - | **0.04% (0.04-0.19%)** | **0.34% (0.34-0.34%)** | **0.04% (0.03-0.04%)** |

## *Severity of surgical adverse events consequences*

Data were only available from two studies, one incident report-based and one record review-based, shown in table 2.1.9. The most fatal and severe adverse event outcomes were in the categories of cardiovascular and gastrointestinal consequences.

Table 2.1.9. Severity of surgical adverse event consequences

| First author | Bilmoria | Griffin | Median (Interquartile range) |
|---|---|---|---|
| **Number of surgical records** | 15524 | 854 | **8189 (4522-11857)** |
| **Cardiovascular** | | | |
| fatal | 26 (0.2%) | 1 (0.1%) | **0.1% (0.1-0.2%)** |
| severe | 1 (0.0%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| moderate | 42 (0.3%) | 6 (0.7%) | **0.5% (0.4-0.6%)** |
| minor | 7 (0.0%) | 18 (2.1%) | **1.1% (0.6-1.6%)** |
| **total** | 76 (0.5%) | 26 (3.0%) | **1.8% (1.1-2.4%)** |
| **Sepsis** | | | |
| fatal | 12 (0.1%) | 0 (0.0%) | **0.0% (0.0-0.1%)** |
| severe | 0 (0.0%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| moderate | 91 (0.6%) | 15 (1.8%) | **1.2% (0.9-1.5%)** |
| minor | 57 (0.4%) | 3 (0.4%) | **0.4% (0.4-0.4%)** |
| **total** | 160 (1.0%) | 17 (2.0%) | **1.5% (1.3-1.8%)** |
| **Gastrointestinal** | | | |
| fatal | 9 (0.1%) | - | **0.1% (0.1-0.1%)** |
| severe | 1 (0.0%) | - | **0.0% (0.0-0.0%)** |
| moderate | 142 (0.9%) | - | **0.9% (0.9-0.9%)** |
| minor | 65 (0.4%) | - | **0.4% (0.4-0.4%)** |
| **total** | 217 (1.4%) | - | **1.4% (1.4-1.4%)** |
| **Respiratory** | | | |
| fatal | 15 (0.1%) | 0 (0.0%) | **0.0% (0.0-0.1%)** |
| severe | 0 (0.0%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| moderate | 64 (0.4%) | 8 (0.9%) | **0.7% (0.5-0.8%)** |
| minor | 9 (0.1%) | 6 (0.7%) | **0.4% (0.2-0.5%)** |
| **total** | 88 (0.6%) | 15 (1.8%) | **1.2% (0.9-1.5%)** |
| **Bleeding** | | | |
| fatal | 10 (0.1%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| severe | 0 (0.0%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| moderate | 138 (0.9%) | 2 (0.2%) | **0.6% (0.4-0.7%)** |
| minor | 27 (0.2%) | 7 (0.8%) | **0.5% (0.3-0.7%)** |
| **total** | 175 (1.1%) | 9 (1.1%) | **1.1% (1.1-1.1%)** |
| **Fluid/electrolytes /renal** | | | |
| fatal | 0 (0.0%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| severe | 0 (0.0%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| moderate | 3 (0.0%) | 0 (0.0%) | **0.0% (0.0-0.0%)** |
| minor | 1 (0.0%) | 6 (0.7%) | **0.4% (0.2-0.5%)** |
| **total** | 4 (0.0%) | 6 (0.7%) | **0.4% (0.2-0.5%)** |
| **Genitourinary** | | | |
| fatal | 0 (0.0%) | - | **0.0% (0.0-0.0%)** |
| severe | 0 (0.0%) | - | **0.0% (0.0-0.0%)** |
| moderate | 14 (0.1%) | - | **0.1% (0.1-0.1%)** |
| minor | 18 (0.1%) | - | **0.1% (0.1-0.1%)** |
| **total** | 32 (0.2%) | - | **0.2% (0.2-0.2%)** |
| **Cerebrovascular** | | | |
| fatal | 6 (0.0%) | - | **0.0% (0.0-0.0%)** |
| severe | 6 (0.0%) | - | **0.0% (0.0-0.0%)** |
| moderate | 18 (0.1%) | - | **0.1% (0.1-0.1%)** |
| minor | 6 (0.0%) | - | **0.0% (0.0-0.0%)** |
| **total** | 36 (0.2%) | - | **0.2% (0.2-0.2%)** |
| **Anaesthesia** | | | |
| fatal | 0 (0.0%) | - | **0.0% (0.0-0.0%)** |
| severe | 0 (0.0%) | - | **0.0% (0.0-0.0%)** |
| moderate | 7 (0.0%) | - | **0.0% (0.0-0.0%)** |
| minor | 3 (0.0%) | - | **0.0% (0.0-0.0%)** |
| **total** | 10 (0.1%) | - | **0.1% (0.1-0.1%)** |

## *Frequency of preventable surgical adverse event consequences*

Overall, wound problems were the most frequent preventable surgical adverse event consequence, followed by fluid and electrolytes, bleeding and gastrointestinal consequences as shown in table 2.1.10. No studies were available for sensitivity or the observational subgroup analyses. Record review and incident report subgroups demonstrated similar results.

Table 2.1.10. Frequency of preventable surgical adverse event consequences

| **First author** | Bilmoria | Calland | Gawande | Kable | Rebasa | **Main analysis Median (Interquartile range)** | **Record review Median (Interquartile range)** | **Incident report Median (Interquartile range)** |
|---|---|---|---|---|---|---|---|---|
| Number of surgical records | 15524 | 6296 | - | 5432 | 3807 | **5864 (5026-8603)** | **5864 (5864-6080)** | **9666 (6736-12595)** |
| Wound problems | - | - | 9 | 62 (1.14%) | - | **1.14% (1.14-1.14%)** | **1.14% (1.14-1.14%)** | **-** |
| Gastrointestinal | 119 (0.77%) | - | - | - | - | **0.77% (0.77-0.77%)** | **-** | **0.77% (0.77-0.77%)** |
| Intra-operative | - | 0 (0.00%) | - | - | 22 (0.58%) | **0.29% (0.14-0.43%)** | **0.00% (0.00-0.00%)** | **0.58% (0.58-0.58%)** |
| Sepsis (including abscess) | 60 (0.39%) | 4 (0.06%) | 21 | - | - | **0.23% (0.14-0.31%)** | **0.06% (0.06-0.06%)** | **0.39% (0.39-0.39%)** |
| Anastomotic leak | - | - | - | - | 10 (0.26%) | **0.26% (0.26-0.26%)** | **-** | **0.26% (0.26-0.26%)** |
| Bleeding | 107 (0.69%) | 7 (0.11%) | 37 | 13 (0.24%) | 26 (0.68%) | **0.46% (0.21-0.68%)** | **0.18% (0.14-0.21%)** | **0.69% (0.69-0.69%)** |
| Fluid/Electrolytes/Renal | 2 (0.01%) | - | - | - | 42 (1.10%) | **0.56% (0.29-0.83%)** | **-** | **0.56% (0.29-0.83%)** |
| Genitourinary | 16 (0.10%) | - | - | - | - | **0.10% (0.10-0.10%)** | **-** | **0.10% (0.10-0.10%)** |
| Cardiovascular | 15 (0.10%) | 3 (0.05%) | 2 | - | - | **0.07% (0.06-0.08%)** | **0.05% (0.05-0.05%)** | **0.10% (0.10-0.10%)** |
| Respiratory | 38 (0.24%) | 0 (0.00%) | 3 | - | - | **0.12% (0.06-0.18%)** | **0.00% (0.00-0.00%)** | **0.24% (0.24-0.24%)** |
| Anesthesia | 7 (0.05%) | - | 3 | - | - | **0.05% (0.05-0.05%)** | **-** | **0.05% (0.05-0.05%)** |
| Cerebrovascular | 17 (0.11%) | 1 (0.02%) | 0 | - | - | **0.06% (0.04-0.09%)** | **0.02% (0.02-0.02%)** | **0.11% (0.11-0.11%)** |

## *Frequency of surgical adverse event causes*

We sorted data regarding the causative error-types of surgical adverse events into commonly used categories in included studies shown in table 2.1.11. All non-operative management errors combined were more frequent than errors in surgical technique. This was consistently shown in the sensitivity and subgroup analyses. Data regarding the severity of surgical adverse event causes were limited to two studies, one incident report-based and one observational, shown in table 2.1.12. All non-operative management errors combined were associated with more fatal and severe consequences than errors in surgical technique.

Table 2.1.11. Frequency of surgical adverse events causes

| **First author** | Adar | Bilmoria | Goldfarb | Kable | Vincent | Wanzel | **Main analysis Median (Interquartile range)** | **Record review Median (Interquartile range)** | **Incident report Median (Interquartile range)** |
|---|---|---|---|---|---|---|---|---|---|
| Number of surgical records | 2313 | 15524 | 53541 | 5432 | 290 | 192 | **3873 (796-13001)** | **2861 (1576-4147)** | **15524 (8919-34533)** |
| **Error in surgical technique/operative management** | 36 (1.56%) | 360 (2.32%) | 513 (0.96%) | 136 (2.50%) | 4 (1.38%) | 7 (3.65%) | **1.94% (1.42-2.46%)** | **1.94% (1.66-2.22%)** | **1.56% (1.26-1.94%)** |
| **All non-operative management errors combined** | 56 (2.42%) | 122 (0.79%) | 416 (0.78%) | 452 (8.32%) | 15 (5.17%) | 24 (12.50%) | **3.80% (1.19-7.53%)** | **6.75% (5.96-7.53%)** | **0.79% (0.78-1.60%)** |
| *Incorrect or delayed treatment* | - | - | 261 (0.49%) | 93 (1.71%) | - | 5 (2.60%) | **1.71% (1.10-2.16%)** | **1.71% (1.71-1.71%)** | **0.49% (0.49-0.49%)** |
| *Error in other invasive procedure* | - | - | - | - | - | 3 (1.56%) | **1.56% (1.56-1.56%)** | **-** | **-** |
| *Medication error* | 27 (1.17%) | - | 39 (0.07%) | - | 3 (1.03%) | 5 (2.60%) | **1.10% (0.79-1.53%)** | **1.03% (1.03-1.03%)** | **0.62% (0.35-0.89%)** |
| *Diagnostic error/delay* | 5 (0.22%) | 36 (0.23%) | 116 (0.22%) | 80 (1.47%) | 2 (0.69%) | 9 (4.69%) | **0.46% (0.22-1.28%)** | **1.08% (0.89-1.28%)** | **0.22% (0.22-0.22%)** |
| *Monitoring error* | 16 (0.69%) | - | - | - | 5 (1.72%) | 2 (1.04%) | **1.04% (0.87-1.38%)** | **1.72% (1.72-1.72%)** | **0.69% (0.69-0.69%)** |
| *Error in judgment/outside expertise* | - | 71 (0.46%) | - | 35 (0.64%) | - | - | **0.55% (0.50-0.60%)** | **0.64% (0.64-0.64%)** | **0.46% (0.46-0.46%)** |
| *Anaesthesia error* | 8 (0.35%) | - | - | - | 2 (0.69%) | - | **0.52% (0.43-0.60%)** | **0.69% (0.69-0.69%)** | **0.35% (0.35-0.35%)** |
| *System error* | - | 15 (0.10%) | - | - | - | - | **0.10% (0.10-0.10%)** | **-** | **0.10% (0.10-0.10%)** |
| **Unavoidable complications** | 58 (2.51%) | 475 (3.06%) | - | - | - | - | **2.78% (2.65-2.92%)** | **-** | **2.78% (2.65-2.92%)** |

Table 2.1.12. Severity of surgical adverse event causes

| First author | Bilmoria | Wanzel | Median (Interquartile range) |
|---|---|---|---|
| **Number of surgical records** | 15524 | 192 | **7858 (4025-11691)** |
| **Error in surgical technique/operative management** | | | |
| fatal | 8 (0.05%) | 0 (0.00%) | **0.03% (0.01-0.04%)** |
| severe | 1 (0.01%) | 1 (0.52%) | **0.26% (0.14-0.39%)** |
| moderate | 291 (1.87%) | 4 (2.08%) | **1.98% (1.93-2.03%)** |
| minor | 60 (0.39%) | 2 (1.04%) | **0.71% (0.55-0.88%)** |
| **total** | 360 (2.32%) | 7 (3.65%) | **2.98% (2.65-3.31%)** |
| **All non-operative management errors combined** | | | |
| fatal | 13 (0.08%) | 0 (0.00%) | **0.04% (0.02-0.06%)** |
| severe | 3 (0.02%) | 2 (1.04%) | **0.53% (0.27-0.79%)** |
| moderate | 86 (0.55%) | 13 (6.77%) | **3.66% (2.11-5.22%)** |
| minor | 20 (0.13%) | 9 (4.69%) | **2.41% (1.27-3.55%)** |
| **total** | 122 (0.79%) | 24 (12.50%) | **6.64% (3.71-9.57%)** |
| *Incorrect or delayed treatment* | | | |
| fatal | - | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| severe | - | 2 (0.04%) | **1.14% (1.14-1.14%)** |
| moderate | - | 1 (0.52%) | **0.52% (0.52-0.52%)** |
| minor | - | 2 (1.04%) | **1.04% (1.04-1.04%)** |
| **total** | - | 5 (2.60%) | **2.60% (2.60-2.60%)** |
| *Error in other invasive procedure* | | | |
| fatal | - | 0 (0.00%) | **0.00% (0.00.0.00%)** |
| severe | - | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| moderate | - | 3 (1.56%) | **1.56% (1.56-1.56%)** |
| minor | - | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| **total** | - | 3 (1.56%) | **1.56% (1.56-1.56%)** |
| *Medication error* | | | |
| fatal | - | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| severe | - | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| moderate | - | 2 (1.04%) | **1.04% (1.04-1.04%)** |
| minor | - | 3 (1.56%) | **1.56% (1.56-1.56%)** |
| **total** | - | 5 (2.60%) | **2.60% (2.60-2.60%)** |
| *Diagnostic error/delay* | | | |
| fatal | 3 (0.02%) | 0 (0.00%) | **0.01% (0.00-0.01%)** |
| severe | 1 (0.01%) | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| moderate | 29 (0.19%) | 6 (3.13%) | **1.66% (0.92-2.39%)** |
| minor | 3 (0.02%) | 3 (1.56%) | **0.79% (0.41-1.18%)** |
| **total** | 36 (0.23%) | 9 (4.69%) | **2.46% (1.35-3.57%)** |
| *Monitoring error* | | | |
| fatal | - | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| severe | - | 0 (0.00%) | **0.00% (0.00-0.00%)** |
| moderate | - | 1 (0.52%) | **0.52% (0.52-0.52%)** |
| minor | - | 1 (0.52%) | **0.52% (0.52-0.52%)** |
| **total** | - | 2 (1.04%) | **1.04% (1.04-1.04%)** |
| *Error in judgement/outside expertise* | | | |
| fatal | 7 (0.05%) | - | **0.05% (0.05-0.05%)** |
| severe | 1 (0.01%) | - | **0.01% (0.01-0.01%)** |
| moderate | 50 (0.32%) | - | **0.32% (0.32-0.32%)** |
| minor | 13 (0.08%) | - | **0.08% (0.08-0.08%)** |
| **total** | 71 (0.46%) | - | **0.46% (0.46-0.46%)** |
| *System error* | | | |
| fatal | 3 (0.02%) | - | **0.02% (0.02-0.02%)** |
| severe | 1 (0.01%) | - | **0.01% (0.01-0.01%)** |
| moderate | 7 (0.05%) | - | **0.05% (0.05-0.05%)** |
| minor | 4 (0.03%) | - | **0.03% (0.03-0.03%)** |
| **total** | 15 (0.10%) | - | **0.10% (0.10-0.10%)** |
| **Unavoidable complications** | | | |
| fatal | 68 (0.44%) | - | **0.44% (0.44-0.44%)** |
| severe | 8 (0.05%) | - | **0.05% (0.05-0.05%)** |
| moderate | 261 (1.68%) | - | **1.68% (1.68-1.68%)** |
| minor | 138 (0.89%) | - | **0.89% (0.89-0.89%)** |
| **total** | 475 (3.06%) | - | **3.06% (3.06-3.06%)** |

## Discussion

I included 19 studies detailing the frequency of surgical adverse events in this systematic review. Overall, 14.4% of surgical patients experienced adverse events and 53.8% of adverse events were preventable. Most surgical adverse events were associated with minor harm, fewer were associated with moderate harm, less with severe harm and fatal outcomes were in the minority. Wound problems were the most frequent and the most frequent preventable consequence of surgical adverse events, but the included studies did not explain how they could have been prevented. Cardiovascular and gastrointestinal complications of surgical adverse events were the types of surgical adverse event consequences associated with the most fatalities and severe harm. Non-operative management errors were more frequently associated with preventable patient harm than errors in surgical technique. Non-operative management errors consisted of incorrect or delayed diagnosis and treatment associated with monitoring, medication, anaesthesia and judgement. Further detail regarding causation was not available. The results from the sensitivity and subgroup analyses of different study designs were generally consistent. However, incident report-based studies tended to demonstrate fewer adverse events, but with a greater proportion of fatal consequences and preventability and observational studies tended to demonstrate more adverse events, but with a smaller proportion of fatal consequences and preventability.

The main limitation of this study was hindsight bias in the original articles. This hindsight bias was manifest as single causes for each adverse event. The causes were often proximal to harm. This subscribed to the person approach to human error and the mistakes that the healthcare workers made were blamed. The less proximal causes of the adverse events including the design of the healthcare products, processes and environment were not identified as causes as frequently.

It is known that different study designs detect varied adverse events in the same population. (Michel, Quenon et al. 2004, Naessens, Campbell et al. 2009) Observational studies might collect more comprehensive data and incidents are selectively reported. Therefore, I incorporated comprehensive evidence from all study designs that demonstrated the incidence or frequency of surgical adverse events including data from 1976-2006 and 10 countries and separated the study designs into separate methodological sub-groups to compare them. We included different study designs consisting of 13 record reviews, 4 incident report-based, 1 observational and 1 mixed record review and observational study. The incorporated populations all included general surgical care. The method of record selection varied, ranging from including only operated patients to including all admitted patients. Only 5 studies did not count multiple adverse events in individual patients, 7 studies reported the total number of surgical records reviewed and 8 studies used the same *exact* definition of adverse event. No article reported case mix in sufficient detail to compare between studies and this precluded the value of any statistical analysis. Even amongst studies that used similar retrospective

methods, the time frame of included adverse events, the threshold for causation, the inter-rater reliability and the categorisation of consequences and causation varied. Some of the included studies were small. The variability of adverse and preventable adverse event rates has been shown to be greater in studies with smaller sample sizes. (Lessing, Schmitz et al. 2010) These factors may account for differences between the results of the studies. The comparison of different sub-groups can only provide tentative conclusions due to these limitations. The original articles classified some adverse events as preventable, but failed to explain how they might have been prevented or how effective preventative measures would have been.

Evidence from other sources can be compared with adverse event data. A review of 446184 surgical incidents reported to the National Reporting and Learning Service between 2005 and 2008 demonstrated a similar pyramidal distribution of harm with an outcome of death in 0.2%, severe harm in 0.9%, moderate in 5.4%, low 22.1% and no harm in 71.4%. (Catchpole, Sukhmeet et al. 2009) The Scottish Audit of Surgical Mortality is a voluntary review of all surgical deaths. In the 2010 report (2009 data), 1691 cases were fully analysed and the most common causes for concern included inappropriate admission of the patient to surgical wards, operations that should not have been done, delay to surgery, communication failure between healthcare workers and poor postoperative fluid balance. The report highlighted that an area of particular concern was the delay in recognition of clinical deterioration in surgical patients. Operative concerns were in the minority (17.3%). Perioperative concerns (24%) were also a smaller group than those at presentation (50.2%) or postoperatively (25.9%). Even amongst the operative concerns the minority were technical. These results support the findings in this review. (SASM 2010) The National Confidential Enquiry into Perioperative Death (NCEPOD) analysed a random sample of 829 high-risk surgical patients from England and Wales. The report recommended several interventions for addressing the high mortality observed in this group: identification of patients at high risk, improved pre-operative assessment and preparation, improved intra-operative care, particularly cardiac output monitoring and improved postoperative care. In postoperative care, the report noted that care needed to be improved and that sufficient resources for adequate monitoring and support of the patient should be provided. (NCEPOD 2011) A systematic review that provided an overview of adverse events throughout hospital care showed that the overall incidence of adverse events was 9.2% and median percentage preventability was 43.5%. (de Vries, Ramrattan et al. 2008) This study did not analyse the causes of adverse events. It was also limited, because it included only record review studies that reviewed more than 1000 records and it excluded studies that were specific to surgical patient populations. My study showed a similar incidence of adverse events and percentage preventability within surgical care. My study also showed a lower percentage of fatal and minor outcomes, but a higher percentage of moderate and severe outcomes. Both studies showed that the most frequent type of adverse events were operation-related. This may give the false impression that operations

are the source of the majority of adverse events. However, both studies also showed that the combination of non-operation-related adverse events collectively formed the majority. The results associated with non-operative management errors suggest that significant preventable patient harm originates from the surgical ward. The studies included in this review did not disclose the location of surgical adverse events in detail. However, 47% of all surgical fatalities occurred in the ward or intensive care unit, 53% of preventable surgical adverse events occurred in general ward care and the majority of all surgical adverse events occurred in post-operative monitoring and daily care. (Andrews, Stocking et al. 1997, Neale, Woloshynowych et al. 2001, Calland, Adams et al. 2002) This confirms that surgical patient safety improvement efforts should focus on the ward as well as the operating room.

Adverse events are highly relevant and established patient safety indicators. They are also well defined and repeatedly investigated. Therefore, they provide good subject matter for a systematic review. I used a high-quality Cochrane standard search strategy. (Higgins and Green 2008) In the paper that I published based on this chapter, I included record review studies only. (Anderson, Davis et al. 2013) However, in this thesis chapter, I included all article types to be comprehensive. I compared a sensitivity analysis composed of only the higher-quality record review studies with the overall results, which were consistent.

In order for future studies to yield more useful data, I recommend that they should: use the strict definition of adverse event, include all patients admitted, report case mix and the total number of records screened, detect all adverse events occurring as a consequence of the index admission with post-discharge follow-up, allow counts of more than one adverse event per patient, report frequency, severity and preventability of consequences and causation using a published 4-point severity scale. All of these components were present within the selection of studies included in this review, but not within the same study. Future studies should also consider ways in which they can more comprehensively assess the systemic causes of the adverse events that they detected and how they might be prevented.

The characteristic of surgical care is that patients have invasive procedures in the operating room and this is where patient safety in surgery has focused. However, the analysis of surgical adverse event causation demonstrates that patient safety improvement efforts should not only target errors in surgical technique, but also in the non-operative management that occurs in the ward. Insights into how we should intervene cannot be gleaned from these studies of surgical adverse events. Other methods are required. We addressed this by using the study detailed in the next chapter.

# A systematic proactive risk assessment of hazards in surgical wards

## Overview

The aim of this chapter was to identify targets for design interventions by analysing risk in surgical wards. We achieved this by carrying out a series of three studies. The first was an observational study of all healthcare processes that occurred in surgical wards. The second was a risk assessment survey. In order to work out which healthcare processes were the most risky, we asked patients and healthcare staff to complete the risk assessment survey for each of the healthcare processes. We identified the five most risky healthcare processes that included hand hygiene, isolation of healthcare-associated infection, vital signs monitoring, handover communication and medication delivery. The third study was a modified Healthcare Failure Mode and Effects Analysis (HFMEA). We took the five most risky healthcare processes and put each through an in-depth failure mode and effects analysis in order to determine where the risky steps in each process were. These risky steps in the risky processes were then subjected to cause analysis to help us understand why they were associated with medical errors. This also helped us think of ways to address them with design interventions later.

Observations

1. Catalogue observed activities in surgical wards and group them into healthcare processes;

Risk assessment survey

2. Allow stakeholders to subjectively rate the frequency and severity of failure associated with the healthcare processes;
3. Calculate hazard scores from the ratings and use them to prioritise the most risky healthcare processes for further assessment in modified Healthcare Failure Mode and Effects Analysis;

Modified Healthcare Failure Mode and Effects Analysis

4. Allow stakeholder teams to subjectively rate the frequency, severity and detectability of failures within each high-risk healthcare process;
5. Calculate hazard scores from these ratings and use them to prioritise the most risky failures for further assessment in cause analysis;
6. Apply the Framework for Analysing Risk and Safety in Clinical Medicine to the prioritised high-risk failures to determine their causes;
7. Recommend interventions that might address the causes.

# Observations

## Methods

### *Setting*

The research was conducted at Imperial College Healthcare NHS Trust and included the five general surgery wards in its three acute hospitals. The Camden and Islington NHS Research Ethics Committee granted the Chief Investigator of the DOME project, Professor Jeremy Myerson approval for observational studies. Reference: 09/H0722/15.

### *Observers*

Two researchers, myself and Andrea Brodie a healthcare psychologist, observed and independently recorded the activities that patients and healthcare workers were engaged in surgical wards.

### *Procedure*

We observed the people in the wards for a total of 70 hours. We split this time equally between 5 general surgical wards at 3 hospitals. We spent a total of 10 hours per ward making observations during the working day and 2 hours per ward making observations during the night time and weekend. The timing of the observations was determined randomly using computer-generated numbers. We wrote down what activities the people in the wards were doing. We grouped together the individual activities that had the same overall purpose into healthcare processes. For example, the activities ‘go to the sink,’ ‘turn the tap on’, ‘use the soap,’ ‘dry hands’ etc were all part of the hand hygiene process.

### *Saturation and reliability*

We continued observing until saturation occurred, i.e. no new activities or processes were observed and we were in 100% agreement regarding the list of activities and healthcare processes. We made observations for the planned length of time independently and then compared our lists of observed activities. Saturation of the lists occurred before we had completed the planned 70 hours of observations.

# Results

## *Activities observed*

Observations of activities in surgical wards identified 81 activities in total, which are shown in table 2.2.1.

Table 2.2.1. Activities and healthcare processes in surgical wards

| **Healthcare process** | **Activities** |
|---|---|
| Domestic cleaning | Changing beds<br>Cleaning floor or bedside equipment<br>Cleaning of vital signs monitoring equipment<br>Move bed/furniture<br>Wet floor safety signs<br>Looking for equipment/supplies in storage areas |
| Post-Operative Mobilisation | Re-positioning patient in the bed/turning<br>Sitting up/out<br>Chest exercises/Coughing<br>Transferring<br>Use of wheelchair<br>Standing<br>Walking on the flat (with or without aid)<br>Walking on the stairs (off the ward)<br>Use of bedside controls<br>Use of bedside rails<br>Move bed/furniture<br>Looking for equipment/supplies in storage areas |
| Use of bedside rails | Use of bedside rails<br>Use of bedside controls |
| Hand-washing | Hand-washing<br>• Alcohol gel<br>• Soap and water |
| Monitoring of vital signs ('Observations') | Observing patient from nursing station<br>Cleaning of vital signs monitoring equipment<br>Vital signs measuring and recording (blood pressure/pulse/respiratory rate/pulse oximetry/temperature/fluid balance/urine output/blood sugars)<br>Use of urinary catheter<br>Use of nasogastric tube<br>Use of drains<br>Move bed/furniture<br>Looking for equipment/supplies in storage areas |
| Correct site surgery | Consent/Marking<br>Pre-operative checklist |
| Medication delivery | Dispensing medication<br>Use of PCA<br>Management of IV lines and drip stands<br>Looking for equipment/supplies in storage areas |
| Ward round | Ward round<br>History taking<br>Examinations<br>Move bed/furniture<br>Writing notes/forms<br>Using the computer<br>Looking for equipment/supplies in storage areas |
| Staff hand-over | Using the telephone<br>Use of bleeps |

| | |
|---|---|
| | Writing notes/forms<br>Hand-over at shift change (at nurse's station)<br>Hand-over at shift change (in staff room)<br>Hand-over at bedside |
| Isolation of infection | Hand-washing<br>Gloves and apron<br>Changing beds<br>Cleaning floor or bedside equipment<br>Cleaning of vital signs monitoring equipment<br>Looking for equipment/supplies in storage areas |
| Percutaneous procedures | Phlebotomy - venepuncture<br>Cannulation<br>Sharps disposal<br>Move bed/furniture<br>Looking for equipment/supplies in storage areas<br>Hand-washing<br>Isolation of infection |
| Wound care | Change of dressing<br>Removal of sutures or clips<br>Looking for equipment/supplies in storage areas<br>Hand-washing<br>Isolation of infection |
| Activities of daily living | Resting/Sleeping/Lying down<br>Eating and drinking<br>Use bed pan/commode/toilet<br>Take waste to the sluice<br>Hygiene - washing/shaving/brushing<br>teeth/showering/bathing/drying/<br>dressing<br>Entertainment - Patient-line TV/radio/<br>phone<br>Move bed/furniture<br>Looking for equipment/supplies in storage areas<br>Call for help - using nurse call button |
| Other | Recording an ECG<br>Taking a mobile Chest X-ray<br>Building maintenance |

## *Healthcare processes derived from observed activities*

We grouped the 81 observed activities with the same overall purposes into 13 healthcare processes. These healthcare processes included: hand hygiene; isolation of infection; vital signs monitoring; medication delivery; handover; domestic cleaning; ward rounds; surgical site marking; post-operative mobilisation; post-operative use of bedside rails; activities of daily living; medical diagnosis and intravenous interventions.

# Risk assessment survey

## *Selection of healthcare processes for risk assessment survey*

The senior investigators, Professor Charles Vincent and Professor George Hanna, in collaboration with the Designing Out Medical Error research team defined the scope of the project. Our remit was to intervene in the clinical environment to improve patient safety. In order not to waste resources, an important step was to identify which healthcare processes were within our remit to improve. Healthcare processes that were outside this remit were excluded from the risk assessment survey. Ten of the original 13 healthcare processes identified by the observations of general surgical wards in the previous section were considered suitable for inclusion in the risk assessment survey including: hand hygiene, isolation of infection, vital signs, medication delivery, handover, domestic cleaning, ward rounds, surgical site marking, post-operative mobilisation and post-operative use of bedside rails. Three further healthcare processes including: activities of daily living, medical diagnosis and intravenous interventions and other activities (i.e. taking an electrocardiogram and mobile x-ray) were excluded from further analysis, because intervening in these processes and activities was outside our remit.

## Methods

### *Subjects*

I obtained a convenience sample by approaching patients, visitors and healthcare workers in surgical wards and asking them to participate in the survey. Healthcare workers were eligible for inclusion if they worked in surgical wards. Patient and visitors were also included if they were present in these wards. Healthcare workers that did not work in surgical wards were excluded, as were patients and visitors who had no experience of these wards. I recruited 59 participants including: 20 nurses, 16 patients and visitors, 14 doctors, 3 domestic staff, 2 dieticians, 1 ward clerk, 1 phlebotomist, 1 physiotherapist and 1 clinical psychologist. Participants included 22 males and 37 females. Their median age was 40 (range 20 to 72). Nobody refused to participate.

### *Risk assessment survey design*

The risk assessment survey was composed of a series of closed questions that required a rating response on a scale. The questions related to 10 healthcare processes including: hand hygiene, isolation of infection, vital signs, medication delivery, handover, domestic cleaning, ward rounds, surgical site marking, post-operative mobilisation and post-operative use of bedside rails. The survey lasted approximately 10 to 15 minutes per participant.

The questions relating to the two risk ratings were:

1. How frequently do you think preventable harm occurs as a result of failures in this healthcare process on one general surgical ward;
2. How severe could these preventable harms be?

## *Procedure*

Participants were approached by the researcher (myself) and asked to give valid consent. If the participants gave valid consent, I asked them to attribute risk ratings to the healthcare processes. Participants rated risk in each healthcare process using two 4-point scales: the frequency of harm resultant from errors in the healthcare process and the maximum potential severity of harm associated with errors in the process. I multiplied the frequency and severity ratings together to calculate hazard scores. I demonstrate this as a risk matrix in table 2.2.2. In order to prioritise, I selected an arbitrary hazard score threshold corresponding to ≤50% of all healthcare processes. This decision was based on the resources available within the project, i.e. I thought we had the resources to apply modified Healthcare Failure Mode and Effects Analysis to five healthcare processes in the next section. I classified healthcare processes with hazard scores reaching or exceeding this threshold as high-risk and carried them forward to modified Healthcare Failure Mode and Effects Analysis in the next section. In this manner, I identified and prioritised suitable healthcare processes in an entire clinical environment.

Table 2.2.2. Hazard matrix for risk assessment survey

| | | Frequency | | | |
|---|---|---|---|---|---|
| | | 5 > years | 2-5 years | 1-2 years | 1 > per year |
| Severity | Death | 4 | 8 | 12 | 16 |
| | Disability | 3 | 6 | 9 | 12 |
| | Increased stay | 2 | 4 | 6 | 8 |
| | None of the above | 1 | 2 | 3 | 4 |

The hazard matrix determined hazard scores attributed to healthcare processes from ratings of severity and frequency of harm.

## Results

In total, 1180 ratings were possible, corresponding with 20 ratings per participant. In total, the participants gave 1137 ratings, because they were unsure how to answer on 43 occasions when they had insufficient experience or knowledge of the healthcare process in question. This was a completeness of 96%. I multiplied the frequency and severity risk ratings given by participants to each healthcare process to calculate a hazard score. I did not calculate a hazard score on 24 occasions when the participant had not given both risk ratings. The full range of potential hazard scores was represented by the data. I show the average severity, frequency and hazard score attributed to each healthcare process in table 2.2.3.

Table 2.2.3. Average risk ratings and hazard scores attributed to healthcare processes in general surgical wards

| Healthcare process | Average severity score | Average frequency score | Average hazard score (standard deviation) |
|---|---|---|---|
| Hand hygiene | 3.0 | 3.7 | 12.0 (4.2) |
| Isolation of infection | 3.1 | 3.2 | 10.3 (3.9) |
| Vital signs | 3.1 | 3.1 | 11.1 (4.3) |
| Medication delivery | 2.8 | 3.5 | 10.0 (4.4) |
| Handover | 3.0 | 3.1 | 9.4 (4.5) |
| Domestic cleaning | 2.8 | 3.0 | 9.0 (4.7) |
| Ward rounds | 2.8 | 2.5 | 7.3 (4.6) |
| Surgical site marking | 3.3 | 1.8 | 6.7 (3.6) |
| Post-op mobilisation | 2.9 | 2.0 | 7.4 (4.4) |
| Post-op use of bedside rails | 2.2 | 2.0 | 4.7 (3.6) |

Risk assessment survey: Results of the risk assessment survey demonstrate the average hazard scores attributed to the ten healthcare processes rated.

### *Prioritisation*

The five healthcare processes (≤50%) that received the highest hazard scores were carried forward to modified Healthcare Failure Mode and Effects Analysis, including: hand hygiene, isolation of infection, vital signs, medication delivery and handover. The hazard scores attributed to the five highest-risk healthcare processes were significantly different to the

hazard scores attributed to the five lowest-risk healthcare processes (Wilcoxon two sample test $W=63513.5$, $p<0.001$).

# Modified Healthcare Failure Mode and Effects Analysis

There are many types of proactive risk assessment available. The Prospective Hazard Analysis toolkit incorporates a representative sample of different techniques and lists their pros and cons. (Clarkson, Ward et al. 2009) Failure Mode and Effects Analysis is an example of a proactive risk assessment tool. It has a favourable set of characteristics and has been adapted for use in healthcare. (DeRosier, Stalhandske et al. 2002) It was used successfully in previous design for patient safety research collaboration between Imperial College London in the Resus:Station project and was employed in the redesign of the purpose-built patient safety hospital, St. Joseph's. (Reiling 2006) The Joint Commission favours Failure Mode and Effects Analysis. For these reasons, we chose to use Healthcare Failure Mode and Effects Analysis as the method of proactive risk assessment in the DOME project. Proactive risk assessment has been used to investigate aspects of healthcare processes in surgical wards, but these are limited to parts of the system, such as communication. (Nagpal, Vats et al. 2010) No study has systematically assessed risk in surgical wards by analysing more than one healthcare process simultaneously to identify and prioritise high-risk failures throughout high-risk healthcare processes to allow targeted interventions to be recommended that might more effectively reduce preventable patient harm.

Table 2.2.4. Failure Mode and Effects Analysis stages

| Stages | Description |
|---|---|
| 1 | Select one or more healthcare processes to investigate |
| 2 | Assemble a team involving all key stakeholders |
| 3 | Make a flow diagram of the healthcare process |
| 4 | Identify potential failure modes and their effects |
| 5 | Risk assess each failure mode and calculate hazard scores |
| 6 | Prioritise the highly hazardous failure modes and perform cause analysis |
| 7 | Make recommendations to address systemic causes |

The stages of a Failure Mode and Effects Analysis are shown in table 2.2.4. The US army created Failure Mode Effects and Criticality Analysis in 1949 in order to improve the reliability of their ammunitions manufacture. (US Army 1949) The National Aeronautics and Space Administration (NASA) then adopted Failure Mode and Effects Analysis and used it to help Apollo 11 land the first man on the Moon. The key advantage here was that Failure Mode and Effects Analysis could be used to risk assess processes that had never been implemented

before. This was important to NASA who developed unique space rockets and could not fire hundreds of prototypes to retrospectively analyse safety incident rates. Aviation was the next industry to adopt Failure Mode and Effects Analysis and used it to objectively improve their safety record. Ford motor company had a commercial disaster with a car called the Pinto that had a number of faults, but most unfortunately, the fuel tank would fracture in minor rear-end shunt road traffic accidents, which could result in a petrol explosion. In order to recover, Ford adopted Failure Mode and Effects Analysis and not only improved their safety record, but became so much more reliable and competitive that the remainder of the American automotive industry had to adopt Failure Mode and Effects Analysis just to stay in contention. It is this impressive record in industry that makes Failure Mode and Effects Analysis a compelling choice for the favoured method of proactive risk assessment in healthcare.

Originally, Failure Mode and Effects Analysis was based on risk ratings of frequency and severity in exactly the same manner as in the risk assessment survey in the previous section, except that these risk ratings are given to the effects of failures at each step in the process and not to the process as a whole. Failure Mode and Effects Analysis then acquired a third rating, detectability. This is an important addition, because some errors might be frequent and potentially result in severe harm, however if the error can be detected easily it is not such as high a priority as an error that is invisible, because this may stop harm from being prevented. DeRosier et al 2002 further adapted Failure Mode and Effects Analysis for use in healthcare by adding two further parameters: single point weakness and effective control measure. These are different parameters to the first three, because they are not rated on a scale, but are just rated yes or no. A single point weakness is a failure that causes the entire process to fail to achieve its main objective. An effective control measure is a working safety measure that is already in place. After the calculation of hazard scores by the multiplication of risk ratings, DeRosier et al 2002 also added a decision matrix. After high-risk failures are identified in the normal way, the additional decision matrix is applied. This progresses only high-risk failures that are single point weaknesses and not associated with effective control measures.

The framework for analysing risk and safety in clinical medicine is part of the London Protocol for systems analysis, which provides 'a window on the system.' (Vincent, Taylor-Adams et al. 1998, Vincent 2004) Cause analysis involves interviewing participants. In Vincent's description of the process, he says that the investigator should use their judgement to differentiate between contributory factors that may occur in the future and one offs. The interview is structured around a list of factors that can contribute to medical error. Asking the participants 'why (does) this happen' is regarded as the most useful way of gaining useful insights. (Vincent 2003)

# Methods

## *Scope of healthcare processes under investigation*

| Healthcare Process | Description |
|---|---|
| Hand washing | Correct use of alcohol-based hand gels and soap & water according to the World Health Organisation's *my 5 moments for hand* hygiene. Alcohol-based hand gel dispensers are placed on the frame of every bed and at the entrance to all the wards. There is approximately one hand-washing sink per bay and side room. Hand hygiene reminder signs are placed at the entrance of the hospitals and on the walls and doors in corridors and in the wards. Movement sensor audible reminders are present occasionally. |
| Vital signs monitoring | The measurement and recording of the patients' pulse, blood pressure, temperature, oxygen saturations and respiratory rate involves physically obtaining the measurements from the patient and plotting the results as graphs on the chart at the end of the bed. In addition to this is the decision making process of interpreting the results and responding to them. |
| Isolation of infection | The detection and barrier nursing of patients with hospital acquired infections is achieved by screening patients for MRSA and testing diarrhoea for C. difficile toxin and moving infected patients into side rooms if possible. Contact precautions signs are used to signal the obligation to use disposable plastic aprons and gloves in addition to hand hygiene. |
| Hand over of information | The formal transfer of information from members of one shift to another occurs between doctors and nurses separately twice a day. Out-going healthcare workers prepare a hand over sheet comprising the patient details and jobs to be done and discuss this with their colleagues before leaving work. |
| Medication delivery | Nurses deliver most oral medication by conducting drug rounds at set times of the day. The Nurses carry commonly prescribed drugs with them (analgesics) and most of the patient's regular medications are kept in a locker by the bedside. Other drugs are kept in a locked drug cupboard in a central location on the ward. The nurses review the drug chart and talk to the patient, deliver the medication into a paper cup and sign the drug chart. If the patient refuses the medication then this is recorded on the chart. |

## *Mapping of healthcare processes into their component steps*

I used a formal modified Healthcare Failure Mode and Effects Analysis procedure to proactively risk assess each of the 5 most hazardous surgical ward processes. (DeRosier, Stalhandske et al. 2002, Smith 2005, Nagpal, Vats et al. 2010) Members of the project including a clinician, designers and psychologist (myself, Grace Davey, Jonathan West and Andrea Brodie) created process flow diagrams by observing the 5 healthcare processes in action in the surgical wards. The stakeholder teams subsequently validated the process flow diagrams.

## *Brainstorming failures at each step*

Failures were generated through literature reviews, ward observations, and interviews with patients and staff, brainstorming sessions by members of the project and focus groups with modified Healthcare Failure Mode and Effects Analysis teams. This ensured that all potential failures were detected through a triangulated approach. The stakeholder teams subsequently validated the process failures.

## *Stakeholder teams*

I assembled five stakeholder teams, one for each healthcare process carried forward from the risk assessment survey. Each stakeholder team consisted of a doctor, nurse and patient, each with first hand experience of surgical wards. Each stakeholder team was supplemented with an expert member, with first hand and research experience of the healthcare process. A facilitator, who was a member of the Designing Out Medial Errors project, led each stakeholder team. Facilitators in different stakeholder teams were trained to apply the same rating definitions. An invigilator (myself) circulated between stakeholder teams and ensured harmonisation of methods. This permitted the results of modified Healthcare Failure Mode and Effects Analysis applied by different stakeholder teams to different processes to be compared.

## *Subjective ratings of frequency, severity and detectability of failures*

I gave a lecture to all participants to explain the modified Healthcare Failure Mode and Effects Analysis risk rating procedure. The effects of each failure were rated on three 4-point scales: frequency, severity and detectability shown in table 2.2.5. Stakeholder teams were issued cards with numbers 1 to 4. These permitted individual stakeholder team members to independently select cards representing ratings, eliminating the influence of other stakeholder team members from the initial ratings (the halo effect). Final ratings were decided through consensus within the stakeholder teams and recorded according to modified Healthcare Failure Mode and Effects Analysis guidelines. (Smith 2005)

Table 2.2.5. Modified Healthcare Failure Mode and Effects Analysis risk ratings

| Score | Severity | Frequency | Detectability |
|---|---|---|---|
| 4 | Death | 1 > per year | Remote |
| 3 | Disability | 1-2 years | Low |
| 2 | Increased stay | 2-5 years | Moderate |
| 1 | None of the above | 5 > years | High |

Ratings of severity, frequency and detectability associated with each failure were multiplied together to give a hazard score.

## *Use of hazard scores to prioritise the most important failures*

In order to prioritise, a hazard score threshold corresponding to ≤33% of failures was selected. I multiplied the three risk ratings including: frequency, severity and detectability that

were attributed to each failure to calculate hazard scores. Failures with hazard scores reaching or exceeding this threshold were classified as hazardous. These were carried forward to cause analysis if they were not associated with effective control measures. Standard Healthcare Failure Mode and Effects Analysis decision trees dictate that only failures that are single point weaknesses i.e. cause the failure of the entire process, are considered further. (DeRosier, Stalhandske et al. 2002) I modified this procedure and also carried forward failures that were not single point weaknesses, because the consequences of some failures were made more hazardous by allowing their process to continue e.g. equipment that continues to function while contaminated is more likely to spread infection.

## *Cause analysis*

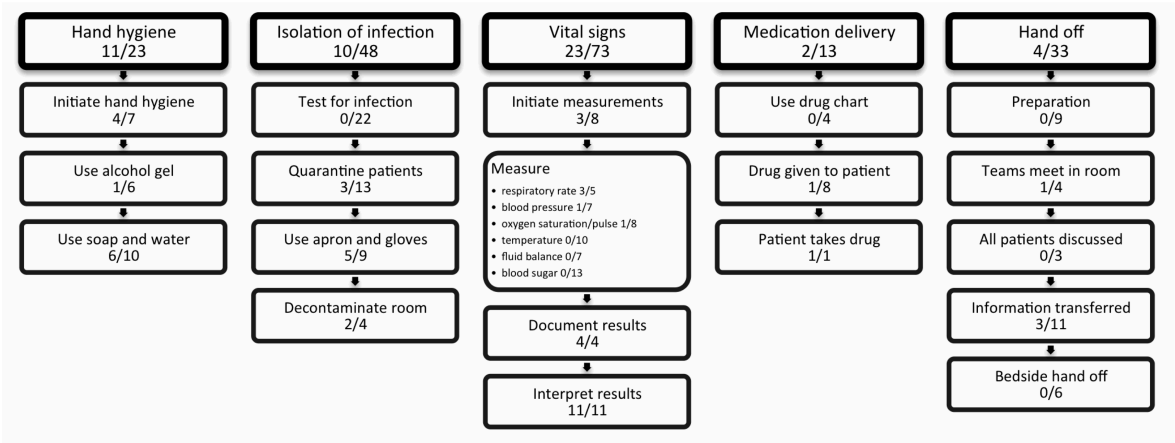
Cause analysis consisted of participants identifying the reasons why each failure occurred using the framework for analyzing risk and safety in clinical medicine. These included: institutional context; organisational and management factors; work environment; team factors; individual (staff) factors; task factors and patient characteristics. (Vincent, Taylor-Adams et al. 1998) The reason for each cause was explored, using the five whys technique, until the causes were exhausted, irrelevant or root causes were identified. (Smith 2005)

# Results

## *Healthcare process maps*

We mapped the five healthcare processes carried forward from the risk assessment survey. I present a summary map of all five high-risk general surgical healthcare processes that we applied modified Healthcare Failure Mode and Effects Analysis to in figure 2.2.1. This demonstrates the distribution of low and high-risk failures throughout these healthcare processes. I present the detailed maps of four of the healthcare processes in appendix 2.2.1-4 including: hand hygiene, isolation of infection, vital signs monitoring and handover.

Figure 2.2.1. Summary healthcare process maps (Anderson, Brodie et al. 2012)




Process maps: Failures identified in each healthcare process and sub-process. The numerator indicates the number of high-risk failures and the denominator indicates the total number of failures rated.

## *Failures*

In total, we identified 277 failures in 190 steps throughout the five healthcare processes. The distribution of healthcare steps associated with high-risk failures is summarised in figure 2.2.1. Full details of all failures are shown in appendix 2.2.5-8.

## *Stakeholder teams*

I assembled stakeholder teams including: 5 patients who had all been treated with an oesophagectomy for cancer, 5 ward nurses, 5 junior doctors and 5 healthcare professionals with research publications relating to the healthcare process under investigation. Members of the DOME project including: 1 anaesthetist (Susanna Walker), 1 human factors expert (Beverley Norris), 1 healthcare psychologist/FMEA expert (Andrea Brodie), 1 business systems analyst (Maria Kapsali) and 2 healthcare designers (Grace Davey & Jonathan West) facilitated stakeholder teams. I trained the facilitators and invigilated the teams to ensure methods were harmonised. Stakeholder teams first reviewed the process maps and the list of failures to check they agreed with them. The stakeholder teams made only minor modifications to these by discarding healthcare process failures that they believed had only trivial consequences.

## *Prioritisation of high-risk failures*

After applying the criteria for determining high and low risk failures, high-risk failures were identified as shown in Tables 2.2.6-9. All the failures along with the low risk failures are shown in appendix 2.2.5-8.

Table 2.2.6. Risk ratings attributed to high-risk failures in hand hygiene

| System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|
| Remember to decontaminate hands | Forget to decontaminate hands | Hands contaminated<br>Infection spread | 4 | 4 | 4 | Yes | No |
| Decide to decontaminate hands | Decide not to decontaminate hands | Hands contaminated<br>Infection spread | 4 | 4 | 4 | Yes | No |
| Decide to use alcohol gel or soap and water | Use alcohol gel, but the patient has diarrhoea due to C. diff (alcohol gel does not kill C. diff spores) | Hands contaminated with C. diff<br>C. diff is spread | 4 | 4 | 4 | Yes | No |
| | Use alcohol gel, but hands are dirty | Hands still contaminated<br>Infection spread | 4 | 4 | 4 | Yes | No |
| Cover all areas of hands | All areas of hands not covered | Hands contaminated<br>Infection spread | 4 | 4 | 4 | Yes | No |
| Operate soap dispenser | Cannot operate soap dispenser | Do not wash hands with soap<br>Hands contaminated<br>Infection is spread | 4 | 4 | 4 | Yes | No |
| Wash all areas of hands | All areas of hands not washed | Parts of hands not decontaminated<br>Infection spread | 4 | 4 | 4 | Yes | No |
| Rinse | Cannot rinse | Cannot perform hand wash effectively<br>Infection is spread | 4 | 4 | 4 | Yes | No |
| Take paper towels | Towels not taken | Hands wet | 4 | 4 | 4 | Yes | No |
| Dry hands | Do not dry hands | Hands wet | 4 | 4 | 4 | Yes | No |
| Turn off taps using paper towel | Turn tap off and touch tap with hands | Hands contaminated from the tap<br>Infection spread | 4 | 4 | 4 | Yes | No |

Table 2.2.7. Risk ratings attributed to high risk failures in isolation of infection

| System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|
| Bay quarantine | Bay not quarantined effectively | Infection spreads | 4 | 4 | 3 | Yes | No |
| Remember to wear apron and gloves | Forget to wear apron and gloves | Infection is spread | 4 | 4 | 3 | Yes | No |
| Decide to wear apron and gloves | Decide not to wear apron and gloves | Infection is spread | 4 | 4 | 3 | Yes | No |
| Find apron and gloves | Cannot find apron and gloves | Infection is spread | 4 | 4 | 3 | Yes | No |
| Take apron and gloves | Contaminate apron and gloves as they are removed from container | Infection is spread | 4 | 4 | 3 | Yes | No |
| Put on apron and gloves | Contaminate apron and gloves as they are put on | Infection spread | 4 | 4 | 3 | Yes | No |
| Use foot pedal to open bin | Do not use the foot pedal<br>Lift the lid with hands | Hands contaminated<br>Infection spread | 4 | 4 | 4 | No | Yes |
| Equipment kept in one patient's bed-space | Equipment isolated incorrectly | Equipment acts as a fomite<br><br>Infection is spread to non-infected patients | 4 | 4 | 4 | Yes | No |
| Equipment washed and disinfected when removing it from the patient's bed-space with chlorine | Equipment not disinfected correctly | Equipment acts as a fomite<br><br>Infection is spread to non-infected patients | 4 | 4 | 4 | Yes | No |
| Clean non-disposable surfaces using chlorine disinfectant | Surfaces not cleaned correctly with chlorine | Surfaces contaminated<br>Infection spread | 4 | 4 | 4 | Yes | No |
| Dispose of disposable equipment in clinical waste | Disposable equipment not disposed of in clinical waste correctly | Disposable equipment contaminated and infection spread | 4 | 4 | 4 | Yes | No |

Table 2.2.8. Risk ratings attributed to high-risk failures in vital signs monitoring

| System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|
| Remember to measure vital signs | Forget to measure vital signs | Vital signs measured later<br>Complication detected later | 4 | 4 | 3 | Yes | No |
| Decide to measure vital signs | Decide not to measure vital signs | Vital signs measured later<br>Complication detected later | 4 | 4 | 3 | Yes | No |
| Clean equipment/ change disposable equipment | Equipment not disinfected /changed | Infections spread | 4 | 4 | 3 | No | No |
| Decide to measure respiratory rate | Do not decide to measure respiratory rate | No respiratory rate measured<br>Respiratory rate guessed and filled in (around 16-18)<br>Complication goes undetected | 4 | 4 | 3 | Yes | No |
| Find a fob watch/clock with a working second hand | Wear a wrist watch | Infection spread | 4 | 4 | 3 | No | No |
| Look at the watch and patient (chest of woman, belly of a man) | Wall clock difficult to see or patient's breathing movements difficult to see | Respiratory rate measurement inaccurate<br>Complication goes undetected | 4 | 4 | 3 | Yes | No |
| Clean BP cuff | Do not clean cuff | Infection spread | 4 | 4 | 3 | No | No |
| Clean BP cuff | Do not clean cuff | Infection spread | 4 | 4 | 3 | No | No |
| Clean $O_2$ sats probe | Do not clean probe | Infection spread | 4 | 4 | 3 | No | No |
| Clean $O_2$ sats probe | Do not clean probe | Infection spread | 4 | 4 | 3 | No | No |
| Written on ad hoc sheet | Written incorrectly on ad hoc sheet | Complication goes undetected | 4 | 4 | 3 | No | No |
| Transcribed onto vital signs chart | Not transcribed correctly | Complication goes undetected | 4 | 4 | 3 | No | No |
| Graph plotted | Plotted incorrectly | Complication goes undetected | 4 | 4 | 3 | No | No |
| Boxes filled in | Boxes filled in incorrectly | Complication goes undetected | 4 | 4 | 3 | No | No |
| Results interpreted | Results not interpreted correctly (or at all) | Complication goes undetected | 4 | 4 | 3 | No | No |
| Use red zones to interpret results | Red zones on the chart not interpreted correctly | Complication goes undetected | 4 | 4 | 3 | No | No |
| Use trends in graph or numbers to interpret results | Trends or numbers not interpreted correctly | Complication goes undetected | 4 | 4 | 3 | No | No |
| Calculate MEWS score | MEWS not calculated correctly (or at all) | Complication goes undetected | 4 | 4 | 3 | No | No |
| Use MEWS score to interpret results | MEWS score interpreted incorrectly | Complication goes undetected | 4 | 4 | 3 | No | No |

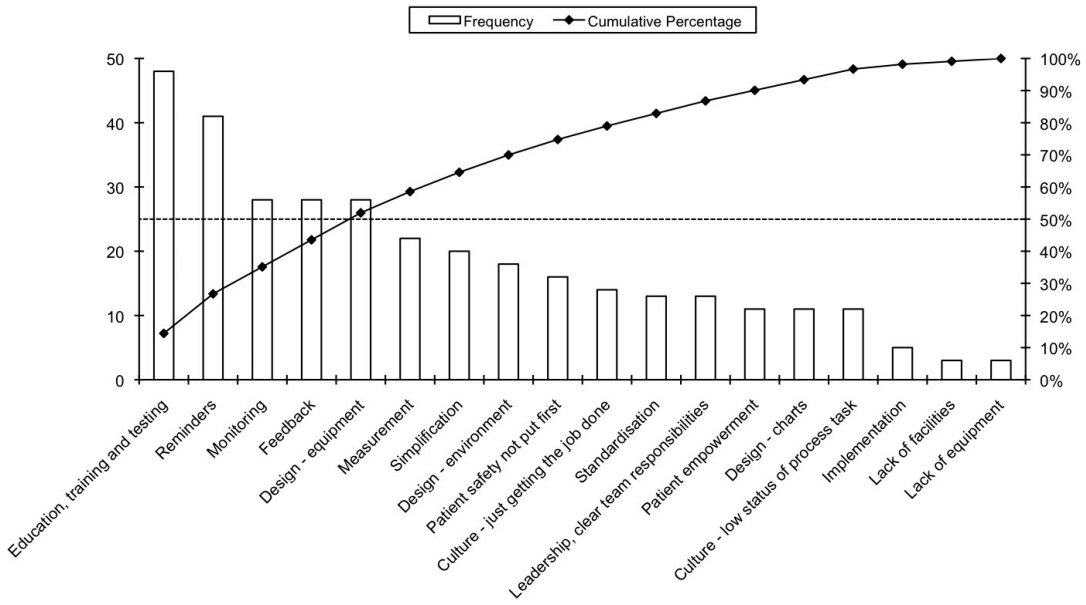
Table 2.2.9. Risk ratings attributed to high-risk failures in handover

| System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|
| Team is informed of time and place of handover | Team is not informed of time and place of handover | Team members missing from handover<br>Patients treated sub-optimally | 4 | 4 | 4 | No | Yes |
| Staff leaving and arriving meet at shift change over time | Leaving or arriving staff are late | Team members missing from handover<br>Patients treated sub-optimally | 4 | 4 | 4 | No | Yes |
| | Meeting place inadequate for handover - noisy | Verbal part of handover difficult<br>Information not communicated<br>Patients treated sub-optimally | 4 | 4 | 4 | No | No |
| Consider first/next patient | Patients and jobs not discussed | Patient does not receive treatment as quickly<br>Patients treated sub-optimally | 4 | 3 | 4 | Yes | Yes |
| How sick the patient is | Inaccurate or no assessment | Treatment not timely (too slow) | 4 | 4 | 4 | Yes | Yes |
| Past Medical History | Past medical history not handed over correctly | Patient treated sub-optimally | 4 | 4 | 4 | Yes | Yes |
| Results<br>*Bloods*<br>*Observations*<br>*Radiology*<br>*Other* | Results not handed over correctly | Patients treated sub-optimally | 4 | 4 | 4 | Yes | Yes |
| Management plan | Management plan not handed over correctly | Patients treated sub-optimally | 4 | 4 | 4 | Yes | No |
| Progress | Progress not handed over correctly | Patients managed sub-optimally | 4 | 4 | 4 | Yes | No |
| Jobs to do | Jobs not handed over correctly | Patients managed sub-optimally | 4 | 4 | 4 | Yes | No |

## *Cause analysis*

A summary Pareto chart representing the frequency with which each major cause was implicated is shown in figure 2.2.2. This showed that causes related to education, training and testing, reminders, monitoring, feedback and the design of equipment accounted for more than 50% of the total. The full detail of causes related to each failure, represented as fish bones tables is shown in appendix 2.2.9-12. What follows is a detailed narrative explaining how insights of causes were used to make recommendations based on existing and potential interventions shown in table 2.2.10.

Figure 2.2.2. Pareto chart of causes



## *Hand hygiene*

### Failures and causes

Inadequate hand hygiene can result in the transmission of healthcare associated infections to patients. The most crucial moment for healthcare staff to sanitise their hands and prevent the spread of infection is just before touching a patient. However hand hygiene reminders are often absent from the bedside. If healthcare workers choose not to sanitise their hands despite remembering, this often goes undetected and uncorrected, because there is insufficient monitoring of hand hygiene adherence. When sanitisers are used, incorrect technique may result in persistent contamination that also goes undetected.

Alcohol gels are ineffective at sanitizing hands contaminated with Clostridium *difficile*. However the bedsides of patients infected with Clostridium *difficile* are still supplied with alcohol gels and not clearly identified with signs, because these might stigmatise the patient. Harsh soaps, abrasive towels and empty dispensers can reduce adherence to hand hygiene guidelines. Hand-actuated taps may immediately re-contaminate washed hands when they are turned off.

### Recommendations

Hand hygiene reminders are required at the bedside to ensure that healthcare workers remember to sanitise their hands just before touching the patient. (Lamb, Studdert et al. 2003) Electronic location-sensitive asset tracking devices worn by healthcare staff can be modified to detect non-adherence to hand hygiene guidelines and provide immediate personal feedback. (Swedberg 2010) Inadequate hand hygiene technique can be corrected with mandatory training programmes and monitored by measuring contamination. (Pittet, Dharan et al. 1999, Boyce and Pittet 2002, Allegranzi and Pittet 2009)

At the bedside of patients infected with Clostridium *difficile*, alcohol gels should be used in addition to soap and water facilities. (Lamb, Studdert et al. 2003, Allegranzi and Pittet 2009) Gentle soaps, soft towels and transparent dispensers encourage adherence to hand hygiene guidelines by being user-friendly and easy to maintain. (Boyce and Pittet 2002, Lamb, Studdert et al. 2003) Non-touch taps (e.g. elbow or infra-red sensor actuated) are recommended to prevent recontamination of hands. (Lamb, Studdert et al. 2003)

## *Isolation of infection*

### Failures and causes

Failure to quarantine patients may lead to outbreaks of infection. Aprons and gloves dispensers that are located at infrequent intervals in corridors impede adherence to isolation of infection guidelines. Any equipment that moves from bed to bed and touches the patients is a high-risk of transmitting infection especially if there is no reminder and no convenient consumables to sanitise it. In particular, single-use equipment for quarantined patients may appear to be reusable and too valuable to throw away. However, standard cleaning techniques may be ineffective.

### Recommendations

Apron and glove dispensers should be available at the bedside of patients requiring their use. (Lamb, Studdert et al. 2003) Modified asset tracking devices can feedback alerts to remind staff when use of apron and gloves and cleaning of equipment is necessary. (Collins 2004) More convenient locations for cleaning consumables e.g. integrated into the equipment would encourage their use. (Boyce and Pittet 2002, Lamb, Studdert et al. 2003) The single-use symbol should be present on the product and not just the packaging and education provided to staff should explain that correct disposal of single-use items is preferable to reducing expenditure through re-use. (Hailey, Jacobs et al. 2008, Rutala and Weber 2008)

## *Vital signs*

### Failures and causes

Mistakes in the process of measuring, recording, interpreting and responding to vital signs may lead to the delayed treatment of patient deterioration when intervention is less likely to be successful. Respiratory rate recordings are frequently inaccurate, because in contrast to the other vital signs, measurement of respiratory rate is not performed by a piece of equipment. The nurse must manually count the number of breaths a patient takes in a timed minute. Interruptions during measurement lead to short cuts such as using less time or estimating the result. The accurate documentation, interpretation and scheduling of repeat vital sign measurements is crucial. However this repetitive process involving calculations of e.g. early warning scores is prone to failures if performed manually.

### Recommendations

Facilitation of accurate respiratory rate measurement with well-designed equipment would significantly improve the utility of this vital sign. (NCEPOD 2005, Hogan 2006) The documentation, interpretation and scheduling of repeat vital signs measurement is amenable to algorithms that may more reliably be executed by automated systems. (Prytherch, Smith et al. 2006) Also, integrating the results of all vital signs in one electronic device would allow the automatic calculation of early warning scores. (Prytherch, Smith et al. 2010)

## *Handover*

### Failures and causes

Incomplete or inaccurate transmission of all necessary information between one shift of healthcare staff and the next can result in mistakes in any aspect of patient care. Healthcare workers conduct handover in rooms that may lack necessary equipment and therefore team members miss parts of handover when they leave the room. The place used for handover may not allow the transmission of information confidentially, inhibiting complete transfer of sensitive information. Unstructured communication is often responsible for mistakes in handing off management plans, progress updates and jobs to be done, which are likely to cause harm.

### Recommendations

Handover rooms should be designated appropriately and supplied with: table, chairs, telephones to answer pagers, computers for checking results, printer for handover documents and necessary consumables (paper, printer-cartridges and pens) to reduce interruptions. (Solet, Norvell et al. 2005, Kitch, Cooper et al. 2008) Handover requires a structured process to ensure the comprehensiveness of necessary information transfer, which can be facilitated through structured handover documentation. (Riesenberg, Leitzsch et al. 2009, Riesenberg, Leisch et al. 2010)

Table 2.2.10. Causes of high-risk failures and recommendations

| *Process steps* | *Failures* | *Causes* | *Recommendations* |
|---|---|---|---|
| **Hand hygiene** | | | |
| Commence hand hygiene | Forget to commence hand hygiene at the bedside | No bedside reminders | Implement bedside reminders |
| | Decide not to commence hand hygiene | Inadequate monitoring and feedback of adherence to guidelines | Monitor adherence and provide individual feedback |
| Decide to use alcohol gel or soap and water | Use alcohol gel, but this is ineffective, because the patient has a Clostridium *difficile* infection | Bedside warning signs avoid stigmatising information that is required by staff to make the right choice<br>No convenient sinks<br>Lack of knowledge & training<br>No feedback of performance | Replace alcohol gels with sinks at the bedsides of C. *difficile* infected patients and indicate use of the sinks on hand hygiene reminders<br>Implement adequate numbers of sinks<br>Ensure all staff attend hand hygiene training<br>Monitor and feedback hand contamination levels |
| | Use alcohol gel, but this is ineffective, because hands are ingrained with dirt | | |
| Operate soap/towel dispenser | Dispenser not used | Harsh soap/abrasive towels<br>Empty dispensers not easily identifiable | Gentle soap/soft towels<br>Transparent dispensers - emptiness is detectible through visual inspection |
| Cover all areas of hands with alcohol gel/soap and water | All areas of hands not covered with sanitizing agent | Lack of knowledge & training<br>No feedback of performance | Ensure all staff attend hand hygiene training<br>Measure and feedback hand contamination levels |
| Rinse with water | Re-contaminate hands when turning off taps | Design of taps | Non-touch taps |
| Turn off taps | | | |
| **Isolation of infection** | | | |
| Quarantine bedside | Contact precautions not initiated | No bedside reminders or equipment to maintain contact precautions | Place equipment necessary to maintain contact precautions including apron and gloves at the bedside of infected patients |
| Remember to wear apron and gloves | Forget to wear apron and gloves | | |
| Decide to wear apron and gloves | Decide not to wear apron and gloves | | |
| Find apron and gloves | Cannot find apron and gloves | | |
| Take apron and gloves | Contaminate apron and gloves as they are removed from their dispenser and put on | Lack of convenient hand sanitization facilities | Place hand sanitization facilities next to apron and gloves dispensers |
| Put apron and gloves on | | | |
| Use equipment for only one patient | Use equipment for more than one patient | Not enough equipment<br>Ineffective reminders, monitoring and feedback of adherence to guidelines | Provide enough equipment<br>Electronic asset tracking systems can detect if equipment moves between patients and provide alerts |
| Disinfect equipment when removing it from the patient's bedside | Equipment not disinfected correctly | Inconvenient cleaning materials<br>Ineffective reminders, monitoring and feedback of adherence to guidelines | Provide convenient cleaning materials<br>Electronic asset tracking systems can detect if equipment moves between patients and provide alerts<br>Measure and feedback contamination levels |
| Clean bedside environment surfaces | Clean bedside surfaces incorrectly | | |
| Place disposable equipment in clinical waste | Reuse single-use equipment | Single-use symbol present on packaging only<br>Lack of knowledge regarding single-use equipment | Locate single-use symbols on products and provide education regarding their proper use |
| **Handover** | | | |
| Staff meet in handover location at shift change-over | Location prevents comprehensive handover | Handover location not confidential<br>Equipment required not present at handover location | Designate confidential handover rooms and supply with all necessary equipment |
| Handover progress report | Progress not handed off | Lack of standardisation of handover procedure | Structure handover procedure and support with structured handover documentation |
| Handover management plan | Plan not handed off | | |
| Handover jobs to be done | Jobs not handed off | | |

| *Process steps* | *Failures* | *Causes* | *Recommendations* |
|---|---|---|---|
| **Vital signs** | | | |
| Remember to measure vital signs | Forget to measure vital signs | Vital signs measured at routine rounds with no reminders to monitor sick patients more frequently | Reminders when vital signs measurements should be repeated based on early warning scores can be delivered by an automated system |
| Decide to measure vital signs | Decide not to measure vital signs | | |
| Clean vital signs equipment before applying it to a patient | Equipment not cleaned | Inconvenient cleaning materials<br>Ineffective reminders, monitoring and feedback of adherence to guidelines | Provide convenient cleaning materials<br>Electronic asset tracking systems can detect if equipment moves between patients and provide alerts |
| Decide to measure respiratory rate | Decide not to measure respiratory rate | No equipment on the vital signs trolley to support respiratory rate measurement | Provide a user-friendly device to support respiratory rate measurement on the vital signs trolley |
| Find a fob watch/wall clock to measure respiratory rate | Wear a wrist watch that can transmit infection | | |
| Count respiratory movements over one minute | Measure respiratory rate inaccurately | Interruptions to manual counting over the course of one minute | |
| Clean blood pressure cuff | Do not clean blood pressure cuff | Inconvenient cleaning materials<br>Ineffective reminders, monitoring and feedback of adherence to guidelines | Provide convenient cleaning materials<br>Electronic asset tracking systems can detect if equipment moves between patients and provide alerts |
| Clean oxygen saturation probe | Do not clean oxygen saturation probe | | |
| Write vital signs results on ad hoc sheet | Written incorrectly on ad hoc sheet | Repetitive process demanding of concentration and mathematical skill for accuracy | Automated systems transcribe data to records, calculate early warning scores and provide reminders when repeat measurements are required and when to escalate care |
| Transcribe vital signs results onto chart | Transcribed incorrectly | | |
| Plot vital signs graph | Plot graphs incorrectly | | |
| Calculate early warning score | Calculate early warning score incorrectly | | |
| Interpret vital signs results | Interpret results incorrectly | | |
| Decide what action to take | Take incorrect action | Lack of knowledge and ineffective reminders that do not give adequate authority to escalate care | |
| Give/change treatment | Treatment changed or given incorrectly/inappropriately | | |
| Get help/advice | Help and advice not sought appropriately | | |
| Communicate abnormal vital signs results in handover | Results not communicated in handover | No access to vital signs results in handover location | Integrate records of vital signs results with handover documentation |

## Discussion

The purpose of this chapter was to systematically proactively identify and prioritise hazards in general surgical wards. We recorded all activities occurring in general surgical wards by observing them for a total of seventy hours. We derived healthcare processes from these activities. We identified 81 separate activities and 13 healthcare processes. We used this list of healthcare processes for a patient and healthcare worker risk assessment survey in the next section. This demonstrated how complex the wards are. The complexity of the work and lack of any clear coordination suggests that this is a high-risk environment for medical error. Fifty-nine patients and healthcare workers quantified the hazard associated with ten healthcare processes in general surgical wards by completing a risk assessment survey. The five most hazardous healthcare processes identified were: hand hygiene; vital signs monitoring; isolation of infection; medication delivery and handover. We carried these high-risk healthcare processes over into the next section for in-depth risk assessment using modified Healthcare Failure Mode and Effects Analysis. We applied modified Healthcare Failure Mode and Effects Analysis to five high-risk, prioritised healthcare processes identified by the risk assessment survey in the previous section. In total, we identified 190 failures and 50 (26%) were considered high-risk and without effective control measures in place. We also sought to gain insight into the causes of these prioritised failures through the cause analysis. Based on these insights, we made recommendations that addressed individual hazardous failures in: hand hygiene, isolation of infection, vital signs and handover that had not previously been effectively controlled. The majority of interventions we recommended aimed to improve education and reminders, monitoring and feedback of performance, simplification and standardisation of processes and design of equipment as these were the most common causes.

Our observations were limited, because we could not see behind privacy curtains and we may not have witnessed rare procedures. This study was based on subjective opinions of risk. This has the disadvantage of introducing participant bias. However, it also has several advantages. Engaging patients and healthcare workers enables more information to be gained than raw quantitative data can demonstrate. It is possible to obtain a feel for what patients and healthcare workers believe is important for patient safety in general surgical wards. This is not only important for identifying high-risk targets, but also important to understand what changes they would find acceptable. A crucial difference between design and traditional scientific enquiry is that design places more emphasis on understanding the problem inextricably linked within the context of the needs of the user rather than in isolation. This simple and easy to understand rating system allowed key stakeholders to become involved in patient safety. Normal patient safety feedback mechanisms, such as incident reports are not available to patients and visitors and probably underused by the majority of non-clinical staff. Proactive risk assessment or hazard analysis is a technique that is used by high reliability organisations that have radically improved their safety record in the past. The

techniques are now being adopted by healthcare as part of the patient safety movement in an attempt to learn from and catch up with other industries. (DeRosier, Stalhandske et al. 2002) In order for American healthcare organisations to receive accreditation, the USA Joint Commission mandates that healthcare organisations under their jurisdiction apply Failure Mode and Effects Analysis to one healthcare process per year. (Smith 2005) At present there is no such requirement in the UK, however proactive risk assessment is increasingly represented in the patient safety literature. Cause analysis is usually conducted after a clinical incident, but can also be used proactively, before an incident occurs. In some ways, this might be better, because there will be less hindsight bias obscuring the inclusion of causes that were not implicated on one occasion. The key advantage of this novel combined evaluation of hazardous failures from differing processes in a single healthcare environment was that cohesive and more powerful multi-modal interventions could be recommended.

The proactive risk assessment also addressed another limitation of using adverse events. The definition of adverse events does not include near misses. Near misses do not result in harm, but represent the most frequently occurring patient safety incidents and can be used to achieve the greatest amount of learning. By learning from near misses it is possible to prevent adverse events before harm ever occurs. The proactive risk assessment also included input from stakeholders in addition to the healthcare workers involved in surgical care. Many of the studies included subjective methods including the risk assessment survey, modified Healthcare Failure Mode and Effects Analysis risk ratings, cause analysis and design process, which all could have been affected by participant bias. Subjective risk assessment of hazards is successfully used by high reliability organisations to improve safety and is recommended by the Government Health and Safety Executive and the NPSA. (HSE 2006, NPSA 2007, NPSA 2008) The validity of these subjective studies was backed up by consistent results from more robust randomised simulation studies and clinical evaluations. Many of the studies used observations and might have been affected by observer bias. It was important to start the process of systematic proactive risk assessment by observing what activities occurred in our chosen healthcare environment. This is the first step of risk assessment carried out by high reliability organisations. (HSE 2006, Latino 2010) We also used observations in the clinical evaluations. We limited the effects of observer bias by using two independent observers and calculating inter-rater reliability.

The modified Healthcare Failure Mode and Effects Analysis method used had limitations, because the assessment of risk was limited to activities observed and risk assessments were subjective and limited to the participants experience and imagination. However, Failure Mode and Effects Analysis has proven to increase the safety of high-risk industries and was useful in this project for filtering the limitless possibilities into a manageable group of design targets and formed the basis for a common language between the clinicians and designers.

Independent teams may inconsistently apply subjective risk assessment tools. (Shebl, Franklin et al. 2009) We ensured harmonisation of methods between modified Healthcare Failure Mode and Effects Analysis teams to address this limitation. We did this by training each FMEA team facilitator to administer the FMEA in the same way and by using an invigilator who circulated amongst FMEA teams to ensure the same methods were being applied. Proactive risk assessment is designed to identify failures that might not yet have been reported, potentially preventing harm from ever occurring. This is not possible with retrospective or prospective methods and modified Healthcare Failure Mode and Effects Analysis identified multiple hazardous failures that had no existing control measures in place. Risk ratings given by participants were skewed, more high-risk ratings were given, but this is in keeping with the high-risk processes that were selected for analysis.

Failure Mode and Effects Analysis makes assumptions about risk and utility. Risk is the combination of the frequency and severity of a negative outcome. However the relationship between frequency and severity is more complex than the rating scale used by Failure Mode and Effects Analysis. The rating scale assigns only a single score of frequency and severity. The severity rating is the maximum potential severity, but the frequency is the frequency of a failure causing harm of any severity. This measures the maximum potential harm associated with a failure and was applied consistently in order to achieve harmonisation of methodology. However, it can be imagined that a failure may extremely rarely be associated with a severe outcome, but is commonly associated with minor harm. Another failure may be associated with a severe harm all of the time. This will not be distinguished in the Failure Mode and Effects Analysis rating scale score and is a limitation of the simplistic rating scale used.

We modified the Healthcare Failure Mode and Effects Analysis decision matrix made by De Rosier 2002. This decision matrix vetoed further consideration of failures that were not single point weaknesses. Single point weaknesses halt the entire process when they occur. In some circumstances, failure to halt the entire process is more hazardous, because halting the entire process can be a fail-safe mechanism that prevents a mistake resulting in harm. For example, failure to clean contaminated vital signs equipment continues to function and therefore spreads infection and causes harm. Therefore, we modified the Healthcare Failure Mode and Effects Analysis procedures described by De Rosier 2002 and included failures that were not single point weaknesses.

Our results are supported by the reports of others. Multi-modal hand hygiene interventions are proven to be effective and incorporate improved reminders, adequate provision of sanitization facilities, education and feedback of performance. (Pittet, Hugonnet et al. 2000, Lamb, Studdert et al. 2003) If complete adherence to hand hygiene guidelines was achieved, it is estimated that infection rates would fall by 40%. (Kampf, Loffler et al. 2009) With limited numbers of single patient rooms, improved design of bedside facilities in open bays has

resulted in reduced failures to isolate infections. (Moore, Ali et al. 2010) The provision of hand sanitisers, aprons and gloves at every bedside necessary is recommended, because the correct use of aprons and gloves is proven to be effective in limiting the spread of infections. (Mangini, Segal-Maurer et al. 2007) The re-use of single-use medical devices requires reliable, auditable processes for decontamination. Without these it is not recommended. (Hailey, Jacobs et al. 2008, Rutala and Weber 2008) Other authors confirm that respiratory rate is the most unreliably recorded vital sign and hypothesise that the reason is because, unlike other vital signs, a well-designed aid for the intermittent measurement of respiratory rate is required. (NCEPOD 2005, Hogan 2006, Cretikos, Bellomo et al. 2008, McGain, Cretikos et al. 2008) Failures of documentation, interpretation and scheduling of repeat vital sign measurements result in delay to appreciate the urgency of patient deterioration with potentially serious consequences. (Buist, Jarmolowski et al. 1999, McGloin, Adam et al. 1999) Calculation of early warning scores has been shown to improve patient outcomes through the earlier detection of sick patients. (Moon, Cosgrove et al. 2011) Failure to deliver or consume preoperative medications was identified as critical in a modified HFMEA of the surgical communication process. (Nagpal, Vats et al. 2010) It is estimated that these failures result in significant harm to surgical patients. (Green, Du-Pre et al. 2009) Failure to handover a management plan, update on progress and jobs to be done is considered hazardous. (Nagpal, Vats et al. 2010) Failures in handover may result in sub-optimal treatment and has been associated with poor patient outcomes, such as increased infection rates. (Virtanen, Kurvinen et al. 2009) Checklists forming structured communications are proven effective at improving the completeness of information transfer. (Akbari, Mayhew et al. 2008, Amato-Vealey, Barba et al. 2008)

This study demonstrates how we comprehensively addressed safety in surgical wards by considering risk associated with all observed activities. This allowed a systematic prioritisation of all health care processes utilizing the knowledge and experience of key stakeholders through a risk assessment survey. Modified HFMEA identified the most hazardous failures, allowing them to be prioritised.

# Respiratory rate recording

## Overview

The aim of this chapter was to determine the need for and the efficacy of the Respiratory Rate Recorder in three studies:

1. audit of respiratory rate recordings
2. simulation Respiratory Rate Recorder comparison
3. clinical Respiratory Rate Recorder comparison

## Introduction

Respiratory rate is the number of breaths per minute. It is one of the vital signs, which also include blood pressure, pulse, temperature, pain and oxygen saturation that are routinely measured together in all acute hospital patients. Each is considered vital, because abnormalities in their measurements can be early signs of patient deterioration. If patient deterioration is detected early, adverse events can be prevented and outcome improved.

Respiratory rate has been singled out as the most unreliably recorded vital sign. Although some authors claim that accurate respiratory rate is the most sensitive of the vital signs for detecting patient deterioration, other authors claim that the clinical implementation of respiratory rate recordings is prone to such error to render it virtually useless in practice. All other vital signs are measured automatically. However, in the majority of patients, respiratory rate continues to be measured manually without specific aids, which is thought to contribute to the problem. (McBride, Knight et al. 2005, Hogan 2006, Cretikos, Bellomo et al. 2008, Kellett, Li et al. 2011, Anderson, Brodie et al. 2012)

We designed a simple counter that we called the Respiratory Rate Recorder. This allowed the user to focus on the patient and tap the screen with every patient breath as the counter timed 60 seconds and calculated the respiratory rate. We hypothesised it would significantly improve the accuracy of manual respiratory rate recordings.

# Methods

## *Study design*

We present three prospective studies of diagnostic accuracy adherent to the *Sta*ndards for *R*eporting of *D*iagnostic Accuracy (STARD) guidelines. (Bossuyt and Reitsma 2003) Study 1 is an audit of clinical respiratory rate recordings to establish their accuracy and inform the design of the intervention, the Respiratory Rate Recorder. Study 2 and 3 are randomised crossover simulation and clinical studies of the Respiratory Rate Recorder versus an analogue watch.

## *Setting*

We conducted these studies at Imperial College Healthcare National Health Service Trust that consists of three acute hospitals between 2010-2012. All healthcare workers including registered staff and senior nurses, student nurses and healthcare assistants who routinely measured vital signs in hospital ward patients were eligible for inclusion. We used convenience sampling to recruit participants. A National Health Service research ethics committee and an Audit, Research & Development department approved the project (NHS Scotland A REC Ref: 10/MRE00/94).

## *Study one: respiratory rate audit*

One of two researchers (study authors OA & AB) directly observed participants performing routine vital signs monitoring in acute hospital wards. The respiratory rate documented on the vital signs record by the participant formed the index measurement. The researchers measured the respiratory rate of the patient simultaneously with the participant. The researchers measured respiratory rate for 60 seconds, which formed the reference standard measurement and timed how long the participant spent making their measurement. Dual independent recordings simultaneously by both researchers confirmed the reliability of the reference standard measurements in the first 97 samples (inter-rater reliability kappa 0.86).

## *Study two: simulation study*

We used the SimMan® (Laerdal, Stavanger, Norway) that is a mannequin designed for resuscitation training, to simulate a breathing patient. We placed the mannequin in a real bed in an acute hospital ward. We asked participants to measure the simulated respiratory rate with both the Respiratory Rate Recorder (intervention) and an analogue watch (control). The researchers asked the participant to use 60 seconds to measure respiratory rate. We randomised the order in which they used both techniques. The calibrated respiratory rate generated by the mannequin formed the reference standard. The simulated respiratory rates were 7, 10, 15, 21, 25 and 29 breaths per minute and were chosen to represent a wide range of abnormal values that would not have been possible with a clinical sample. We presented

the respiratory rates to the participants in a randomised order. We timed how long the participant spent making their measurements.

## *Study three: clinical study*

One of two researchers (study authors AS & AM) recruited a sample of participants who had not participated in the simulation study. The researchers randomly assigned the participants to use either the Respiratory Rate Recorder or analogue watch first. The researchers asked the participant to use 60 seconds to measure respiratory rate. The participants completed one vital signs monitoring round of patients and then the researchers returned to the same participant on a separate day to use the other method on a separate vital signs monitoring round. The researchers directly observed the participants while they performed the measurements. The respiratory rate documented on the vital signs record by the participant formed the index measurement. The researchers measured the respiratory rate of the patient simultaneously with the participant and timed how long the participant spent making their measurement. The researchers measured respiratory rate for 60 seconds, which formed the reference standard. Dual independent recordings simultaneously by both researchers confirmed the reliability of the reference standard measurements in the first 110 samples (inter-rater reliability kappa 0.94).

We performed all randomisation in the second and third studies using a random number generator (Microsoft Excel 2008, Redmond, Washington).

## *Statistical methods*

We defined an accurate index respiratory rate recording as ±1 breath per minute from the reference standard. We used the related samples Wilcoxon signed rank test to compare the accuracy of recordings made by participants that were not normally distributed. We defined a normal respiratory rate from 9 to 14 breaths per minute to determine sensitivity and specificity. (Subbe, Kruger et al. 2001, Subbe, Davies et al. 2003) We analysed the data using Statistical Package for Social Sciences (SPSS version 19, an IBM company, New York, USA).

# Results

## *Study one: respiratory rate audit*

The flow diagram is shown in figure 2.3.1. We recruited 61 participants who included 82% registered nurses14% healthcare assistants and 4% student nurses. They all completed the study and made a total of 561 respiratory rate recordings, but 21 recordings were excluded from the analysis, because 16 times the participant did not document a respiratory rate on the vital signs record and 5 times the researchers were interrupted in their attempt to record the reference standard. This removed 2 participants from the analysis. The accuracy of the remaining 59 participants' index respiratory rate recordings was 34% (95% confidence interval 26 to 42%). The index recordings were 63% sensitive and 82% specific as shown in table 2.3.1. The participants used less than 60 seconds to record respiratory rate for 95% of their measurements.

Figure 2.3.1. Audit flow diagram

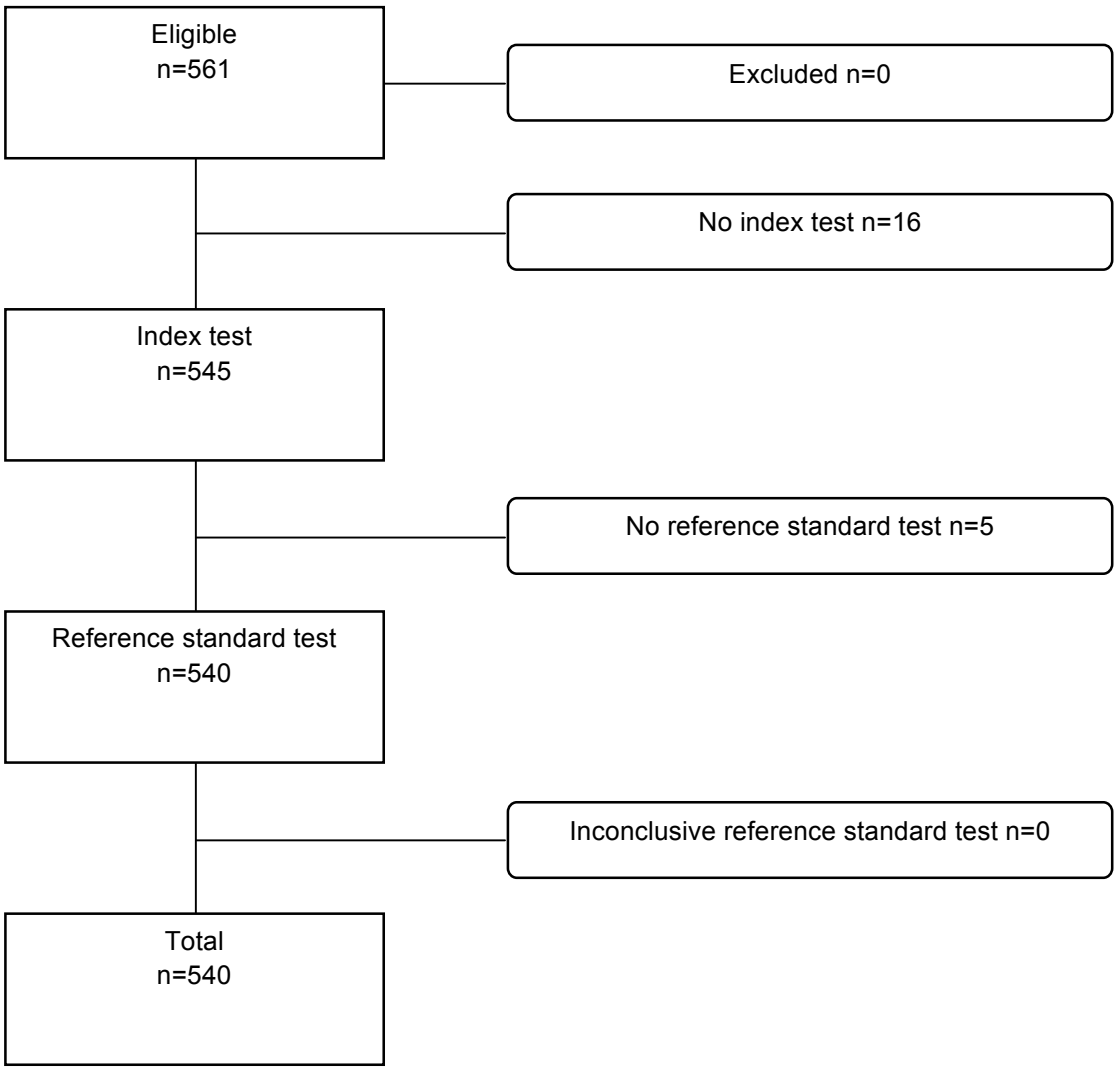


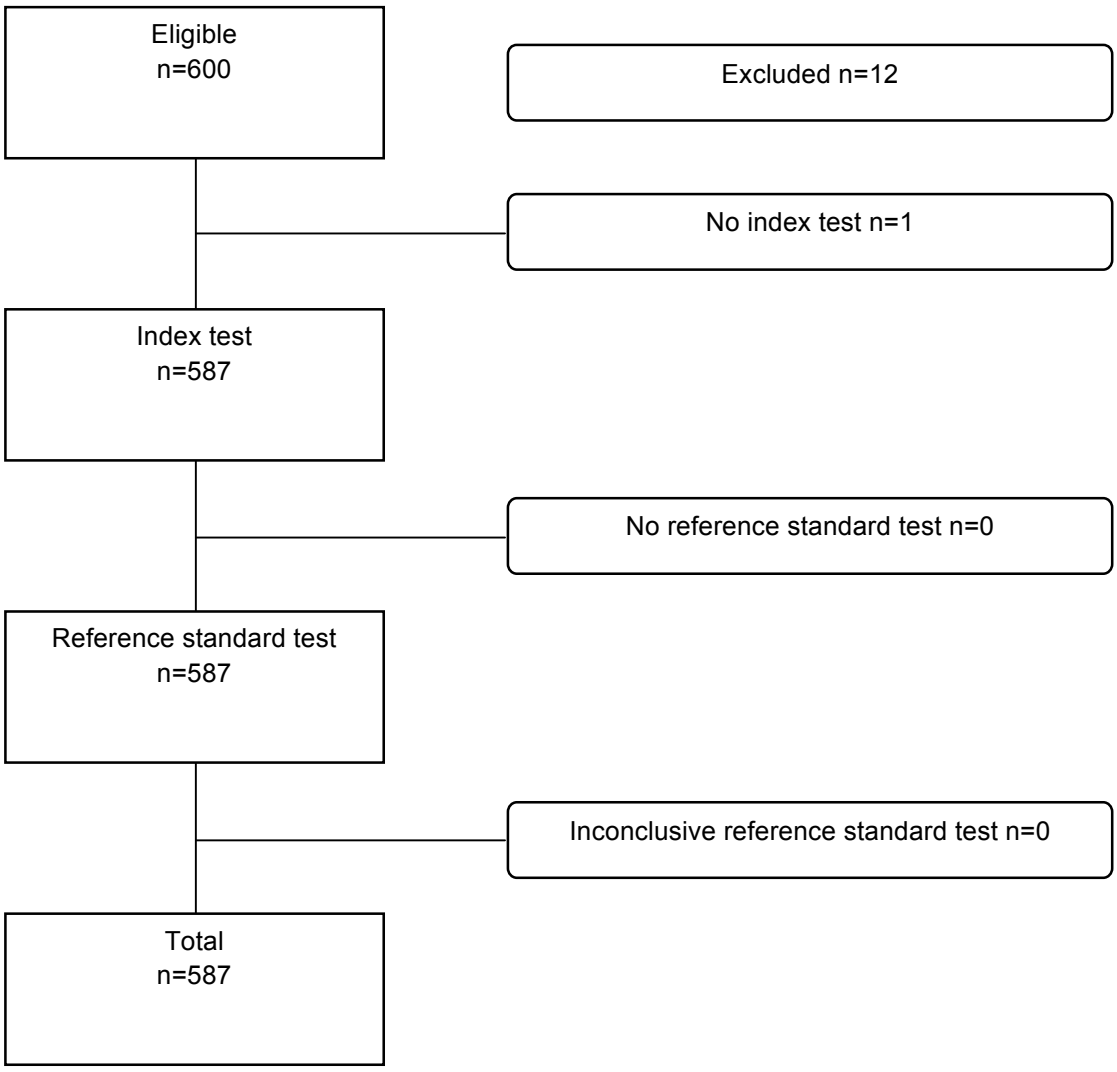
Table 2.3.1. Respiratory rate audit results

| | index | | |
|---|---|---|---|
| reference standard | abnormal | normal | total |
| abnormal | 319 | 6 | 325 |
| normal | 188 | 27 | 215 |
| total | 507 | 33 | 540 |

## *Study two: Respiratory Rate Recorder simulation study*

The flow diagram is shown in figure 2.3.2. We recruited 50 participants who included 44% student nurses, 34% registered nurses, 20% healthcare assistants and 2% physiotherapists. One participant did not complete the study, because they were not available to use the second technique and none of their data were analysed. All other participants completed the study, but one missed out a single recording, but the rest of their data were analysed. The accuracy of the remaining 49 participants' respiratory rate recordings was 70% with the analogue watch (95% confidence interval 64 to 76%) and 95% with the Respiratory Rate Recorder (95% confidence interval 87 to 95%, related-samples Wilcoxon signed rank test $p<0.001$). Participants used 60 seconds to record respiratory rate for all of their measurements.

Figure 2.3.2. Simulation study flow diagram



## *Study three: Respiratory Rate Recorder clinical study*

The flow diagram is shown in figure 2.3.3. We recruited 108 participants who included 57% were registered nurses, 24% were healthcare assistants and 19% were student nurses. They made a total of 1314 respiratory rate recordings 51% with the analogue watch and 49% with the Respiratory Rate Recorder. Three participants did not complete the study as they were not available to use the second technique and none of their 34 recordings were analysed. The accuracy of the remaining 105 participants' respiratory rate recordings was 61% with the analogue watch (95% confidence interval 56 to 66%) and 94% with the Respiratory Rate Recorder (95% confidence interval 92 to 97%, related samples Wilcoxon signed rank test $p<0.01$). The index recordings made with an analogue watch were 90% sensitive and 58% specific and with the Respiratory Rate Recorder were 98% sensitive and 88% as shown in table 2.3.2. The participants used less than 60 seconds to record respiratory rate for 17% of their measurements.

Figure 2.3.3. Clinical study flow diagram

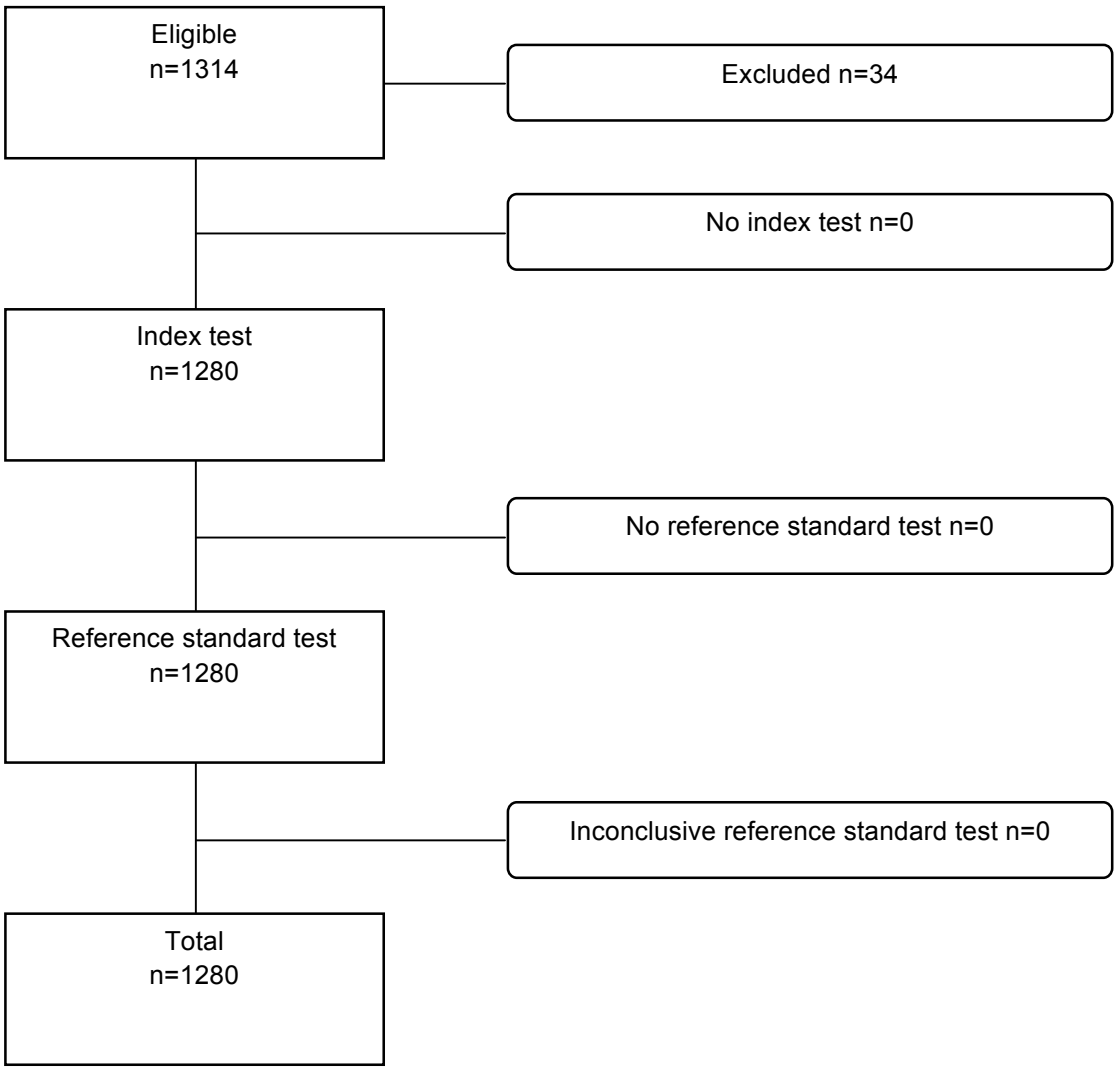


Table 2.3.2. Analogue watch and Respiratory Rate Recorder results

| | analogue watch | | |
|---|---|---|---|
| reference standard | abnormal | normal | total |
| abnormal | 459 | 57 | 516 |
| normal | 52 | 79 | 131 |
| total | 511 | 136 | 647 |

| | Respiratory Rate Recorder | | |
|---|---|---|---|
| reference standard | abnormal | normal | total |
| abnormal | 460 | 20 | 480 |
| normal | 11 | 142 | 153 |
| total | 471 | 162 | 633 |

## Discussion

In the first of three studies, we demonstrated that routine intermittent manual respiratory rate recordings are inaccurate. We designed a simple intervention, a counter that we called the Respiratory Rate Recorder. We tested the intervention in a simulation and clinical study and demonstrated that the accuracy of respiratory rate recordings was significantly improved when compared to the control measure, an analogue watch.

This study demonstrated that manually measuring respiratory rate with an analogue watch is intrinsically difficult and prone to inaccuracy even over 60 seconds. Other authors have shown that using less than 60 seconds is a cause of inaccurate respiratory rate recordings. (Simoes, Roark et al. 1991) In the clinical environment, which was uncontrolled and included distractions, healthcare workers frequently used less than 60 seconds to measure respiratory rate with an analogue watch, which increased inaccuracies.

This is the first study to report these observations of healthcare workers in the act of recording respiratory rates or test an intervention that aimed to improve the accuracy of manual respiratory rate recordings. (Smith 2011) The alternative to manual respiratory rate recordings is automatic respiratory rate recordings. Intermittent recordings have been made with handheld Radar. However, its usability, accuracy and safety have not been fully evaluated in the clinical environment. In a trial of 24 patients, the 95% confidence interval of the Doppler measurements was within ±5 breaths per minute of the reference standard. Therefore, it might not be as accurate as use of the Respiratory Rate Recorder that demonstrated a 95% confidence interval within ±2 breaths per minute of the reference standard. (Droitcour, Seto et al. 2009) Continuous monitoring of respiratory rate is already implemented in healthcare through the use of electrocardiogram electrodes attached to the patient's chest that monitor changes in electrical impedance as the patient breathes. The use of these devices is usually limited to patients who are not ambulatory, because the wires usually lead back to a stationary receiver that is encumbering. Mobile versions of these devices are in development and are composed of wireless stick on electrode chest patches, but cost and infrastructure requirements might limit their implementation to selected patients. Another worn device is the respiratory belt that measures chest excursions, but is unsuitable for clinical use, because it is restrictive. (Rauvala, Jyrkinen et al. 1996, Kellett, Li et al. 2011) The RespiR8$^{TM}$ measures respiratory rate by monitoring airflow through a meter built into a facemask for delivering oxygen, but is not suitable for patients who do not require supplementary oxygen. (Smith, Mackay et al. 2011)

The Hawthorne effect will have influenced the results, because the participants knew they were being observed. However, this should not affect the meaning of the study, because healthcare workers perform this procedure more rigorously when observed. (Lovett, Buchwald et al. 2005) The participants were blinded to respiratory rate recordings made by the

researchers and vice versa. However, neither was blinded to the intervention and control condition. In the simulation study, there was no wash out period. However, both the simulation and clinical study used a randomised crossover design, so half the participants used the intervention and then the control and half used the control and then the intervention so any carry over effects did not bias the study. The SimMan® has a constant respiratory rate, which does not simulate the variable respiratory rate that patients sometimes have over the course of one minute and participants were never interrupted during this study, even though they were in their hospital ward during working hours. This arguably made the task of recording respiratory rate easier. An easy task should favour the control condition, but we still demonstrated a significant improvement in accuracy with use of the Respiratory Rate Recorder over the analogue watch and therefore the meaning of the study was unaffected.

Our future work includes the design and development of a vital signs trolley that integrates the Respiratory Rate Recorder into a touchscreen and will be more suitable than a smartphone application for clinical implementation. (Schwappach and Conen 2012, Norris, West et al. 2014)

Abnormal accurate respiratory rate recordings are the earliest and most sensitive sign of patient deterioration. (Schein, Hazday et al. 1990, Goldhill, Worthington et al. 1999, Ridley 2005) This study demonstrates the inaccuracy of documented manual respiratory rate recordings. The Respiratory Rate Recorder improves accuracy and might reduce the delay to detect patient deterioration and improve outcome. (Fieselmann, Hendryx et al. 1993, Hodgetts, Kenward et al. 2002, Subbe, Davies et al. 2003, Goldhill, McNarry et al. 2005, Smith, Prytherch et al. 2006, Cretikos, Chen et al. 2007, NPSA 2007)

# The CareCentre®

## Overview

The aim of this chapter was to determine the efficacy of the CareCentre® in two studies:

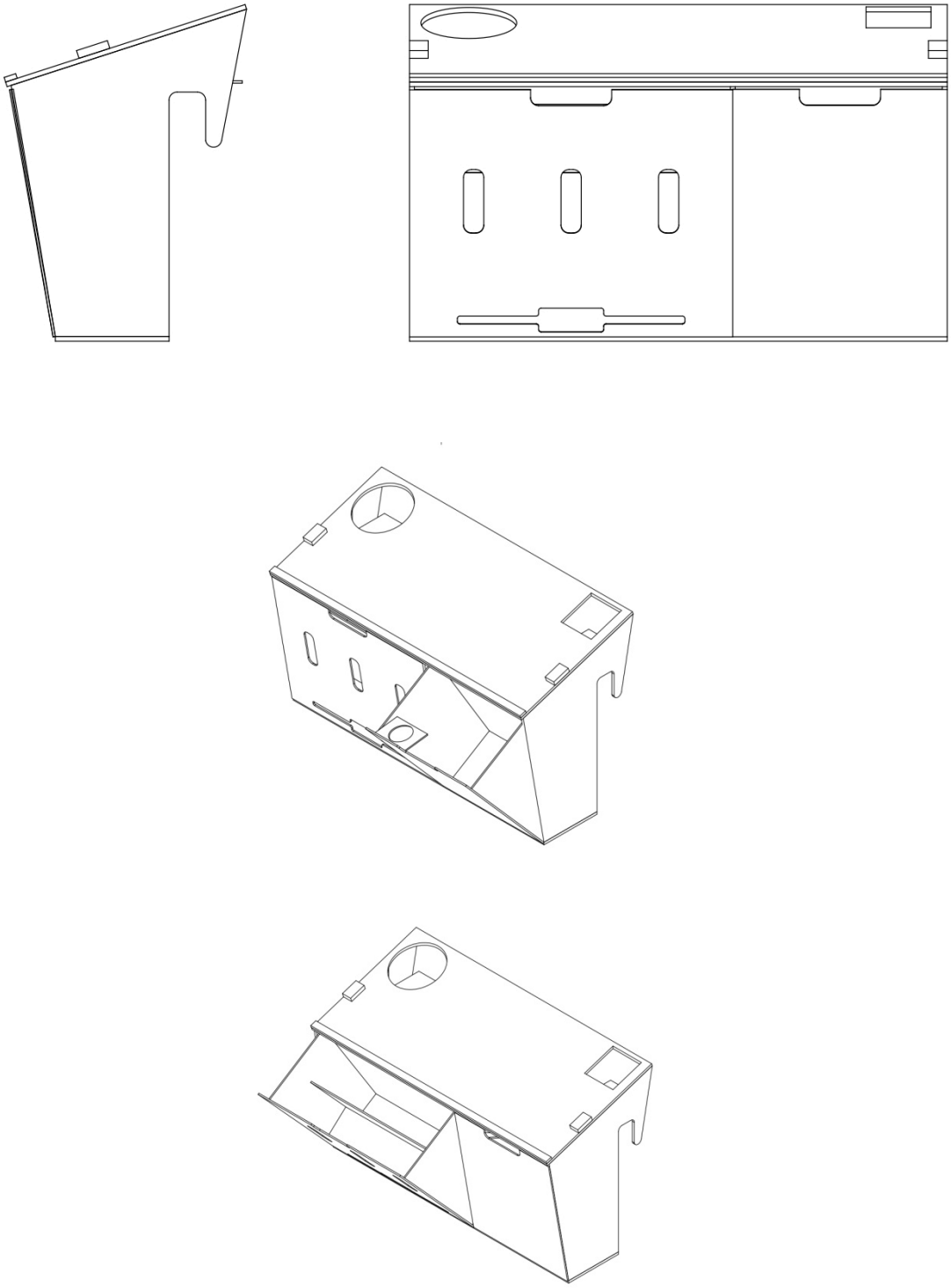
1. simulation CareCentre® comparison
2. clinical CareCentre® comparison

## Introduction

Improved bedside hygiene is associated with reduced healthcare-associated infection rates. Adherence to hand hygiene is considered the single most important factor. (Boyce and Pittet 2002) It has been estimated that complete adherence to hand hygiene guidelines would reduce the rate of healthcare-associated infections by 40%. (Kampf, Loffler et al. 2009) Other infection prevention strategies, such as wearing gloves and aprons as contact precautions are also proven to reduce healthcare acquired infection rates. (Mangini, Segal-Maurer et al. 2007) However, the adherence of healthcare workers to hand hygiene and contact precautions has repeatedly been shown to be sub-optimal despite multi-modal interventions (education, reminders, increasing hand hygiene facilities & feedback). (Allegranzi and Pittet 2009) Design changes, such as more numerous alcohol-based hand rub dispensers and reminders placed in the line of sight of healthcare workers have resulted in improvements in hand hygiene adherence that were sustained and associated with reduced healthcare associated infection rates. (Pittet, Hugonnet et al. 2000) The hand hygiene guidelines from the Centers for Disease Control and the World Health Organisation (WHO) state that alcohol-based hand rub should be made available at the entrance to the patient's room or other convenient locations, but these reports do not consider any other factors concerning the location of hand hygiene facilities that may affect adherence. (Boyce and Pittet 2002, WHO 2006) There is no published evidence for an ergonomic intervention to improve adherence to bedside hygiene and the value of this component is unknown. One of the objectives for future research of the WHO is the implementation and evaluation of individual components of multimodal hand hygiene interventions to assess their value. (WHO 2009)

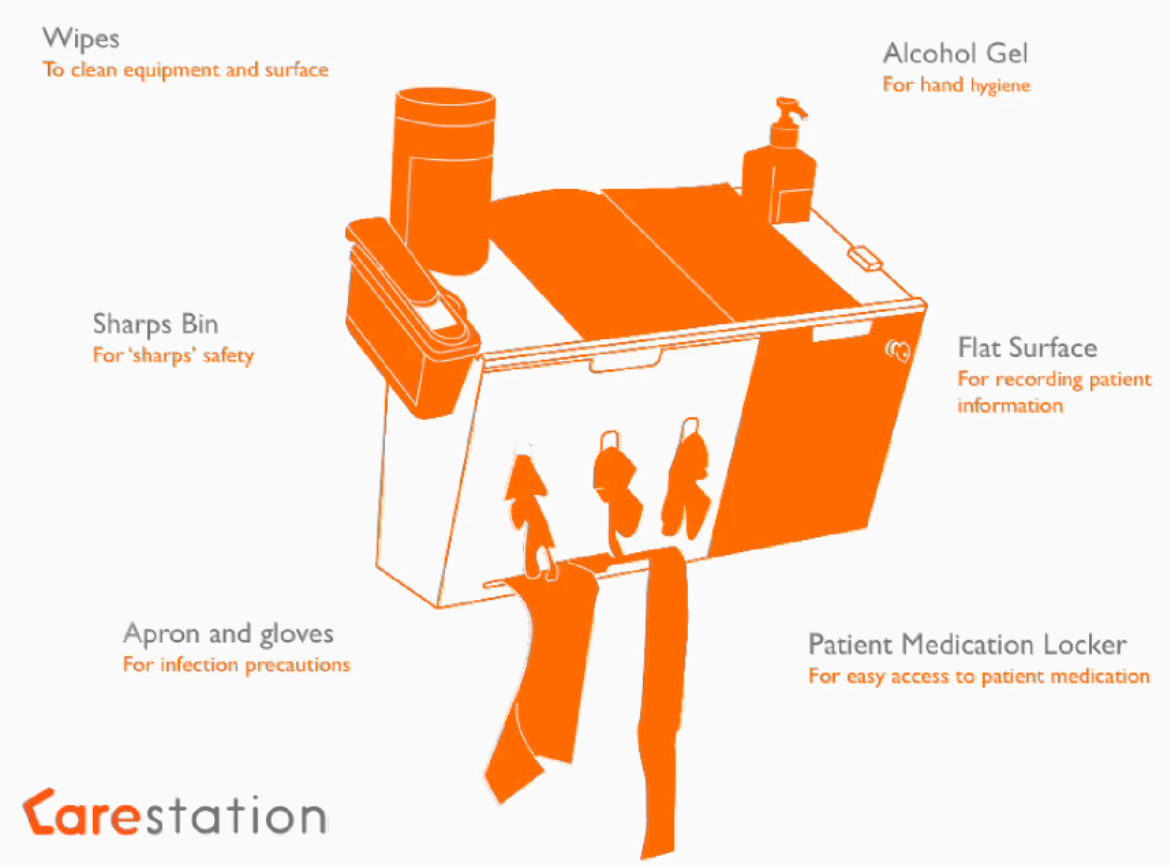
We designed the CareCentre® to improve bedside hygiene by providing the equipment needed to maintain hygiene and perform common bedside tasks at a convenient location. The CareCentre® is an end-of-hospital-bed table incorporating a writing surface, patient charts, alcohol-based hand rub, aprons, gloves, medications locker and waste bin shown in figure 2.4.1-3. We conducted two studies detailed in this chapter to determine the efficacy of the CareCentre® that included a simulation and clinical evaluation.

Figure 2.4.1. Computer-aided design images of the CareCentre® mark I prototype



(Jonathan West, Grace Davey and myself made these images using SolidWorks, Dassault Systemes SolidWorks Corp., Massachusetts, USA)

Figure 2.4.2. Explanatory Flash animation video of the CareCentre® mark I




(Grace Davey made the Flash animation video)

This is the last image in the animation, which highlighted the features of the design of the CareCentre® mark I (the image shows the original name 'Care Station').

Figure 2.4.3. Photos of the CareCentre® mark 1 prototype on Charles Pannett Ward, St. Mary's Hospital



The top photo above demonstrates how the CareCentre® mark I prototype attached to the Arjo-Huntleigh 3000 hospital bed footboard. This is the hospital bed at St. Mary's Hospital, but other hospitals have a variety of bed models. The bottom photo above demonstrates how an open drug chart could be updated with ease.

# Methods

## *Study design*

We present two prospective studies of the CareCentre® versus standard control conditions in simulation and clinical evaluations.

## *Setting*

We conducted these studies at Imperial College London National Health Service Trust between 2011-2012. The Bloomsbury Research NHS Research Ethics Committee granted the Chief Investigator, Professor George B Hanna approval for the clinical trial of the CareCentre® to proceed as an audit/service evaluation. Reference: 11/LO/1188.

## *Study one: simulation evaluation*

This was an individually randomised crossover evaluation. We used a purpose-built simulated ward in a dedicated clinical skills centre at St. Mary's Hospital, Imperial College London. We used paraphernalia in use in the hospital wards as props including beds, bedside furniture and ward equipment. More realism was added by playing sounds recorded from hospital wards into the room at 60dB. (Pai 2007) An actor, dressed in appropriate garb, played the role of a patient who had a Methicillin-resistant *Staphylococcus aureus* (MRSA) hospital-acquired infection and was situated in a two-bedded bay with a patient who was not infected in the other bed. The infected patient had an isolation precautions sign hanging beside their bed. All healthcare workers including registered staff, senior nurses and student nurses who routinely delivered medication, measured and documented vital signs and removed cannulas were eligible for inclusion. We used convenience sampling to recruit participants. We asked 20 participants to perform three tasks on the infected patient: deliver their medication, measure and document their vital signs and remove a cannula from their arm. We then randomised the participant to either receive the experimental or control condition first. After completing the tasks with the first condition, the participant then crossed over and performed the same tasks again with the alternative condition. In the control condition, an alcohol-based hand rub was attached to the foot of the bedframe, the vital signs and drug charts were attached to a clipboard also at the foot of the bedframe and the patient's medications were in the bedside cabinet. In the experimental condition, the alcohol-based hand rub, vital signs and drug charts and patient medications were all in the CareCentre®. In both conditions, placed by the sink were aprons, gloves and cleaning wipes. A sharps bin, cotton wool, bandages, tape and pith trays were placed on a procedures trolley next to a trolley baring equipment for measuring vital signs. Participants were filmed and data were extracted from the recordings.

## *Study two: clinical evaluation*

This was a cluster-randomised crossover evaluation. We included 9 acute adult medical and surgical wards that had at least two 4-6 bedded bays each at St. Mary's hospital. We randomised each pair of bays. One received the experimental condition and the other received the control for one week and then the conditions were reversed during the subsequent week. The run in period was 3 days. One researcher observed each bay for 20 minutes at a randomly allocated time between 9am and 8pm once a day from Monday through to Friday. (Sax, Allegranzi et al. 2009, WHO 2009)

## *Randomisation, outcome measures, statistics and reliability*

We performed all randomisation using a random number generator (Microsoft Excel 2008, Redmond, Washington). Hand hygiene was the main outcome measure in both studies. We assessed the adherence of the participant to the World Health Organisation's my 5 moments for hand hygiene. The denominator was the number of opportunities for hand hygiene and the numerator was the number of opportunities associated with any attempt by the participant to sanitise their hands regardless of technique. (Sax, Allegranzi et al. 2009) We also assessed the use of gloves and aprons. The denominator was the number of opportunities that the participant had to don or dispose of aprons and gloves at the bedside and the numerator was the number of times that the participant donned or disposed of aprons or gloves at the bedside. Aprons and gloves either not donned or disposed at all or not at the bedside were counted as non-adherent to contact isolation of infection guidelines. In the simulation study, the secondary outcome measures of distance moved and time spent moving were extracted from the video tape. We analysed the data using Statistical Package for Social Sciences (SPSS version 19, an IBM company, New York, USA). We compared continuous normally distributed data using paired two-tailed student's t-tests and data that did not meet these conditions was compared with the two-tailed Wilcoxon signed rank test. In order to assess the reliability of the observations, two researchers independently made simultaneous observations for ten 20-minute sessions using the same methods as in the clinical evaluation, which showed close agreement (Cohen's kappa = 0.92).

# Results

## *Study one: simulation evaluation*

The twenty participants included 15 registered (12 staff nurses and 3 senior nurses) and 5 student nurses. They had a median age of 30 years (range 21 to 53) and 90% were female. The results are summarised in table 2.4.1. The participants were significantly more adherent to the WHO's my 5 moments for hand hygiene and donned and disposed of their gloves and aprons at the bedside significantly more often. Participants also moved a significantly shorter distance and spent significantly less time moving in order to complete their tasks.

Table 2.4.1. Simulation evaluation results

| | Control | CareCentre® | P value |
|---|---|---|---|
| Adherence to the WHO's my 5 moments for hand hygiene | 48% (31%) | 67% (33%) | 0.04 |
| Donning and disposing of gloves at the bedside | 19% (25%) | 79% (32%) | <0.001 |
| Donning and disposing of aprons at the bedside | 14% (27%) | 78% (35%) | <0.001 |
| Mean distance moved in metres | 39 (10) | 23 (5) | <0.001 |
| Mean time spent moving in seconds | 109 (30) | 78 (27) | 0.002 |

Figures in brackets are standard deviations

## *Study two: clinical evaluation*

Nine wards participated and completed the study. The results are summarised in table 2.4.2. The CareCentre® was associated with significant improvements in adherence to the WHO's my 5 moments for hand hygiene and donning and disposing of gloves at the bedside. The improvement in donning and disposing of aprons at the bedside did not reach statistical significance.

Table 2.4.2. Clinical evaluation results

| | Number of opportunities with control | Number of opportunities with CareCentre® | Adherence with control | Adherence with CareCentre® | P value |
|---|---|---|---|---|---|
| WHO's my 5 moments for hand hygiene | 584 | 412 | 14% (9-18%) | 40% (30-50%) | <0.001 |
| Donning and disposing of gloves at the bedside | 88 | 78 | 30% (13-47%) | 65% (49-82%) | 0.014 |
| Donning and disposing of aprons at the bedside | 31 | 15 | 10% (0-22%) | 53% (30-77%) | 0.180 |

Figures in brackets are 95% confidence intervals

Figure 2.4.4. Scale diagram of the simulated ward




This scale map of the simulation ward shows its configuration. There were two beds. The actor occupied the bed on the left. The bed on the right was occupied by SimMan™ 3G, a robotic resuscitation mannequin who was set up to breath at a rate of 16 breaths per minute. I represented the presence of a second patient who did not have a healthcare acquired infection next to the subject patient who did to stimulate correct infection control behaviour in the participant.

Figure 2.4.5. The simulated ward in use



Figure 2.4.6 The CareCentre® mark III prototype during the clinical trial



## Discussion

This report showed the effectiveness of the CareCentre® at improving bedside hygiene. In both simulation and clinical prospective randomised evaluations, we determined that the CareCentre® significantly improved adherence to the WHO's my 5 moments for hand hygiene and increased the frequency that gloves were donned and disposed of at the bedside. Aprons were also donned and disposed of significantly more frequently in the simulation study, but this did not reach statistical significance in the clinical study. In the simulation study we also demonstrated that use of the CareCentre® was associated with significantly less distance moved and significantly less time spent moving.

The CareCentre® might work by providing a convenient writing surface and by raising the prominence of the alcohol-based hand rub. Nurses report that lack of space to write at the bedside hampers delivery of good clinical care. (Gurses and Carayon 2007, Gurses and Carayon 2009) The feeling that hand hygiene takes too much time is thought to be a factor that detrimentally affects adherence. (Weeks 1999) With the CareCentre®, the alcohol-based hand rub can be used while viewing documents. Other studies have shown that moving the alcohol-based hand rub into the line of sight at the bedside improved adherence. (Birnbach, Nevo et al. 2010)

Both studies presented in this chapter used randomised crossover designs, which eliminated allocation bias. The simulation evaluation allowed participants to be filmed and accurate measurements made whilst the clinical evaluation allowed the intervention to be tested in the field and the researchers observations were validated by a period of independent simultaneous observation. The clinical study was underpowered to detect a clinically significant improvement in donning and disposing of aprons at the bedside, because the intervention was applied to multi-bedded bays, none of which had patients with contact precautions due to healthcare-associated infections. Analysing the efficacy of several CareCentres® together allowed the field effect of the CareCentres® to be assessed. Neither the assessors nor the participants were blinded to the intervention, which could have resulted in bias, but it was not possible to blind the participants as the effect of the CareCentre® is partly through the way it looks. The Hawthorne effect was addressed by observing the intervention and control groups in the same manner. Therefore, it is unlikely that the participant's knowledge of being observed significantly favoured the intervention over the control. We provided no washout period in either evaluation, i.e. a break in time between the intervention and control conditions. However, randomisation of the sequence of conditions equalised any carry over effect of learning from the first exposure to the second across the entire sample and eliminated any preferential effect of learning.

This study proves that ergonomic design intervention is an effective approach to improve compliance in the healthcare system, which is frequently forgotten in conventional research. Nevertheless, such innovations should be based on inclusive design approach by a multidisciplinary team of clinicians, allied health professionals, human factor specialists and designers. The current project to design out medical errors, has demonstrated the value of this multidisciplinary approach to improve essential and basic standards in clinical care such as bedside hygiene.

The most successful ward or patient room entrance hand hygiene intervention reported is an electronic motion sensor-triggered audible reminder that improved adherence to hand hygiene guidelines at the entrance to hospital wards by 42.3% to 63.7%. (Fakhry, Hanna et al. 2012) A similar device increased adherence to hand hygiene at the exit of single-patient rooms by 8.2% to 27.3%. (Swoboda, Earsing et al. 2004) A conspicuous red sign at the entrance to a surgical ward increased adherence to hand hygiene by 38% to 62%. (Davis 2010) Comprehensive multimodal hand hygiene interventions have demonstrated improvements in adherence to hand hygiene of between 18 to 74.9%. (Pittet, Hugonnet et al. 2000, MacDonald, Dinah et al. 2004, Won, Chou et al. 2004, Rosenthal, Guzman et al. 2005, Picheansathian, Pearson et al. 2008) However, none of these studies reported hand hygiene in terms of adherence to the WHO's my 5 moments for hand hygiene at the bedside. One study had reported this outcome after implementing the WHO's recommended multimodal hand hygiene intervention, which demonstrated a significant improvement of 13.8% to 21.8%. (Allegranzi, Sax et al. 2010) No results of other interventions that evaluated donning and disposing of aprons or gloves or use of a flat or clean surface at the bedside have been reported.

The CareCentre® improved adherence to bedside hygiene guidelines and might help reduce healthcare-associated infection rates as part of a multimodal hygiene strategy. A large scale and long-term implementation of CareCentres® will give sufficient power to study infection rates, morbidity, length of stay and cost effectiveness and assess whether the benefits are sustained.

Figure 2.4.7. The CareCentre® exhibition version



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Figure 2.4.8. The CareCentre® production version




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## Appendix 2.1.1. Search strategy

### Cochrane Central Register of Controlled Trials (Wiley InterScience)

The Cochrane Library 1980 to 2011, searched on 25 February 2011, 2305 records retrieved.

#1. INTRAOPERATIVE COMPLICATIONS single term (MeSH)
#2. POSTOPERATIVE COMPLICATIONS single term (MeSH)
#3. (#1 and #2)
#4. MEDICAL ERRORS single term (MeSH)
#5. IATROGENIC DISEASE single term (MeSH)
#6. ((adverse next event) or error*)
#7. (#3 or #4 or #5 or #6)
#8. INCIDENCE single term (MeSH)
#9. (incidence or occurrence or (complication next rate) or frequency or preventab*)
#10. (#8 or #9)
#11. HOSPITALS single term (MeSH)
#12. GENERAL HOSPITAL single term (MeSH)
#13. HOSPITALIZATION single term (MeSH)
#14. PUBLIC HOSPITAL single term (MeSH)
#15. COMMUNITY HOSPITAL single term (MeSH)
#16. TEACHING HOSPITAL single term (MeSH)
#17. ACADEMIC MEDICAL CENTERS single term (MeSH)
#18. (hospital* or (surgical and department) or (surgery and department) or (general next surgery))
#19. (#11 or #12 or #13 or #14 or #15 or #16 or #17 or #18)
#20. (#7 and #10 and #14)

## MEDLINE (Ovid SP)

Ovid MEDLINE(R) without Revisions 1996 to February Week 3 2011, Ovid MEDLINE(R) 1988 to 1995, Ovid MEDLINE(R) 1980 to 1987 searched on 25 February 2011, 2710 records retrieved.

1. Intraoperative Complications/ep
2. Postoperative Complications/ep
3. and/1-2
4. Medical Errors/
5. Iatrogenic Disease/
6. ((adverse adj1 event*) or error*).tw.
7. or/3-6
8. Incidence/
9. (incidence or occurrence or (complication adj1 rate) or frequency or preventab*).tw.
10. or/8-9
11. Hospitals/
12. Hospitals, General/
13. Hospitalization/
14. Hospitals, Public/
15. Hospitals, Community/
16. Hospitals, Teaching/
17. Academic Medical Centers/
18. (hospital* or ((surgery or surgical) and department) or (general adj1 surgery)).tw.
19. or/11-18
20. Prospective Studies/
21. Retrospective Studies"/
22. Medical Audit/
23. (prospective or retrospective or report$ or record$).tw.
24. or/20-23
25. and/7,10,19,24

## EMBASE (Ovid SP)

EMBASE 1980 to 2011 Week 07 searched on 25 February 2011, 2710 records retrieved.

1. Peroperative Complication/Ep
2. Postoperative Complication/Ep
3. and/1-2
4. Medical Error/
5. Iatrogenic Disease/
6. ((adverse adj1 event*) or error*).tw.
7. or/3-6
8. Incidence/
9. (incidence or occurrence or (complication adj1 rate) or frequency or preventab*).tw.
10. or/8-9
11. Hospital/
12. General Hospital/
13. Hospitalization/
14. Public Hospital/
15. Community Hospital/
16. Teaching Hospital/
17. University Hospital/
18. (hospital* or ((surgery or surgical) adj1 department) or (general adj1 surgery)).tw.
19. or/11-12
20. Prospective Study/
21. Retrospective Study/
22. Medical Audit/
23. (prospective or retrospective or report$ or record$).tw.
24. or/20-23
25. and/7,10,19,24

## PsycINFO (Ovid SP)

PsycINFO 1967 to February Week 4 2011, searched on 25 February 2011, 260 records retrieved.

1. Errors/
2. ((adverse adj1 event*) or error*).tw.
3. or/1-2
4. (incidence or occurrence or (complication adj1 rate) or frequency or preventab*).tw.
5. Hosptials/
6. (hospital* or ((surgery or surgical) and department) or (general adj1 surgery)).tw.
7. or/5-6
8. Prospective Studies/
9. Retrospective Studies/
10. ? Medical Audit/
11. (prospective or retrospective or report$ or record$).tw.
12. or/8-11
13. and/3,4,7,12

## CINAHL (National Health Service Health Information Resources)

CINAHL 1982 to 25 February 2011, 836 records retrieved.

1. exp Health Care Errors/
2. Iatrogenic Disease/
3. Adverse Health Care Event/
4. ((adverse and event*) or error*).ti,ab
5. or/1-4
6. Incidence/
7. (incidence or occurrence or (complication and rate) or frequency or preventab*).ti,ab
8. or/6-7
9. Hospitals/
10. Hospitals, General/
11. Hospitalization/
12. Hospitals, Public/
13. Hospitals, Community/
14. Hospitals, Teaching/
15. Academic Medical Centers/
16. (hospital* or ((surgery or surgical) and department) or (general and surgery)).ti,ab
17. or/9-16
18. Prospective Studies/
19. Record Review/
20. Audit/
21. (prospective or retrospective or report* or record*).ti,ab
22. or/18-21
23. and/5,8,17,22

## Appendix 2.1.2. Excluded full-text articles

| First author | Reason for exclusion |
|---|---|
| *Identified in search* | |
| Andrews[1] | Incorrect definition of AE |
| Antonacci[2] | Unable to extract all AEs in surgical patients |
| Bellomo[3] | Sampling strategy not designed to determine incidence of AEs |
| Carroll[4] | Unable to extract all AEs in surgical patients |
| Couch[5] | Incorrect definition of AE |
| Forster[6] | Unable to extract all AEs in surgical patients |
| Fowler[7] | Sampling strategy not designed to determine incidence of AEs |
| Garcia-Martin[8] | Unable to extract all AEs in surgical patients |
| Gawande[9] | Sampling strategy not designed to determine incidence of AEs |
| Healey[10] | Incorrect definition of AE |
| Jackson[11] | Unable to extract all AEs in surgical patients |
| Lagoe[12] | Unable to extract all AEs in surgical patients |
| Marang-van de Mheen[13] | Sampling strategy not designed to determine incidence of AEs |
| Mendes[14] | Unable to extract all AEs in surgical patients |
| Michel[15] | Cross sectional survey, cannot determine rate of AE/admission |
| Morris[16] | Sampling strategy not designed to determine incidence of AEs |
| Nascimento[17] | Unable to extract all AEs in surgical patients |
| O'Hara[18] | Unable to extract all AEs in surgical patients |
| Sari[19] | Unable to extract all AEs in surgical patients |
| Soop[20] | Unable to extract all AEs in surgical patients |
| Veen (a)[21] | Incorrect definition of AE |
| Veen (b)[22] | Incorrect definition of AE |
| Wolff[23] | Unable to extract all AEs in surgical patients |
| Zegers[24] | Sampling strategy not designed to determine incidence of AEs |
| *Identified in reference lists* | |
| Ehsani[25] | Unable to extract all AEs in surgical patients |
| Feldman[26] | Unable to extract all AEs in surgical patients |
| Hutter[27] | Unable to extract all AEs in surgical patients |
| Moje[28] | Unable to extract all AEs in surgical patients |

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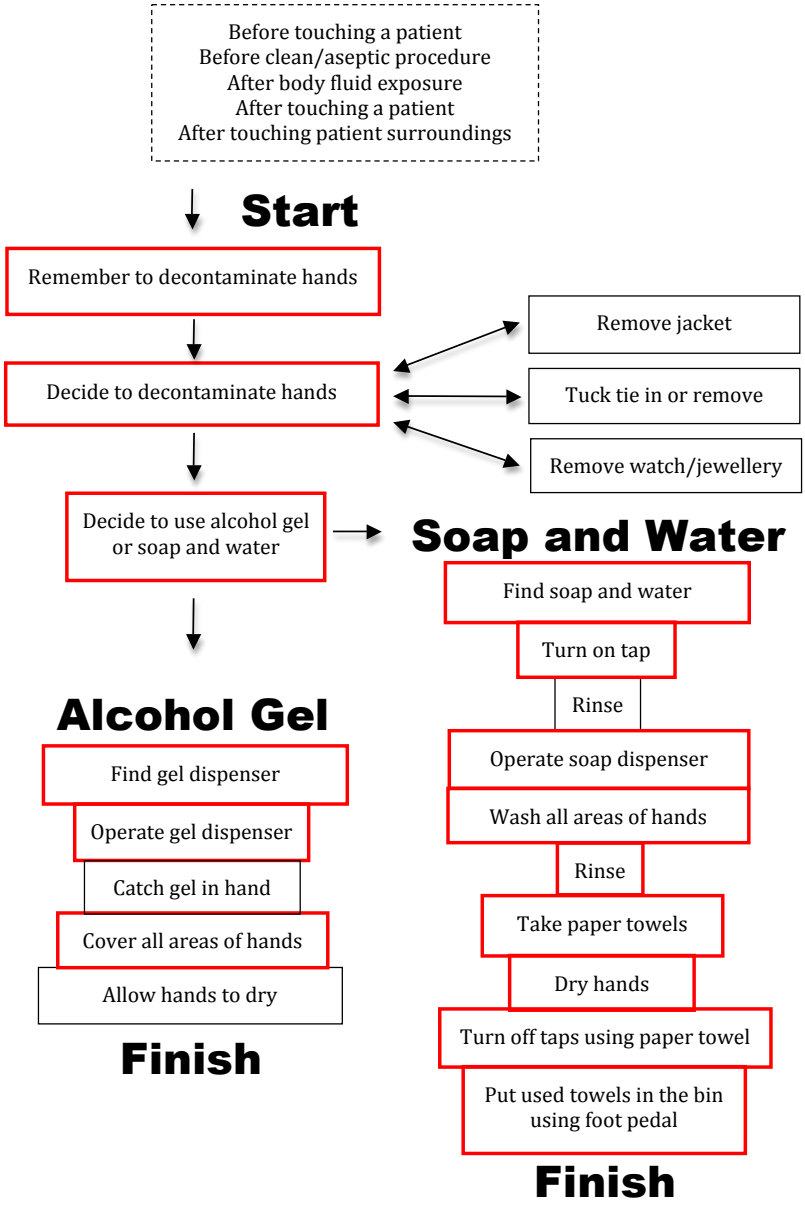
# Appendix 2.1.3. Included articles

| First author of main article | First author of other articles from the same study |
|---|---|
| Adar | |
| Aranaz-Andrés | Aranaz-Andrés[1] |
| Baker | |
| Bilmoria | |
| Brennan | Leape[2]<br>Brennan[3]<br>Brennan[4] |
| Briant | Davis[5]<br>Brown[6]<br>Davis[7]<br>Briant[8]<br>Briant[9] |
| Calland | |
| Forster | |
| Gawande | Thomas[10]<br>Thomas[11] |
| Goldfarb | |
| Griffin | |
| Kable | |
| Letaief | |
| Michel | |
| Rebasa | |
| Vincent | Neale[12] |
| Wanzel | |
| Williams | |
| Wilson | |

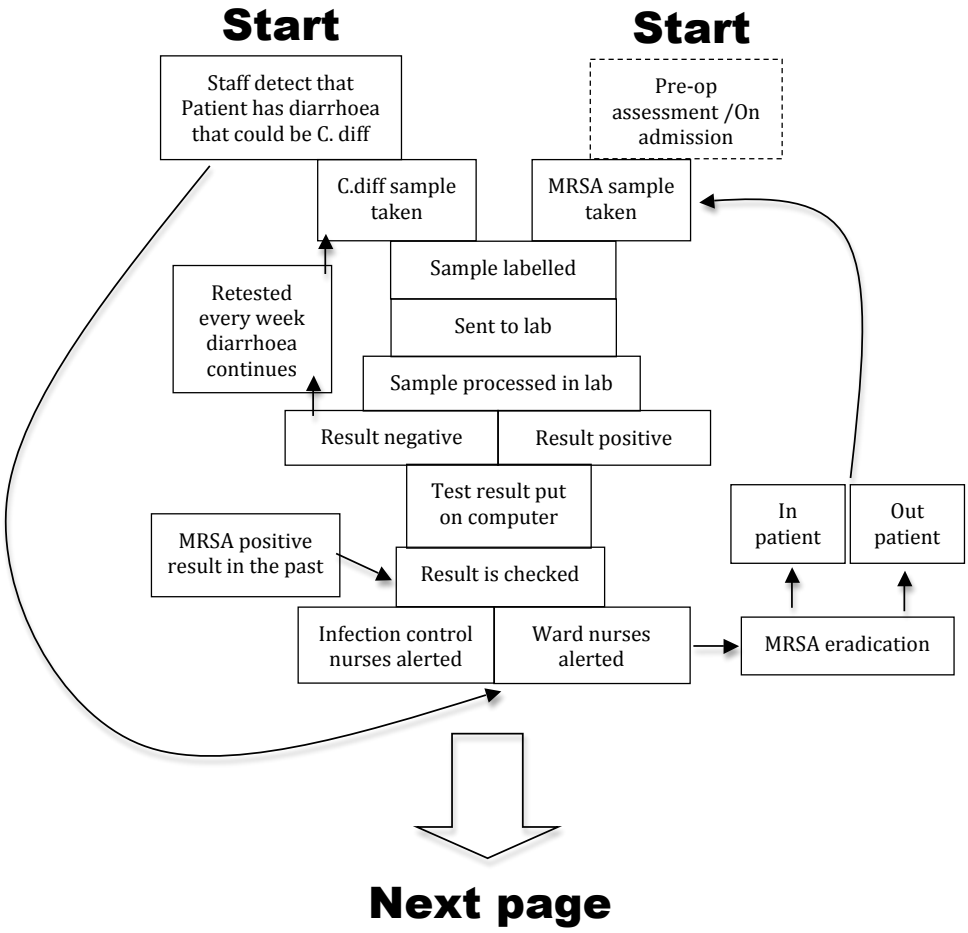

References

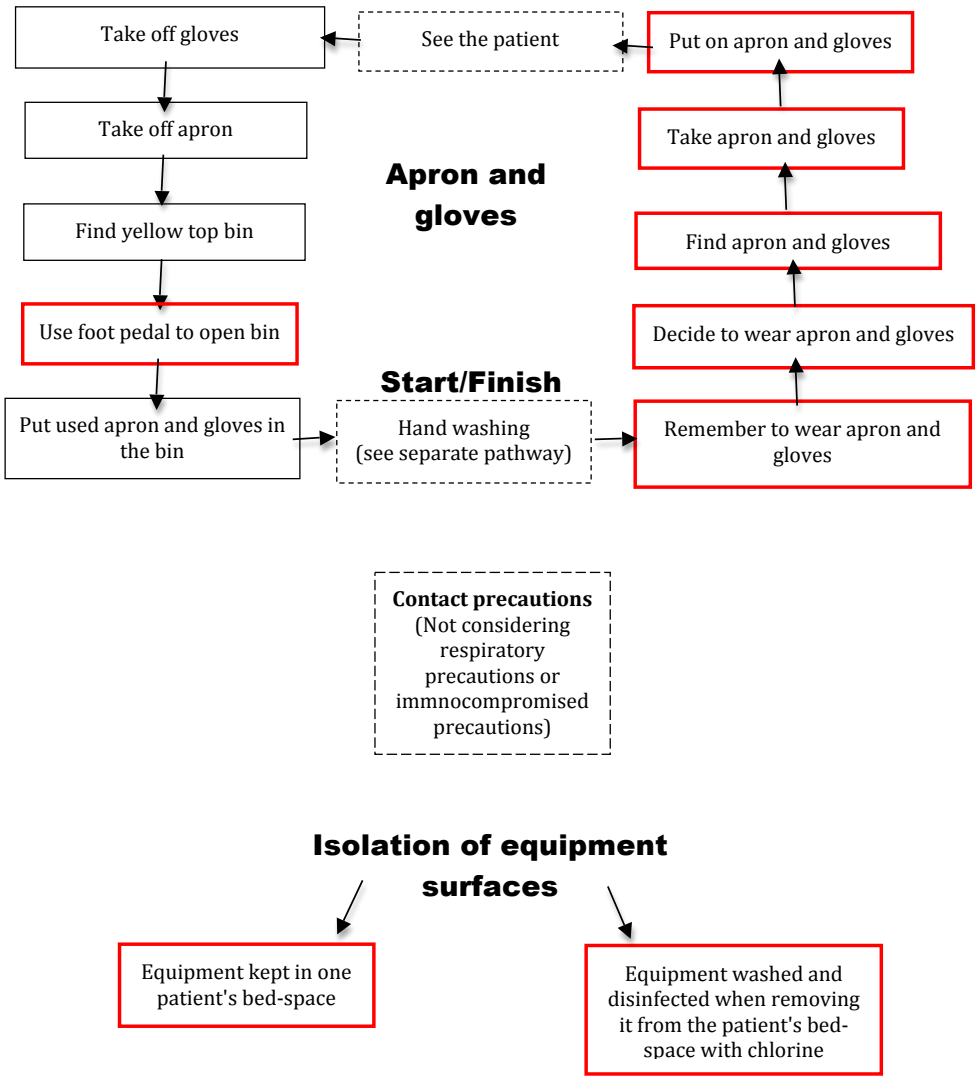
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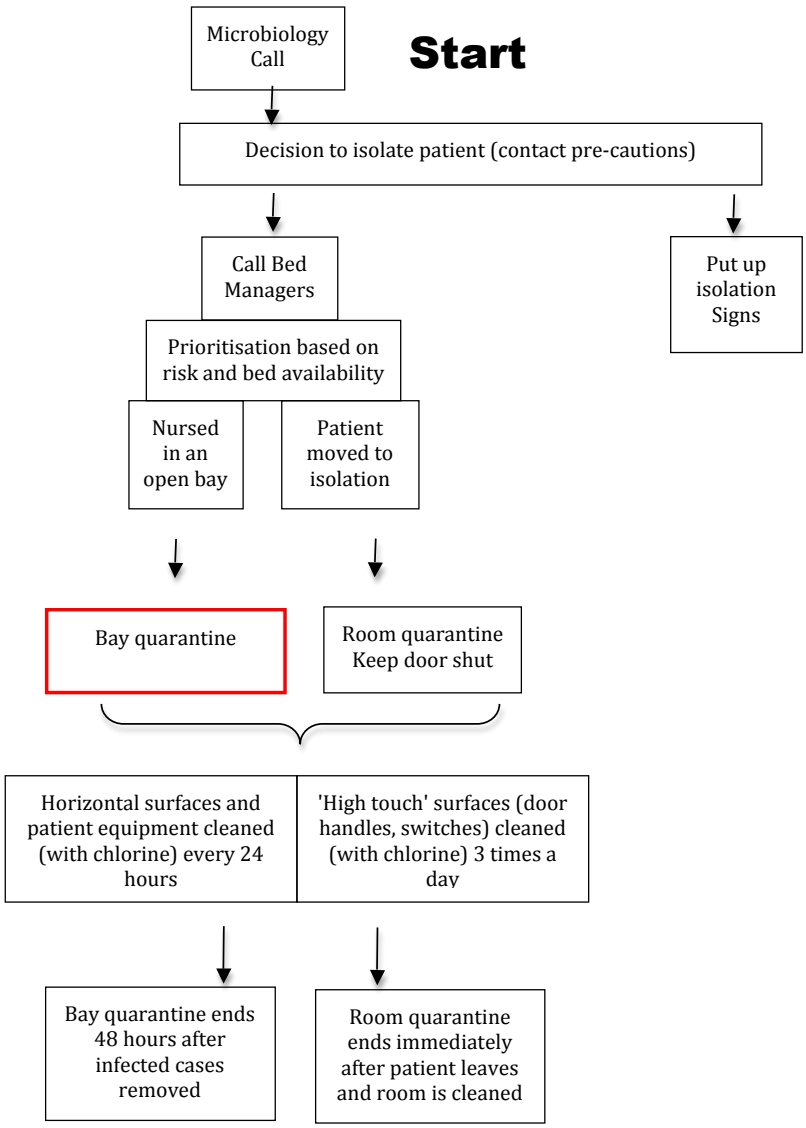
## Appendix 2.2.1. Healthcare process map: Hand hygiene

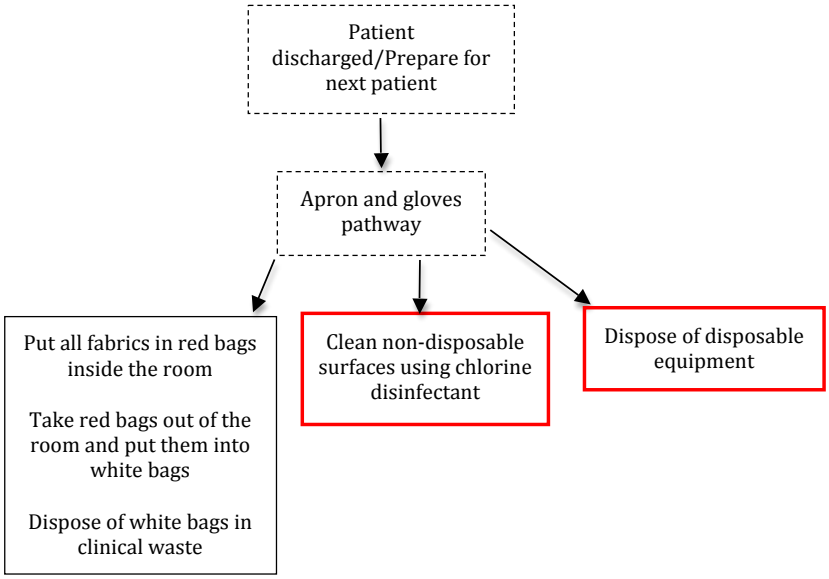


## Appendix 2.2.2. Healthcare process map: Isolation of infection

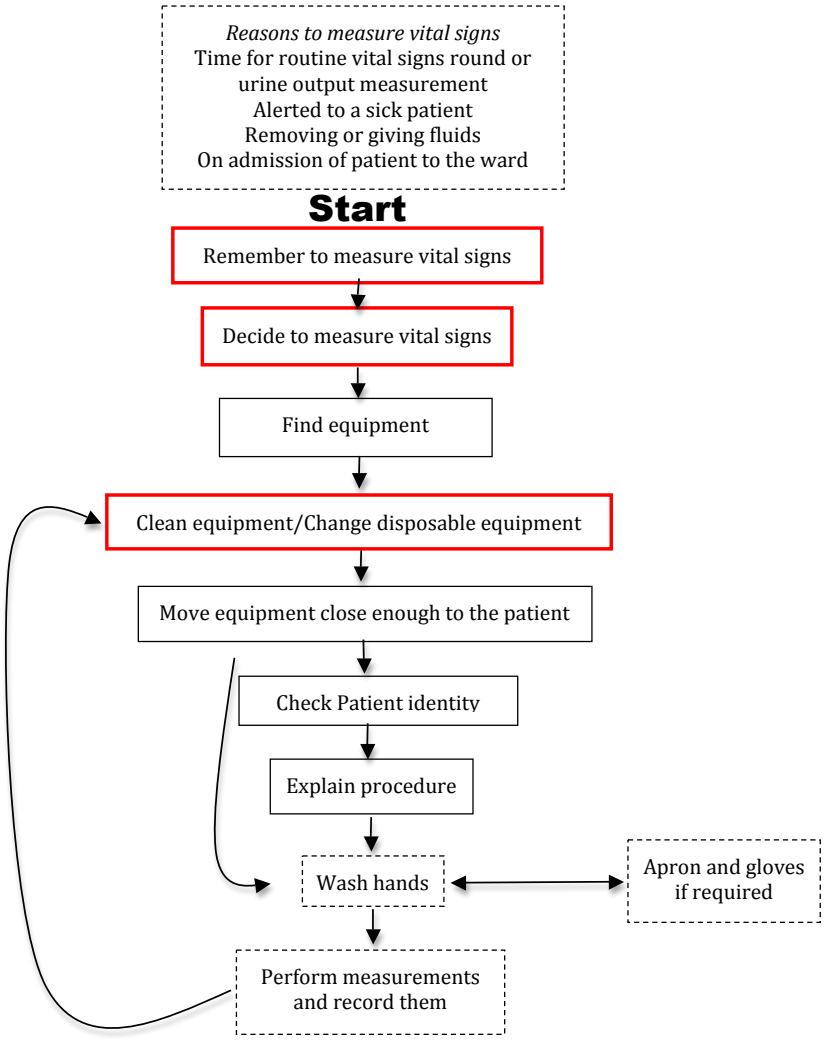



Take off gloves
See the patient
Put on apron and gloves
Take off apron
Take apron and gloves
Apron and gloves
Find yellow top bin
Find apron and gloves
Use foot pedal to open bin
Decide to wear apron and gloves
Start/Finish
Put used apron and gloves in the bin
Hand washing (see separate pathway)
Remember to wear apron and gloves
Contact precautions (Not considering respiratory precautions or immnocompromised precautions)
Isolation of equipment surfaces
Equipment kept in one patient's bed-space
Equipment washed and disinfected when removing it from the patient's bed-space with chlorine

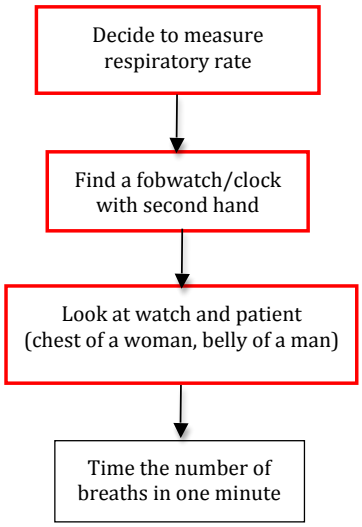

Microbiology Call
Start
Decision to isolate patient (contact pre-cautions)
Call Bed Managers
Put up isolation Signs
Prioritisation based on risk and bed availability
Nursed in an open bay
Patient moved to isolation
Bay quarantine
Room quarantine Keep door shut
Horizontal surfaces and patient equipment cleaned (with chlorine) every 24 hours
'High touch' surfaces (door handles, switches) cleaned (with chlorine) 3 times a day
Bay quarantine ends 48 hours after infected cases removed
Room quarantine ends immediately after patient leaves and room is cleaned


Patient discharged/Prepare for next patient
Apron and gloves pathway
Put all fabrics in red bags inside the room
Take red bags out of the room and put them into white bags
Dispose of white bags in clinical waste
Clean non-disposable surfaces using chlorine disinfectant
Dispose of disposable equipment

## Appendix 2.2.3. Healthcare process map: Vital signs monitoring

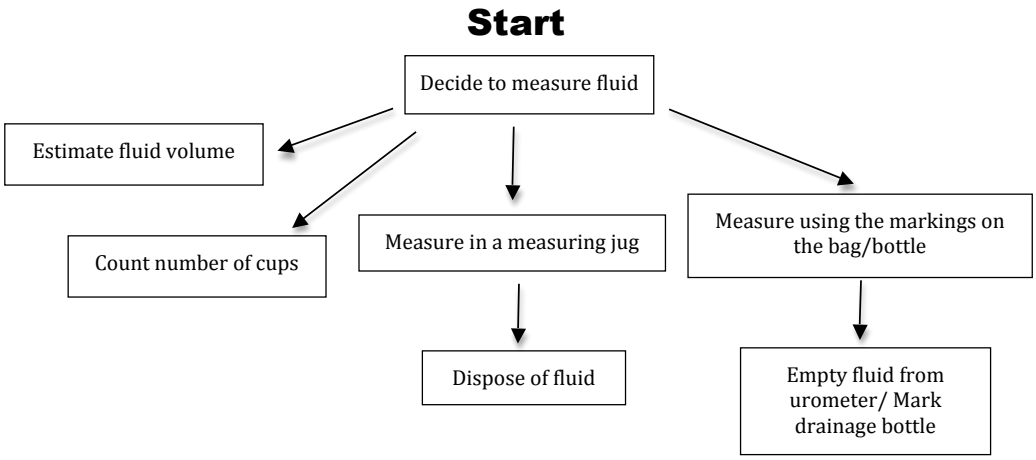


# Respiratory Rate

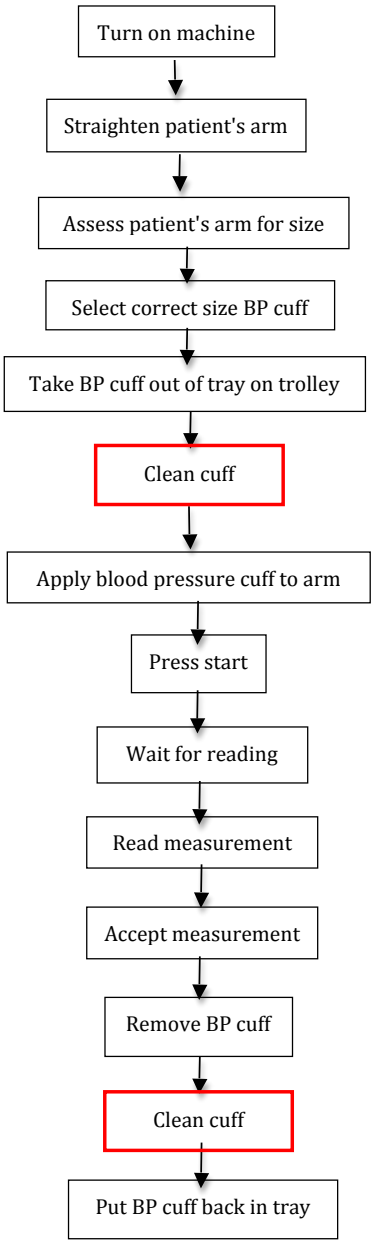


# Fluid balance

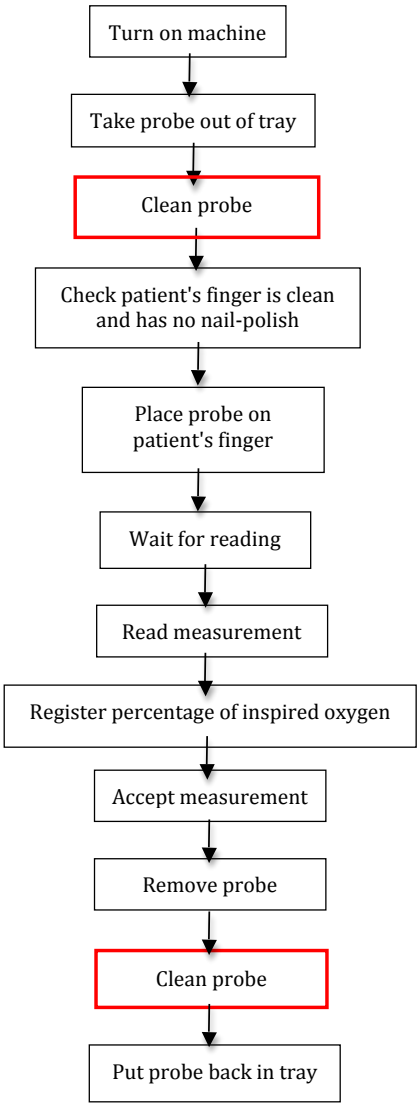
*Reasons to measure fluid balance*
Time to measure urine output
Removing fluids from bag/pan/other
Giving a patient oral or IV fluids who is having fluid balance monitored



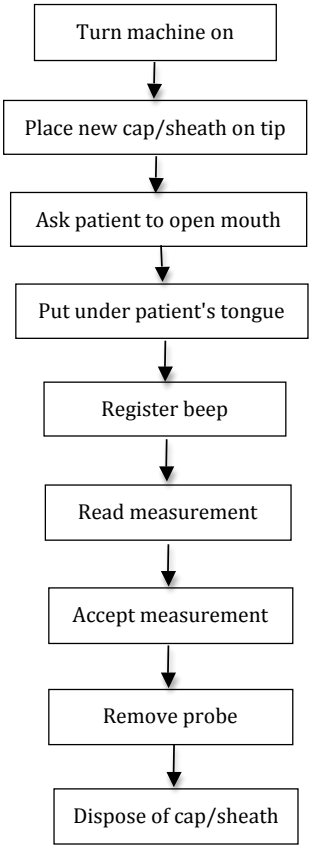
# Blood Pressure

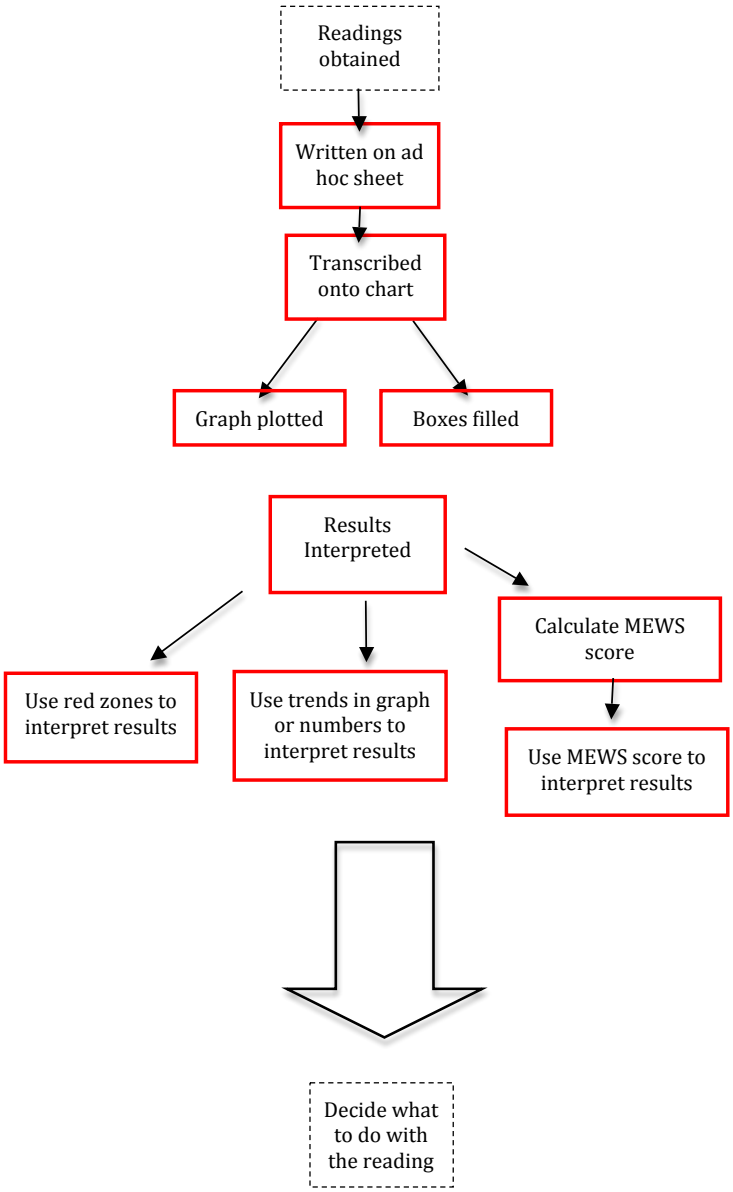


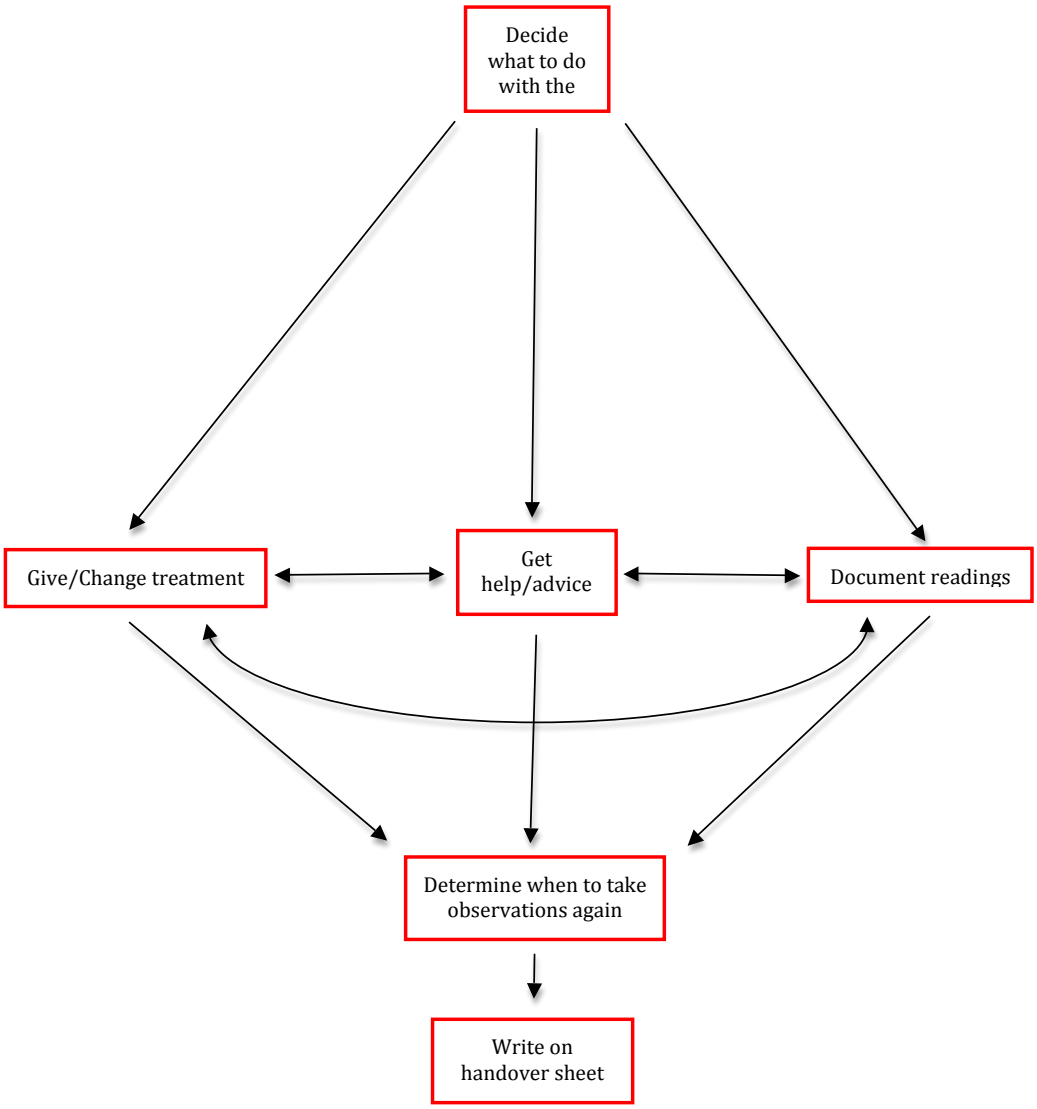
# Oxygen Saturation



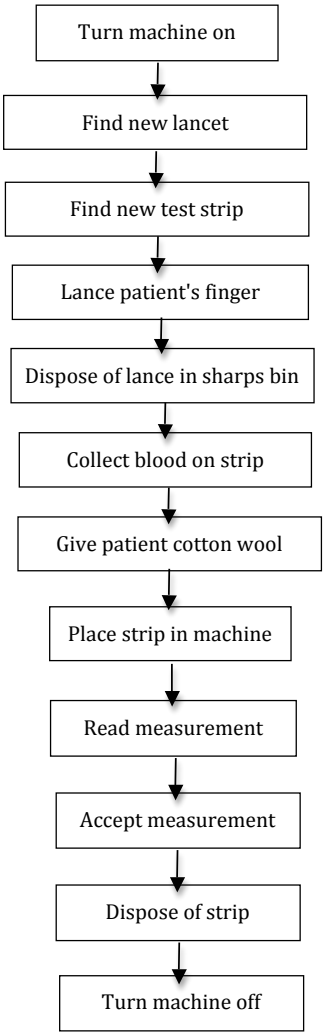
# Temperature



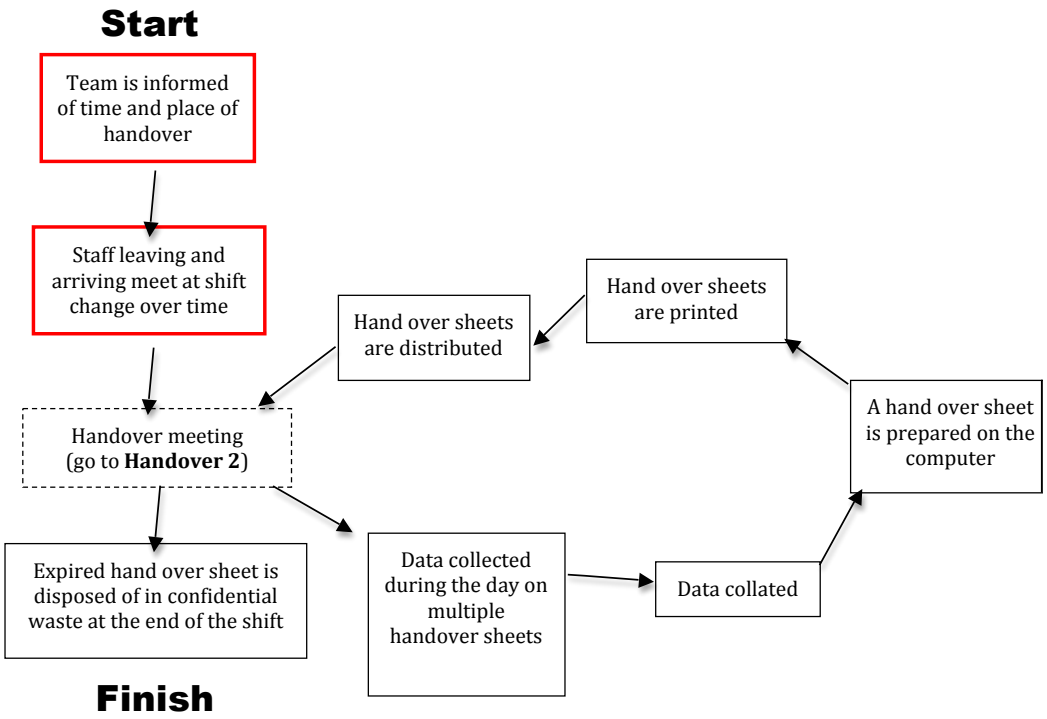

Readings obtained
Written on ad hoc sheet
Transcribed onto chart
Graph plotted
Boxes filled
Results Interpreted
Use red zones to interpret results
Use trends in graph or numbers to interpret results
Calculate MEWS score
Use MEWS score to interpret results
Decide what to do with the reading

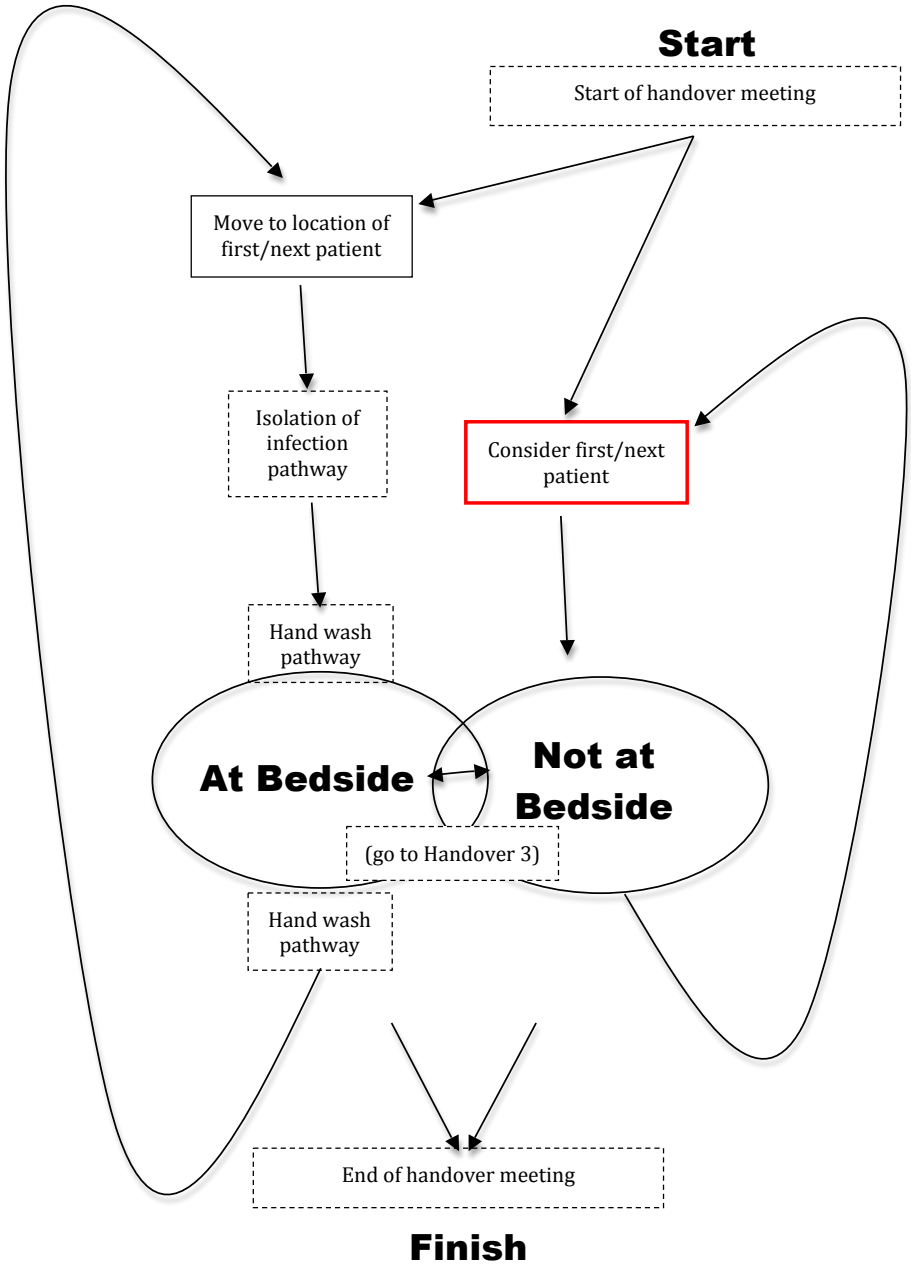

Decide what to do with the
Give/Change treatment
Get help/advice
Document readings
Determine when to take observations again
Write on handover sheet

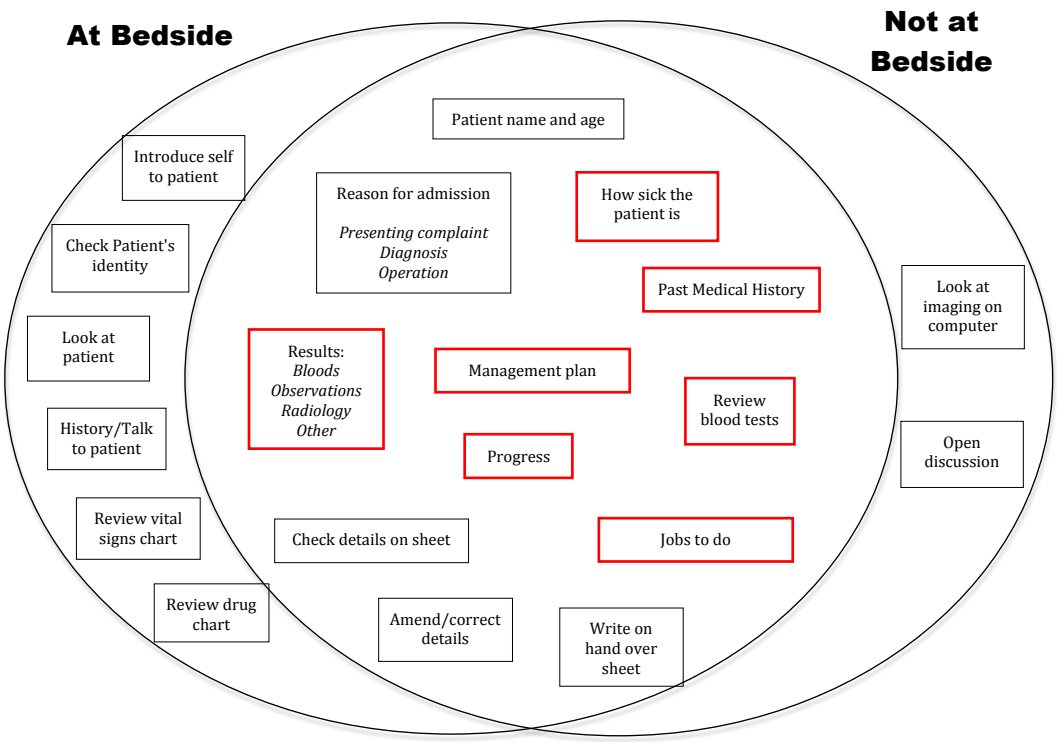
# Blood Sugars



## Appendix 2.2.4. Healthcare process map: Handover




Start
Start of handover meeting
Move to location of first/next patient
Isolation of infection pathway
Consider first/next patient
Hand wash pathway
At Bedside
Not at Bedside
(go to Handover 3)
Hand wash pathway
End of handover meeting
Finish


At Bedside
Not at Bedside
Patient name and age
Introduce self to patient
Reason for admission
Presenting complaint
Diagnosis
Operation
How sick the patient is
Check Patient's identity
Past Medical History
Look at imaging on computer
Look at patient
Results:
Bloods
Observations
Radiology
Other
Management plan
Review blood tests
History/Talk to patient
Progress
Open discussion
Review vital signs chart
Check details on sheet
Jobs to do
Review drug chart
Amend/correct details
Write on hand over sheet

# Appendix 2.2.5. Healthcare process failure risk ratings: Hand hygiene

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Start** | | | | | | | | |
| 1 | Remember to decontaminate hands | Forget to decontaminate hands | Hands contaminated<br>Infection spread | 4 | 4 | 4 | y | n |
| 2 | Decide to decontaminate hands | Decide not to decontaminate hands | Hands contaminated<br>Infection spread | 4 | 4 | 4 | y | n |
| 3 | Remove jacket | Do not remove jacket | Jacket contaminated<br>Infection spread | 4 | 4 | 1 | y | n |
| 4 | Tuck tie in or remove | Do not tuck tie in or remove | Tie contaminated<br>Infection spread | 2 | 2 | 1 | n | n |
| 5 | Remove watch/ jewellery | Do not remove watch/jewellery | Jewellery contaminated<br>Infection spread | 4 | 4 | 1 | y | n |
| 6 | Decide to use alcohol gel or soap and water | Use alcohol gel, but the patient has diarrhoea due to C. diff (alcohol gel does not kill C. diff spores) | Hands contaminated with C. diff<br>C. diff is spread | 4 | 4 | 4 | y | n |
| 7 | | Use alcohol gel, but hands are dirty | Hands still contaminated<br>Infection spread | 4 | 4 | 4 | y | n |
| **Alcohol Gel** | | | | | | | | |
| 8 | Find gel dispenser | Cannot find gel dispenser | Hands contaminated<br>Infection spread | 4 | 4 | 4 | y | y |
| 9 | Operate get dispenser | Cannot operate gel dispenser | Hands contaminated<br>Infection spread | 4 | 4 | 1 | y | y |
| 10 | | Abuse of alcohol gel<br>Patient drinks alcogel | Intoxication | 4 | 4 | 3 | y | y |
| 11 | Catch gel in hand | Gel not caught in hand | Hands contaminated<br>Infection spread | 4 | 2 | 4 | y | n |
| 12 | Cover all areas of hands | All areas of hands not covered | Hands contaminated<br>Infection spread | 4 | 4 | 4 | y | n |
| 13 | Allow hands to dry | Hands used before they are dry | Alcohol gel not effective<br>Hands contaminated<br>Infection is spread | 1 | 1 | 4 | n | n |

## Soap and Water

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| 14 | Find soap and water | Cannot find soap and water | Hands contaminated<br>Infection is spread | 4 | 4 | 4 | y | y |
| 15 | Turn on tap | Turn tap on and touch tap with hands | Hands contaminated<br>Infection spread | 4 | 4 | 4 | y | y |
| 16 | Rinse | Cannot rinse | Cannot perform hand wash effectively<br>Hands contaminated<br>Infection spread | 2 | 1 | 4 | n | n |
| 17 | Operate soap dispenser | Cannot operate soap dispenser | Do not wash hands with soap<br>Hands contaminated<br>Infection is spread | 4 | 4 | 4 | y | n |
| 18 | Wash all areas of hands | All areas of hands not washed | Parts of hands not decontaminated<br>Infection spread | 4 | 4 | 4 | y | n |
| 19 | Rinse | Cannot rinse | Cannot perform hand wash effectively<br>Infection is spread | 4 | 4 | 4 | y | n |
| 20 | Take paper towels | Towels not taken | Hands wet | 4 | 4 | 4 | y | n |
| 21 | Dry hands | Do not dry hands | Hands wet | 4 | 4 | 4 | y | n |
| 22 | Turn off taps using paper towel | Turn tap off and touch tap with hands | Hands contaminated from the tap<br>Infection spread | 4 | 4 | 4 | y | n |
| 23 | Put used towels in the bin using foot pedal | Use hands, not foot pedal | Infection picked up off the bin onto hands<br>Hands contaminated<br>Infection spread | 4 | 4 | 4 | y | y |

# Appendix 2.2.6. Healthcare process failure risk ratings: Isolation of infection

| Number | Process step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Isolation 1 Start** | | | | | | | | |
| 1 | Staff detect that Patient has diarrhoea that could be C. diff | Staff do not detect that patient has diarrhoea that could be C. diff | C. diff spread<br><br>Patient not diagnosed | 4 | 4 | 2 | y | n |
| 2 | C. diff sample taken | C. diff sample not taken | C. diff spread<br><br>Patient not diagnosed | 4 | 4 | 1 | y | n |
| 3 | | C. diff sample taken incorrectly - patient has C. diff but test will be negative | C. diff is spread<br><br>Patient not diagnosed | 4 | 4 | 1 | y | n |
| 4 | MRSA sample taken | MRSA swabs not taken | MRSA is spread<br><br>Patient not diagnosed | 4 | 3 | 1 | y | y |
| 5 | | MRSA swabs taken incorrectly - patient has MRSA but test will be negative | MRSA is spread<br><br>Patient not diagnosed | 4 | 3 | 1 | y | n |
| 6 | Sample labelled | Sample not labelled completely enough to be processed | Lab do not process sample<br><br>Patient with infection does not have a test on admission<br><br>Infection is spread to non-infected patients | 3 | 3 | 1 | y | n |
| 7 | | Sample labelled incorrectly - resulting in the wrong test or the wrong patient details | Positive result attributed to incorrect patient<br><br>Patient with infection does not have a test on admission<br><br>Infection is spread to non-infected patients | 3 | 3 | 2 | n | n |
| 8 | Sample sent to the laboratory | Sample not sent to the laboratory | Patient with infection does not have a test on admission<br><br>Infection is spread to non-infected patients | 4 | 4 | 2 | y | n |
| 9 | Sample processed in the laboratory | Sample not processed in the lab | Patient with infection does not have a test on admission<br><br>Infection is spread to non-infected patients | 4 | 2 | 1 | y | y |

| Number | Process step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| 10 | | Sample processed incorrectly in the laboratory | Patient with MRSA does not have an MRSA test on admission<br><br>MRSA is spread to non-infected patients | 4 | 4 | 2 | y | n |
| 11 | Test result put on computer | Results not on the computer | Patient with infection does not have a test result on admission<br><br>Infection is spread to non-infected patients | 4 | 3 | 1 | y | n |
| 12 | | Incorrect results on the computer | Positive test result attributed to incorrect patient<br><br>Patient with infection does not have a test on admission<br><br>Infection is spread to non-infected patients | 4 | 3 | 1 | y | n |
| 13 | Result positive | Result is a false positive | Patient without infection gets treated | 2 | 1 | 1 | n | n |
| 14 | Result negative | Result is a false negative | Patient with infection does not get treated<br><br>Patient with infection does not get isolated<br>Infection spreads | 4 | 2 | 2 | y | ? |
| 15 | Retested every week diarrhoea continues | Not tested every week diarrhoea continues | Infection not diagnosed or isolated<br>Infection spreads | 4 | 4 | 2 | y | y |
| 16 | MRSA positive result in the past on the computer | Result not on computer | MRSA is spread to non-infected patients | 4 | 3 | 1 | y | y |
| 17 | Result is checked | Result is not checked | Patient with infection is not treated<br><br>Infection is spread to non-infected patients | 4 | 3 | 1 | y | y |
| 18 | Infection control nurses alerted | Infection control nurses not alerted | Ward not informed quickly<br>Infection spread<br>Treatment delayed | 4 | 3 | 1 | n | y |
| 19 | Ward nurses alerted | Ward nurses not alerted | Infection spread<br>Treatment delayed | 4 | 4 | 1 | y | y |
| 20 | MRSA eradication | Eradication not initiated (delay) | MRSA spread | 4 | 3 | 2 | n | y |
| 21 | In patient | Eradication not | MRSA spread | 4 | 4 | 2 | y | y |

| Number | Process step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| | | completed | | | | | | |
| 22 | Out patient | Eradication not completed | MRSA spread | 2 | 2 | 2 | n | y |
| **Isolation 2 Start** | | | | | | | | |
| 23 | Decision to isolate patient (contact pre-cautions) | Decision not made | Infection is spread to non-infected patients | 4 | 4 | 1 | n | n |
| 24 | Call Bed Managers | Bed Managers not called correctly | Isolation not carried out quickly<br><br>Infection spread | 2 | 2 | 1 | n | y |
| 25 | Prioritisation based on risk and bed availability | Prioritisation not done correctly | Infection spread | 4 | 4 | 2 | y | y |
| 26 | Patient moved to isolation | Patient not moved to isolation | Infection spread | 4 | 2 | 1 | y | y |
| 27 | Bay quarantine | Bay not quarantined effectively | Infection spreads | 4 | 4 | 3 | y | n |
| 28 | Room Quarantine Keep door shut | Door not kept shut | Infection is spread | 2 | 1 | 1 | n | n |
| 29 | Horizontal surfaces and patient equipment cleaned (with chlorine) every 24 hours | Not cleaned correctly | Infection spreads | 4 | 1 | 4 | n | y |
| 30 | 'High touch' surfaces (door handles, switches) cleaned (with chlorine) 3 times a day | Not cleaned correctly | Infection spreads | 4 | 1 | 4 | n | y |
| 31 | Bay quarantine ends 48 hours after infected cases removed | Quarantine ends too early | Infection spreads | 4 | 2 | 1 | y | y |
| 32 | Room quarantine ends immediately after patient leaves and room is cleaned | Quarantine ends too early | Infection spreads | 4 | 2 | 1 | y | y |
| 33 | Put up isolation signs | Isolation signs not put up correctly | Quarantine broken<br><br>Infection is spread to non-infected patients | 4 | 4 | 1 | n | y |
| **Isolation 3 Apron and gloves** | | | | | | | | |
| 34 | Remember to wear apron and gloves | Forget to wear apron and gloves | Infection is spread | 4 | 4 | 3 | y | n |
| 35 | Decide to wear apron and gloves | Decide not to wear apron and gloves | Infection is spread | 4 | 4 | 3 | y | n |
| 36 | Find apron and gloves | Cannot find apron and gloves | Infection is spread | 4 | 4 | 3 | y | n |

| Number | Process step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| 37 | Take apron and gloves | Contaminate apron and gloves as they are removed from container | Infection is spread | 4 | 4 | 3 | y | n |
| 38 | Put on apron and gloves | Contaminate apron and gloves as they are put on | Infection spread | 4 | 4 | 3 | y | n |
| | See the patient | | | | | | | |
| 39 | Take off gloves | Do not take off gloves correctly | Infection spread | 4 | 4 | 1 | y | n |
| 40 | Take off apron | Do not take off apron correctly | Infection spread | 4 | 4 | 1 | y | n |
| 41 | Find yellow top bin | Do not locate yellow top bin | Apron and gloves put in wrong bin<br><br>Infection spread | 1 | 1 | 2 | n | y |
| 42 | Use foot pedal to open bin | Do not use the foot pedal<br>Lift the lid with hands | Hands contaminated<br>Infection spread | 4 | 4 | 4 | n | y |
| | Hand washing | | | | | | | |

**Isolation of equipment surfaces**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 43 | Equipment kept in one patient's bed-space | Equipment isolated incorrectly | Equipment acts as a fomite<br><br>Infection is spread to non-infected patients | 4 | 4 | 4 | y | n |
| 44 | Equipment washed and disinfected when removing it from the patient's bed-space with chlorine | Equipment not disinfected correctly | Equipment acts as a fomite<br><br>Infection is spread to non-infected patients | 4 | 4 | 4 | y | n |

**Isolation 4**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Patient discharged/Prepare for next patient | | | | | | | |
| | Apron and gloves pathway | | | | | | | |
| 45 | Put all fabrics in red bags inside the room | Fabrics not put into red bags in room. | Fabric acts as a fomite<br><br>Infection is spread to non-infected patients | 4 | 2 | 2 | n | y |
| 46 | Take red bags out of the room and put them into white bags | Red bags not put into white bags inside the room correctly | Infection is spread | 1 | 1 | 1 | n | y |

| Number | Process step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| 47 | Clean non-disposable surfaces using chlorine disinfectant | Surfaces not cleaned correctly with chlorine | Surfaces contaminated Infection spread | 4 | 4 | 4 | y | n |
| 48 | Dispose of disposable equipment in clinical waste | Disposable equipment not disposed of in clinical waste correctly | Disposable equipment contaminated and infection spread | 4 | 4 | 4 | y | n |

# Appendix 2.2.7. Healthcare process failure risk ratings: Vital signs monitoring

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| | | | **Vital Signs 1** | | | | | |
| | | | **Start** | | | | | |
| 1 | Remember to measure vital signs | Forget to measure vital signs | Vital signs measured later<br>Complication detected later | 4 | 4 | 3 | y | n |
| | | Measure vital signs too often | Patients don't get enough rest | Not relevant | | | | |
| 2 | Decide to measure vital signs | Decide not to measure vital signs | Vital signs measured later<br>Complication detected later | 4 | 4 | 3 | y | n |
| 3 | Find equipment | Cannot find equipment | Vital signs measured later<br>Complication detected later | 4 | 4 | 2 | y | n |
| 4 | Clean equipment/ change disposable equipment | Equipment not disinfected /changed | Infections spread | 4 | 4 | 3 | n | n |
| 5 | Move equipment close enough to the patient | Moving equipment injuries the patient or staff | Patient/staff injured | 2 | 4 | 4 | n | n |
| 6 | | Do not move equipment | Patient/staff injured | 4 | 4 | 2 | y | n |
| 7 | Check Patient identity | Do not check identify of Patient | Record the observations on the wrong chart | 4 | 3 | 2 | y | n |
| 8 | Explain procedure | Do not explain procedure | Patient does not understand | 1 | 2 | 3 | n | n |
| | *Wash hands* | | | | | | | |
| | *Apron and gloves (if required)* | | | | | | | |
| | *Perform measurements and record them (next pagees)* | | | | | | | |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|

**Vital Signs 2**
**Respiratory Rate**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9 | Decide to measure respiratory rate | Do not decide to measure respiratory rate | No respiratory rate measured<br>Respiratory rate guessed and filled in (around 16-18)<br>Complication goes undetected | 4 | 4 | 3 | y | n |
| 10 | Find a fobwatch/clock with a working second hand | Wear a wrist watch | Infection spread | 4 | 4 | 3 | n | n |
| 11 | | No timing device available | Guess respiratory rate<br>Complication goes undetected | 4 | 4 | 2 | y | n |
| 12 | Look at the watch and patient (chest of woman, belly of a man) | Wall clock difficult to see or patient's breathing movements difficult to see | Respiratory rate measurement inaccurate<br>Complication goes undetected | 4 | 4 | 3 | y | n |
| 13 | Time the number of breaths in one minute | Breaths timed incorrectly | Inaccurate respiratory rate<br>Complication goes undetected | 3 | 4 | 3 | y | n |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Vital Signs 3<br>Fluid balance** | | | | | | | | |
| 14 | Decide to measure fluid | Decide not to measure fluid | Fluids not measured<br>Patient fluid chart inaccurate<br>Complication goes undetected | 4 | 4 | 2 | y | n |
| 15 | Estimate fluid volume | Inaccurate measurement | Inaccurate fluid balance chart<br>Complication goes undetected | 3 | 4 | 2 | n | n |
| 16 | Count number of cups | Inaccurate measurement | Inaccurate fluid balance chart<br>Complication goes undetected | 3 | 4 | 2 | n | n |
| 17 | Measure in measuring jug | Measuring jug used incorrectly | Measurements inaccurate or not made<br>Inaccurate fluid balance chart<br>Complication goes undetected | 3 | 4 | 2 | n | n |
| 18 | Dispose of fluid | Don't dispose of fluid correctly | Contamination/Infection spread | 3 | 4 | 3 | n | n |
| 19 | Measure using the markings on the bag | Not measured accurately | Measurements inaccurate<br>Inaccurate fluid balance chart<br>Complication goes undetected | 3 | 4 | 2 | n | n |
| 20 | Empty fluid from urometer/Mark drainage bottle | Not emptied/marked correctly | Fluid output over-estimated<br>Complication goes undetected | 4 | 4 | 2 | n | n |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Vital signs 4<br>Blood pressure** | | | | | | | | |
| 21 | Turn on machine | Cannot turn machine on | Cannot take BP reading<br>Take reading later with another machine<br>BP reading delayed<br>Complication goes undetected | 3 | 4 | 1 | y | n |
| 22 | Straighten patient's arm | Cannot/will not straighten arm correctly | Cannot take BP from that arm<br>If both arms, cannot take accurate BP<br>Complication goes undetected | 3 | 1 | 1 | y | n |
| 23 | Assess patient's arm for size | No assessment made | May use the incorrect cuff size and get an inaccurate reading (if this always happens the readings will be consistent)<br>Complication goes undetected | 2 | 2 | 3 | n | n |
| 24 | Select correct size BP cuff | Wrong size BP cuff selected | May use the incorrect cuff size and get an inaccurate reading (if this always happens the readings will be consistent)<br>Complication goes undetected | 2 | 2 | 2 | n | n |
| | Take blood pressure cuff out of tray on trolley | ? | | Not relevant | | | | |
| 25 | Clean cuff | Do not clean cuff | Infection spread | 4 | 4 | 3 | n | n |
| 26 | Apply blood pressure cuff to arm | Do not apply cuff correctly | Inaccurate BP reading<br>Complication goes undetected | 2 | 3 | 3 | n | n |
| 27 | Press start | Machine does not start | Take BP reading with another machine later<br>BP reading delayed<br>Complication goes undetected | 3 | 4 | 1 | y | n |
| 28 | Wait for reading | Do not wait for reading<br>Machine struggles to get a reading | Inaccurate BP reading<br>Complication goes undetected | 3 | 4 | 1 | y | n |
| 29 | Read measurement | Read measurement incorrectly | Inaccurate BP recorded<br>Complication goes undetected | 3 | 4 | 3 | n | n |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| 30 | Accept measurement | Do not accept accurate measurement | Measurement outside of normal range not accepted. Repeated with same or different equipment. Not recorded. Complication goes treated. | 3 | 4 | 2 | n | n |
| 31 | | Accept inaccurate measurement | Abnormlity not acted upon. Complication goes undetected | 3 | 4 | 3 | n | n |
| | Remove BP cuff | ? | | Not relevant | | | | |
| 32 | Clean BP cuff | Do not clean cuff | Infection spread | 4 | 4 | 3 | n | n |
| | Put BP cuff back in tray | ? | | Not relevant | | | | |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Vital signs 5<br>Oxygen Saturation** | | | | | | | | |
| 33 | Turn on machine | Do not turn machine on | Cannot take sats reading<br>Take reading later with another machine<br>Sats reading delayed<br>Complication goes undetected | 3 | 3 | 3 | y | n |
| | Take probe out of tray | ? | | Not relevant | | | | |
| 34 | Clean probe | Do not clean probe | Infection spread | 4 | 4 | 3 | n | n |
| 35 | Check patient's finger is clean and no nail polish | Do not check and try to measure oxygen saturations despite something disrupting the light | Inaccurate oxygen saturation reading (lower than normal)<br>Complication goes undetected | 1 | 1 | 1 | n | n |
| 36 | Place pulse oximetry probe on finger | Cannot place probe on finger correctly | Inaccurate oximetry reading (too low)<br>Complication goes undetected | 3 | 3 | 2 | y | n |
| 37 | Wait for reading | Reading is inaccurate | Complication goes undetected | 3 | 3 | 2 | n | n |
| 38 | Read measurement | Read measurement incorrectly | Inaccurate oximetry recording<br>Complication goes undetected | 3 | 3 | 3 | n | n |
| 39 | Register percentage of inspired oxygen | Inaccurate inspired oxygen registered | Result misinterpreted<br>Complication goes undetected | 3 | 4 | 3 | n | n |
| | Accept measurement | Do not accept accurate measurement | Measurement outside of normal range not accepted. Repeated with same or different equipment. Not recorded. | Not relevant | | | | |
| 40 | | Accept inaccurate measurement | Abnormality not acted upon. | 3 | 4 | 3 | n | n |
| | Remove probe | ? | | Not relevant | | | | |
| 41 | Clean probe | Do not clean probe | Infection spread | 4 | 4 | 3 | n | n |
| | Put probe back in the tray | ? | | Not relevant | | | | |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Vital Signs 6 Temperature** | | | | | | | | |
| 42 | Turn on machine | Machine does not turn on | Temperature measured later<br>Pyrexia detected later<br>Complication goes undetected | 3 | 3 | 2 | y | n |
| 43 | Place new cap/sheath on tip | Use an old cap/sheath | Infection is spread | 3 | 3 | 4 | n | n |
| 44 | | Caps/sheaths run out | Don't take the temperature<br>Complication goes undetected | 3 | 3 | 2 | y | n |
| 45 | Ask patient to open mouth | Patient cannot open mouth | Measure temperature another way - via ear probe<br>Otherwise can't measure temperature<br>Complication goes undetected | 1 | 2 | 1 | n | n |
| 46 | Put under patient's tongue | Don't put under patient's tongue | Reading inaccurate<br>Complication goes undetected | 2 | 2 | 4 | n | n |
| 47 | Register beep | Do not realise that beep means that temperature has been taken | Take temperature again | 1 | 1 | 1 | n | n |
| 48 | Read measurement | Read measurement incorrectly | Inaccurate temperature recording<br>Complication goes undetected | 3 | 3 | 3 | n | n |
| 49 | Accept measurement | Do not accept accurate measurement | Measurement outside of normal range not accepted. Repeated with same or different equipment. Not recorded.<br>Complication goes undetected | 3 | 3 | 3 | n | n |
| 50 | | Accept inaccurate measurement | Abnormality not acted upon. | 3 | 3 | 3 | n | n |
| | Remove probe | ? | | Not relevant | | | | |
| 51 | Dispose of cap/sheath | Use an old cap/sheath | Infection is spread | 3 | 3 | 4 | n | n |
| | | Bin is not yellow top | Infection is spread | Not relevant | | | | |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| | | | **Vital Signs 7** | | | | | |
| | Readings obtained | | | | | | | |
| 52 | Written on ad hoc sheet | Written incorrectly on ad hoc sheet | Complication goes undetected | 4 | 4 | 3 | n | n |
| 53 | Transcribed onto vital signs chart | Not transcribed correctly | Complication goes undetected | 4 | 4 | 3 | n | n |
| 54 | Graph plotted | Plotted incorrectly | Complication goes undetected | 4 | 4 | 3 | n | n |
| 55 | Boxes filled in | Boxes filled in incorrectly | Complication goes undetected | 4 | 4 | 3 | n | n |
| 56 | Results interpreted | Results not interpreted correctly (or at all) | Complication goes undetected | 4 | 4 | 3 | n | n |
| 57 | Use red zones to interpret results | Red zones on the chart not interpreted correctly | Complication goes undetected | 4 | 4 | 3 | n | n |
| 58 | Use trends in graph or numbers to interpret results | Trends or numbers not interpreted correctly | Complication goes undetected | 4 | 4 | 3 | n | n |
| 59 | Calculate MEWS score | MEWS not calculated correctly (or at all) | Complication goes undetected | 4 | 4 | 3 | n | n |
| 60 | Use MEWS score to interpret results | MEWS score interpreted incorrectly | Complication goes undetected | 4 | 4 | 3 | n | n |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Vital Signs 8** | | | | | | | | |
| 61 | Decide what to do with the reading | Do not decide correctly | Complication treatment delayed | 4 | 4 | 3 | n | n |
| 62 | Give/Change treatment | Treatment not changed or given correctly/appropriately | Complication treatment delayed | 4 | 4 | 3 | n | n |
| 63 | Get help advice | Help and advice not sought appropriately | Complication treatment delayed | 4 | 4 | 3 | n | n |
| 64 | Document readings | Readings documented incorrectly | Complication goes untreated | 4 | 4 | 3 | n | n |
| 65 | Determine when to measure vital signs again | Do not determine when to take repeat vital signs correctly | Patient deterioration not monitored until Patient gets vital signs checked at next routine vital signs round | 4 | 4 | 4 | n | n |
| 66 | Write on handover sheet | Do not write on handover sheet correctly | Treatment not given or observations not repeated at the appropriate time | 4 | 4 | 4 | n | n |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Vital Signs 9<br>Blood sugar** | | | | | | | | |
| 67 | Turn machine on | Machine is not switched on | Blood sugar measurement delayed<br>Complication goes undetected | 4 | 4 | 2 | y | n |
| 68 | Find new lancet | New lancet not found | Blood sugar measurement delayed<br>Complication goes undetected | 3 | 3 | 2 | y | n |
| 69 | Find new test strip | New test strip not found | Blood sugar measurement delayed<br>Complication goes undetected | 3 | 3 | 2 | y | n |
| 70 | Lance patient's finger | Patient's finger not lanced correctly | Blood sugar measurement delayed<br>Complication goes undetected | 3 | 3 | 2 | y | n |
| 71 | Dispose of lance in sharps bin | Lance not disposed of in sharps bin | Sharps injury | 4 | 2 | 2 | n | y |
| 72 | Collect blood on strip | Blood not collected on strip | Need to lance again | 1 | 1 | 1 | y | y |
| 73 | Give patient cotton wool | Patient not given cotton wool | Patient's blood contaminates environment | 1 | 1 | 1 | n | n |
| 74 | Place strip in machine | Do not place strip in machine | Repeat with another strip | 3 | 3 | 2 | y | n |
| 75 | Read measurement | Measurement not read correctly | Incorrect measurement read<br>Complication goes undetected | 4 | 3 | 3 | n | n |
| 76 | Accept measurement | Do not accept accurate measurement | Measurement outside of normal range not accepted. Repeated with same or different equipment. Not recorded.<br>Complication goes undetected | 4 | 3 | 3 | n | n |
| 77 | | Accept inaccurate measurement | Abnormality not acted upon.<br>Complication goes undetected | 4 | 3 | 3 | n | n |
| 78 | Dispose of strip | Do not dispose of strip | Strip contaminates the environment with blood | 1 | 1 | 1 | n | n |
| 79 | Turn machine off | Do not turn machine off | Machine runs out of batteries | 4 | 2 | 1 | n | y |

# Appendix 2.2.8. Healthcare process failure risk ratings: Handover

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| | | | **Handover 1 Start** | | | | | |
| 1 (if only one team member) | Team is informed of time and place of handover | Team is not informed of time and place of handover | Team members missing from handover Patients treated sub-optimally | 4 (1) | 4 | 4 | n | y |
| 2 | Staff leaving and arriving meet at shift change over time | Leaving or arriving staff are late | Team members missing from handover Patients treated sub-optimally | 4 | 4 | 4 | n | y |
| 3 *Dr. **Nurse | | Meeting place inadequate for handover - noisy | Verbal part of handover difficult Information not communicated Patients treated sub-optimally | 4 | 4 | 4 | n | n y* n** |
| 4 | | Meeting place inadequate for handover - overheard | Confidential information not protected - Confidentiality breeched | 4 | 1 | 4 | n | y |
| | *Handover meeting (go to **Handover 2**)* | | | | | | | |
| 5 | Data collected during the day on multiple handover sheets | Data not collected correctly (not accurate or complete) | Information missing from handover Patients treated sub-optimally | 4 | 3 | 3 | y | n |
| 6 | | Too much data is collected/not focused on what is important | Handover takes a long time/important points not emphasised Patients treated sub-optimally | 2 | 3 | 1 | y | y |
| 7 | Data collated | Data not collated correctly | Information missing or inaccurate from handover Patients treated sub-optimally | 4 | 4 | 1 | y | y |
| 8 | A handover sheet is prepared on the computer | Handover sheet is not prepared | Information missing or inaccurate from handover Patients treated sub-optimally | 4 | 3 | 1 | y | y |
| 9 | | Handover sheet is inaccurate | Information missing from handover Patients treated sub-optimally | **4** | 3 | 1 | y | y |
| 10 | | Handover sheet is too long/lacking in focus/emphasis on important aspects | Handover takes a long time/important points not emphasised Patients treated sub-optimally | 4 | 3 | 1 | y | y |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| 11 | Hand over sheets are printed | Handover sheets are not printed | Verbal handover only with hand written notes<br>Information missing from handover<br>Patients treated sub-optimally | 1 | 2 | 1 | n | n |
| 12 | Handover sheet is distributed | Handover sheet is not distributed | Verbal handover only with hand written notes<br>Information missing from handover<br>Patients treated sub-optimally | 1 | 2 | 1 | n | n |
| 13 | Expired hand over sheet is disposed of in confidential waste at the end of the shift | Handover sheet is not disposed of in confidential waste | Patient confidentiality is breached | 4 | 1 | 4 | n | y |
| | **Handover 2**<br>**Start** | | | | | | | |
| | Start of handover meeting | | | | | | | |
| 14 | Move to location of first/next patient | Patient not present | No visual check of the patient | 2 | 4 | 3 | n | y |
| 15 | | Incorrect patient | Patient receives incorrect treatment | 4 | 3 | 2 | y | y |
| | *Isolation of infection pathway* | | | | | | | |
| | *Handwashing pathway* | | | | | | | |
| 16 | Consider first/next patient | Patients and jobs not discussed | Patient does not receive treatment as quickly<br>Patients treated sub-optimally | 4 | 3 | 4 | y | y |
| | ***At Bedside/Not at Bedside*** *(go to* ***Handover 3****)* | | | | | | | |
| | *Handwash pathway* | | | | | | | |
| | *End of handover meeting* | | | | | | | |
| | **Handover 3**<br>**At Bedside** | | | | | | | |
| 17 | Introduce self to patient | Don't introduce self | Offend patient | 1 | 1 | 1 | n | y |
| 18 | Check Patient's identity | Don't check Patient's identity | Patient receives the wrong treatment | 4 | 4 | 1 | y | n |
| 19 | Look at the Patient | Don't look at the Patient | Don't see that the Patient looks in need of attention | 4 | 2 | 4 | n | n |
| 20 | History/Talk to the Patient | Don't talk to the Patient | Mistakes on hand over not corrected by | 3 | 3 | 2 | n | y |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| | | | the Patient | | | | | |
| 21 | Review vital signs chart | Do not review the vital signs chart correctly | Miss a deterioration in the Patient | 4 | 4 | 2 | n | y |
| 22 | Review drug chart | Do not review drug chart correctly | Miss a mistake on the drug chart<br>Patient receives wrong medication | 4 | 3 | 2 | y | y |

**Both at bedside and not at bedside**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 23 | Patient name and age | Incorrect name/age | Wrong patient treated | 4 | 1 | 1 | y | n |
| 24 | Reason for admission<br>*Presenting complaint*<br>*Diagnosis*<br>*Operation* | Incorrect reason for admission | Wrong treatment given | 4 | 2 | 1 | y | n |
| 25 | How sick the patient is | Inaccurate or no assessment | Treatment not timely (too slow) | 4 | 4 | 4 | y | y |
| 26 | Past Medical History | Past medical history not handed over correctly | Patient treated sub-optimally | 4 | 4 | 4 | y | y |
| 27 | Results<br>*Bloods*<br>*Observations*<br>*Radiology*<br>*Other* | Results not handed over correctly | Patients treated sub-optimally | 4 | 4 | 4 | y | y |
| 28 | Management plan | Management plan not handed over correctly | Patients treated sub-optimally | 4 | 4 | 4 | y | n |
| 29 | Progress | Progress not handed over correctly | Patients managed sub-optimally | 4 | 4 | 4 | y | n |
| 30 | Jobs to do | Jobs not handed over correctly | Patients managed sub-optimally | 4 | 4 | 4 | y | n |
| 31 | Amend/correct details | Do not amend/correct details correctly | Mistakes on handover sheet<br>Patient receives incorrect treatment | 3 | 4 | 2 | y | n |
| 32 | Write on hand over sheet | Staff make different notes to each other | Handover sheets don't match exactly<br>Only one member of the team has all the necessary information regarding certain patients | 3 | 4 | 2 | y | n |

| Number | System step | Failure mode | Effects | Severity | Frequency | Detectability | Single point | Control |
|---|---|---|---|---|---|---|---|---|
| **Not at Bedside** | | | | | | | | |
| 33 | Look at imaging on computer | Do not look at imaging on the computer | Miss important infomation from imaging | 4 | 3 | 2 | y | y |
| | Open discussion | Do not have an open discussion | Cannot speak openly about concerns about the Patients | Not relevant | | | | |

# Appendix 2.2.9. Hand hygiene fishbone tables

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Remember to decontaminate hands
Failure Mode Forget to decontaminate hands

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patients are not empowered to ask Staff to wash their hands<br><br>Patient's not informed that they should remind Staff to wash hands<br><br>**Lack of patient empowerment** | Wearing gloves causes people to forget to wash hands, because they believe that their hands do not need to be washed while before or after wearing gloves.<br><br>Interrupted by active problems, while hand washing is passively forgotten<br><br>**Lack of effective reminders**<br><br>**Process not standardised** | Don't remember or know when to wash hands<br>Guidelines ambiguous<br>Not aware of the WHO 5 moments of hand washing<br><br>Inadequate training<br>Training not revised often enough<br><br>Consequences of not washing hands aren't made obvious<br><br>Traceability of infection. Impossible to trace infection back to staff member.<br><br>**Education, training and testing**<br><br>**Measurement** |
| **Organisational management** | **Work environmental** | **Team** |
| Understaffed<br><br>Little training and teaching<br><br>No disciplinary action for poor performance and no reward for good performance - no feedback<br><br>Battle of priorities (e.g. other issues take precedence)<br><br>Lack of standardisation (e.g. 5 moments, WHO)<br><br>**Patient safety not put first**<br><br>**Monitoring and feedback** | Reminders such as posters are not effective, because they are hidden amongst other posters and do not give a consistent message<br><br>Posters are in the wrong place, on the wall and notice board and not in the patient's bed space<br><br>Posters are badly designed<br><br>Badly positioned gels and sinks<br><br>Not enough sinks and gels<br><br>Interruptions from other people<br><br>**Lack of effective reminders**<br><br>**Lack of equipment**<br><br>**Design of environment** | Few people observing and checking/reminding.<br><br>Can get away with doing it wrong.<br><br>Lack of leadership and lack of leaders leading by example.<br><br>Lack of motivation<br><br>Dependent on good team leader ("this is so much more important than number of sinks etc.")<br><br>**Culture of just getting the job done**<br><br>**Lack of leadership clear team roles and responsibilities** |

*DOME Cause Analysis Data Collection Sheet*

Process Hand washing
Process Step Decide to decontaminate hands
Failure Mode Decide not to decontaminate hands

| Patient | Task and technology | Individual staff |
|---|---|---|
| ~~Patient may be acutely unwell and spending time hand washing may be inappropriate, but this is rare.~~<br><br>Patients do not know or feel confident enough to ask staff to wash their hands.<br><br>**Lack of patient empowerment** | Wearing gloves causes people to decide not to wash their hands, because it is difficult to get damp hands into gloves and it takes longer to wash hands and dry them before and after using gloves.<br><br>Alcohol gel irritates broken skin<br><br>Over hand washing can damage skin<br><br>Confusion over when to wash hands – Guidelines ambiguous<br>No detailed knowledge of the WHO 5 moments of hand washing<br><br>Being asked to wash hands when entering and leaving wards has no scientific rational and is more of a PR exercise and therefore dilutes the message of hand washing at the correct times<br><br>**Process not standardised** | Feel too busy and under pressure to cut corners wherever possible to get the job done<br><br>Don't really believe that not washing hands causes infections<br>Inadequate training<br>Training not revised often enough<br><br>Cannot be identified as the culprit if a patient does get an infection<br>Impossible to trace infection back to staff member.<br>Consequences of not washing hands aren't made obvious<br><br>No feedback on performance of hand washing<br><br>**Measurement**<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| Organisation does not put patient safety first, but getting the job done and this attitude is taken up by the employees<br><br>Audits imposed on Staff from management require 95% compliance with hand washing. If not then the audit has to be done again however no effort has been made to address the cause of the problem. Therefore most audits are 100% compliant and the problem is hidden.<br><br>Lack of standardisation means people are confused as to when they should wash their hands/use gel. (WHO 5 points)<br><br>Lack of, or inappropriate training conducted<br><br>**Monitoring and feedback**<br><br>**Patient safety first (rather than hitting the target)** | Not enough gel dispensers and sinks<br><br>Badly positioned gel dispensers and sinks<br><br>Gel or sink is too far away. Even at the end of the bed.<br><br>Introduction of sinks/gels needs to be in combination with other initiatives.<br><br>Interruptions when you were going to wash your hands<br><br>**No personal gel dispensers** | Policing of hand washing regarded as a Nurse's job. Doctors exert their authority by disobeying the guidelines.<br><br>Leadership: leaders not seen to hand wash as a high priority and juniors follow the leader<br><br>Inappropriate interruptions by team members<br><br>Lack of motivation, can't be bothered to wash hands as nobody else does.<br><br>**Policing occurs across teams rather than within teams**<br>**Leadership**<br>**Culture of just getting the job done** |

*DOME Cause Analysis Data Collection Sheet*

Process Hand washing
Process Step Decide to use alcohol gel or soap and water
Failure Mode Use alcohol gel, but the patient has diarrhoea due to C. diff (alcohol gel does not kill C. diff spores)

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patients don't know that the staff should use soap and water when they have diarrhoea or why<br><br>**Lack of patient empowerment** | No reminders on the alcohol gel container that soap and water should be used for all patients with diarrhoea<br><br>Using soap and water takes longer than using the alcohol gel.<br><br>**Lack of effective reminders** | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| Reluctance to put stigmatizing signs up around patients with diarrhoea reminding staff that the patient has diarrhoea and/or must wash their hands with soap and water<br><br>**Lack of effective reminders** | Signs not put up or taken down appropriately<br><br>Signs not clear<br><br>Signs not specific for patients with diarrhoea or C. Diff<br><br>Signs should be positioned on way out of side room<br><br>Sinks not next to patients with diarrhoea<br><br>Not enough sinks<br><br>Gel is everywhere (convenient) but sinks are not.<br><br>Not enough side rooms, if patient is in side rooms it is a trigger that they might have an infections. Plus more difficult to indicate they have infection on bay<br><br>**Lack of effective reminders** | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Decide to use alcohol gel or soap and water
Failure Mode Use alcohol gel, but hands are dirty

| Patient | Task and technology | Individual staff |
|---|---|---|
| | | Unaware that you need to use soap and water when you have alcohol gel residue on your hands or your hands are physically dirty<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| | Not enough sinks or signs.<br><br>**Lack of effective reminders**<br><br>**No sink in every bedspace** | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Find alcohol gel dispenser
Failure Mode Cannot find alcohol gel dispenser

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Alcohol gel dispensers not visible enough<br><br>Alcohol gel dispenser on the end of the bed is too low (when bed lowered)<br><br>Not enough alcohol gel dispensers<br><br>**Location of gel dispensers and visibility** | |
| **Organisational management** | **Work environmental** | **Team** |
| ~~There are audits to check that gel dispensers are not empty and working~~ | | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Operate alcohol gel dispenser
Failure Mode Abuse of alcohol gel. Patient drinks alcohol gel

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient (or visitor) alcoholic or drug mis-user and steals the alcohol gel. | Alcohol gel dispensers in unoccupied areas and not fixed in position (new locked containers used in corridors outside wards) | |
| **Organisational management** | **Work environmental** | **Team** |
| | | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Cover all areas of hands with alcohol gel
Failure Mode All areas of hands not covered

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Alcohol gel hurts on broken skin | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| Difficult to monitor/feedback | | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Find soap and water
Failure Mode Cannot find soap and water

| Patient | Task and technology | Individual staff |
|---|---|---|
| | | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| Patient safety not put first<br><br>~~Audits to check if they are in full working order~~<br><br>~~No appointed member of staff to check if they are in full working order and fully stocked~~ | Not enough sinks | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Turn on tap
Failure Mode Turn tap on and touch tap with hands

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Design of taps or installation inadequate<br>Not elbow taps<br>Not installed with enough space to use elbows<br>Sensor operated taps to be installed<br>**Design of taps** | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| Old designs not replaced yet<br>**Implementation** | Obstacles near the sinks | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Operate soap dispenser
Failure Mode Cannot operate soap dispenser

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Soap dispenser empty/broken<br><br>No signal that soap dispenser is empty/broken<br><br>No back up (alcohol gel)<br><br>**Lack of effective reminders** | |
| **Organisational management** | **Work environmental** | **Team** |
| Soap dispenser empty<br><br>Need regular audits and rewards for refilling soap dispensers<br><br>**Monitoring and feedback** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Wash all areas of hands
Failure Mode All areas of hands not washed

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Takes longer to do properly than it takes to cut corners<br><br>**Time** | Don't know importance of technique<br>Don't know correct technique<br><br>**Education, training and testing**<br><br>**Measurement** |
| **Organisational management** | **Work environmental** | **Team** |
| Difficult to monitor<br>No feedback<br><br>**Monitoring and feedback** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Rinse
Failure Mode Cannot rinse

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Design of taps or installation inadequate<br>Not elbow taps<br>Not installed with enough space to use elbows<br>Sensor operated taps to be installed<br><br>**Design of equipment** | |
| **Organisational management** | **Work environmental** | **Team** |
| Old designs not replaced yet<br><br>**Implementation** | Obstacles near the sinks<br><br>**Design of environment** | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Take paper towels
Failure Mode Towels not taken

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Paper towels run out<br><br>Paper towel holder does not signal that it has run out<br><br>Towels rough (unpleasant to use)<br><br>**Lack of effective reminders** | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| No reward or penalty for not auditing/restocking paper towels<br><br>**Monitoring and feedback** | | Not viewed as important |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Dry hands
Failure Mode Do not dry hands

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Paper towels run out<br><br>Paper towel holder does not signal that it has run out<br><br>Towels rough (unpleasant to use)<br><br>**Lack of effective reminders** | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| | | |

*DOME Cause Analysis Data Collection Sheet*
Process Hand washing
Process Step Turn off taps using paper towels
Failure Mode Turn tap off and touch tap with hands

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Presence of old style taps that have hand controls<br><br>New taps with elbow controls should not be a problem<br><br>Tap designed for hand operation, not with towel<br><br>**Design of equipment** | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| Old designs not replaced yet<br><br>**Implementation** | | |

*DOME Cause Analysis Data Collection Sheet*

Process Hand washing
Process Step Put used towels in the bin using foot pedal
Failure Mode Use hands, not foot pedal

| Patient | Task and technology | Individual staff |
|---|---|---|
| | New bins are not possible to open with hands<br><br>**Design of equipment** | Don't know importance of technique<br><br>**Education, training and testing** |
| **Organisational management** | **Work environmental** | **Team** |
| Old designs not replaced yet<br><br>**Implementation** | Presence of old bins that can be opened with hands | |

# Appendix 2.2.10. Isolation of infection fishbone tables

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Bay quarantine
Failure Mode Bay not quarantined effectively

| Patient | Task and technology | Individual staff |
|---|---|---|
| Other patients on the ward might be afraid if a patient in a bay was isolated and all visitors wore apron and gloves<br><br>Patients do not remind the staff to wear apron and gloves and wash their hands<br><br>Patients are not properly informed - staff do not have a conversation with them<br><br>Patient may move and touch other patients<br><br>~~Patients are given information packs~~<br><br>~~Patient moves and touches other patients~~<br><br>~~Treatment of index case~~<br><br>**Patient empowerment** | Impossible to see the infection and it's spread, impossible to see contaminated fomites and hands and impossible to see decontaminated fomites and hands<br><br>**Detectability** | Lack of knowledge as to what "contact precautions" means<br><br>Incorrect use of protective clothing<br><br>No consequence (symptoms/signs) from staff picking up an infection<br><br>**Education and training** |
| **Organisational management** | **Work environmental** | **Team** |
| Conflicting priorities - getting the job done and dignity comes before patient safety, infected patients left in bays with un-infected patients due to pressure on beds.<br><br>At risk patients not isolated as a precaution<br><br>No penalty for staff that transmit infections and no reward for staff that don't transmit infections.<br><br>At risk patients not isolated prophylactically<br><br>~~No routine screening of staff when a patient has an MRSA infection, because most staff have transient carriage and patients are more likely to be reservoirs~~<br><br>Entire bay quarantined for C. diff (not for MRSA) - as C. diff has a higher political profile<br><br>Patients with potential infectious diseases are not isolated in A+E. Admissions not isolated until proven to have diarrhoea or an infection. (Need data from | Signs not effective - signs are designed to be ambiguous to reduce stigmatization with "Contact Precautions" that is not universally understood to mean - "wash your hands and wear apron and gloves"<br><br>**Lack of effective reminders**<br><br>Signs not put up - signs are stigmatizing especially when put on around a patient on an open ward rather than one in a side room<br><br>Less than a 1 meter clearance between an infected patient and neighbouring un-infected patients<br><br>**Lack of physical barrier around the patient**<br><br>Pressure to get the job done and therefore corners are cut in infection control procedures<br><br>Ideally all infected patients would be moved to a side room, so **lack of side rooms** prevents this | Team organised around getting the job done and not with patient safety or isolation of infection as their primary concern<br><br>Nurses work in an infected side-room and then move to an uninfected bay<br><br>**Culture of just getting the job done** |



| | | |
|---|---|---|
| Lewisham microbiologists to show how isolation of all admissions was achieved and lowered infection rates)<br><br>Hospitals built to last for 50 years and are only infrequently updated<br><br>Less than a 1 meter clearance between an infected patient and neighbouring un-infected patients<br><br>Organisation puts emergency and elective patients on the same ward. Emergency patients may have acute infections and pass them on to the elective patients who have low immunity due to the stress response of surgery.<br><br>**Patient safety not put first** | **Not enough room in a bay for a yellow bin and a sink.**<br><br>Need 3 metres between the beds.<br><br>**No isolated toilet**<br><br>No quarantine of bay before turnaround<br><br>Not enough equipment for single patient use | |

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Remember to wear apron and gloves
Failure Mode Forget to wear apron and gloves

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patients do not remind the staff to wear apron and gloves and wash their hands<br><br>**Patient empowerment** | Gloves and apron not beside infected patients<br><br>Placed on the wall out of the way<br><br>Process is complicated, because some patients do and some do not require contact precautions. However, well adhered to standard precautions would be better and simpler<br><br>**Ineffective reminders**<br>**No standardization** | Too busy<br>Don't see sign<br>Don't know when they should wear gloves and apron<br><br>**Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | No gloves and apron signs<br>(signs say "contact precautions" that is open to misinterpretation)<br><br>Not in a side room<br>No physical barrier<br>However doors are often open<br>So it's the **lack of a clear visual barrier** | Junior staff do not remind senior staff to wear apron and gloves<br><br>Senior staff forget/do not remind junior staff<br><br>Junior staff follow the leader's example<br>**Leadership** |

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Decide to wear apron and gloves
Failure Mode Decide not to wear apron and gloves

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patients do not insist the staff to wear apron and gloves and wash their hands | ~~Design of gloves~~ | Staff make a risk assessment of their own based on what they are planning to touch in the room and how sick the patient is<br><br>Staff don't believe that apron and gloves will prevent infection<br><br>Staff do not feel at risk themselves (open TB provokes strict protocol adherence)<br><br>Staff think they can get away with it<br><br>Staff may wear apron and particularly gloves at inappropriate times, because they feel protected and it is a visible sign that hands are clean<br><br>Nurses use them to make beds<br><br>Doctors don't use them at all<br><br>**Education** |
| **Organisational management** | **Work environmental** | **Team** |
| Correct size of glove not available<br><br>**No glove audits**<br><br>**No penalties or rewards** | Signs do not say why the precautions are necessary<br><br>No **anteroom** just for isolation precautions<br><br>Not in a side-room<br>No physical barrier<br><br>Not enough gloves and apron dispensers<br><br>Badly positioned gloves and apron dispensers. Too far away<br><br>Interruptions when you were going to put apron and gloves on<br><br>**Space (1m around the curtain)** | Policing of contact precautions regarded as a Nurse's job. Doctors exert their authority by disobeying the guidelines.<br><br>**Policing across teams rather than within teams**<br><br>Leaders don't see contact precautions as a high priority and juniors follow the leader<br>**Leadership**<br><br>Inappropriate interruptions by team members |

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Find apron and gloves
Failure Mode Cannot find apron and gloves

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient in bay, not in side room therefore apron and gloves not immediately to hand<br><br>~~Patient does not wear apron and gloves~~ | Apron/gloves dispenser is empty<br><br>Apron and glove dispenser not by patient isolated in a bay<br><br>**Lack of effective reminders** | |
| **Organisational management** | **Work environmental** | **Team** |
| No apron and glove audits to restock dispensers<br><br>**No audit or feedback** | Positioning of apron/gloves dispenser inconvenient<br><br>**Design of environment** | |

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Take apron and gloves
Failure Mode Contaminate apron and gloves as they are removed from container

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Gloves are difficult to put on if hands are damp<br><br>Time required for hands to dry<br><br>Hand dryers are noisy and slow and circulate micro-organisms<br><br>~~Not technique~~<br><br>No alcohol gel attached to the glove and apron container<br><br>**Lack of efficient reminders and conveniently designed equipment** | Don't wash hands<br><br>Difficult to put gloves onto damp hands<br><br>Do not believe that it is important<br><br>No way of telling if hand wash has been done when gloves are on<br><br>**Education and training** |
| **Organisational management** | **Work environmental** | **Team** |
| **Monitoring and feedback** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Put on apron and gloves
Failure Mode Contaminate apron and gloves as they are put on

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Gloves are difficult to put on if hands are damp<br><br>Time required for hands to dry<br><br>Hand dryers are noisy and slow and circulate micro-organisms<br><br>~~Not technique~~<br><br>No alcohol gel attached to the glove and apron container<br><br>**Lack of efficient reminders and conveniently designed equipment** | Don't wash hands<br><br>Difficult to put gloves onto damp hands<br><br>Do not believe that it is important<br><br>No way of telling if hand wash has been done when gloves are on<br><br>**Education and training** |
| **Organisational management** | **Work environmental** | **Team** |
| **Monitoring and feedback** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Use foot pedal to open bin
Failure Mode Do not use the foot pedal. Lift the lid with hands

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Bin design should not allow the lid to be opened by hand.<br>**Design** | |
| **Organisational management** | **Work environmental** | **Team** |
| Organisation has not replaced all the old bins.<br>**Implementation** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Isolation of infection
Process Step Equipment kept in one patient's bed-space
Failure Mode Equipment isolated incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient does not own their own equipment (disposable and non-disposable)<br><br>**Patient empowerment** | Equipment is mobile and removable<br><br>Not indication that it has been removed in error<br><br>No indication equipment has been cleaned<br><br>**Lack of effective reminders** | Do not know<br><br>**Education and training** |
| **Organisational management** | **Work environmental** | **Team** |
| **Monitoring and feedback** | Not enough equipment | **Culture of just getting the job done**<br><br>**Culture that the hospital owns the equipment, not the patient** |

*DOME Cause Analysis Data Collection Sheet*

Process Isolation of infection
Process Step Equipment washed and disinfected when removing it from the patient's bed-space with chlorine
Failure Mode Equipment not disinfected correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Can't tell if equipment is clean<br><br>**Lack of effective reminder**<br><br>**Lack of measuring device for cleanliness** | Do not know what or how to clean<br><br>**Education and training** |
| **Organisational management** | **Work environmental** | **Team** |
| **Patient safety not put first** | No space to clean equipment properly<br><br>**Design of bed space (space)** | **Culture - low status of cleaning (not my job)** |

*DOME Cause Analysis Data Collection Sheet*

Process Isolation of infection
Process Step Clean non-disposable surfaces using chlorine disinfectant
Failure Mode Surfaces not cleaned correctly with chlorine

| Patient | Task and technology | Individual staff |
|---|---|---|
| | High touch areas are cleaned more often (3 times a day) during an outbreak<br>Could identify high touch areas with a specific colour<br><br>Chlorine Solution incorrectly diluted (correct container for dilution does not come with the tablets and needs to be ordered separately)<br><br>Curtains - can't tell when they were last cleaned (non-disposable ones)<br><br>Chlorine damages some materials (metallic/commode) and needs to be cleaned off (with a Clinell wipe)<br><br>Chlorine remains effective for 8 hours - then a new solution has to be made<br><br>Time taken to clean a bay is 3 hours and cannot be done<br><br>Green tape can be used incorrectly<br><br>Complexity of cleaning is high<br><br>*Clinell wipes used if patient not infected and Chlorine (Actichlor plus) used for infected patients*<br><br>*Red Clinell wipes used for patients with C. diff and needs tap water activation*<br><br>*Alcohol is used for metal*<br><br>*CCSD to professionally clean non-disposable equipment*<br><br>**Lack of effective reminders**<br>**Complexity of process** | **Education and training** |
| **Organisational management** | **Work environmental** | **Team** |
| Department of health wants 100% compliance<br><br>NPSA wants 70% compliance - more useful, | Sluice not big enough to avoid contaminating clean items | **Low status**<br>**Just get the job done** |

| | | |
|---|---|---|
| because problem areas can be identified<br><br>Patient's bed is cleaned between each patient and sheets are changed, however this is different to the equipment<br><br>**Monitoring and feedback** | **Ward design** | |

*DOME Cause Analysis Data Collection Sheet*

Process Isolation of infection
Process Step Dispose of disposable equipment in clinical waste
Failure Mode Disposable equipment not disposed of in clinical waste correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| Single use equipment belongs to the ward and not to the actual patient<br><br>No identification of equipment with the patient - name<br><br>Allow the patient to own the equipment (and clean it!)<br><br>**Patient Empowerment** | Unclear signs on equipment<br><br>Complicated process requires simplification<br><br>Disposable curtains - more expensive, can tell when they were changed - can't be changed for every patient (changed every 3 months, or for any patient with a known infection MRSA/C.diff)<br><br>Curtain shared (communal) and touches more than one patient<br><br>Disposable equipment is expensive and does not look disposable so they are reused<br><br>Universal symbol (crossed out 2) only printed on the packaging and not on the item of equipment itself<br><br>**Lack of effective reminders**<br>**Complexity of process**<br>**Design of the ward** | Don't know that equipment should not be reused. Universal symbol (crossed out 2) that signifies for single use not universally understood<br><br>Perception that reusing disposable equipment is saving money<br><br>Lack of detectability when reusing equipment<br><br>Lack of knowledge regarding waste disposal<br><br>**Education and training** |
| **Organisational management** | **Work environmental** | **Team** |
| More complex waste streams introduced to try and reduce costs, but this makes it more difficult to dispose of waste safely<br><br>**Patient safety not put first** | No signs explaining waste streams (there is colour coding/yellow for clinical waste)<br>No signs on bins<br><br>**Lack of effective reminders** | |

# Appendix 2.2.11. Vital signs monitoring fishbone tables

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Remember to measure vital signs
Failure Mode Forget to measure vital signs

| Patient | Task and technology | Individual staff |
|---|---|---|
| | No system of reminders of when to measure vital signs<br>**Lack of effective reminders**<br><br>~~There is a recommendation from NICE of when to repeat observations - so a protocol and a standard exist~~ | HCA's untrained and responsible for taking vital signs<br>**Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| HCAs employed who are untrained and asked to perform tasks that require training<br>**Lack of trained permanent employees**<br>**No audit or feedback** | | Trained nurse leaders do not have power over HCAs<br>**Lack of leadership of nurses over HCAs** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Decide to measure vital signs
Failure Mode Decide not to measure vital signs

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient looks OK<br>Easier not to do the job<br>Other jobs prioritized | **No reminders that persist until the task is done** | HCA's untrained and responsible for taking vital signs **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| HCAs employed who are untrained and asked to perform tasks that require training **Lack of trained permanent employees**<br><br>No penalty for doing a bad job and no reward for doing a good job **No audit or feedback** | | Trained nurse leaders do not have power over HCAs HCAs are not aware of who they should go to for help/advice **Lack of leadership of nurses over HCAs**<br><br>**Culture of getting the job done and not patient safety first** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Clean equipment/change disposable equipment
Failure Mode Equipment not disinfected/changed

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient does not know that they should not be treated with equipment that is not cleaned or is their personal equipment<br>**Patient empowerment** | Lack of reminder to clean equipment<br><br>Lack of signal to show that equipment is clean<br><br>Equipment wheeled from infected areas to uninfected areas - no dedicated infected patient equipment - no effective cleaning of equipment - equipment not personalised to patient - equipment highly mobile and removable<br><br>Complex cleaning process and lack of instructions<br><br>Equipment is cluttered and uncleanable (basket)<br><br>**Lack of reminders**<br>**Lack of clean status signal**<br>**Mobile equipment that is difficult to clean effectively**<br>**Complex cleaning process**<br>**Equipment designed for convenience and not ease of cleaning** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | No anterooms to clean in<br>**Cleaning areas not designed into hospitals** | Cleaning seen as a low status task<br>Nobody specifically given the task<br>People delegate the task to someone who does not do it<br>**Low status of cleaning**<br>**Nobody allocated the job, or allocated to someone who doesn't/can't do it**<br>**Culture of getting the job done and not patient safety first** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Decide to measure respiratory rate
Failure Mode Do not decide to measure respiratory rate

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient looks well, therefore respiratory rate not measure and filled in as normal on the observation chart | No equipment to easily measure respiratory rate<br>Difficult to measure manually because you have to stare at the patient without telling them why<br>~~Normal respiratory rate is controversial~~<br>~~Devices would not help~~<br>**No reminder to measure respiratory rate** | Perception that respiratory rate is not important<br>**Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | | **Culture of getting the job done and not patient safety first** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Find a fobwatch/clock with a working second hand (to measure respiratory rate)
Failure Mode Wear a wrist watch

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Observations trolley has no clock<br>Have to time 30 secs and count the number of breaths<br>**No convenient device to measure 30 seconds** | Don't tell each other not to wear watches<br><br>**Reminders** |
| **Organisational management** | **Work environmental** | **Team** |
| Fob watches not provided for free to all staff<br><br>Nurses uniforms have nowhere to hand a wrist watch<br>**No audit or feedback** | Clocks not visible, not working or no second hand | **Culture of getting the job done and not patient safety first** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Look at the watch and patient (to measure respiratory rate)
Failure Mode Wall clock difficult to see or patient's breathing movements difficult to see

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient covered in layers of bedclothes | No clock on vital signs trolley<br>No fobwatch<br>Curtains should be drawn around the patient and there are no clocks in the bed spaces<br>**No convenient device to measure 30 seconds** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | Clocks poorly positioned | |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Clean blood pressure cuff
Failure Mode Do not clean blood pressure cuff (failure mode occurred twice)

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient does not know that they should not be treated with equipment that is not cleaned or is their personal equipment<br>**Patient empowerment** | Lack of reminder to clean equipment<br><br>Lack of signal to show that equipment is clean<br><br>Equipment wheeled from infected areas to uninfected areas - no dedicated infected patient equipment - no effective cleaning of equipment - equipment not personalised to patient - equipment highly mobile and removable<br><br>Complex cleaning process and lack of instructions<br><br>Equipment is cluttered and uncleanable (basket)<br><br>**Lack of reminders**<br>**Lack of clean status signal**<br>**Mobile equipment that is difficult to clean effectively**<br>**Complex cleaning process**<br>**Equipment designed for convenience and not ease of cleaning** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | No anterooms to clean in<br>**Cleaning areas not designed into hospitals** | Cleaning seen as a low status task<br>Nobody specifically given the task<br>People delegate the task to someone who does not do it<br>**Low status of cleaning**<br>**Nobody allocated the job, or allocated to someone who doesn't/can't do it**<br>**Culture of getting the job done and not patient safety first** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Clean oxygen saturation probe
Failure Mode Do not clean probe (failure mode occurred twice)

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient does not know that they should not be treated with equipment that is not cleaned or is their personal equipment<br>**Patient empowerment** | Lack of reminder to clean equipment<br><br>Lack of signal to show that equipment is clean<br><br>Equipment wheeled from infected areas to uninfected areas - no dedicated infected patient equipment - no effective cleaning of equipment - equipment not personalised to patient - equipment highly mobile and removable<br><br>Complex cleaning process and lack of instructions<br><br>Equipment is cluttered and uncleanable (basket)<br><br>**Lack of reminders**<br>**Lack of clean status signal**<br>**Mobile equipment that is difficult to clean effectively**<br>**Complex cleaning process**<br>**Equipment designed for convenience and not ease of cleaning** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | No anterooms to clean in<br>**Cleaning areas not designed into hospitals** | Cleaning seen as a low status task<br>Nobody specifically given the task<br>People delegate the task to someone who does not do it<br>**Low status of cleaning**<br>**Nobody allocated the job, or allocated to someone who doesn't/can't do it**<br>**Culture of getting the job done and not patient safety first** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Readings written on ad hoc sheet
Failure Mode written incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | No space on handover sheet for this purpose, therefore can fill in measurements for the incorrect patient<br><br>Measurements not automatically sent to the chart from the equipment | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Readings transcribed onto vital signs chart
Failure Mode transcribed incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Repetitive task<br>Small boxes on chart<br>**Design of chart** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Plot graphs on vital signs chart
Failure Mode plotted incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Small boxes on chart<br>Equipment displays values that fall between the lines on the chart and encourages numbers to be written on as well as the lines<br>**Design of chart/readings from equipment**<br>**No example on the chart** | Unscientific methods of plotting graphs practiced<br>**Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Fill in boxes on vital signs chart
Failure Mode filled in incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Boxes small<br>**Design of chart** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Interpret results of vital signs measurements
Failure Mode interpreted incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | A downward/upward trend increases anxiety, but a stable trend decreases anxiety, especially if it persists.<br>**No escalation of reminder with persistent stable abnormal results - reminders** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | | Poor quality of vitals signs leads to them being ignored even when they are accurate<br>**Culture - perceived lack of accuracy and value of vital signs measurements and charting - low status of process task** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Use the red colour zones to interpret the vital signs
Failure Mode red zones used incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | A downward/upward trend increases anxiety, but a stable trend decreases anxiety, especially if it persists.<br>**No escalation of reminder with persistent stable abnormal results** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | Poor quality of vitals signs leads to them being ignored even when they are accurate<br>**Culture - perceived lack of accuracy and value of vital signs measurements and charting - low status of process task** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Use the trends in the graphs or numbers to interpret the vital signs
Failure Mode trends interpreted incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | | Unscientific methods of plotting graphs practiced<br>**Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | Poor quality of vitals signs leads to them being ignored even when they are accurate<br>**Culture - perceived lack of accuracy and value of vital signs measurements and charting - low status of process task** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Calculate the MEWS (modified early warning score)
Failure Mode MEWS not calculated or calculated incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Not done as more work<br>**Not automatic**<br>**Reminder**<br>**Design of equipment**<br>**Simplification** | Value underestimated<br>**Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | | **Culture of getting the job done and not patient safety first** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Use MEWS to interpret results
Failure Mode MEWS interpreted incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Not automatically calculated or interpreted<br>**No effective reminder** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Decide what action to take
Failure Mode take incorrect action

| Patient | Task and technology | Individual staff |
|---|---|---|
| | **No automatic decision making process**<br>**Reminder**<br>**Design of equipment**<br>**Simplification** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | Decision deferred to ward round<br>Ward round does not pay attention to vital signs recordings<br>Don't know what to do with them<br>Surgeons not interested/available<br>No medic allocated to cover medical problems in surgical patients<br>**No medical cover of surgical patients**<br>**Difficulty asking for help from seniors** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Give/change treatment
Failure Mode treatment not changed or given correctly/appropriately

| Patient | Task and technology | Individual staff |
|---|---|---|
| | **No automatic decision making process**<br>**Reminder**<br>**Design of equipment**<br>**Simplification** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | Decision deferred to ward round<br>Ward round does not pay attention to vital signs recordings<br>Don't know what to do with them<br>Surgeons not interested/available<br>No medic allocated to cover medical problems in surgical patients<br>**No medical cover of surgical patients**<br>**Difficulty asking for help from seniors** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Get help/advice
Failure Mode Help and advice not sought appropriately

| Patient | Task and technology | Individual staff |
|---|---|---|
| | **No automatic decision making process**<br>**Reminder**<br>**Design of equipment**<br>**Simplification** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | Decision deferred to ward round<br>Ward round does not pay attention to vital signs recordings<br>Don't know what to do with them<br>Surgeons not interested/available<br>No medic allocated to cover medical problems in surgical patients<br>**No medical cover of surgical patients**<br>**Difficulty asking for help from seniors** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Document readings in the notes
Failure Mode Readings documented incorrectly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | **No automatic transcription of vital signs measurements into the notes**<br>**Reminder**<br>**Design of equipment**<br>**Simplification** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | Ward round very brief<br>Not enough time | Culture of writing 'apyrexial obs stable'<br>Poor quality of vitals signs leads to them being ignored even when they are accurate<br>**Culture - perceived lack of accuracy and value of vital signs measurements and charting** |

*DOME Cause Analysis Data Collection Sheet*

Process Vital signs
Process Step Decide when to measure vital signs again
Failure Mode Do not decide when to take repeat vital signs correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | **No automatic decision making process**<br>**Reminder**<br>**Design of equipment**<br>**Simplification** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| **No audit or feedback** | | Poor quality of vitals signs leads to them being ignored even when they are accurate<br>**Culture - perceived lack of accuracy and value of vital signs measurements and charting** |

*DOME Cause Analysis Data Collection Sheet*
Process Vital signs
Process Step Write on handover sheet
Failure Mode Do not write on handover sheet correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | **No automatic transcription of the vital signs onto the handover sheet**<br>**Reminder**<br>**Design of equipment**<br>**Simplification** | **Lack of training** |
| **Organisational management** | **Work environmental** | **Team** |
| | | Poor quality of vitals signs leads to them being ignored even when they are accurate<br>**Culture - perceived lack of accuracy and value of vital signs measurements and charting** |

# Appendix 2.2.12. Handover fishbone tables

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Team is informed of time and place of handover
Failure Mode Team is not informed of time and place of handover

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Bleeps and emails do not have automatic on call reminders<br><br>No set technology used to remind about handover, sometimes mobiles, sometimes bleeps.<br><br>**No reminders of when to be on call** | Location of handover not known by individual member of staff<br><br>Member of staff not at induction<br><br>Does not/forgets to ask other team members<br><br>Element of stress starting new job so forgets to ask/find out when handover is.<br><br>People forget to inform new doctors<br><br>New doctors may finish previous job on nights and miss induction in the new hospital.<br><br>**No backup if new doctor misses induction**<br><br>No **training** in handover<br><br>No **protocol** for handover<br><br>On-calls often swapped so remembering when to go to handover is more complicated<br><br>No reminders of when you are on call<br><br>**No reminders of when to be on call** |
| **Organisational management** | **Work environmental** | **Team** |
| No regular single point of information about when/where handover is to be held<br><br>Place of handover may not be mentioned in an induction<br><br>Lack of checklist for induction process<br><br>If induction does not include a tour, so even if people are told where and when handover is they might not get there<br><br>**Handover locations not standardized** | **On call shifts are swapped**<br><br>No common handover place<br>No signs<br><br>Different teams handover at different places<br><br>**Handover locations not signposted or standardized** | Assumed knowledge of time and place of handover (always 12 hour shift)<br><br>New members of the team are usually informed of the time and place of handover by other team members - team leader<br><br>On-calls often swapped so remembering when to go to handover is more complicated<br><br>Confusion over who takes the lead (least busy? Most important) so don't know who to ask about handover.<br><br>Different teams handover at different places |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Staff leaving and arriving meet at shift change over time
Failure Mode Leaving or arriving staff are late

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient care comes first (not handover)<br><br>If someone is seeing a patient handover might happen at bedside (change of location) | Bleeps and emails do not have automatic on call reminders<br><br>No set technology used to remind about handover, sometimes mobiles, sometimes bleeps.<br><br>**No reminders of when to be on call** | On-calls often swapped so remembering when to go to handover is more complicated<br><br>No reminders of when you are on call<br><br>**No reminders of when to be on call** |
| **Organisational management** | **Work environmental** | **Team** |
| Not allowed to work over 12 hours, therefore no time between 2 x 12 hour shifts for handover<br><br>**No overlap in shifts (staff use their own time)** | On call shifts are swapped - **no reminders**<br><br>No common handover place<br>No signs<br><br>Different teams handover at different places<br><br>**Handover locations not signposted or standardized** | Too busy/detained at other jobs<br><br>On-calls often swapped so remembering when to go to handover is more complicated<br><br>*Team applies social pressure to come to handover on time* |

*DOME Cause Analysis Data Collection Sheet*

Process Handover of information
Process Step Staff leaving and arriving meet at shift change over time
Failure Mode Meeting place inadequate for handover

| Patient | Task and technology | Individual staff |
|---|---|---|
| Too close to patient (breeches patient confidentiality) | No specifically designed hand over area (quiet, other teams nearby, computers and printers, radiology quality screens, paper, pens, confidential, phones, coffee/food, away from the ward, but close to the wards/A+E/theatres, access to protocols and information/books, space and chairs)<br><br>**Design of handover area - top priority is confidentiality - second is that handover is facilitated** | |
| **Organisational management** | **Work environmental** | **Team** |
| Handover place should be close to emergency areas - A+E resus/theatres - so if staff are called away they can be reached<br><br>**Proximity to sick patients**<br><br>Pause in emergency operation lists for hand over | Not quiet<br><br>Patient confidentiality breached<br><br>No access to information (printer, working monitor, coffee! etc)<br><br>**Due to design of handover area** | Interruptions from other staff<br>**Due to design of handover area** |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Consider first/next patient
Failure Mode Patients and jobs not discussed

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient may not be that ill, but next in the list to a seriously ill patient, therefore might get skipped<br><br>No system of alerting to un-discussed patients | Lists get lost<br><br>No auto-back up of list or synchronisation of list<br><br>**Auto back up and sync of handover sheet** | Forget to talk about the patient - forgot to add patient to the list - lost list - just referred a patient - patient is under another team - interruptions/other priorities/distractions/stress (affects memory)<br><br>Less experienced - the less you remember/understand<br><br>No back up - usually unable to call person who was on call when they have gone home to ask them a question<br><br>**No back up system of patient lists (with more than one team)**<br><br>However nurses generally call doctors if a patient isn't seen |
| **Organisational management** | **Work environmental** | **Team** |
| Night staff might look after patients from many teams, therefore overlap/gaps in handover<br><br>Handover list not linked up with bed management so patients get missed off list<br><br>Night team look after take patients and elective patients and therefore may not meet the day team of the elective patients<br><br>**Elective teams don't go to the handover and handover sheets not accessible to on call team** | Patient not present so they are forgettable (handover at bedside would remind doctor of details)<br><br>One teams patients are spread across the hospital so they can get forgotten - especially if they belong to other teams primarily | Interruptions/distractions - due to design of the handover area |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step How sick the patient is
Failure Mode Inaccurate or no assessment

| Patient | Task and technology | Individual staff |
|---|---|---|
| Complex/unusual patient<br><br>Patient appears well and falsely reassuring | Handover sheet does not convey urgency<br><br>Handover sheet does not contain a consistent measure across patients (such as MEWS)<br><br>Referral so not a usual patient to be looking after<br><br>**No link with the handover sheet with vital signs (MEWS)** | Forget<br>No effective reminders<br><br>Lack of prioritization<br><br>No **training** in handover<br><br>No **protocol** for handover |
| **Organisational management** | **Work environmental** | **Team** |
| No ubiquitous standard method of spotting sick patient<br><br>**Standardization** | | |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Past Medical History
Failure Mode Past medical history not handed over correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient has no significant past medical history<br><br>Patient has long and complex past medical history (not focused)<br><br>Patient has been in the hospital a long time and everyone knows them | Handover sheet is too small to fit past medical history onto it<br><br>Person who writes handover sheet is not the person who takes the history from the patient<br><br>**No link between handover sheet and the notes**<br><br>**No place on the handover sheet to remind that past medical history should be discussed** | Forget, because there is no effective reminder on the handover sheet<br><br>No **training** in handover<br><br>No **protocol** for handover |
| **Organisational management** | **Work environmental** | **Team** |
| ~~Notes unavailable~~ | | Prioritize other tasks - low priority given to past medical history |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Results (bloods/observations/radiology/other)
Failure Mode Results not handed over correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | No computer in handover room<br><br>**Design of handover area**<br><br>Pathology can't easily inform doctor about abnormal results<br><br>**No integration between results and handover sheet/no feedback to pathology** | Pathology unable to contact doctor who is busy and doesn't answer every bleep<br>No other way of contacting a doctor apart from the bleep<br>Could send a text |
| **Organisational management** | **Work environmental** | **Team** |
| Pathology can't easily inform doctor about abnormal results | Pathology can't easily inform doctor about abnormal results | Pathology unable to contact doctor or be part of handover and no feedback to pathology |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Management plan
Failure Mode Management plan not handed over correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| Patient is on handover sheet for a long time – team assumes everyone knows the plan | | Inexperienced staff may handover plan incorrectly, as they do not understand it |
| **Organisational management** | **Work environmental** | **Team** |
| | | Patient is on handover sheet for a long time – team assumes everyone knows the plan<br><br>Junior members who do not understand the plan may feel unable to question senior members handing over |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Progress
Failure Mode Progress not handed over correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | No effective reminder on the handover sheet<br><br>No record of previous handover sheets<br><br>No link with the notes<br><br>No link with blood test results or vital signs that can show a trend over time<br><br>**No standardized measure of progress summarized on the handover sheet** | |
| **Organisational management** | **Work environmental** | **Team** |
| | | |

*DOME Cause Analysis Data Collection Sheet*
Process Handover of information
Process Step Jobs to do
Failure Mode Jobs not handed over correctly

| Patient | Task and technology | Individual staff |
|---|---|---|
| | Jobs for doctors of all levels should be represented on handover sheets for all levels<br><br>Jobs to do are not allocated to a specific person on the handover sheet<br><br>No tickbox facility on the handover sheet | |
| **Organisational management** | **Work environmental** | **Team** |
| | | Jobs for different levels of doctors not given the same priority in the handover meeting - such as house officer jobs that the Registrar does not wait to listen to<br><br>Whole team should listen to the whole handover<br><br>No **training** in handover<br><br>No **protocol** for handover |