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A Safer Surgical Ward:

Real-time Patient Safety Risk Assessment for the Post-operative Care Environment

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Thesis submitted for the degree of Doctor of Philosophy (PhD)

November 2021

Statement of Originality

I hereby declare that the work presented in this thesis is my own work, under the guidance of my supervisors (Mr Philip Pucher, Mr Maximilian Johnston, Mr Pritam Singh and Professor Ara Darzi). Collaborations are appropriately described. Other scientific literature drawn upon and used in this thesis has been appropriately cited within the text and referenced in the bibliography.

Copyright Declaration

Acknowledgments

Firstly, I would like to thank Professor Ara Darzi for giving me the opportunity to undertake a PhD. I am grateful for all the support that I have received throughout this process and the wonderful experiences that came with being a clinical research fellow within the unit. I am also deeply grateful to the wonderful trio of co-supervisors who have helped me on this journey- Phil, Max and Pritam. You have been ever-present, ready to advise and guide, while also juggling your own higher surgical training. Your knowledge and attention to detail has been invaluable in completing this project.

I would like to also thank Hutan, Steve and Tony for their support- and a very special thanks to Karen Kerr. Your door was always open- figuratively and literally! – and you administered advice, reassurance and encouragement generously. I hope you continue to thrive in your latest role.

To my cohort of fellow clinical research fellows- we are forever bonded through this process! You have been my indispensable morale boosters. I look forward to many more years of friendship and many more adventures.

I am lucky enough to have the most supportive family. Aman- my patient husband who has been the rock of our family throughout this process. To my children, Naila and Abdella – mummy is ready to put the laptop down now. For a bit. This summer, we have also been fortunate enough to add our beautiful daughter Ayat to our brood.

I don't know if I can ever thank my mother, Kedija Hassen, enough. I will never be able to repay the sacrifices you have made throughout my life- supporting my education, then my career unwaveringly. Your love, encouragement and belief keep it all going.

Finally, I dedicate this thesis to my late father, Abdella Hassen, who passed away in my second year. Baba taught me everything about hard work, resilience and fulfilling your potential- doused in a big helping of unconditional love, laughter and endless wisdom. I miss you terribly.

My father was so proud when I told him I was thinking of doing a PhD- and so I conclude it in his honour.

Abstract

The inpatient ward environment is the basic unit of a healthcare facility. Both intrinsic and extrinsic influences on this unit often dictate the quality and safety of care. For surgical patients, although significant focus has been given to care quality in the peri-operative phase, it has become increasingly evident that the overall outcome is determined during the post-operative period of care on the surgical ward. This is demonstrated through the concept of failure to rescue, where stark differences in mortality rates between institutions are seen despite similar complication rates. Research to identify the drivers of these variations often focus on specific themes, rather than evaluating the surgical ward as a system. Furthermore, much of the research examines large administrative datasets with analysis conducted at the institutional, rather than unit level.

This thesis assesses the degree of variation that exists on surgical wards and identifies contributors to error that span the Donabedian model; this considers how processes are performed and how structural factors may influence outcomes. A close examination at the grassroots level has facilitated the identification of granular new metrics with direct relevance to day-to-day care at the ward level. With this approach, the potential for real-time risk assessment of this environment has been proposed, along with future directions to realise this objective.

This has been achieved via a sequence of studies that utilise a range of methods. Following a review of the current literature, a semi-structured interview study was conducted across multiple sites. The experiences of surgical patients, nurses, doctors

and managers was explored through 51 interviews. Stakeholders were acutely aware that some surgical wards were safer than others and were able to identify errors within a number of processes, such as the conduction of ward rounds, communication among healthcare staff and medication administration. Furthermore, the development of potential errors was seen as embedded in complex structural influences; the effective performance of processes was impacted by factors such as staffing shortages, organisational bed pressures (i.e., leading to outlier patients) and a potentially challenging physical environment, with layout and lack of space presented as a potential obstacle to safe care. Participants were also able to propose a range of quality markers that reflected the range of influences at play on the ward.

This was followed with a Delphi Consensus study which organised the wide range of factors identified in the previous study and prioritised those deemed to have the most influence on the delivery of safe care on the surgical ward. An international panel of experts in patient safety and patient advocates considered multiple facets of this environment. Sixty-four of the 85 statements in the final questionnaire achieved consensus, highlighting the inherent complexity of the surgical ward. This led to an ethnographic observational study of surgical wards, with the aim to assess the degree of variability and measurability of these prioritised factors. Three broad domains were observed – processes of care, the care environment and organisational health. Alongside this observation, patients and nurses also completed validated questionnaires that measure safety culture.

There was a high degree of disparity with respect to how a ward behaves as a system from day-to-day. Variation in timings and features of the ward round as well as timeliness of clinical and nursing task completion was demonstrated. Organisational influences (e.g., staffing levels, skill mix, use of temporary staffing, ward occupancy, outlier patients etc) were highly dynamic.

The final study establishes an association between measurable factors identified in the observational study and patient outcomes and presents the feasibility of using these as real-time measures of safe care on the surgical ward. Many of these risk factors are retrievable from routinely collected data and were extracted from electronic health records and duty rostering programmes. The patient outcomes identified were also available from the same data sources, namely wrong time medication errors and clinical deterioration. Preliminary statistical models of harm are presented in this study, thus demonstrating that local routinely collected data may have a role in predictive modelling of the risk of harm within a specific setting. Local teams may be able to harness their own data to predict their own risk. This could help guide future policies and improvement strategies.

In conclusion, this thesis has comprehensively explored the entirety of the surgical ward as a system of care delivery, examined the complex array of factors at play as well as their potential interactions with one another and proposed new granular safety metrics that have a role for predictive modelling of the risk of harm at the local level. Further work is needed to develop these predictive models further, such as establishing methods to measure those factors that are not currently available through routinely collated data. This will allow future iterations of the predictive model to incorporate a wider range of factors that are potentially influencing care quality on the surgical ward, with the aim of enhancing sensitivity and applicability of the final model.

Peer-reviewed publications originating from this thesis

1. Hassen Y, Singh P, Pucher PH, Johnston MJ, Darzi A. **Identifying quality markers of a safe surgical ward: An interview study of patients, clinical staff, and administrators.** Surgery. 2018;163(6):1226-33.

2. Hassen YAM, Johnston MJ, Singh P, Pucher PH, Darzi A. **Key Components of the Safe Surgical Ward: International Delphi Consensus Study to Identify Factors for Quality Assessment and Service Improvement.** Annals of Surgery. 2019; 269(6):1064-72.

Presentations to Learned Societies

1. American College of Surgeons Clinical Congress. Washington DC, USA, Oct 2016 Y. Hassen, P. Singh, P. Pucher, M. Johnston, A. Darzi **Identifying Quality Markers of a Safe Surgical Ward: An Interview Study of Patients, Clinical staff and Administrators**

2. American College of Surgeons- Accredited Education Institutes Consortium Meeting. Chicago, IL, USA, March 2017 Y. Hassen, M. Johnston, P. Pucher, P. Singh, A. Darzi **International Delphi Consensus on Critical Components of the Safe Surgical Ward: Identification of Factors for Educational Interventions and Quality Assessment**

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1. Thesis Introduction

Almost 30 years ago, the term “adverse events” entered the healthcare lexicon. At a time when the magnitude of errors in healthcare was not yet fully appreciated, Brennan et al. applied a now classic definition to this phenomenon: ‘an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both’ (1). Furthermore, the extent to which these errors could be avoided resulted in the concept of ‘*preventable* adverse events’, with an eventual recognition of the contribution of pervasive systemic factors acting beyond the individual directly administering care.

Furthermore, the occurrence of preventable adverse events is not unique to any particular healthcare setting or nation and has rather proven to be a shared global reality. This has resulted in a collective sense of responsibility to realise harm-free care, and the focus on ‘patient safety’ has been endorsed at both national and international levels. The concept of patient safety rapidly evolved into an academic discipline, with research centres related to this area founded in multiple countries. A more nuanced understanding of how adverse events arise has led to a number of strategies and interventions to minimise their occurrence. Although this has borne fruit in reducing harm in some areas of healthcare delivery, certainly this success has not been seen in others.

Despite over 20 years of focused patient safety research and intervention, the burden of harm from preventable adverse events persists. In May 2019, the World Health Organisation established the World Patient Safety Day- to be marked annually on 17 September- in recognition that harm from adverse events remains one of the top 10 causes of mortality and disability, that most of these are preventable and that despite the preceding two decades of efforts to reduce harm from unsafe care, we still have a significant burden to deal with (2, 3).

1.1. Safety in Surgery

The seminal report from the Institute of Medicine, *to Err is Human*, universally acknowledged as the 'big bang' moment of the patient safety movement of the last 20 years, highlighted the magnitude of adverse events that were occurring (4). Of 33.6 million hospital admission in the Unites States in 1997, the report surmised that death from adverse events could be as high as 98,000 (almost 0.3% of all admissions)- though also adding that this may be a modest underestimation of the overall rate. Of more concern is that over half of these events were deemed preventable. The report goes on to emphasis the significance of this number, adding that even at its most modest estimates, death from adverse events outstrips those related to breast cancer or motor vehicle accidents.

Ultimately, though this report captured the interest of the public and produced some uneasiness in certain healthcare circles, it emphasised system failures as the main culprit. The report recommended a huge cultural shift, with the establishment of performance standards, standardised care processes and national accountability for safety and funding research. It also encouraged public reporting of safety incidents so that future practice can be informed by these occurrences. Moreover, the responsibility for instigating change was not only laid at the door of frontline medical and nursing teams, but also apportioned to chief executive officers of organisations, regulators, professional bodies and even Congress, as an issue of public health concern. The five-year period immediately after the report's publication demonstrated an expansion in both funding and outputs of patient safety research (5). Furthermore, the specific subject matter of publications shifted significantly, with pre-report topics dominated by malpractice and the post-report period emphasising research into organisational culture and systems analysis.

Almost simultaneously, the department of health in the UK published their report, *An Organisation with a Memory* (6). Insightfully, the report introduced the problem of adverse events in healthcare in that they '*often have a familiar ring, displaying strong similarities to the incidents which have occurred before, and in some cases almost replicating them*'- akin to the IOM's position that these issues had only previously been *'discussed only behind closed doors'*. Also much like the IOM, the position was that healthcare needed to follow the lead of other high-risk industries and draw lessons from failures through effective reporting, analysis of failures as well a cultural transformation to facilitate this without fear of blame or repercussions to staff. Riding on the wave of this collective epiphany, a number of publicly funded national organisations, such as the National Centre for Patient Safety and The Joint Commission in the USA and the National Patient Safety Agency in the UK, were established to begin examining and tackling unsafe care.

An emerging concern, however, was the particular vulnerability of the surgical patient; one of the seminal studies that contributed to the IOM study was the Harvard Medical Practice Study (HMPS) published in the *New England Journal of Medicine* as a two-part study. Led by a physician and a surgeon, the notes of 30,000 patients who received care in the state of New York in 1984 were reviewed, determining the incidence and nature of adverse events that occurred in this place and time (1, 7). In addition to providing the data for overall incidence of adverse events, that subsequently informed the IOM report's estimations, the study also highlighted the rate of adverse events in the surgical specialties, ranging from 4.1% for orthopaedics to just over 16% in vascular surgery. The range of those attributable to negligence ranged from 18% to 28%. Another critical study also included in the report, led by Atul Gawande and co-authored by Troyen Brennan of the HMPS, compounds this further by demonstrating that two-thirds of adverse events occurred amongst surgical patients (8). Like the HMPS, over half of these were deemed preventable. However, in both the HMPS and the study by Gawande et al., it was shown that surgical patients are also vulnerable to errors outside of the operating room and beyond the perioperative period. In the HMPS, 27% of adverse events occurred at the bedside. Gawande et al. reported that 12% of surgical adverse events were independent of the primary procedure itself. Wilson et al.'s 1995 Australian study also demonstrated this trend (9). Here, the authors detected adverse events in 16.6% of cases, with 51% judged as preventable. Although this study did demonstrate that operative adverse events accounted for half of all adverse events, with 44% of these determined preventable, 25% of adverse events were shown to occur at the bedside, with 63% demonstrating preventability.

Soon after in 2001, Charles Vincent et al. released two important papers that informed the landscape further. The first was a pilot case note review estimating that 10.8% of patients in the NHS experienced an adverse event, with 48% judged to be preventable (10). The second paper reviewed almost equal numbers of surgical, medical and orthopaedic patients' notes and demonstrated that errors linked to ward-based care account for 53% of all preventable errors (11).

However, though errors were occurring both in the peri-operative and post-operative points of the surgical patient's care pathway, it is unsurprising that the initial focus was on the peri-operative period due to the nature of the speciality. The reason for this was two-fold: firstly, errors within the operating room can be immediately damaging, such as wrong site surgery, and evident. In addition to the harm to patients, intra-operative errors can have a devastating effect on the psychological well-being of all staff involved and undermine the patient-healthcare provider interaction (12, 13). Furthermore, these events can impact the financial well-being and reputation of institutions involved. A 2006 study of closed malpractice claims related to surgical care demonstrated that 75% of cases brought forward related to care in the peri-operative period (14). In addition, this study- which included over 250 case reviews – was able to identify that in the majority of these cases, the events that led to that error were as a result of systematic failures, thus reinforcing the theories put forward in the IOM's report, but making it specific to the surgical setting.

Secondly, as all aspects of care within the operating room are focused on the performance of one task (the operation), it lends itself to a focused examination of errors and how they may have been allowed to occur. Researchers have been able to draw parallels between the procedures that occur in this environment before, during and after surgery is performed and the procedures of other high-risk settings, such as aviation. Here, an appreciation of the role of human factors has made errors a rarity. Successful adoption of some of the strategies used in aviation to maintain safe air travel has resulted in improved safety in aspects of care delivery within the operating room.

1.2. The Role of Human Factors

Since its endorsement in both the Institute of Medicine (4) and Department of Health (6) reports, healthcare has attempted to emulate the application of human factors by aviation and other high-risk industries to reduce error. James Reason studied these industries- specifically US Navy nuclear aircraft carriers, nuclear power plants and air traffic control- and illustrated in his 1990 publication, *Human Error*, how systematic flaws culminate in potentially devastating error (15). Although multi-layered defences existed, flaws in each layer could align perfectly rendering those defences impotent- a concept that is now instantly recognisable as the aptly named '*Swiss Cheese model of Accident Causation*' as demonstrated in figure 1.1 (16, 17).

Furthermore, Reason separated active and latent failures. Active failures are immediately evident, such as human error that garners interest and is invariably apportioned blame. However, these are usually influenced by the latent failures, as illustrated in figure 1.2, which are the subtle and ever-present cracks in the system whose origins lie in decisions made at an executive level (18).

Figure 1-1: James Reason's Swiss Cheese Model of Accident Causation

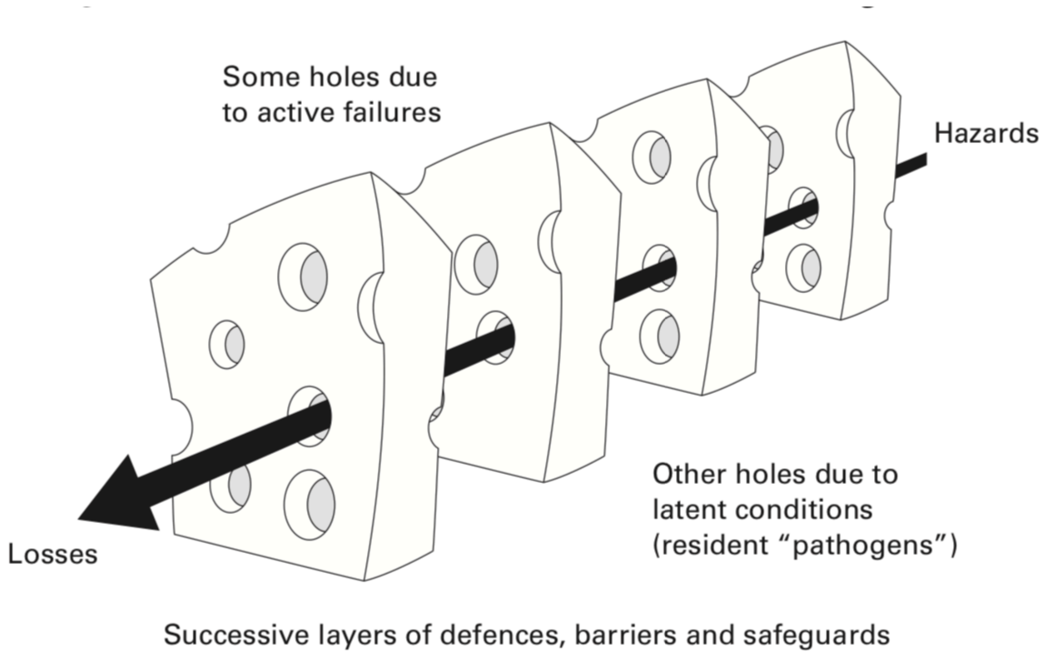
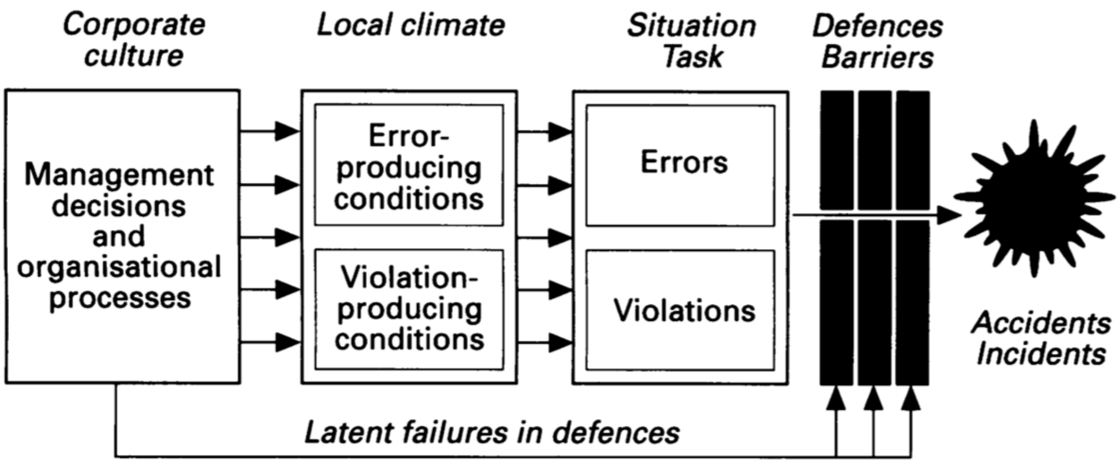


Illustration from Reason, et al. 2001 paper, **Diagnosing "Vulnerable System Syndrome": an essential prerequisite to effective risk management** Quality in health care : QHC. 2001

Figure 1-2: James Reason's illustration of the stages of development of organisational accidents



Taken from Reason, 1995 (18)

These high-risk organisations, unlike healthcare, deliver their services with relatively infrequent failures. Though similar in complexity and dynamism, these industries boast comprehensive integration of human factors principles into daily processes and interpersonal interactions. Human factors as a model has many recognised definitions, but at the centre is the understanding that human fallibility is almost certain, and thus the environment and organisation within which humans are undertaking tasks or processes must be addressed to mitigate error (19). Strategies such as prescriptive checklists, crew resource management, simulation training, incident reporting and confidential feedback from staff on organisational adherences to safe practice are embedded in these industries (20). Many of these strategies have found a role within the peri-operative care setting.

1.3. Lessons from the operating room: the integration of human factors

1.3.1.Standardised care

Processes within the operating room paralleled those of aviation and the nuclear industry- before the commencement of the surgery itself, there is an opportunity to ensure all appropriate checks have been performed to prevent error. Thus, the first adoption of a human factors strategy was the surgical checklist. The mandate for checklists in aviation itself can be traced back to a crucial incident in 1935, when a technical oversight led to the crash of a Boeing aircraft during a military demonstration (21).

Around the time of the IOM publication, the newly established National Quality Forum outlined a list of surgical 'never events'. These included surgery on the wrong site, wrong patient or the wrong procedure as well as an incident of retained foreign material or intra-operative/immediate post-operative death in a patient who is ASA class 1 (22). Along with the Joint Commission on Accreditation of Health Care, wrong-site surgery was later labelled as a ‘sentinel event’, and was subject to national reporting; a similar approach was also adopted in the UK (23).

As reporting started to gather pace, the incidence of sentinel events was higher than anticipated, and even then, deemed likely to still be an underestimation of the true extent. In response, the Universal Protocol- a checklist- was released by the Joint Commission as part of their National Patient Safety Goals. The Protocol consisted of essential sign-post moments before the initiation of surgery; firstly the pre-procedure verification to confirm the procedure, patient and site as well confirmation of available resources to conduct the procedure; secondly marking of the site and finally the time out immediately before commencing surgery (24). The final step involved all care providers participating in the procedure and served to confirm the fidelity of the information provided in the first two steps.

However, despite widespread adoption, wrong site surgery has still not been eradicated. The potential reasons for this are myriad, but include unstandardised marking practices and failure of the involved team members to engage fully in the process, so-called ‘checklist fatigue’ (25). Later, the WHO gathered stakeholders from around the world to discuss safety during surgery, culminating in the 2009 publication, *Safe Surgery 2009: Safe Surgery Saves Lives* (26). Various processes in delivering peri-operative care were evaluated, and a prototype safety checklist for local adoption and adaptation was introduced that incorporated the Universal Protocol. In addition to a checklist, the guidelines addressed other areas of safe practice, including processes to minimise skin infection, improve instrument counts, and brought a focus to team culture and communication.

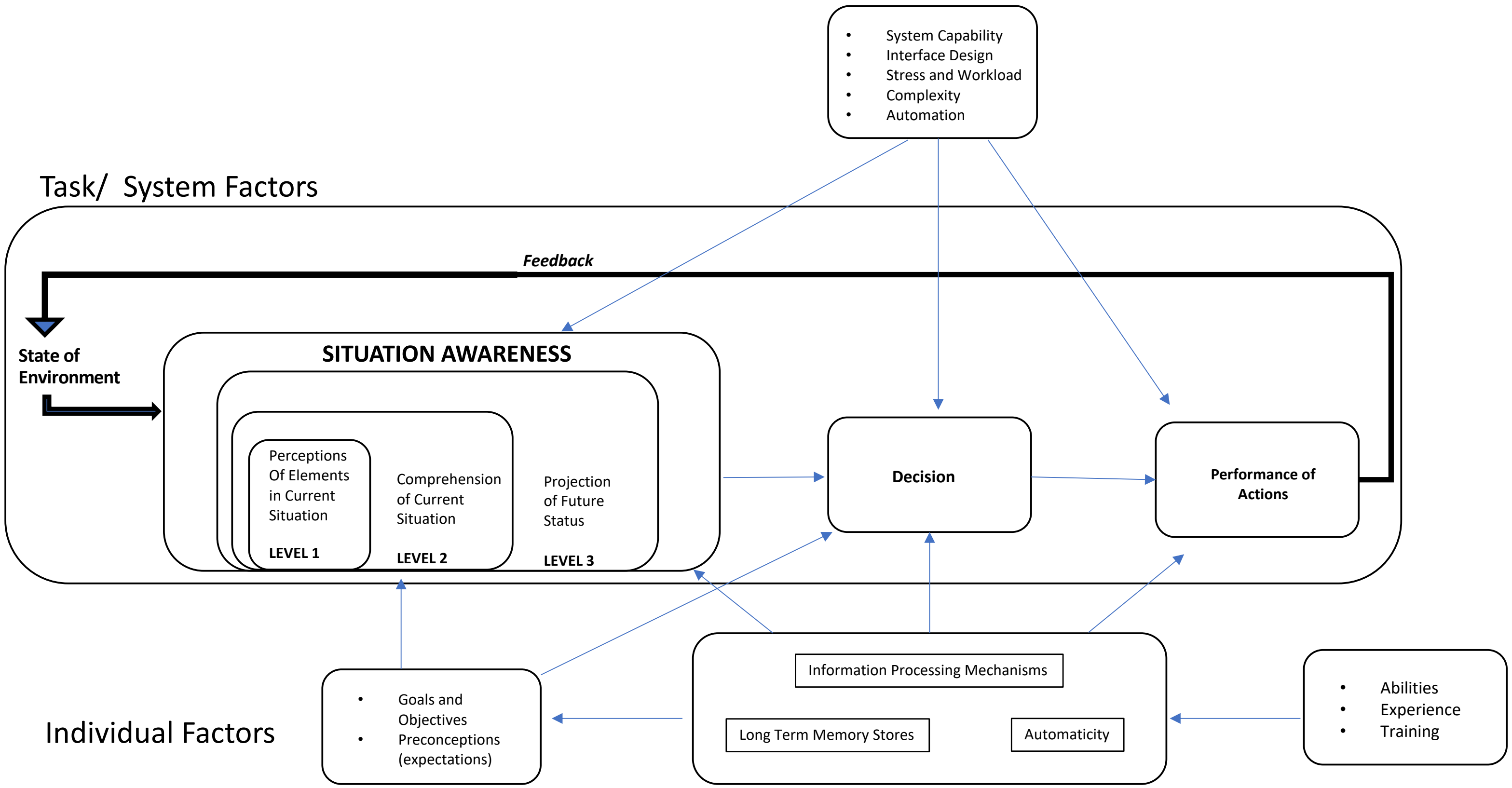
The WHO checklist was generally proclaimed as a success (27, 28) but this was not replicated in all systems (29). Although a useful tool, the context within which it was deployed became relevant (30, 31). For example, an Australian study published in 2013 demonstrated that the checklist was only correctly utilised in 10% of cases; in more than half of the observations, all the required team members were not present and in three-quarters of the time, the anaesthetist's portion of the checklist was left incomplete (32). Challenges identified were external pressures including audits of theatre start time, overbooked sessions and demand to maintain workflow. In other parts of the world, the lack of communication between surgeon and anaesthetist was also noted, as well as a perception of the checklist as an added burden to established workload (33). As demonstrated by the Safe Surgery 2015 South Carolina Programme (34) and the Quality Keystone ICU Project (35), success was noted where checklists were introduced on a vehicle of education, training and support. Although standardisation of care is promising, other aspects of the human factors paradigm needed to come into play to swing the pendulum of safety.

1.3.2. Non-technical Skills

Within the operating room, the key factors that dictate safety of care delivered lay beyond technicalities of task completion by the surgeon or anaesthetist. As had already been well-established in aviation, the communication between personnel, leadership, resource management and decision making played a significant role in the successful completion of any task without error. An additional important aspect is situational awareness- constituting an individual's perception of their predicament and the potential outcomes of their action in the context of their setting. As Endlsey says of situational awareness (36), it '*represents a level of focus that goes beyond traditional information processing approaches in attempting to explain human behaviour in operating complex systems*' (figure 1.3).

More astutely, Endlsey highlights that loss of situational awareness can occur even while following a standardised protocol, citing the tragic targeting of a commercial aircraft by a Navy cruiser - having been erroneously identified as hostile, the protocol for such encounters was then followed leading to a disastrous outcome.

Figure 1-3: Adaptation of Endlsey's Model of Situational Awareness in Dynamic Decision Making (Endlsey, 1995)



In aviation, the development of the Crew Resource Management (CRM) training sought to address human factors and situational awareness. Developed in the 1970s, CRM has gone through iterations from an initial generalised concept with non-aviation scenarios to illustrate ideas, to prescriptive curricula incorporating specific learning objectives, protocols and utilising scenarios embedded in aviation (37). Further, CRM has been established as an integral element of training, revisited repeatedly over the course of career development.

In healthcare, this had not been the case. However, in the UK, the unexpected death of a young woman and the aviation expertise of her grieving widower intersected to bring human factors to the forefront. In 1995, Elaine Bromiley was admitted for routine sinus surgery. However, in the anaesthetic room, three senior anaesthetists were confronted with the 'can't ventilate, can't intubate' scenario. Despite the surrounding team's increasing concerns, suggestions of a tracheostomy from nurses went unheeded. Following an investigation into this event, the list of contributing factors- including the obstructive nature of hierarchy and the loss of situational awareness of the senior clinicians- was recognisable to Martin Bromiley from his pilot training (38). Bromiley set up the Human Factors Group, amalgamating the expertise of people from industry, healthcare and academia, to advocate for the role of human factors training in healthcare. Although human factors had been considered in to *Err is Human* a decade before this group, its manifestation in healthcare up until the early 2010s had been evolving rather than established.

A boon of research into the non-technical elements of surgical practice in the last 10 years has demonstrated that these factors predominately account for errors in the operating room, and included communication breakdowns, excess workloads, interruptions and distractions (39-

42). Furthermore, the development of adverse events was a result of a chain of errors, a phenomenon clearly described by Reason. Even when errors could be deemed to be the result of inexperience or poor judgement, deficiency in systemic factors were shown to potentiate and compound these errors.

A number of tools to improve teamwork within the operating room and to measure its quality were developed (43-46) and the analysis of the effectiveness of these measures has been at times positive, with reduced medical error and improved patient outcomes (47). However, it has not resulted in uniform change amongst healthcare professionals, possibly as a result of resistance to change existing culture, or difficulty overcoming hierarchal barriers (44).

1.3.3. Transforming a culture

It is now widely accepted that although interventions such as checklists have been integral to reducing untoward events occurring, the overall 'safety culture' that they are delivered within dictates their success. Safety culture, a term first used by the International Atomic Energy Agency after the disastrous events of Chernobyl, has been defined by the Health and Safety Executive (48) as the:

> *'product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determines the commitment to, and the style and proficiency of, an organisation's health and safety management.' (page 3)*

In the last 10 years since the release of the WHO guidelines, there certainly has been a cultural shift within the operating room; an analysis of barriers to successful implementation emphasised the importance of the context within which the intervention is introduced (49). Pivotal elements include clinician- led utilisation and the associated leadership, as well as local adaptation to make the process relevant to the specialty and team, was shown to create a sense of ownership, engendering improved adherence. However, overall, healthcare has not attained the maturation of the aviation or nuclear industries with respect to safety culture. Tools to measure safety culture such as the safety attitudes questionnaire have been developed but changing the culture has been slow (50).

The Health Foundation attempted to collate evidence to characterise the cultural barriers to implement safety measures in the NHS (51). Multiple themes emerged both at a local and NHS-wide level. Locally poor leadership styles (lacking a clear shared vision or accountability for improvement or the existence of a hierarchy), resource poverty and poor use or communication of available information were implicated as well as an overall ongoing culture of blame and defensive practice. At the national level, serial reforms and restructuring, frustration with perceived political rhetoric and a disconnect between the focus of policy makers and healthcare professionals have been described.

Many key issues preventing the transformation of the safety culture in healthcare still persists- in the operating room and beyond. In 2018, the Care Quality Commission acknowledged that though the occurrence and reporting of never events presents an opportunity to learn where failures in the processes of care where occurring, the fact that the rates remain static speaks volumes of how errors are perceived and treated within the NHS (52). Further, much in the human factors and safety culture vein, the efforts of frontline staff under a potentially unsupportive setting are acknowledged. Additionally, a lack of education or understanding of human factors by staff may hinder the progress of safety initiatives, along with the more prevailing themes at the national level identified in the Health Foundation report.

1.4. Error in Ward Based Care

Unlike the operating room, the ward environment is a more heterogenous and relatively nebulous environment, with inter-institution variation in local policy and structure, performance of processes and subsequent variations in outcome. As outlined earlier, the post-operative ward environment accounts for the lion's share of inpatient medical time and errors. For the surgical patient, care in this phase of the inpatient stay appears to be the main determinant of overall outcome.

1.4.1. Accounting for variation in Ward Based Care- Failure to Rescue

In 1992, Silber and colleagues set out to understand if the factors that predict mortality differ from those that predict complications (53). They described failures as the proportion of mortalities amongst patients who experienced complications, with these deaths labelled as a 'failure-to-rescue' (FTR). This milestone study helped to establish the existence of variation in post-operative recovery after surgery at an institutional level. FTR evaluates, with high fidelity, the qualities of care received in the post-operative environment.

Building on this, Ghaferi and colleagues compared risk-adjusted mortality rates nationally for patients aged 65-99 undergoing one of six major procedures associated with significant risk of operative mortality (Silber's study included cholecystectomies and transurethral prostatectomies only) and found similar associations between FTR and certain hospital characteristics (54). Though there was no discernible variation in complication rates, the FTR rate was up to three times higher in the worst performing hospitals than the best. Factors identified include failing processes (failure to recognise evolving complications) and structural shortcomings (nurse staffing levels, hospital size or availability of intensivists and other specialist care). Further studies have found similar associations with such factors (55-57).

FTR was swiftly incorporated as an important quality indicator by the Agency for Healthcare Research and Quality (AHRQ) and became one of the patient safety indicators (58). With the value it offers, many research groups have now used FTR as a quality benchmark to understand care in the context of a number of organisational properties (56, 59-61). Further, FTR has spawned subgroups such as FTR-A (certain complications), FTR-S (all surgical deaths) and FTR-L (abnormally long hospital stays counted as FTR) as well as FTR-N (FTR in nurse sensitive complications) to better examine the underlying reasons for variations in specific outcomes.

1.4.2. Escalation of Care

The process through which a patient with a complication is brought to the attention of clinicians has also been scrutinised, especially as FTR gained prominence. However, this escalation of care is impeded by several barriers (62). Many of these barriers fall into the human factors paradigm, such as rigid hierarchical clinical team arrangements which may promote communication breakdowns by diminishing the confidence of junior medical staff or nurses to raise the alarm (63). The development of early warning scores, therefore, not only served to facilitate the recognition of the unwell or deteriorating patient, but also provided an agreed prompt for when senior clinical input should be instigated (64, 65).

However, similarly to the interventions introduced within the operating theatre and the peri-operative period, the effectiveness of a protocolised approach to the unwell patient can only succeed when embedded in a positive safety culture; interventions are merely the vehicle by which an engaged and motivated organisation can direct improvement in care quality and safety (66, 67).

Other barriers to escalation of care identified include a range of other non-technical skills in addition to the communication barriers described. Studies that focus on the process of recognition of unwell patients demonstrate that these can be influenced by the experience or knowledge level of nurses, the level of familiarity between the nurse and patient as well as the team dynamics that allow for involvement or aid from more senior members within the nurse's team when required (68-71). Situational awareness is also another key area that determines response to deterioration (72). Additionally, the influence of organisational and environmental factors has also been implicated (73, 74).

With this increased appreciation of the complexity of care delivery, and how errors may arise, it becomes vital to also address how quality is therefore best measured. Measures need to be more granular, and thus more directly relatable to the care environment's variable conditions.

1.5. Quality Metrics in Healthcare

1.5.1. Morbidity and Mortality

Traditional quality metrics focus on patient outcomes – primarily morbidity and mortality. These concrete endpoints, relevant to the patient and the healthcare provider in their visible effect, have been shown to be too coarse to detect the subtle variations in care quality at the local level, which may otherwise only be measured through large multicentre studies (75). A move to more practical and informative measures that can help inform future policy around care quality is a developing area.

1.5.2. Length of Stay and Hospital Readmission Rates

Length of stay and hospital readmission rates have long been used as a surrogate for care quality, with an association to patient outcomes demonstrated in some cases (76, 77). However, more pertinently, there is a tangible financial burden to these occurrences, and their reduction presents a significant cost saving measure. In the United States, the 2007 report to Congress released by The Medicare Payment Advisory Commission proposed a two-pronged approach to reduce readmission rates; firstly by promoting public reporting at the institutional level, as well as incentivising reduction of readmissions either through penalising under performers or rewarding good performance (78). Overall, there was a responsive drop in readmission rates in the 5 years following this proposal (79). However, there are several issues with the use of readmissions in particular as a quality indicator; firstly, there does not appear to be a direct relationship between readmission and mortality, and thus the impact of this metric on overall care quality is difficult to determine (80). Secondly, the use of this metric may unfairly penalise vulnerable communities, where readmission reasons maybe complex and beyond what could have been achieved prior to discharge (81). Finally, the inclusion/exclusion criteria have allowed some creative licence in how patients are managed; as patients admitted for observation are excluded in the readmission data, clinical decision units for patients who need less than a 24- hour period of observation have sprung up in association with emergency units (82). Interestingly, the development of these units has not decreased overall readmission rates.

However, although these metrics serve a broader purpose- namely monitoring of institutional performance and inter-institution comparisons- their lack of granularity makes them removed from understanding how this relates to local care quality specifically.

1.5.3. Patient Safety Indicators

Patient safety indicators (PSI) were developed by the Agency for Healthcare Research. They are a collection of complications across multiple medical specialties, identified through literature review and expert opinion, that are deemed to be potentially avoidable patient safety events (83). This includes, for example, pressure ulcers and death in low-mortality diagnoses. Therefore, PSIs not only serve as a performance metric but are also events that merit further investigation, allowing for exposure of precipitating factors that may be remedied to prevent future events (84). In the United States, the measurement of PSIs has been used to financially incentivise institutions to reduce their rates. In addition to non-payment for the treatment of PSIs, the Centres for Medicare and Medicaid Services introduced a 1% penalty on the bottom 25% of institutions with the highest rates, although there have been suggestions that rate of reports of PSIs do not necessarily correlate with poor care (85).

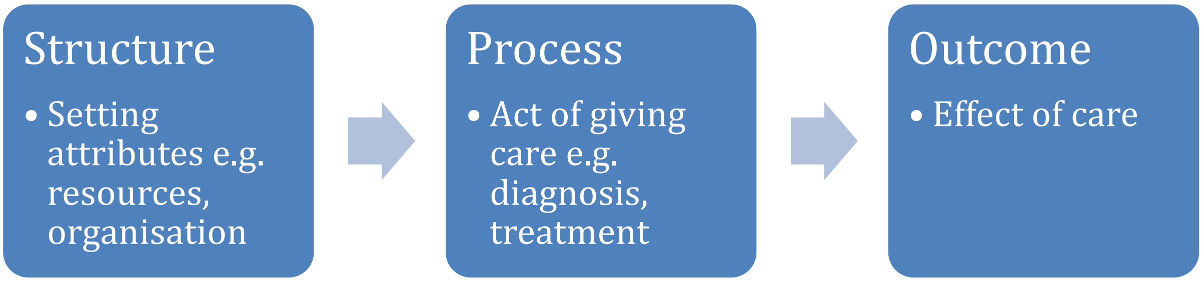
Compared to simple mortality and morbidity data, the focus on measuring potentially avoidable events allows for a more directly relevant evaluation of the quality and safety of care provided by an organisation. However, in terms of immediately understanding where failures are occurring, measurement of PSIs can only highlight the level of harm that is occurring in an institution.

1.6. The Donabedian Model: Consideration of process and structure as well as outcome

Avedis Donabedian considered the measurement of quality in the phase of the evolution of the task rather than the final outcome alone, with focus on structures and processes within healthcare delivery as illustrated in figure 1.4 (86, 87). Although ultimately, patient outcome is the most important representation of safe and effective care, Donabedian recognised that examining the decisions that are made about resources (organisation and environment) and how this dictates the actual steps in task completion during administration of care (process) is the most pertinent path to understanding how these outcomes are ultimately affected. Donabedian summarises the value of this approach in his 1988 paper (87), simply stating that '*good structure increases the likelihood of good process, and good process increases the likelihood of a good outcome*'. Measuring these areas, of process and structure, is thus a more immediately relevant way of measuring care quality.

Donabedian's conceptual model of structure, process and outcome has since been adopted to study care quality in a wide range of healthcare settings and of varying scales. It can be used to assess one discrete area of service provision e.g. facilitators and barriers to nurses regularly rounding on their patients (88), to an overall assessment of a system of care delivery, such as an evaluation of trauma services (89). This conceptual model can therefore uncover key elements that are ultimately contributing to poor process performance and thus potentially resulting in poorer outcomes.

Figure 1-4: The Donabedian Model for Measuring the Quality of Care



Consideration of aspects of structure and process when working backwards from the occurrence of an adverse event has also proven integral to understanding where errors in care may occur. Utilising human factors centric ethos, Vincent and colleagues built on Reason's model of organisation accidents and developed a framework for analysing risk and safety in healthcare (90). The authors produce a scoping tool that allows for analysis of factors ranging from the financial circumstances and primary goals of the whole organisation to the motivation levels of individual staff members (figure 1.5). Later frameworks, such as the Systems Engineering Initiative for Patient Safety (SEIPS) go one step further and describes the 'work system' under which care is undertaken and explores how elements from each of the structure-process-outcome paradigm may modulate one another, as demonstrated in figure 1.6 (91). This also includes the physical qualities of the environment- such as layout, space, noise etc- and available technology, in addition to other aspects of structure. Additionally, multiple elements within the work system may be sub-optimal and require simultaneous consideration. Finally, the SEIPS model also considers the role and/or importance of employee and organisational outcomes alongside patient outcomes.

Figure 1-5: Vincent et al.'s Organisational Accident Model (modelled on the work of Reason)

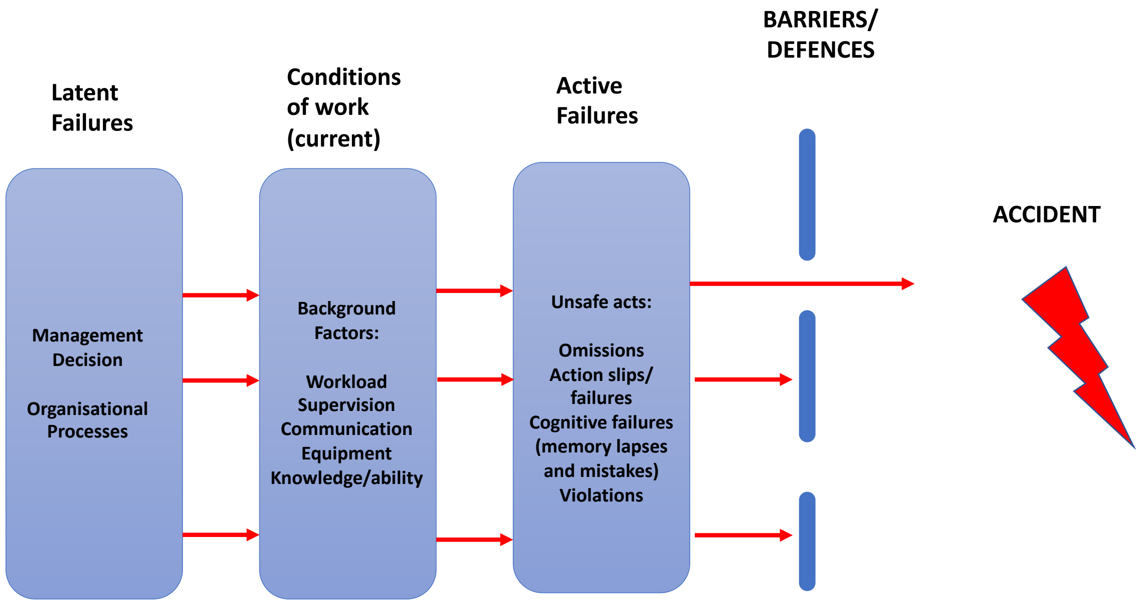


Figure adapted from Vincent et al., 1998.(90)

Figure 1-6: SEIPS model of work system and patient safety (figure from Carayon et al., 2006)

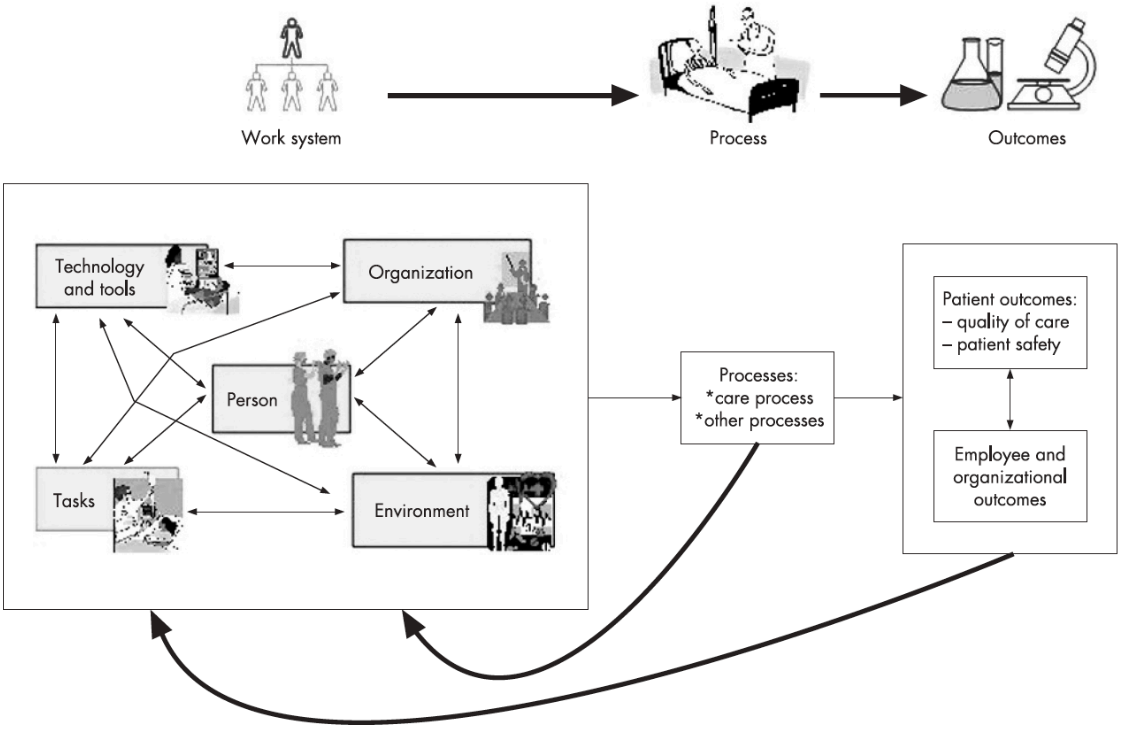


Figure taken from Carayon et al., 2006.(91)

1.7. Patient involvement in care quality metrics

There has been an increasing focus on patient involvement in safety research. Initial involvements have been fairly rudimentary, with a reliance on feedback on experiences. These range from the simple ‘Friends and Family Test’ to the Patient Reported Outcomes Measures (PROMs). The friends and family test first introduced in 2013, remains a staple NHS quality metric, with monthly reports broken down by services and individual organisations, with the percentage of patients who would recommend or not recommend the service quoted (92). However, concerted focus on ensuring data is collected and submitted as well as ensuring a favourable overall opinion, which may introduce selection bias at the front line, due to the mandatory nature of the test has been seen as problematic; it occupies the attention of local teams and may distract from more fruitful quality improvement activities (93).

Probably a more insightful measure that utilises patient feedback are PROMs; originally this focused on four core procedures (hip replacement, knee replacement, varicose veins and groin hernia surgery) but is now streamlined to the two orthopaedic procedures. PROMs probe the effect of treatment on symptoms, quality of life, and functionality. PROMs have been shown to inform policy change; for example, PROMs data has shown better responses with certain techniques, and pairing with the National Joint Registry, informed implant use (94). Again, PROMS as a metric also suffers with some limitations including how best to inform practice, how to analyse the data and the generalisability of findings (95).

1.8. The Current Status of Patient Safety 20 years on- are we still Erring?

Undoubtedly, there has been a cultural revolution within healthcare with respect to how we tackle safety since the IOM and Department of Health publications. As outlined thus far, research to explore the root causes of error has resulted in the establishment of quality metrics that not only allow for comparisons but can also instigate improvement strategies. At the time of submission of this thesis, evidence indicates that safety in inpatient care still remains a timely issue. The oft quoted number, that 10% of patients in hospital experience adverse events (96), has not greatly changed (97). In addition, a recent NCEPOD publication, *Themes and Recommendations Common to all Hospital Specialties,* published in 2018 highlights poor patient outcomes and even death, as a result of the effect of relatively easily modifiable factors; for example, lack of senior clinician input, multidisciplinary input, and failure to recognise a deteriorating patient (98). Key issues remain rooted in organisational failures e.g., the availability of intensive care and critical outreach teams, lack of protocolised care delivery etc. Furthermore, although gradual quality improvement has helped reduce the rate of complications and associated mortality (99), there is variation in the rate of improvement between institutions (100). The reduction in mortality for the best performers appears to stem mainly from a reduction in failure to rescue, indicating a likely focus on improving processes of care.

Moreover, a wide variation in safety and basic standards in care quality exists. The disastrous failures at the Mid Staffordshire Foundation Trust (revealed by the 2013 Francis enquiry) were rooted in failures at every point of the human factors paradigm- a culture of blame, poor leadership, chronic understaffing, disengagement from patient-centred care- and has served as a tragic watershed moment that crystallised why a sweeping cultural change is necessary (101).

1.9. Summary

Ward-based post-operative care is yet to achieve full optimisation with respect to the delivery of safe care. The last 20 or more years of patient safety research has successfully demonstrated that the lion's share of safety incidents involving the surgical patient is occurring in the post-operative environment, as well as exhibiting that there is institution-level variation in care quality. Although a rich landscape of health services research exists, with emphasis on human factors, there is a lack of concentration of research to characterise how wards vary and the potential process- and structural based metrics that can be derived to guide future quality improvement initiatives.

1.10. Hypothesis

There are multiple factors contributing to the overall risk of errors or adverse events during ward-based care of the surgical patient. These factors span both the process and structural arms of the Donabedian Model, and key areas of this environment have been interrogated. However, it is likely that these factors are acting in tandem in creating this risk. Therefore, ward-based care must be assessed in its entirety to better understand the interactions and contributions of these various elements. Key factors – if variable and measurable – may present new care quality metrics to assess safety at the unit-level.

1.11.Thesis Aims

This thesis presents an analysis and evaluation of ward-based post-operative care, with the intention of fully assessing all aspects of this environment and determining which factors are likely to be contributing to error in this period of care. Ultimately, metrics of care quality will be derived from this investigation.

The specific aims are:

1. To identify, prioritise and aggregate the key contributors to error in ward -based care of the surgical patient, by assessing the processes of care and the organisational constructs within which that care is delivered.

2. To observe the surgical ward in real-time, assess sources of variation and derive measurable metrics rooted in ward-level processes and structural factors.

3. To develop a statistical model of risk of harm using these real-time quality metrics through a proof-of-concept study using routinely collected administrative data.

1.12. Thesis outline

To achieve the aims proposed, the thesis is structured as follows:

- Chapter 2 examines the relevant literature to determine aspects of ward-based care that have been characterised. These findings are aggregated to build an overall understanding of this environment. This is achieved using a framework for analysis of critical events.

- Chapter 3 is a semi-structured interview study conducted across multiple NHS sites and involving 51 participants. This work explores the experiences of members of the nursing, clinical and management teams- as well as that of patients themselves- to understand the barriers to the delivery of safe care.

- Chapter 4 is a Delphi Consensus study involving an international panel of patient safety experts and advocates. This work seeks to organise and focus further research on the most pertinent of themes. This study informs areas to investigate in the next chapter.

- Chapter 5 is an observational study using ethnographic methodology. Factors prioritised in Chapter 4 are assessed for their variability and measurability, and their suitability for real-time measurement.

- Chapter 6 uses validated questionnaires to assess the role of patient- and nurse-reported outcomes of care quality as potential adjunct metrics that can be used alongside objectively measured quality markers identified in Chapter 5. This study was run alongside the observational study.

- Chapter 7 uses administrative data to establish if the quality markers identified in Chapter 5 offer the potential to be real-time metrics of care quality using statistical modelling on routinely collected administrative data.

- Chapter 8 summarises the key points from this body of work, along with potential implications for policy design and interventions, to improve safety of ward-based care.

2. Narrative Review: Analysing and integrating what is known about the factors that influence patient safety during ward-based care.

2.1. Introduction

Deficiencies in care affect patient safety, care quality, and outcomes (102). Variance in surgical post-operative care is known to be a major contributor to differences in clinical outcomes. In particular, ward-based care is subject to multiple forces and interactions that may be antagonistic to safe care. Existing studies have focused on several aspects of post-operative care including staff- (61, 103-105), process- (106) and organisational-based factors (107-109). The collective effect of some of these factors may lead to negative outcomes such as failure-to-rescue (54, 56, 109, 110).

As described in the previous chapter, modern measures of care quality metrics beyond mortality and morbidity rates must be developed. Ideally, these should be granular metrics which are easy to measure, frequent enough to observe regularly, and ideally represent precursors to patient harm such that actual harm or injury may be avoided (75). Additionally, such measures may aid healthcare teams to identify local issues and address these rapidly.

Some relatively granular metrics are in use currently. For example, the AHRQ's PSIs were developed to facilitate identification of complications and specific potentially preventable events during inpatient care (83). Other measures such as the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP)(111) includes process-based measures of care and offers tools to improve performance in these (112); the program has resulted in improvement in surgical outcomes across large numbers of participating institutions (113). Furthermore, valuable insights into how structures and processes may relate to patient outcomes have been gained: the ACS-NSQIP data demonstrated that positive outliers for incidence of surgical site infections experienced lower staff turnover, greater perioperative efficiency, a positive safety culture, stronger leadership in quality improvement initiatives, and an atmosphere that promoted communication (114). In addition, survey data for 87 Veteran Affairs (VA) hospitals demonstrated an association between higher observed-expected ratios for morbidity and a number of structural variables that ranged from nursing staff shortage to clinicians' occupational requirements such as affiliation to another primary institution or school (115).

Such evidence supports that to achieve a satisfactory patient outcome, i.e., safe care, requires the knitting together of a number of factors – and that these factors are rooted in the processes of care and structure within which care is delivered. Thus, it can be argued that measuring the effective execution of processes by a determined standard (e.g., successful completion or omission, completed within an appropriate timeframe or delayed) and consideration of the work environment (i.e., stressors that may hinder this effective execution of processes) can in themselves serve as indirect measures of care quality and safety.

However, the ward is a complex unit within which several simultaneous processes occur, executed by variable team members. The large volume of work performed on quality and safety of inpatient care addresses discrete areas at a time– but what is required is a comprehensive synthesis of the data, across the whole Donabedian paradigm.

To this end, this chapter undertakes an exploration of the literature as it pertains to ward-based care. Using a critical event analysis framework, potentially modifiable factors across process, structure and outcome are identified.

2.2. Methods

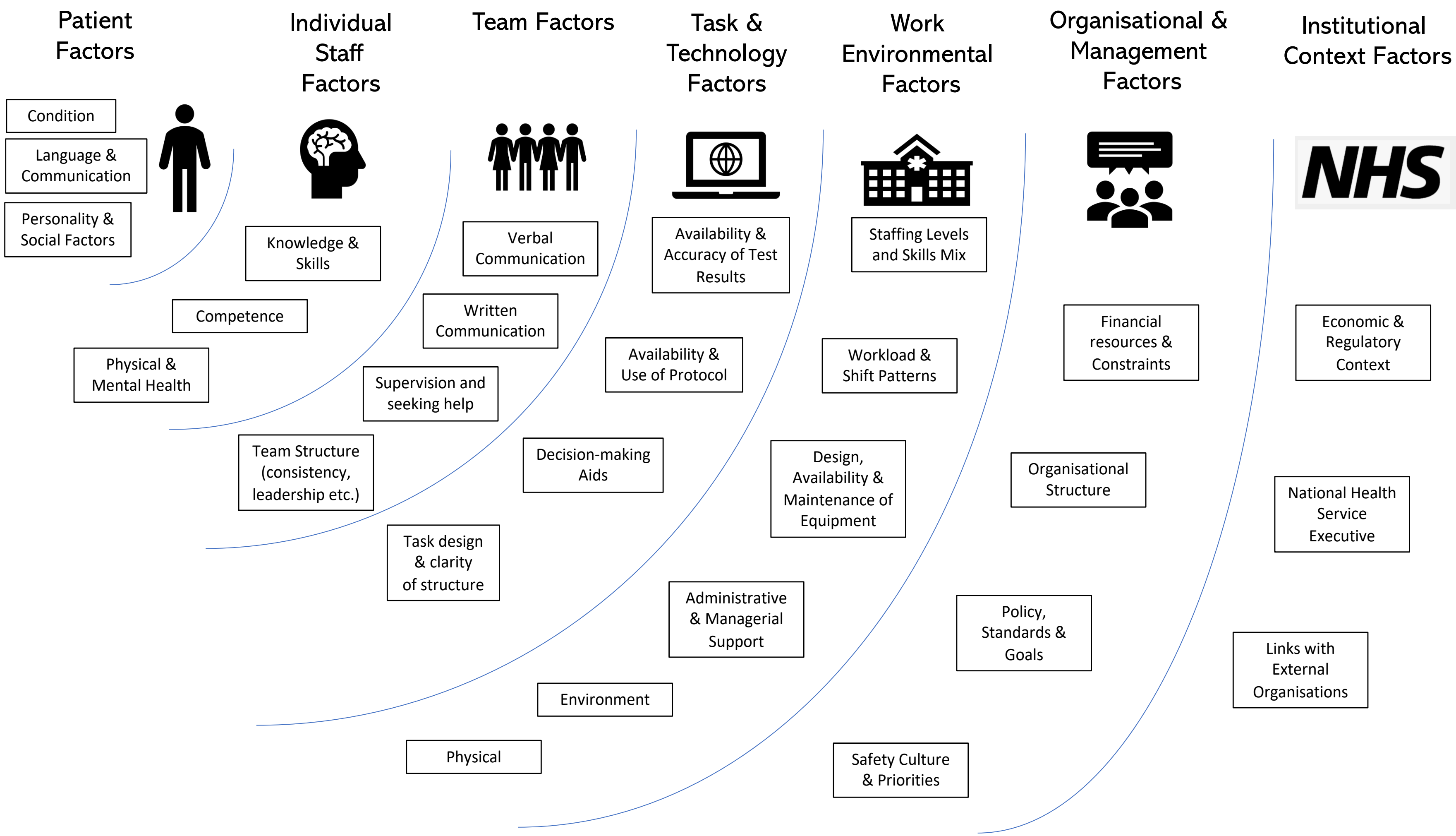
2.2.1. Search Strategy

A comprehensive literature search of the Medline, Embase and psychINFO databases was performed for the dates from inception of the database and updated over the course of the thesis up to December 2019. Search terms used were "patient safety", "harm", "medical error", "adverse event*","surg*", "risk", "dashboard", "assessment", "tool", "operating room", "ward", "morbidity", "mortality", "intervention", "prevent*", "improv*", "outcome*" References were inspected to ensure all pertinent papers were included.

2.2.2. Review Strategy

Factors in this review were considered according to domains as defined by the London Protocol System Analysis of Clinical Incidents (see figure 2.1) (116). This is a structured approach to the analysis of causes of adverse events. Originally developed by the UK National Patient Safety Agency, it has been endorsed for use by the Institute for Health Improvement (117). Contributory factors are split into five domains: individual, team, task, environmental and patient factors- with subgroups within each domain.

Figure 2-1: An illustration of the London Protocol, used as a framework to assess the contributory factors to understand the occurrence of errors (adapted from Taylor -Adams & Vincent, 1999).



2.3. Results

2.3.1. Qualities of the Nursing Team

Nurses are the bedrock of the post-operative care environment. Many of the domains of the London Protocol feature amongst or directly influence nurse- related factors. Nursing factors have been meticulously researched. Not only have individual (education level, motivation, burnout) and team factors (leadership within nursing, skill mix, use of temporary nursing staff) been examined, but also the influence of particulars of the ward environment itself (availability of technology, resources, physical spaces and their organisation) and how it may impede or facilitate good quality care.

Outcomes measures that have been employed vary, from well-established safety metrics (30-day mortality, failure to rescue, PSIs) to newly accepted ones such as nurse- and patient-reported outcome measures. Furthermore, the contribution of each of these aspects of nursing care do not only run in parallel, but also modulate one another, e.g., safety culture (organisation and management factor) can influence individual (knowledge and skill, health and well-being), team (support or training of ward leaders), task and technology (availability of standardised care pathways) as well as environmental factors. In turn- elements of an effective team (e.g., good leadership) can help the individual in the team, as well as feeding back to the organisational and managerial ranks observed deficiencies at the ward level. Specific emerging themes are examined further.

Nurse Staffing Levels

Nurse staffing has strong associations with patient outcomes (61, 105, 118-122). Needleman's seminal 2002 study published in the *New England Journal of Medicine*, demonstrated an association between increased nursing hours per patient and care quality for both medical and surgical patients (123). For both groups of patients, a greater number of registered nurse hours was associated with significantly lower rates of FTR. More importantly, this effect was seen where nursing case mix and patients' level of risk was controlled for. Contemporary studies yielded similar results (61, 120), as have more recent studies (124).

In 2003, legislation in California came to effect proposing a minimum nurse staffing level for various areas within the hospital setting; specific to medical and surgical wards, a ratio of 6 patients to each licensed nurse, reducing to 5:1 by 2005, was mandated (125). Interestingly, this represented a middle ground between the priorities of hospitals (California healthcare association proposed 10:1) and nursing unions (the California Nurses Association proposed 3:1). In the year following the introduction of the legislation, total registered nurses hours of care per patient increased by more than 20% (126). Subsequently in California, and in hospitals in other states with similar ratios, 30-day mortality and failure to rescue rates improved (127). However, other studies have used other outcomes measures, such as development of pressure ulcers and falls, and have not demonstrated such positive effects (126, 128). Despite the apparent mixed results, the effect on mortality and FTR is still replicated in even more recent evaluations of the legislation. (129, 130) However, no other state has mandated minimum numbers for general medical and surgical wards. Internationally, the state of Victoria in Queensland, Australia is one of the few places with a similar legislation, with a 4:1 daytime maximum ratio since 2001.

In the UK, nursing groups have advocated for minimum staffing levels. A survey conducted by the Royal College of Nursing in 2017 revealed that there were gross fluctuations in staffing levels with subsequent impact on nurse perceptions of care delivered (only 31% felt they delivered the care they would have desired) as well as damage to staff wellbeing (59% did not take sufficient breaks and 65% worked beyond the shift's end) (131). However, recommendations published in 2014 by NICE only guide local decision making strategies, ceding to insufficient data to make ratio suggestions. (132) Aiken et al.'s much cited study showed that postoperative mortality rates increased from 14% to 31% when nurse to patient ratios were increased from 1:6 to 1:8 (61). Thus, this is the only threshold that is explicitly mentioned as a concern in the guide. More recent work confirms that this association remains (104).

The effect of nurse staffing shortages is also demonstrated through a ward process measure-missed care. This is where nurses as individuals are pushed to prioritise tasks; this measure has robust associations with work burden and understaffing (133-135). Furthermore, this association has also been shown in post-operative care in particular (136). In a British survey, 86% of nurses reported that, on average, they were omitting four items of care due to perceived understaffing (137).

However, resistance to introducing prescriptive legislation is likely linked to a potential detrimental economic effect (mainly from US studies) as well as stifling local flexibility (129, 138). Investing in increased nursing numbers has equivocal cost saving effects from the economic benefit but reduced adverse events (139) and thus may actually result in limited financial incentive (140). Thus, local policy makers in already resource poor areas may struggle with meeting these staffing requirements, despite the safety benefit.

Nursing Skill Mix

Nurse staffing levels must be addressed in conjunction with skill mix, as nursing care is often provided by a combination of both registered nurses (RNs) and unqualified nursing staff or heath care associates. In at least one large-scale study from the United States, administrative data covering 11 states and 6 million discharges showed that increasing the proportion of RNs making up a team (as well as increasing the RN hours per day) resulted in shorter length of stay and reduced complication rates; a higher proportion of RNs also resulted in fewer cases of pneumonia, shock, cardiac arrest or failure to rescue (123). Each additional nursing hour per patient, it has been suggested, can decrease the length of stay by up to 9% (141). Additionally, studies comparing levels of education have suggested that each 10% increase in staff with a nursing degree may be associated with a decrease in 30-day inpatient morality by as much as 4% (142).

However, there is a potential advantage of the presence of unregistered nurses or similar care workers in a supportive capacity; one Australian study showed that adding such team members, who did not require formal nursing qualifications, can allow nurses to focus their time on other aspects of care (143). In this study, 'assistants in nursing' formed part of the team. In those units where these assistants accounted for 5% or more of the team, there were significantly fewer delayed responses to patient call bells and nursing care planning. To a lesser extent, there were also fewer delays in measuring routine vital signs. The assistants' presence allowed nurses to unburden themselves of routine tasks- such as housekeeping and clearing trays -and focus on direct care tasks.

Nurse Work-Related Burnout

Beyond increasing nurses' work burden and subsequent potential for errors, the chronically stressful conditions of an understaffed unit can manifest as burnout. Aiken et al. showed that those who worked in ratios of 1:8 had a two-fold experience of work-related burnout compared to those working at 1:4 (61). With this burnout comes the potential for further errors (144, 145). In addition, these stressful conditions are a contributory factor to nurse attrition, with the UK's Nursing and Midwifery Council demonstrating a net loss of nurses from the NMC register (146).

Low morale and burnout are multifactorial in their aetiology. Low staffing and training levels can contribute to this but are resource-intensive to improve. Local implementation of strategies such as visible and effective leadership in conjunction with adequate team support and empowerment may create a more encouraging work environment (147, 148).

Nurse Leadership

There is an established association between nursing leadership and certain patient outcomes including successful infection control (149) and patient mortality (150). One study specifically looking at leadership styles identified two main branches – task-orientated (45%) and relations-orientated (49%)- which were interchanged depending on the ward condition, such as staff shortages, patient flow and competing administrative tasks (151). There was a positive association between an element of these leadership styles (monitoring and recognising behaviours) and safety compliance of staff as well as decrease in severe injury to patients. However, leadership in the transformational vein significantly improves job satisfaction, organisational commitment as well as staff wellbeing, with reductions in anxiety and stress (152). Further, effective leadership may also be able to mitigate job dissatisfaction and attrition (153, 154). Focused training in effective leadership, with a concentration on communication, collaboration and fostering improvement in the working environment resulted in decrease of absenteeism by 50% (147). This approach in itself may locally halt the spiral initiated by understaffing – where difficult working conditions result in burnout and absence from work. This potentially can have a knock-on effect on patient outcomes.

2.3.2. Qualities of the Clinical Team

Unlike that of their nursing counterparts, the role of the surgical team in the delivery of ward-based care has not been elucidated as thoroughly. As noted in the last chapter, a great focus was placed primarily on the intra-operative environment. However, studies of clinician working patterns have emerged, and came into particular prominence with the case of Libby Zion - a critically unwell patient who received fatally suboptimal care (155). The effects of a punishing resident work schedule and poor senior supervision were implicated.

Clinical staffing levels and work patterns

Prolonged working hours can lead to error-prone behaviour prompting certain industries to impose limitations and allocation of appropriate rest periods (156). Similarly, prolonged duty hours and ensuing fatigue has been implicated as a factor in medical errors (157). In shifts that extend beyond 24 hours, residents are 3.5 times more likely to make a significant medical error if working 1-4 of these shifts per month (158). This increases to 7.5 times if working more than

5 such shifts. In comparing traditional 24-hour work schedules and shift-based rotas, degradation of diagnostic accuracy and increased prescribing errors were demonstrated with the former; the total rate of serious errors here were 22% higher with the traditional schedule (159). Attentional failures were also improved by decreasing the number of consecutive duty hours (160).

The introduction of legislated working time directives in North America and Europe aimed to improve working conditions, while also reducing the risk of fatigue- related error (161-164). However, the results overall have been mixed; while at least one study has reported the reduction of fatigue-related errors (157), others have failed to demonstrate any change in procedural efficiency or rates of post-operative complications with acute sleep deprivation in surgeons (165). For instance - surgeons seem to be able to maintain operative skills despite fatigue; Vinden and colleagues' 2013 study showed no difference in outcomes for laparoscopic cholecystectomies performed by surgeons who had undertaken overnight emergency operations (166). In a more recent study, Govindarajanan and colleagues evaluated a wider array of elective procedures that included in addition to cholecystectomy- gastric bypass, colon resection and a number of orthopaedic and cardiothoracic procedures. Using administrative data, the study concluded that there were no significant variations between those attending surgeons who performed elective surgery after night-time duties with regards to mortality, complications or readmission within 30 days (167). However, where rest periods have fallen below 6 hours, there was a significant association with complications (168).

The overall evidence for sleep deprivation and performance is inconclusive. A recent systematic review assessing the impact of insufficient sleep on physician and patient outcomes did not demonstrate a robust association (169). However, the potency of burnout is evident in self-reported occurrences of error (170-172). It would be prudent to consider this factor in the delivery of safe care, especially given the emphasis placed on adequate rest periods in other high-risk industries. Local practical measures need to be centred around rescheduling of on call duties, especially for more junior colleagues and senior surgeons working under more extreme pressures. Other sectors have developed ways of combating exhaustive timetables through the use of tools, such as The Fatigue Avoidance Scheduling Tool (FAST); based on an algorithm developed by the United States Army, this tools helps to identify potential sources of fatigue within a work roster and suggest improvement measures (173). The use of this tool in the clinical setting highlighted that 50% of the time, clinical residents were working on a rota that promoted fatigue; the introduction of countermeasures as a result of this tool lowered this to 1.9% (174).

Additionally, the alteration in working patterns has necessitated the development of other areas of health care; for example, the more frequent shift turnover of the new work schedule may have contributed to increased communication errors amongst clinicians and between clinicians and nurses- thus focus has shifted onto effective handover (175). Addressing this particular process, in one study, was associated with a lower 30-day risk adjusted mortality for particular patients, namely those with pneumonia (176).

Hierarchy within the clinical team

When assessed for seven relationship characteristics as outlined in the Lanham framework, patients under the care of teams that performed well experienced significantly fewer complications (177). In a further example, when assessing the process of escalation of care, communication delays (either from nurses to doctors or junior doctors to senior doctors) were frequently identified (63). It was suggested that obstacles in communication might be attributed to the presence of hierarchy, which would need to be addressed to facilitate a more efficient escalation process. The most junior of the team are frequently the first point of contact in the setting of acute deterioration. The ease and speed with which they communicate with senior colleagues will facilitate timely instigation of definitive management plans. Along with their nursing colleagues- who are often the first to recognise deviation in observational parameters- and patients who may volunteer information that may result in prompt treatment of complications, junior members of the clinical team must feel empowered in escalating care (178).

2.3.3. Institutional Factors

Safety Culture

Perhaps one of the most important considerations when assessing what influences ward safety is the prevailing cultural attitude within an organisation. An institution's preventative action against, and response to, serious adverse events is dependent on organisational leadership, resource management, teamwork and sophistication of training policy (107, 179). The presence of these qualities can significantly impact mortality (180).

When new protocols and guidelines are published, mandatory implementation may be introduced without a supporting programme to educate staff and maximise engagement. In the example of the mandatory implementation of the WHO Surgical Safety Checklist in Ontario, Canada- it is unsurprising that self-reported compliance by hospitals exceeded 90% (181). However, unlike other studies (28, 182), there were no significant improvements in mortality, complication rates or 30-day readmission after discharge. Rather than the introduction of a lone implementation (such as a checklist) to improve safety, it is rather the context within which the intervention is deployed that will allow for the change intended. As noted by one prominent safety expert, there was no evidence of local modification of the checklist in 90% of hospitals suggesting, '*team building needed for local adaptation did not occur*' (30).

Current measurements of safety culture are mainly through surveys including the Hospital Survey on Patient Safety Culture(183) or Safety Attitudes Questionnaire (SAQ)(50) completed by members of an organisation. Where a poor safety culture has been identified, an opportunity is presented to local leaders to address this head on and explore the concerns and ideas of their staff.

Availability of protocol and decision-making aids

Patient safety experts have long recognised that principles of the systems approach, as outlined in Chapter 1(18, 184). The WHO Surgical Safety Checklist has demonstrated reduced mortality and complication rates when employed with the correct supporting framework (28). The Surgical Patient Safety System (SURPASS) checklist was developed to track the entire patient journey and was also shown to reduce complication rates (185, 186). The SURPASS checklist also highlighted that a significant portion of errors occur in the post-operative environment-30% of all intercepted errors occurred at this stage (187). Further checklists for specific processes, such as the ward round (188) and handover (189) have also been developed; there is an association between standardising information delivery in this way to improve information transfer, and reducing the time taken to convey information (190, 191).

Similarly, the enhanced recovery after surgery (ERAS) programme delivers post-operative patient care through a protocol based on the best evidence-based practice for multiple processes including the use of drains and catheters, pain management, nutrition and rehabilitation (192).

Although the initial principles were not speciality specific (193), ERAS is now well-established in colorectal surgery (194) demonstrating reduced morbidity (195, 196) as well as up to a 50% reduction in complications and a 30% reduction in length of stay (197, 198). Other surgical specialties have confirmed favourable outcomes as well (199-203). However, deviation from a standardised care pathway may be required where complications have arisen. To avoid a resurgent potential for error, secondary standardised measures for common complications will need to be developed (188).

Patient ward allocation within institution

The presence of outlying patients (patients placed on wards not aligned with the specialty team leading their care) can present safety challenges; communication between the ward and the patient's specialty team can be fractured and nursing experience may be inadequate to deal with the unfamiliar clinical presentation (204). In addition, there may be issues with equipment availability to ensure adequate care and timely clinical review may not always be achieved (204).

In one retrospective study following 109 outlying patients with heart failure, outliers experienced a mean of 2.6 days longer hospital stay than those cared for on a cardiology ward (205). A further Australian study used an administrative database from a single hospital to extract details of 19,923 patients of whom 2592 were outliers; in the case of the latter, risk-adjusted in hospital mortality was increased by 40% with 50% of deaths in the outlier group occurring in the first 48 hours (206). Outliers have also been shown to suffer with higher readmission rates (207) as well as triggering more emergency calls (208).

With ever-growing bed pressures, logistics may dictate the need to house patients on outlying wards. Wherever possible, local efforts should be made to repatriate patients to their specialty ward. This will likely need active involvement of a member of staff to champion for the patient's transfer. Active involvement at the managerial level may allow for an overarching view of bed allocations to facilitate this process.

2.3.4. Physical Factors

The environment in which doctors, nurses, patients and all others may interact is also an important consideration. The interplay between ward layout, ward organisation, and the clinical working environment determines much of how patient care is delivered and increasingly plays a role in hospital and care area design.

Ergonomic and environmental considerations

Ergonomic inefficacies can cause inertia in task completion and compromise the safety and well-being of staff; poor design of nurses stations and supply areas and manual lifting of patients may all be such factors (209). Indeed the Centres for Disease Control & Prevention note that rates of musculoskeletal injuries from overexertion are more common on hospital wards than in agriculture, mining and construction (210). This in turn may affect patient safety by either impeding effective care or reducing staffing levels through sick leave. Therefore, a well-organised and ergonomically efficient ward should be pursued.

Ergonomic considerations are also important to compliance with safety measures; a systematic risk assessment of surgical wards revealed a number of ward processes that were not being carried out correctly including hand hygiene and isolation of infection (211). Although expected factors such as lack of training were highlighted, it was noted that empty dispensers and poorly designed taps were also to blame. Increased workload as a result of disorganised supplies and poor workspace design also result in the sacrifice of these safety measures to meet the demands of higher priority tasks (212).

Manipulating ergonomic factors may therefore have a role in improving patient safety in the post-operative environment. For example, employing the principle of Lean, McCulloch's group at Oxford demonstrated an improvement in compliance for five processes of safe care on a 38-bed surgical ward (106). Although it did not show a change in adverse events rates, there was a reduction in transfer to ITU or theatre, suggesting potential timely interventions on the ward as a result of the intervention.

A further study, the designing out medical error (DOME) project, involving a multi-skilled team of clinicians, designers and human factors experts, re-designed end-of-bed care stations with multiple processes in mind – including isolation of infection, hand hygiene, vitals monitoring and medication administration (213). This exercise serves as a proof of concept of how ergonomic and human-factors sensitive design can be introduced at the bedside, although creative thinking is required to deliver this within existing resources.

Finally, environmental factors such as noise may be considered as a hindrance to delivery of safe care; the WHO recommends a limit of 30 dB LAeq (equivalent continuous noise level) to avoid disruption of communication and sleep disturbance for patients (214). However, it is likely that this is exceeded regularly (215-217). Drawing attention to unnecessary noise sources and introducing 'quiet times' for certain periods may represent a simple but potentially effective intervention to indirectly improve patient safety by reducing distractors in the environment.

Ward Layout

A number of ward floor layouts exist. Modern wards consist of bays within wards, typically accommodating 4-6 patients per bay, or individual patient rooms. A combination of these arrangements is ideal in balancing infection control, privacy and ability to maintain safe nursing access. However, unlike its predecessor layout- the Nightingale wards - bay-based care increases levels of indirect care, handover times, and decreases the ready visibility of staff to patients (218). Additionally, a wide variation in occupancy of bays can result in marked fluctuation nursing work burden.

One possible compromise of the two designs is the 'racetrack' design, with bays or rooms arranged around a central hub comprised of nurses' stations and supply stores. Here, staff time is economised by the central location of facilities and is associated with reduced features of burnout such as 'time-out' and 'down-time' (219). The advantages of the racetrack design suggest further research into layout is warranted. The centrality of nursing stations also has implications for the patient experience, with increased visibility of staff being associated with improved patients' perceptions of care in at least one study (220).

2.3.5. Regional and National Resources

The role of governmental bodies that are responsible for national policies is acutely felt at the ward level. Although the overarching ethos for safe care is developed in the board rooms of the highest executive echelons, the implementation and local data collection that each new implementation invariably entails can prove challenging, as discussed in the initial chapter.

One prominent ward-based quality improvement (QI) intervention was introduced with relative, though short-lived success.

The Productive Ward

The Productive Ward initiative was first launched in 2007 by NHS England to empower frontline clinical teams to improve their ward, using the lean philosophy (221). The programme consisted of several modules tackling care processes and the immediate ward environment and its arrangement with accompanying guidance for specific team leaders (ward, project and executive leaders). A toolkit was also included. The initiative was widely reported to have increased time for care, cost efficiency, patient experience as well as improving the morale of staff, as demonstrated by increased satisfaction and reduced sickness (222).

Facilitators to the initiative were noted; firstly as this was a national initiative, ward leaders at the local level felt they had enough support to request the resources suggested within the programme, whilst at the same time being confronted by staff who may already be working under existing constrained pressure and are unable to muster enthusiasm to participate (223). However once buy-in was achieved, incremental improvements were being made in patient flow. Additionally, enthusiasm was facilitated by the voluntary, rather than mandatory, nature of the initiative.

The long-term results of the Productive ward demonstrated that the initiative was sustained for an average of 3 years , with some residual effect on practice, although the external and internal executive support had discontinued as new QI projects come to the fore (224). This in itself highlights the dynamic and sometimes impermanence of national policy. It is difficult to understand why the Productive Ward was not sustained as a long-term intervention considering its promising staff engagement, effect on performance and low resource requirements (225). Furthermore, the human factors elements which are yet to be embedded into NHS culture were effectively demonstrated within the Productive Ward Initiative. A potential revival is currently being explored in collaboration with King's College and may be a welcome development in the current conditions (226).

2.4. Discussion

Patient safety and patient care is a complex process influenced by both process-driven and structural factors. These factors enjoy complex relationships that have a synergistic effect on care quality and safety and require a systems approach to their assessment to optimise patient care. This review has identified key factors amenable to local change, which may contribute to improved patient outcomes, and described the underlying evidence base for each (see table 2.1).

It is clear that interventions to improve safety on the surgical ward must go beyond the manipulation of factors in isolation.

Table 2.1: Summary of key factors that inform safe care on the Surgical Ward, categorised by the London Protocol, and potential amenability to improvement at the local level

Amenability to Quality Improvement within Existing Resources	Patient Factors	Individual Staff Factors	Team Factors	Task & Technology Factors	Work Environmental Factors	Organisational & Management Factors	Institutional Context Factors
Fully	***Outlier patients*** *(re-allocate to specialty specific bed as a matter of priority)*	***Nurse Motivation Nurse Burnout*** *(transformative leadership)* ***Junior Clinician Confidence*** *(flattened hierarchy)*	***Nurse Leadership*** *(local training initiatives)* ***Hand Hygiene/ infection Control Measures*** *(Productive Ward Initiative)* ***Clinical Leadership*** *(flattened hierarchy, relationship characteristics)*	***Standardised Care Processes*** *(Introduce established checklists/ protocols e.g., SURPASS, ERAS)*	***Re-organisation of storage/ supplies*** *(Productive Ward Initiative)* ***Ward Layout*** *(reorganise location of patients depending on acuity with respect to ward layout)* ***Noise distraction*** *(Scheduled quiet times on ward,*	***Overall Safety Culture*** *(transformative leadership, engagement at managerial/ executive level with QI initiatives, executive division engage with frontline stuff to empower team to participate in QI)* ***Response to adverse events*** *(Employ human factors critical analysis to understand systemic failure)*	***Established online resources and learning tools*** *(Productive Ward Initiative)*

					address noisy equipment/ doors)		
Partially	*Work burden/ Patient complexity* ***(Employ "Lean" approach to streamline specific care processes e.g., IV administration)***	*Nurse Training* ***(local initiatives, freed from ward duties for training days)***	*Establish generous nursing skill mix* ***(use of e-rostering technology to plan existing work force)*** *Clinician working pattern* ***(Comply with minimum rest times as per legislation)***		*Human factors-based redesign of certain ward areas* ***(modest budget, human factors expertise if exists within organisation)***	*Resource Management* ***(Redistribution of resources, review budgeting for ward needs)***	
Not Amenable		***Nursing Education Level*** *(Recruitment criteria)*			***Ward Layout*** *(Restructuring/ renovations)*	***Improving Staff Shortage*** *(Recruitment)*	

Within the range of staff-related items identified, the shortage of nurses is widely recognised. We know that increasing nursing care is associated with improved patient outcomes (61, 118, 119, 121). However, recruitment alone is not a viable solution; firstly, poor retention of existing staff, fuelled by job dissatisfaction or burnout, is eroding numbers (227-229). Secondly, recruitment itself is expensive and may not be financially feasible for many organisations. Ironically, temporary staffing serves as the current default measure despite its extreme expense (230). An estimated £980 million was spent on temporary staffing in the UK in the financial year 2014/2015 representing a significant financial burden (231).

Therefore, the initial focus must be on maintaining existing staff. Three components within the work environment have been shown to have a significant association with job satisfaction and quality of care; these are nurse-physician relations, unit level management and hospital/organisation level management and support (232).

In addressing this, strategies may include smaller working teams to foster team-building and active participation from all members (153). Also, allowing for local control such as decision-making regarding delivery of care or setting targets for improvement, as encouraged by the Productive Ward programme, can promote frontline staff's sense of empowerment (233). In this case, staff were provided with the tools to allow for local design and implementation of efficiency and safety initiatives. Similar approaches grounded in strong local leadership and staff engagement with subsequent improvement programmes are necessary.

The next rung on the ladder would be a medium-to-long term solution that includes increasing the proportion of RNs; this has been shown to off-set the costs of increased staffing by decreasing financial expenditure with respect to length of stay and complications (234). A recent study demonstrated that there is financial incentive to avoid complications as it can increase the cost of care by 106% (risk-adjusted third payer costs: $35,870 with complications vs. $17 373 without complications) (235).

Process-driven errors may be addressed by standardising delivery of care and thus reducing the memory-recall burden placed on staff. Strategies such as ERAS and the SURPASS checklist introduce the opportunity to consolidate the multiple processes that occur during the patient journey. Again, this allows for improvements of care quality within resource constraints. With ERAS, the long-term savings have been shown to be $7,129/ patient, mainly as a result of decreased length of stay (198). In another study, length of stay reductions led to an annual saving of $400,000 for a single institution (236).

Patient satisfaction has also been shown to improve with ERAS (198). Patient satisfaction as an indicator of surgical quality and safety remains controversial but there is some evidence that higher patient satisfaction scores are associated with lower risk adjusted rates of FTR and minor complications (237). Elements within safety culture as measured with Safety Attitudes Questionnaire data, such as teamwork and safety climate, job satisfaction, working conditions and perceptions of management were all significantly associated with patient satisfaction scores (238). Patients may be involved in safety in three ways - intervening to promote safety, education to manage own treatment safely and invitation to provide feedback (239). Certainly, in the case of the latter, a novel perspective may identify locally modifiable factors.

Finally, the actual ward environment may be amenable to small but effective local measures to improve safety; local strategies to streamline ward processes, such as improved organisation of storage and bed space, have shown gains in efficiency (106). Although a direct effect on safety may not be demonstrated, releasing nurses from unnecessarily time-consuming processes allows greater focus on patient care. Additionally, rationalising the most frequently performed tasks can serve a similar purpose. In the example of interdisciplinary communication in the inpatient setting, archaic pager systems still represent the primary approach- with unpredictable response times. The use of Internet-based communication platforms demonstrates reduced response times between team members (240). However, disadvantages that need to be addressed include lack of integrated communication with nurses/allied healthcare workers and lack of access to patient records through a shared platform. There is a potential to simplify communication between all ward staff with the possible implication of a direct (i.e., quicker escalation of care) or indirect (minimising the time a nurse is waiting by the phone) impact on patient safety.

2.5. Conclusion

This review highlights the fact that the causes of the known variability in ward-based and post-operative care are multifactorial. Crucially, the factors associated with patient outcomes go beyond the direct provision of care, relating to structural, organisational, and environmental factors. Their consideration is particularly important given that many such factors are amenable to intervention and improvement on a local scale. Further research to more clearly identify the means to most efficiently monitor and intervene upon these factors is required. In this way, establishing appropriate targets for change, with achievable strategies to tackle these, has the potential to address and prevent a significant proportion of avoidable harm and improve patient care.

The next chapter employs qualitative methodology, in the form of a semi-structured interview, to further characterise the sources of variation in ward-based care as perceived by those giving and receiving surgical ward-based care.

3. Identifying Quality Markers of a Safe Surgical Ward: An Interview Study of Patients, Clinical Staff and Managers

The data in this chapter has been published previously as:

Hassen Y, Singh P, Pucher PH, Johnston MJ, Darzi A. *Identifying quality markers of a safe surgical ward: An interview study of patients, clinical staff, and administrators.* Surgery. 2018;163(6):1226-33.

Author permissions to reproduce this data has been granted by the publishing journal, *Surgery* (see appendix A)

3.1. Introduction

There is considerable variation in the quality and safety of care with respect to the surgical patient, with this cohort also displaying particular vulnerability to adverse events overall (1). As high as 65% of inpatient adverse events have been shown to occur in patients receiving surgical care (241). The literature review summarises the comprehensive enquiry that has been conducted to ascertain the extent and potential sources that may explain why these events occur. There has been a focus on perioperative care, in part due to the level of risk involved in this part of the surgical patient's journey. Also, the cluster of early seminal studies from the UK, USA, Australia, New Zealand and Canada revealed that events related to an operative procedure account for anywhere between 24 – 50% of cases of adverse events overall, although these definitions varied with events that could extend beyond the operating room and into the post-operative period (8, 9, 29, 242, 243). A concerted focus on peri-operative care in the last two decades has resulted in a detailed examination of the processes and structure at play in the operating room, leading to the introduction of a wide-range of interventions and accompanying culture change (28, 244, 245). One of the most widely adopted interventions has been the World Health Organisation's Surgical Safety Checklist, which from its earliest practice, demonstrated a reduction in perioperative mortality and morbidity (28), albeit when conducted in the spirit of full engagement with the process (246).

However, it has become increasingly evident that the post-operative environment remains an important source of error and adverse events in the surgical/ post-operative patient; this is crystallised by the variability in risk-adjusted mortality in the case of

FTR despite comparable complication rates (8, 9, 11, 54). A range of fundamental factors pertaining to care delivery in the surgical ward environment have been exhaustively examined as outlined in the previous chapter, including features of the nursing team in number or skill-mix (118, 122, 247, 248), clinician working patterns (249), communication breakdowns (250-252) and the impact of the work environment on those healthcare providers in being able to discharge their duties safely (145, 253).

However, the surgical ward has not been comprehensively and systematically assessed in the same manner as the operating room as an environment in its totality. Furthermore, the approach to examining this environment, with respect to patient care outcomes, has been through a reliance on administrative level data (122, 247, 248) - requiring an element of speculation to draw conclusions and explain associations, which misses the ward level nuances of care variation that cannot be captured by such data. Indeed, it has already been demonstrated that hospital characteristics alone cannot explain these variations in care quality (109). Other approaches, such as survey data, though complimentary, may also deny investigators the full benefit of the experience of care provision at the surgical ward level.

Essentially, an up-close evaluation of this setting is required with exploration of both structures and processes promoting or hindering safety, as the evolution of errors in this environment is not yet fully understood. Characterising the sources of errors at the unit level may help to bridge this gap in knowledge.

Finally, if such factors can be identified and the degree of their measurability and influence on outcome demonstrated, this could be a step towards the generation of more granular care quality metrics than currently available.

With this in mind, it was determined that a qualitative approach was necessary to gather this information. This would allow for a far more textured assessment of the challenges to care delivery at the patient-healthcare provider interface in the surgical ward setting. This would be a first step to attempt to understand where variation in care quality and safety arises from at the unit level.

3.1.1. Aims of Chapter

This study explored the experiences of those who co-ordinate, those who deliver and those who receive care in the surgical ward environment with the following aims:

1. Identify potential sources of error in the main processes of the surgical ward
2. Ascertain the influence of organisational and environmental factors.
3. Derive safety indicators rooted in both process- and structure.
4. Explore potential strategies to address these factors from the stakeholder perspective.

3.2. Methods

3.2.1. Research Strategy

Qualitative studies have successfully migrated from the social sciences into healthcare and facilitated our understanding of the human experience behind the trends (254). For the purposes of this study, this style of enquiry was necessary for an in-depth examination of the barriers and facilitators to the delivery of safe ward-based care, which would not be otherwise garnered through quantitative analysis of available hospital-level data alone.

Of the potential methods available (e.g., a survey, focus group etc.), an interview study was deemed to offer the best opportunity to obtain detailed data as it will allow individual participants to express their opinions and views without the relative inflexibility of a survey and without the undue influence of peer opinion as maybe seen with a focus group.

As one of the most widely employed qualitative methods- with its use in healthcare having risen exponentially since first appearing in the literature in the 1990s (255)- interviews, and in particular the semi-structured approach, allows for a layering of enquiry as topics, ideas or themes emerge in the course of the process. Participants can be engaged to freely communicate their opinions and concerns pertaining to the topic, while still addressing the fundamental research question being explored (256). Later, amalgamation and analysis of collected viewpoints can produce a richer understanding of the complexities of this environment from the perspective of those most familiar with the day-to-day processes of care.

3.2.2. Patient Involvement

Patient and public involvement and engagement (PPIE) has become an integral part of high-quality research, and even a prerequisite to successful grant applications (257). Patients are able to contribute a unique perspective on health services delivery that may otherwise be neglected if research is healthcare-provider focused, attaching greater relevance and quality (258, 259). The nature of qualitative research lends itself to the participation of patients, shining a light on their perspectives on even the most elemental aspects of care delivery. Interview studies involving patients provide an opportunity to explore and characterise the patient perspective beyond a Likert scale of satisfaction or dissatisfaction.

Increasingly, a convergence of patient-centred patient safety research and qualitative methodology has allowed the characterisation of the patient experience (260, 261), especially with regards to prevention of adverse events (262).

3.2.3. Participants

Participants were recruited from the following groups, reflecting those who provide and receive care in the surgical ward:

- Doctors (D)
- Nurses (N)

- Elective surgical patients (P)
- Managers (M)

Purposive sampling was employed to recruit the first three groups, ensuring a variety of experience levels and backgrounds were included. This is an approach that has been employed in previous interview studies to allow for a breadth of information to be acquired, and thus to fully inform the research question being investigated (263). Given that they are fewer in number, managers were approached individually via email or in person to participate in this study.

3.2.4. Setting

Each interview was arranged at least 24 hours in advance. All participants were provided with appropriate information sheets and a consent form at initial contact so that enough time was given to read and understand the information provided.

Interviews were conducted in a quiet setting: for patients, this consisted of either the bedside if appropriate, or otherwise a consultation or day room where privacy could be assured. Staff interviews were conducted in private offices.

Interviews took place from February to May 2015 at three institutions within Greater London. Collectively, these reflected urban teaching and district general settings.

3.2.5. Collection of data

The interview protocol is outlined in Appendix B and was designed to explore six key areas:

1. Identifying the problem
2. Defining processes
3. Defining structural/ organisational factors
4. Defining environmental factors
5. Identifying quality markers for safety on the surgical ward
6. Identifying how practice could be improved

This approach allowed for participants to describe their experiences of care on the surgical ward, as well as allowing for a focused exploration of particular areas. Although prompts were utilised, they only served to open a further area for discussion. If participants were unable to expand on the topic following a prompt, then their agreement alone was not incorporated into the analysis. This was piloted prior to recruitment to ensure feasibility. Further amendments of the protocol were not required.

Interviews were held face-to- face by a single interviewer (thesis author) and digitally recorded.

3.2.6. Data Analysis

Anonymised recorded interviews were transcribed by an external service (Page Six Transcription Services Limited, www.pagesix.co.uk).

Thematic analysis was employed for this study data to draw out patterns in responses. This is a method that is a cornerstone of qualitative analysis techniques, employed both within a broader qualitative theoretical framework or as a standalone method in its own right (264). To this end, *In vivo* coding was performed before categorising data to extract themes. This meant that each transcript was subjected to line-by-line content analysis with statements addressing the research questions being drawn out. These were listed on an excel spreadsheet. Each subsequent transcript was analysed in this fashion, and any statements that were similar to those expressed by preceding interviewees were tallied up (see figure 3.1).

Eventually, thematic saturation was achieved i.e., no further new statements were being generated, and rather the statements expressed by preceding interviews were being reiterated. Subsequently, these statements were categorised according to emerging themes, constructing an understanding of what constitutes or impedes safe care on the surgical ward from the view of the defined stakeholders.

A second reviewer with experience in qualitative research (PS) assessed 25% of transcripts, selected via a random number generator, performing both in *vivo* coding and categorising data to themes.

Though saturation was achieved, in the interest of gaining a balanced view across stakeholder group, interviews were continued until there was similar representation amongst nurses, doctors and patients. There were fewer surgical managers, and thus a smaller number was accepted.

Figure 3-1: Snapshot of statement-by-statement content analysis

Formula Bar

		1	2	3	4	5	6	7	8	9	10	11	12	
1	**Surgical Ward Safety Interview Analysis**													
3		Nurse 1	Nurse 2	Nurse 3	Nurse 4	Nurse 5	Nurse 6	Nurse 7	Nurse 8	Nurse 9	Nurse 10	Nurse 11	Nurse 12	N
4	**IDENTIFY THE PROBLEM**													
27	Having access to equipment you require at night													
28	Ability to manage complex patients- doctor/ nurses													
29	ability to recognise sick patients - doctors/ nurses										1			
30	ability to implement acute intervention - doctors/ nurses													
31	ability of nurse to recognise deteriorating patient and alert team													
32	Nursing experience level				1		1				1			
33	Recognising sick patients despite normal CEWS score													
34	Alerting doctors early to the possibility of a sick patient													
35	Alerting doctor frequently for important/ unimportant things - masks sick patients													
36	Organised matron/ manager - good leadership	1		1		1	1			1	1			
37	well managed												1	
38	staffing levels or shortages (including staff levels against size of ward)	1		1		1			1	1	1			
39	understaffing of nurses - become task orientated eg meds and may fail to pick up deteriorations						1							
40	relationship within the nursing team/ how well team work together	1		1				1		1				
41	nurse-patient ratio		1				1		1					
42	staff morale/ motivation/ engagement			1			1			1				
43	Ensuring patients well informed on discharge											1		
44	abseentism due to poor staffing (tired workforce)						1							
45	team work between different professions/ disciplines			1										
46	adherence to policy and procedure			1	1					1		1		
47	availability of protocols			1										
48	monitoring patients' general condition (nurses)				1									
49	Checking operation notes when receiving patients post - op				1									
50	Single specialities ward safer than multi-speciality					1								
51	hospital culture													
52	Multi-site duties- so doctor in clinic or list in one hospital but inpatients are in a different hospital													
53	Depends on space and infrastructure													
54	Depends on what safety procedures are already in place													
55	Attitude and culture of those working on the wards									1				
56	don't communication properly/ communication between doctors and nurses							1					1	
57	don't handover properly													
58	don't write in the notes properly													

3.2.7. Ethical Considerations

This study was reviewed and approved by an NHS Research Ethics Committee (REC reference 15/NS/0014).

3.3. Results

3.3.1. Participant Demographics

Participant demographics are illustrated in table 3.1. Fifteen patients, fifteen doctors, sixteen nurses and five managers were recruited, for a total of 51 interviewees. Interview lengths varied from 10-60 minutes.

Table 3.1: Demographical data of participants

DOCTORS				
	Number		**Experience**	
Consultant Surgeons	4		6 years as consultant (range 3-18 years)	
Higher Surgical Trainees	6		5 years as doctor (range 4-10 years)	
Foundation & Core trainees	5		8 months (range 8 months -4.5 years)	
NURSES				
	Number	**Band 5: Band 6**	**Experience**	
	16	12:4	9.5 years (range 6 months – 23 years)	
MANAGERS				
	Number		**Length of experience in current role**	**Length of experience in healthcare**
	5		2.5 years (2-11 years)	20 years (range 5-24)
PATIENTS				
	Number	**M: F**	**Age**	
	15	7:8	65 years (31-80 years)	

3.3.2. Identifying the problem

Almost every professional interviewed in this study (35/36; D=15/15, N= 15/16, M=5/5) attested to variation in safety between surgical wards. Participants detailed points as follows:

> *"...depending on the facilities and physical layout…the number of beds and the disability of the patients that are in the beds and the level of staff or the skill mix that you've got looking after those particular patients"*- **Manager 2**

> *"It depends on the space and infrastructure, what safety procedures are already in place, but most importantly is the attitude and culture of who's working on those wards and the individuals that manage, run and deliver care on that ward."*- **Doctor 1, Consultant**

> *"Yes, I definitely think that some wards have more [risk]… in mostly the surgical ward you've got more sick patients… I would say wards that are less busy are more safe than the other wards.* - **Nurse 16, 10 years' experience**

Although 67% (10/15) patients had previous experiences from other surgical wards, only 2/15 (13%) were aware of any variation. One comment in particular demonstrated this sense of variability:

"I've witnessed the best and the worst I think…the best has been, you know, do you need this, do you need that? Let's do this, let's do that… And you are attended to in good time… And you feel as if you matter and you know what's happening…" – **Patient 5, female, 67 years old**

In addition, 93% (14/15) of patients felt safe on their current ward at the time of interview.

3.3.3. Defining Processes: where can errors occur?

Participants identified several processes that may be prone to error. The most prominent of these were the ward rounds (29/51, 57%), medication prescribing and administration (25/51, 49%) and communication amongst staff (22/51, 43%). A number of steps within these processes were identified by participants as being particularly disposed to error; these are illustrated in table 3.2.

Table 3.2: Processes and where errors occur

PROCESS	Total (/51)	Doctors (/15)	Nurses (/16)	Managers (/5)	Patients (/15)
WARD ROUNDS (57% overall)					
Lack of nursing presence on the ward round	12 (23.5%)	7 (46.7%)	5 (31.3%)	0	0
Multiple teams performing rounds at same time	7 (13.7%)	5 (33.3%)	2 (12.5%)	0	0
Lack of senior presence within clinical team	7 (13.7%)	2 (13.3%)	2 (12.5%)	0	3 (20%)
MEDICATION ERRORS (49% overall)					
Administration and drug round errors	21 (41.2%)	5 (33.3%)	11 (68.8%)	2 (40%)	3 (20%)
Prescribing errors	5 (9.8%)	4 (26.7%)	1 (6.3%)	0	0
COMMUNICATION DEFICIENCIES (43% overall)					
Poor communication between doctors and nurses	12 (23.5%)	6 (40%)	4 (25%)	1 (20%)	1 (6.7%)
Handover quality	10 (19.6%)	8 (53.3%)	1 (6.3%)	1 (20%)	0
Communication quality (verbal & written)	9 (17.6%)	2 (13.3%)	7 (43.8)	0	0
OTHER					
Patient mobilisation	15 (29.4%)	2 (13.3%)	3 (18.8%)	0	10 (66.7%)

Interestingly, the most potentially hazardous process identified by patients was their ability to mobilise once on the ward (10/15, 66.7%):

> *"I first came here, after my operation, I couldn't walk – well, I could walk, but very slow and I was afraid I was going to fall – and a nurse came with me every time I wanted to go to the [toilet]. She used to walk up and wait outside, walk me back, help me back in bed."*- **Patient 15, female, 80 years old**

> *"there's a couple of instances when even as a gesture, you know, you might have preferred a little bit more assistance"*- **Patient 5, female, 67 years old**

Only a small number of staff recognised this process: less than 20% of nurses, and only 13% of doctors. Managers did not mention this process in their interview. Mobilising was mentioned in the context of being omitted due to structural issues:

> *"The other thing is for example particularly mobilising patients post operatively which is very important for improving their health and thus patient safety as well, if a patient is in a side room they can lie in bed for ages and ages and a nurse is not actually seeing that they've [not] mobilised to the chair."*- **Doctor 13, Registrar**

> *"mobility – especially when you don't have the right number of staff to mobilise the patient. That puts both the patient and the member of staff at risk"*- **Nurse 2, 17 years' experience**

Ward rounds

One of the pertinent requirements for the ward identified was the importance of a member of the nursing team participating in the clinical ward round. This was only recognised by the staff who participate in this activity: almost half of doctors and a third of nurses (D=7/15, 46.7%; N=5/16, 31.3%) highlighted this, with an emphasis on the importance of this factor in enabling the effective transfer of information pertaining to patient care:

> *"We might make lots of important decisions on a ward round and it may not happen. We aim to find a nurse to relay the information to but it's often somebody else who will say "I'll handover to that nurse" so we're already exchanging several hands of information in potentially important things. And it's not unusual for me to ask for a drain to be removed and the next day the drain is still there, or a drug to be given – sure it's prescribed but perhaps not given as quickly as we would've liked – a decision made on something or another that has to wait until the next day because the nurse didn't get the information"* – **Doctor 3, Consultant.**

> *"We don't count the charge nurse as a number, a number meaning moving and handling the patients. So, what she does is she does the ward round*

> *with the doctors and she liaises with our nursing team about changes in the patients… I think it works really well"* - **Nurse 6, 3 years' experience**

There was an additional dimension that hindered effective presence of nurses on these ward rounds, specifically when simultaneous ward rounds were conducted. One-third of doctors (5/15, 33.3%) noted that this impeded nursing presence on ward rounds:

> *"When you have three teams …coming at eight o'clock in the morning to do a ward round and trying to find a nurse and they don't find a nurse then the information is not being passed on timely and effectively and correctly because there are not enough nurses to join the ward round…, You may say "Yeah okay, you can stagger the ward rounds" …but in practical terms everybody wants to get on with the ward round ASAP"*. - **Doctor 2, Consultant.**

Medication prescribing and administration

Prescribing and administering errors were highlighted by almost half of the participants across all groups (25/51; N= 12, D= 8, M= 2, P= 3). A number of contributory factors were identified, including the potential roles of time pressure not allowing for the level of care and attention that would be required for these processes and similarly the effect of workload burden. Interruptions occurring during medication preparation and communication issues pertaining to new prescriptions were also highlighted.

"So, the ward rounds are very quick; often, the registrar will be like, 'Oh just put this patient on antibiotics,' for a chest infection ... some [foundation year 1 doctor] on the team has forgotten to check the allergies and prescribed. Normally it is picked up by the pharmacist or the nurses but one time it wasn't picked up and the patient got the antibiotic. Thankfully [they] didn't come to any harm". – **Doctor 5, Foundation Doctor**

"the pharmacists are really good at picking up on ... admission drugs that we haven't been giving or drugs that interact with each other. These are the sorts of things that we do quite quickly maybe in the morning and don't check ...or we just haven't had a chance to look over admission medications yet."- **Doctor 7, Foundation Doctor**

"We are a very, very busy unit with very dependent patients, so when you are giving out medications you could be interrupted constantly, which isn't ideal, obviously". - **Nurse 3, 5 years' experience.**

"things are written in medical notes- a change of plan, drug charts are filled in with other medication, ... at 12 o'clock [you]...check the drug chart and say, "Oops, there's something here for 8 o'clock, who's written it?"- **Nurse 6, 3 years' experience**

"I have, on some wards, not particularly this ward, been brought the same medication twice because someone is not communicating that I've already had the medication"- **Patient 7, Female, 57 years old.**

"When the wards are overstressed, medications can go ungiven for longer than they normally would…" - **Patient 14, Male, 34 years old**

Communication

Communication issues were highlighted by 22/51 (43%) participants spanning across all groups. In particular two elements came to the fore. These were occasions of poor communication between doctors and nurses (12/51; N=4, D=6, P=1, M=1) and the quality of information exchanged in processes such as written or verbal handover communication (13/51; N=7, D=5, M=1). These issues run in both directions between nurses and doctors also.

"So, at the moment our team is currently doing an audit … about 30% of the time there's miscommunication between what's written on the patient whiteboard, the nursing handover and what's actually documented in the notes. So yes, there are errors in… the transfer of that documented information to what's actually being practiced on the ward itself"- **Doctor 12, Registrar**

"Sometimes … the patients say, "No, the doctor told me I can eat and drink," but … if they don't document it, it can be confusing. "- **Nurse 7, 3 years' experience**

"sometimes doctors will document things in notes but not actually tell the nursing staff that actually that's what they want to happen so investigations or new treatment" – **Manager 3**

Within the context of structural challenges- the effects on communication were also highlighted as noted in the next section.

3.3.4. Structural Factors contributing to safety: What can make the surgical ward prone to errors?

Participants identified a number of structural influences – the top factors are presented in table 3.3.

Table 3.3: Structural factors that can contribute to error

Structural Factor	Total (/51)	Doctors (/15)	Nurses (/16)	Managers (/5)	Patients (/15)
ORGANISATIONAL					
WORKFORCE FACTORS					
Staffing shortage	20 (39.2%)	6 (40.0%)	8 (50.0%)	4 (80%)	2 (13.3%)
Use of temporary staff/ agency staff	14 (27.5%)	5 (33.3%)	7 (43.8%)	1 (20%)	1 (6.7%)
Review of outliers* at end of ward round	12 (23.5%)	7 (46.7%)	3 (18.8%)	0	2 (13.3%)
Difficulty in obtaining home team review for outlier patients	9 (17.6%)	2 (13.3%)	5 (31.3%)	2 (40%)	0
WORKLOAD FACTORS					
Complexity of patients and nursing needs	12 (23.5%)	3 (20%)	6 (37.5%)	2 (40%)	1 (6.7%)
Nurses not experienced in caring for outlier patient needs (unfamiliar speciality)	12 (23.5%)	6 (40%)	5 (31.3%)	1 (20%)	0
ENVIRONMENTAL					
PHYSICAL FACTORS					
Layout- visibility of patients to nurses	25 (49.0%)	9 (60.0%)	10 (62.5%)	3 (60.0%)	3 (20.0%)
Noise disturbance	19 (37.3%)	0	11 (68.8 %)	2 (40.0%)	6 (40.0%)
Environmental clutter/ equipment in corridors	16 (31.4%)	2 (13.3%)	10 (62.5%)	1 (30.0%)	3 (20.0%)
Amount of available space	16 (31.4%)	3 (20.0%)	7 (43.8%)	1 (20.0%)	5 (33.3%)
Ward cleanliness	15 (29.4%)	3 (20.0%)	7 (43.8%)	2 (40.0%)	3 (20.0%)
RESOURCE FACTORS					
Lack of rest space for staff on ward	15 (29.4%)	3 (20.0%)	9	2 (40.0%)	1 (6.7%
Lack of computer stations	12 (23.5%)	3 (20.0%)	8	1 (20.0%)	0
Lack of adequate space for medication preparation and checks	11 (21.6%)	3 (20.0%)	6	2 (40.0%)	0
Safety of bathroom facilities	10 (19.6%)	0	6	2 (40.0%)	2 (13.3%)
* outliers represent patients that are being cared for on a ward that is not aligned with their clinical team's specialty e.g., a medical patient being cared for on a surgical ward.					

Organisation of care delivery within the healthcare system

One of the primary concerns expressed was the impact of staff shortage (20/51, 39.2%). Participants were able to provide their insight into how this effects how safely care can be delivered by altering how individual care givers may otherwise discharge their duties:

> *"… she will be more task orientated, so she knows that medication has to be given and she will try and do it as quick as possible, she will not look into extra … if the patient's deteriorating- she will fail to rescue, definitely. Because in your mind when you do one medication, one patient, and you're back- you're really thinking, "Oh my God, I've still got nine to go and I'm working against the clock." …If you've got ten patients who've got quite a lot of needs it's impossible for one nurse to deliver the care"*- **Nurse 6, 3 years' experience**

Along with this, there was concern about how this was mitigated – specifically the need for temporary or agency staff. 14/51 (27.5%) identified a possible further hindrance to safety by the reliance on this service.

> *"… most of what's happened from the [organisational] level you can only assume at best only perhaps two thirds of staff will be aware because one third are always transient"*- **Doctor 4, Consultant**

> *"I think because they're not necessarily always here, they won't have the continued care… or they miss things out… it means you've got a lot to do*

then from that shift you're taking over from"- **Nurse 12, 6 months' experience**

The arrangement of out-of-hours care, when staffing levels are often reduced, was also noted as an area that may generate error by multiple participants (10/51, 20%):

"I do often wonder whether the level of one single registrar for general surgery for the whole hospital is safe. If you are stuck with one significant emergency that lands you in theatre for several hours and you have one other sick patient and a junior on the ward, you can run into significant trouble"- **Doctor 14, Registrar**

"I think the biggest issue with the handover is the manpower of the hospital is very heavy nine to five and all of a sudden it becomes thinner during five and eight, and after eight it's extremely thin… you may have good handover but at the end of the day you need the manpower to sort the problems out… I don't think that a junior doctor should be looking after 89 patients during the night" **Doctor 2, Consultant**

".. there were nights when they were understaffed, and it all just starts to snowball, because when you've got one nurse and one healthcare assistant trying to run three bays, trying to look after 18 patients, with maybe 3/4 side[rooms]… So maybe 20-something-odd patients. Even just doing basic things, like observations, takes up a lot of time, and then when you go and do things like medications, they always start to fall behind, and then it just

gets worse and worse. And that's assuming you don't have any emergency …- **Patient 8, Male, 53 years old**

There was also an illustration of the competing commitments that middle grade doctors experience due to how care is arranged, with some expression that it affects the quality of care they are able to provide:

> *"you may have a very, very busy ward with lots of patients and you may have other commitments such as clinic and the operating theatre, so when you go to review the patients, you are also conscious of the fact that you need to get to your commitment and therefore may not have the time to be as attentive as you fully want to be."*- **Doctor 13, Registrar**

Placement of outlier patients on the ward

Due to bed pressures within an institution, frequently patients are accommodated on a ward that is not in line with the specialty that is responsible for their care, e.g., a medical patient with a bed on a surgical ward. These patients are commonly referred to as outliers.

The challenges of accommodating outlier patients on a surgical ward were mentioned by two-thirds of staff; it was recognised that these patients were often reviewed much later than other patients, as the responsible clinical team will often prioritise the round on their home ward; this was mentioned by one-third of all staff members (12/36, 33.3%; D=7, N=3, M=2). Beyond the resulting delays in management for the patient, staff implied that there were logistical impediments to the running of the ward:

> *"if the patient is an outlier – they are not reviewed on time ... we have elective patients coming in and theatre is asking for a bed; unless I discharge this patient, I cannot take on the patient from recovery"*- **Nurse 1, 19 years' experience**

There were also implications regarding the suitability of care that nursing teams could provide to outlier patients, especially if their clinical presentations are not within their area of expertise or training: (12/36, 33.3%; D=6, N=5, M=1):

> *"We can anticipate how our patients are going to be post-operatively and, therefore, look out for problems and try to nip them in the bud before they escalate. I don't think it's good when we have to care for outliers, partly because we are not familiar with their particular medical or surgical problems, so we don't have the capacity to anticipate as much as we do with our own patients."*- **Nurse 3, 5 years' experience**

> *"So, we had an issue about pin site care ...because they weren't habitually in the routine of doing that ... there have been instances where education issues have been flagged up; but I wouldn't expect them to know that, they don't work in an orthopaedic ward"*- **Manager 5**

A further aspect raised by participants was that obtaining a clinical review from the parent team for the outlier patient could be challenging, and this had the potential to result in delays in patient care. (9/36, 25.0%; N= 5, D=2, M=2). This seems to also be a reflection of the lack of familiarity between the nursing team and the patient's parent team as they are not accustomed to working together:

> *"– the home team is not in the building, it's very hard to get a review – even a routine ward round... They come way after lunchtime; discharges get stuck in the pipeline. So, it's very, very hard to try and implement plans for the day."*- **Nurse 2, 17 years' experience**

> "*Sometimes [the patient's] team is not coming, you have to [page] them and it's difficult to find their [pager number] ... who is responsible for that patient."*- **Nurse 7, 3 years' experience**

Although the doctors in this study were surgical doctors discussing surgical ward care, their experiences of caring for outlier patients meant they were able to recognise this feature of the organisation as a barrier to provide effective care from the clinical side as well:

> ***"…****the doctors' office is right next to [the surgical ward] and the nurses can just literally [come to] the doctor's office and say, "Can you come and see this patient quickly?" ... if a patient is unwell and is on an outlying ward, that sort of easy access to the medical team is suddenly gone"*- **Doctor 10, Registrar**

> *"The other things about outliers is although most consultants do see the outliers, they're often seen last. So, if there was an emergency that drags the consultant away, they'll often get dragged away before they get to see that patient"*- **Doctor 15, Registrar**

3.3.5. Environmental influences on ward safety

Staff readily recognised the safety compromises that may be presented by the ward layout. The majority of each of the staff subgroups were concerned about how readily patients could be kept in view of the ward team (25/51, 49.0%; N=10, D=9, M=3, P=3). To this end, the potential challenge in achieving this by having patients cared for in side rooms was also highlighted; 10/51 (20%) participants noted this:

> *"ideally all patients are visible from the nurses' station…. You get some argument like having lots of side-rooms is really beneficial then as well because it reduces infection and all the rest of it, but practically it's really poor*" - **Manager 4**

> *"I was quite glad I was in a room with other people which I feel safer like that. In a room on your own you've got no one to really to reach out to or have a chat with. I think that's part of safety as well isn't it"*- **Patient 14, Male, 34 years old**

16 participants (31.4%) identified the importance of adequate space for care delivery.

> *"there's bedside space, there's natural light, patients feel comfortable, it's easier to look after patients if someone gets sick, there's lots of space around the bed. But if you look at [Ward], it's very crowded. So just that physical space is very important.* – **Doctor 1, consultant**

> *"some of our rooms are so small, it's so hard..., patients, they have two or three stands with PCA, fluids and everything. So, because of the small room... [there is] not enough space to work"* – **Nurse 16, 1.5 years' experience**

Further considerations highlighted by participants including areas for medication preparation (11/51, 21.6%) and rest space for staff on the ward (15/51, 29.4%). An important aspect also related to how patients navigate a part of their recovery, partaking in post-operative mobilisation, in an often-crowded environment such as the surgical ward:

> *"[patients] need to be able to mobilise ...so they need space to be able to do that and they need a safe space to be able to do that and clearly there's no day room here, there's no physio gym and they're just up and down the corridors wherever nurses are busily rushing past. So that's inappropriate."* **- Doctor 10, Registrar**

There was a recognition also that patients require particular facilities to promote safety, such as bathrooms with adequate assisted access (10/51, 20%):

> *"the hospital I work in at the moment doesn't have fantastic amount of bathroom facilities for patients; they are quite few and far between. I think that's got potential risk because if you've got patients getting lost or patients walking further than they necessarily should be that's not great. You've got patients who are ... often unwell so they're often confused, it's*

often dark… I suppose I'm talking about falls risk but it's not insignificant."

– **Doctor 11, Core Surgical Trainee**

Other environmental factors such as cleanliness (15/51, 29%) and corridor cluttered with equipment (16/51, 31%) were recognised by participants.

Participants also highlighted impediments in the environment that hindered their ability to discharge care in a timely and effective manner. In particular, with the increased uptake of hospital technology such as online platforms for investigation requests and results retrieval, the adequacy of access to computer terminals becomes vital; this was mentioned by 23.5% of interviewees:

"You need enough computers for all the different teams too – because all the requesting is now online. That can cause a problem in the morning because the lists are on the computer, the requesting system is on the computer, so there can be a shortage of that going on…"- **Doctor 12, Registrar**

3.3.6. Identifying quality markers of a safe surgical ward

The most frequently mentioned quality markers identified by participants are outlined in table 3.4. There was a wide range of themes that emerged in this part of the interview, and indeed -although available on the interview template- the strength of the answers in this section meant that prompts were not required. Participants demonstrated factors that span the full gamut of this environment, with many factors rooted in process, organisation and environment.

Table 3.4: Identified quality markers for a safe surgical ward

	Total (/51)	**Doctors (/15)**	**Nurses (/16)**	**Managers (/5)**	**Patients (/15)**
Staff experience level	16 (31.4%)	5 (33.3%)	9 (56.3%)	0	2 (13.3%)
Overall layout of ward	14 (27.5%)	6 (40.0%)	6 (37.5%)	0	2 (13.3%)
Cleanliness of the ward	14 (27.5%)	3 (20.0%)	3 (18.8%)	3 (60%)	5 (33.3%)
Good leadership (nursing/ managerial)	14 (27.5%)	4 (26.7%)	7 (43.8%)	3 (60%)	0
Attentive Staff	13 (25.5%)	0	0	0	13 (87.7%)
Tidy, well- organised ward	12 (23.5%)	1 (6.7%)	6 (37.5%)	3 (60%)	2 (13.3%)
Nurse: patient ratio/ staffing levels	12 (23.5%)	3 (20.0%)	2 (12.5%)	3 (60%)	4 (26.7%)
Spacious wards	11 (21.6%)	3 (20.0%)	2 (12.5%)	1 (20%)	5 (33.3%)
Staff morale, motivation and engagement	8 (15.7%)	2 (13.3%)	3 (18.8%)	1 (20%)	2 (13.3%)
Appropriate equipment in good condition	8 (15.7%)	2 (13.3%)	6 (37.5%)	0	0
Overall atmosphere i.e. calm	8 (15.7%)	1 (6.7%)	1 (6.3%)	1 (20%)	5 (33.3%)

Staff experience level was the most frequently mentioned (16/51, 31.4%) followed by overall layout of the ward, cleanliness and nursing leadership (all 14/51, 27.5%); a leadership presence within the nursing team was mentioned by almost half of nurses (7/16) as well as the majority of managers (3/5).

Primarily, patients identified the level of attentiveness demonstrated by staff as a quality marker and was mentioned by 88%. Interestingly, this was not something that was explicitly described by staff themselves:

> *"… they're attentive to you rather than, you need something you're left waiting…"* - **Patient 2, male, 63 years old**

> *"the staff are very vigilant. They're constantly looking after us"*- **Patient 3, female, 64 years old**

The general morale and motivation amongst staff was identified as a quality indicator by participants across all the subgroups – and how this may influence the delivery of safe care (8/51, 16%; N=3, D=2, P=2, M=1):

> *"Staff morale and staff motivation. There are other factors such as how well the team work together and how well the different professions work together as well"*- **Nurse 3, 5 years' experience**

> *"Morale is very important on a ward because that means there is more retention of good nurses, continuity, ownership of the ward, teamwork; if*

your morale is low people start avoiding working in that ward or resigning and then the ward has to resort to locum agencies, agency nurses, bank nurses to fill up the nights, the unsociable hours. I think all that contributes significantly to … unsafe practices."- **Doctor 3, Consultant**

"I'm a firm believer that happy staff make happy patients, and I do think it contributes to the safety"- **Manager 4**

3.3.7. Improving practice – how to make surgical wards safer

Much like the wide range of quality markers proposed, a similarly varied range of improvement measures were proposed: these included higher nurse staffing levels (7/51, 13.7%), standardising processes (6/51, 12%) and improving interdisciplinary communication (5/51, 10%) possibly with the use of electronic notes.

With respect to standardising processes, the suggestions were around the introduction of policy or protocol to guide care. One participant recognised the benefit that this has already brought to one aspect of care delivery within their institution:

"we use a lot of intravenous heparin and there have been a number of incidents relating to prescription/ administration of intravenous heparin...the [organisation] brought in a new protocol for the administration of IV heparin… the protocol is very well adhered to on the unit. Where errors happen is when you are receiving a patient from another area [where the protocol is not adhered to]". - **Nurse 3, 5 years' experience**

Further suggested improvement measures included the introduction of more regular training sessions for nurses and doctors (4/51, 7.8%; N=2, D=1, M=1), as well as the designation of an individual to perform daily assessments of the environment including equipment and supplies (4/51, 7.8%) and improvement of adherence to existing policy (4/51, 7.8%). There was also an expression that single specialty wards (i.e., eliminating outliers) and minor amendments such as glass panes in place of walls to improve visibility may also help improve safety on a surgical ward.

3.3.8. Who should be involved in making changes?

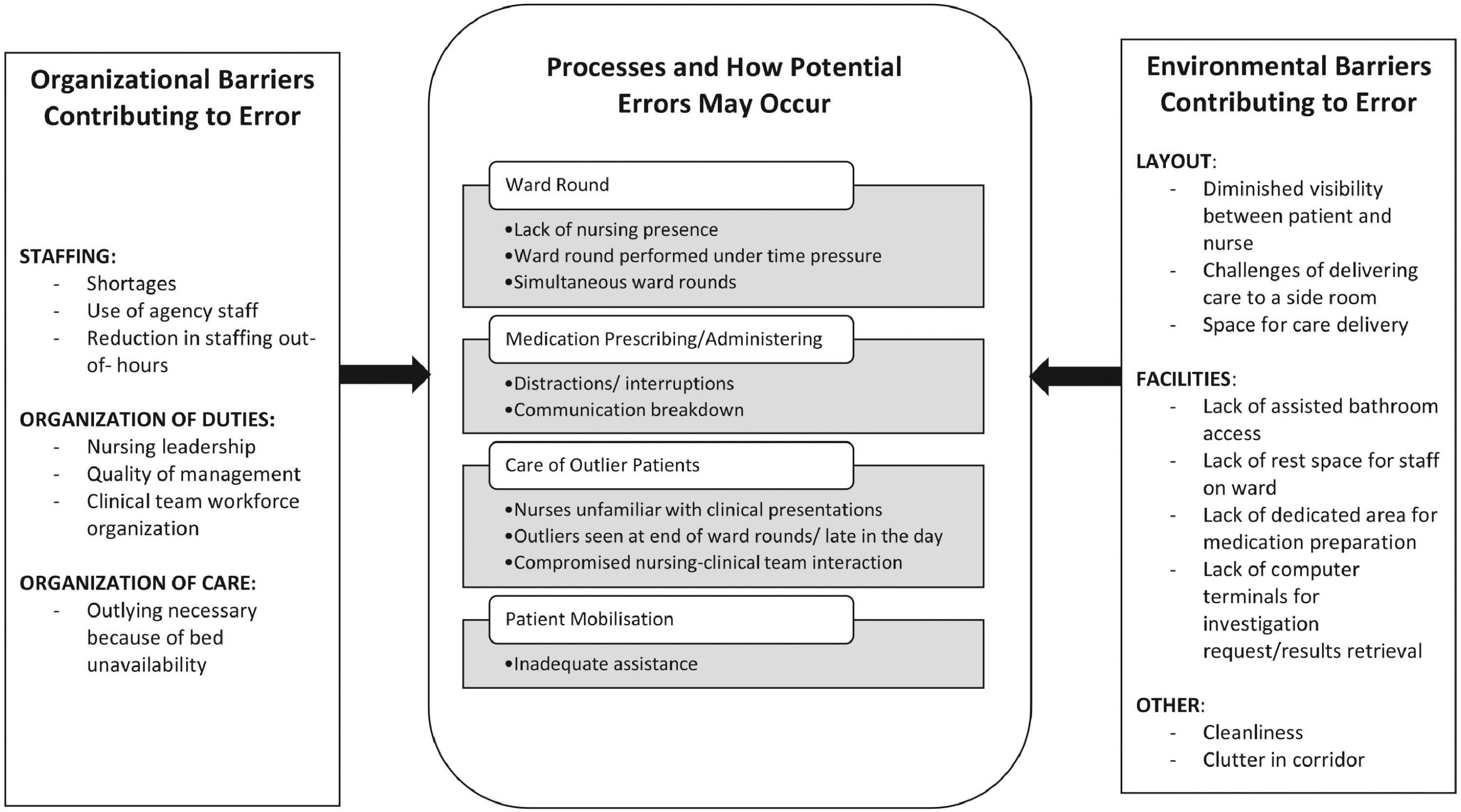
Participants recognised that multiple stakeholders have a role to play in effecting changes on the surgical ward (15/51 (29.4%) identified "everyone" as having a role). However, the most frequently mentioned figures were nurses (20/51, 39.2%), managers (19/51, 37.2%) and consultants (14/51, 27.4%). Patient involvement was not necessarily immediately brought forth by participants but when prompted, half of interviewees (26/51 (51.0%)- D=10, N=4, P=8, M=4) expressed that patients could have a role in making changes to improve patient safety on the surgical ward.

3.4. Discussion

This novel study attempts to understand the potential extent of variation in care quality and safety at the unit level and identify barriers and facilitators to safe care from the viewpoint of stakeholders active in that environment. Through interviews with nurses, doctors, managers and patients, this study clearly demonstrates that there is variation across processes (actions taking place in the provision of care) and structure (organisational and environmental factors which affect or influence the giving of care), in accordance with the care quality paradigm described by Donabedian (265). Not only does this study confirm the findings of previous work with regards to many of these process-driven (266-270) and structural factors (204, 205, 213, 218) that determine safe care, but new areas of concern which were outside of the scope of previous studies have been identified. Many of these have the potential to be addresses at the local level (see figure 3.2, taken from Hassen et al., 2018 (271)).

Numerous qualitative enquires surrounding safety on the surgical ward have been made previously; nursing, clinical and managerial team perspectives have been gathered via survey and interview studies. However, these studies tend to focus on specific aspects of care delivery within this environment, such as leadership behaviours or work burden (137, 151, 272, 273). However, the surgical ward is far more nuanced and an assessment of the entire setting and the interaction between various factors is more revealing. The range of suggestions for markers of a safe surgical ward, the significance placed on various factors by different groups and the range of possible improvement measures highlights the complexity of this environment. Therefore, this warrants that the surgical ward should be treated more like an ecosystem, where improvement measures should consider a more all-encompassing effect than addressing any issue in isolation.

Figure 3-2: Summary of key findings: potential process-related and structural factors that can lead to errors in care delivery on the surgical ward (taken from Hassen et al., 2018)



The most pertinent theme to emerge is that the generation of errors within processes previously recognised as particularly vulnerable (e.g., communication, medication administration) should be considered in context of complexities of the organisation and immediate environment that they are carried out in- i.e., medication errors in the context of time pressures or organisation of duties. Addressing deficiencies in these areas, such as reducing work-place pressures, may result in a secondary impact of reducing these errors.

Additionally, this study demonstrates that certain sources of errors/ work-place pressure are being potentially exacerbated by the established methods of remedying this. For example, participants recognised that staff shortage (39%) had a bearing on safety in terms of how effectively care processes can be executed, an issue already recognised globally (61, 274). However, the response to this, the use of temporary staffing, was deemed to also have its own inherent safety concerns. While the expense of this has been acknowledged (230, 275), local concerns included omissions in care or lack of knowledge regarding local protocols that could ultimately increase the workload of other team members were highlighted in this study. Safety issues related to the use of temporary staff has had limited exposure in the literature, with a predominantly organisational level analysis of administrative data to determine the effect, or lack of, on patient outcomes (276, 277). However, a more grass roots assessment, as performed in this study, is necessary to understand what local effect this mitigating measure has. Certainly, further targeted investigation is warranted.

The involvement of patients, as the ultimate stakeholders in care quality, in patient safety research has been increasingly encouraged (278, 279). This study demonstrates that patients present a unique and valuable perspective in contrast to healthcare workers, shedding light on variations that may have eluded investigators previously. For example, patients were able to provide safety indicators not considered by staff - such as safe mobilisation. In addition, the concept of "attentiveness" was also ranked very highly by patients. Although not an immediately obvious indicator of care quality, there is support in the literature that patient satisfaction as a variable demonstrates a strong association with nurse burnout (280) and staffing levels (272). Specifically- Vahey et al. demonstrated that patients on units with higher-than-average levels of emotional exhaustion among nurses were only half as likely to be highly satisfied with nursing care, with the opposite demonstrated on wards where nurses had higher levels of personal accomplishment (280). Under challenging work conditions, nurses' response to patients' needs may by delayed and patients in turn could interpret this as lack of "attentiveness". However, further work will be required to understand this, and discern what associations may exist with care quality.

There were some important omissions that may appear surprising in the context of patient safety; first infection control as a theme did not emerge. However, potentially this may be explained by universal acceptance of infection control measures (hand hygiene, barrier protection etc) as part of standard healthcare delivery (281-283). Rather, there may be a concerted focus on other aspects of care quality that are yet to be addressed. Furthermore, participants recognised barriers to infection control within structural elements e.g., availability of side rooms, rather than the presence of these measures themselves.

Another seeming discrepancy is the acknowledgement of staffing shortages being a safety issue, but a less frequent mention of addressing this within suggested improvement measures. Participants may have recognised that this is a complex issue that cannot be ameliorated immediately – and thus suggesting higher staffing levels was not a realistic option. As one senior clinician pointed out, *"These are not easy things; they are things that have been inflicted by bad decision-making year after year … they have reached now a crisis point… there will be expensive solutions, but there is no other way around it."*

3.4.1. Strengths and Limitations

This study does have limitations; although the total number of participants is large, the breadth of included stakeholders meant that the number of individual subgroup interviewees was limited. The large spread of interests and backgrounds also meant that consensus of opinion was less likely to be reached than in conventional interview studies involving only a single interviewee group. In addition, despite this breadth – not all stakeholders were involved (e.g., pharmacists, physiotherapists etc.). The initial aim of this study was to gain a focused understanding of the complexities of the surgical ward environment, and it was determined that this would be best served by focusing on key members with the highest exposure to this area.

Additionally, patients were interviewed as inpatients for logistical reasons. However, it is difficult to know if this may have made them reluctant to critique their experience while still under the care of the clinical and nursing teams. Indeed, literary evidence of patient participation in error reporting considers the possibility that a number of influences may deter or encourage patients to participate in patient safety activities

(284). Finally, we approached elective surgical patients who had undergone colorectal, upper gastrointestinal, bariatric or vascular surgery and had to rely on their willingness to participate. This may have introduced some selection bias.

Overall, this study has succeeded in understanding perspectives from a range of key members in what determines safe care on a surgical ward, beyond the patterns and trends demonstrated in previous large quantitative studies. Furthermore, it has brought into sharp focus the co-dependency of processes and the structural constraints within which they are performed, painting a complex representation of this environment. These findings suggest that certain factors that are not immediately evident through these larger studies can come to the fore when investigators pursue this type of ground level assessment of a system. The factors highlighted in this study may be contributing to the variability in care quality and safety, that has previously remained unaccounted for. Indeed, many of the features identified of a safe surgical ward are not just unique to the surgical ward. Ultimately these findings may be extrapolated to other inpatient settings.

3.5. Conclusion

This study has demonstrated the complexity of the surgical ward environment through the experiences of multiple members of each of the stakeholder groups. Multiple factors across process and structure are shown as interacting to dictate the safety of this care environment.

The next section will further evaluate these factors, with the aim of gauging the relative contributions of each of the identified factors to overall safety, with the ultimate aim of translating these findings into new measures of patient safety. This involved the design of a Delphi Consensus study, which is detailed in the next chapter.

4. Key components of the safe surgical ward: International Delphi consensus study to identify factors for quality assessment and service improvement

The data in this chapter has been published previously as:

Hassen YAM, Johnston MJ, Singh P, Pucher PH, Darzi A. *Key Components of the Safe Surgical Ward: International Delphi Consensus Study to Identify Factors for Quality Assessment and Service Improvement.* Annals of surgery. 2019;269(6):1064-72.

Author permissions to reproduce this data has been granted by the publishing journal, *Annals of Surgery* (see appendix C)

4.1. Introduction

Surgical patients remain a vulnerable group when it comes to error during inpatient care; data from 2013 demonstrates the rate of adverse events to be as high as 15%, of which the majority were deemed preventable (285). This is in line with what has been demonstrated in previous studies indicating that little progress has been made to reduce the significant burden in this cohort of patients (1, 8, 10). In addition, it has long been implicated that the post-operative care environment is a frequent and critical source of error and is likely to outweigh the volume of errors that originate in the operating room overall; often, these ward-based errors relate to monitoring, delay or error in diagnosis or treatment (286).

The post-operative care environment suffers from a lack of an integrated assessment of the underlying factors that dictate the quality and safety of care delivered. By comparison, the operative environment has benefited from up-close assessment of processes of care and subsequently appropriate interventions to address or mitigate failures have been proposed (40, 44, 287). Much of what is known about the source of variations in care quality at the surgical ward level, the focus of post-operative care, has been garnered through the interrogation of administrative datasets, and typically involves the use of measures such as complication rates as a surrogate for outcome (56, 60, 288). Furthermore, the role of a limited selection of pre-defined factors are studied in such work, e.g., nursing hours or patient: nurse ratio. This is not to demote the value of such studies in helping uncover patterns that can affect patient outcomes; to some extent, hospital level outcome measures such as FTR have helped crystallise the magnitude of variation in quality and safety that can originate from the post-operative care environment. Measuring FTR has already demonstrated that it is not the evolution of a complication alone that warrants collective concern, but rather the response to that complication at the unit level that can determine the ultimate outcome. Indeed, one systematic review demonstrates that most institutions probably have comparable complication rates, but mortality can differ by as much as 17% (289). Nonetheless, analysis at this level can only account for 36 – 80% of the variation in FTR, as demonstrated by Sheetz et al. in their 2016 study, highlighting that there are more salient factors that need consideration (109).

The data gathered in the interview study (Chapter 3) demonstrates an array of unit-level factors at play that may explain this variability. Essentially, the data gathered conveys an intricate environment where care outcomes are likely to be simultaneously influenced by factors spanning organisational and process-related domains. From the viewpoints of both patients and staff, the post-operative care environment appears to be far more complex and potentially unstable environment than previously understood. Furthermore, this group was able to indicate potential markers of safe surgical care. However, it is difficult to understand what role these factors actually play in the delivery of safe post-operative care, and the degree of their influence. Conclusions cannot be drawn with regards to the effect on patient outcomes nor the cumulative effect of multiple factors on safety. Furthermore, the way these factors interact with one another- i.e., in either a positive or negative way- is not known.

To aid further analysis of these factors, it is necessary to prioritise key areas to focus further research. Therefore, a Delphi consensus study was undertaken in order to guide the direction of further studies in this thesis through the input of a panel of experts with an interest in patient safety.

4.1.1. Qualitative Methodology: The Delphi Consensus Technique

The Delphi consensus technique is a systematic examination of a research question by a panel of experts in that field of interest, with the aim of attaining convergence of opinion. It has become an established tool in health services research to determine clinical management strategies and appropriate care pathways (290-293).

The Delphi technique relies on an iterative process of serial questionnaire delivery to a panel of experts until a convergency of opinion is achieved. However, there are specific hallmarks to the technique as outlined by Dalkey (294); firstly, the experts are blinded from one another, thus maintaining complete anonymity. This eliminates undue influence introduced by potentially dominant participants, and thus promoting '*independent thought on the part of the experts*' (295).

Secondly, there is '*controlled opinion feedback*'. Questionnaires are delivered to the blinded experts in rounds. After the first questionnaire round, a summary score for each statement in the questionnaire is calculated and then presented to the panel at the time of the second round. The purpose of this is to present the overall group position on the research items in question following the initial round, in order to offer individual participants the opportunity to review their opinion or replies in the light of the results- hence producing convergence of opinion.

Thirdly, there is a final result representing the overall group opinion, which may be a numerical result with an attached measure of spread.

The end point to the study is pre-defined by the investigators e.g. the number of rounds or the level of consensus to be achieved (296).

Modifications have been made to the technique over time: the classical Delphi technique described by Dalkey et al. at the RAND corporation consists of a first-round qualitative approach, gathering free-flow information on the research question from participants. The second round is the point at which a questionnaire with defined statements is developed from this information and signals the start of the serial questionnaire phase. However, a number of studies employing the Delphi technique have launched with a questionnaire at the outset, as it has been performed in continuation to previous research (296). Where this has been the case, studies have relied either on the examination of existing definitions or policy to ascertain applicability to a certain system (297, 298), previous qualitative research such as interview studies or focus groups (299, 300), literature review (301-303) or a combination of these methods (304).

There are advantages to the Delphi method in comparison to group discussion beyond the removal of the undue influence of more prominent personalities; it is a practical way of benefiting from the input of a group of high-calibre experts, who may be geographically disparate, through easily accessible mediums, e.g., online platforms for questionnaire delivery. Furthermore, as a window of opportunity is given, the questionnaire can be completed at their convenience.

However, there has been some criticism of this aspect of the design; Sackman's evaluation of the technique in a 1975 paper outlined a number of concerns – predominantly with regards to the rigour of questionnaire design- but also a potential weakness in the lack of direct interaction between participants in depriving the process of '*exploratory thinking*' (305). Some researchers have therefore opted to modify the Delphi technique, introducing a face-to-face panel for specific steps. This has been either for the initial qualitative round where ideas are generated (306), or in cases where there has been difficulty in achieving consensus, and thus further discussion and definition of the question became necessary (307).

For the purposes of this study, the Delphi consensus technique was chosen in order to identify the key areas that are likely to determine safety on the surgical ward. The factors thus far identified in Chapters 2 and 3 are scattered through the realms of process-related obstacles in care delivery, to organisational and environmental pressures. To untangle this data – and tease out the areas that warrant further research efforts- this study was designed to select key elements through the knowledge and experience of those who are involved in, and influence, patient safety research and policy. Furthermore, as already indicated in the literature review, many of the themes that pertain to safe delivery of care in the post-operative phase are present across different geographical settings. This technique allows for the engagement of an international panel, improving the overall applicability of findings to health systems outside of the UK.

4.2. Method

4.2.1. Study Design

The data used to formulate the statement for the Delphi questionnaire was acquired through a systematic review of the literature using the London Protocol (117) and the semi-structured interview study of all stakeholders of the post-operative care environment (271). These encompassed scrutiny and discussion of issues around nursing care, clinical care and other environmental and organisational factors. The statements presented to the panel were phrased with the intent to ascertain if the factor had a role in safety, e.g., “factor x can influence safety, factor x can have a negative/ positive impact on safety” rather than establish a threshold at which safety is compromised. This is so that all factors deemed pertinent to safety across process- and structural factors can be aggregated through this consensus process.

4.2.2. Identification of international experts in Patient Safety

Two broad categories of experts were invited – patient safety *experts* and patient safety *advocates*.

Patient safety experts represented clinical and academic expertise. Invitations were made to patient safety researchers, who lead or are affiliated with prominent research units, or academic surgeons with significant research output. Additionally, patient safety experts (both clinical and non-clinical backgrounds) who serve on international or national committees for the development of patient safety policies were invited. Experienced patient advocates who fulfilled leadership roles of advocacy organisations and had influence on safety policy were also invited.

4.2.3. Delivery of the questionnaire

The questionnaire was delivered via an online platform (Qualtrics, Provo, UT) in two rounds. The questionnaire was sent via an electronic link embedded in an invitational email to participants, with an attached participant information sheet. The email detailed the aims of the research projects and the number of rounds anticipated.

Participants were sent two reminder emails at two-week intervals for each round. No financial renumeration was extended, but participants were informed that they would be acknowledged on all future reports if they agreed at the end of the study.

The questionnaire consisted mainly of statements presented alongside a 5-point Likert scale ranging from strong disagreement (equivalent to 1) to strong agreement (equivalent to 5). Ranking questions were also employed and free text boxes were available to gather further expert opinion.

At the end of the first round, the results were analysed by calculating the mean score for each statement alongside the standard deviation. The questionnaire was then modified to include this result by each statement so that participants would be informed of how much agreement there was at the end of the first stage. Furthermore, any opinion expressed in the free text box by more than one expert was incorporated as a new statement in the second iteration of the questionnaire. This was done to further inform the breadth of the study.

Participants were then invited to submit further ratings in the second round, taking the scores from the first round into consideration.

Questionnaires for Rounds 1 and 2 can be found in Appendix D.

4.2.4. Definition of consensus & statistical analysis

Consensus was pre-defined as 80% or more of participants scoring a statement as a 4 or higher, a well-established threshold that has been used in previous studies (290, 308). In addition, Cronbach's alpha was used as a statistical measure of internal consistency of each questionnaire and set at 0.80 – consistent with previous methodology (252, 308).

Analysis was completed using IBM SPSS Statistics for Macintosh Version 22.0.

4.3. Results

4.3.1. Demographics

Out of a total of 54 invitations, 27 individuals (50%) from eight countries participated in the study (table 4.1, adapted from Hassen et al, 2019 (309)). In round 1 there were 23 participants. In round 2, there were 20 participants. Four of the participants in the second round had not taken part in the first round, though invited from the outset of the study, but responded to the second-round questionnaire.

Table 4.1: Profiles of Patient Safety Experts and Advocates comprising the Delphi Consensus Panel (Table adapted from Hassen et al., 2019)

	Country	Participant Title	Expertise	Active Clinician	Affiliation	Round 1	Round 2	Citations (Dec 2017)
1	Netherlands	Professor of Surgery, Academic	Research	Yes	University	✓	✓	10997
2	UK (England)	Attending- Colorectal Surgery, Academic	Research	Yes	University	✓	x	2597
3	UK (England)	Professor of Epidemiology & Public Health, Head of Research Unit	Research	No	University	✓	x	5266
4	USA	President of Patient Advocacy Group	Informing policy	No	Independent Organisation	✓	✓	N/A
5	Belgium	Health Services Researcher	Research/ informing policy	No	Government-affiliated institution that helps inform health policy	✓	x	3542
6	USA	Associate Professor of Surgery	Research	Yes	University	✓	✓	2622
7	UK (England)	Surgical Resident	Research	Yes	National Trainee's Association	✓	✓	141
8	UK (England)	Associate Director of Patient Safety Board	Implementing policy	No	Governmental Health	✓	x	N/A

					Commissioning Board			
9	UK (Wales)	Chair of Safety Forum/ Member of advisory board	Informing policy	Yes	Non-university institution	✓	✓	N/A
10	UK (England)	Professor of Primary care, Head of research unit	Informing Policy	No	University	✓	✓	5496
11	Canada	Head of Research Unit	Research	Yes	University	✓	✓	13912
12	Australia	Head of Research Unit	Research	No	University	✓	x	1519
13	UK (Scotland)	Professor of Management & Health Services Research	Research	No	University	✓	✓	Unavailable
14	UK (England)	Member of governmental advisory board	Informing Policy	Yes	Non-university institution	✓	✓	N/A
15	UK (Scotland)	Lead of National Patient Safety programme (governmental)	Implementing Policy	No	Government-affiliated	✓	✓	N/A
16	UK (England)	Associate Professor, Psychology and Behavioural Science	Research	No	University	✓	x	1479
17	UK (England)	Professor of Anaesthesia, Head of Research Unit	Research	Yes	University	✓	✓	Unavailable
18	USA	Professor of Anaesthesia, Head of Research Unit	Research	Yes	University	✓	✓	2448
19	UK (England)	Academic, patients for patient safety champion	Research/ Policy	No	Non-governmental Health Organisation	✓	✓	97

20	UK (England)	National and International leadership in health policy design and implementation	Implementing policy	No	University	✓	x	N/A
21	UK (England)	Academic	Research	No	University	✓	✓	2892
22	UK (Scotland)	Professor of Psychology	Research	No	University	✓	✓	10909
23	UK (England)	Senior Lecturer in Public Health	Research	No	University	✓	✓	370
24	UK (England)	Attending- Upper gastrointestinal surgery, Academic	Research	Yes	University	x	✓	Unavailable
25	Australia	Professor of Nursing	Research	No	University	x	✓	403
26	UK (England)	Professor of Nursing	Research	No	University	x	✓	4696
27	UK (England)	Professor of Implementation Science and Patient Safety	Research	No	University	x	✓	7287

**Citations as of December 1, 2017; collated from panellists' professional online profiles maintained either on ResearchGate, Google Scholar, or Institutional website. Publicly unavailable information is indicated as ''unavailable.'*

Of the 74 statements included in the first-round questionnaire, 50 achieved the required threshold for consensus. The Cronbach's alpha at this stage was 0.959.

In round two, a further 11 statements were added, based on the free text feedback provided by participants in the first round, for a total of 85 statements. Sixty-four of these statements achieved consensus. The Cronbach's alpha for the second-round questionnaire was 0.944.

Statements that met the criteria for consensus are reported in table 4.2. The answers that did not achieve consensus are presented in Appendix E.

Table 4.2: Summary of Statements that Achieved Consensus (Table adapted from Hassen et al., 2019)

Stem	Statement	Mean Score	Standard Deviation	Score 4-5 (%)
Some wards are safer than others		4.3	0.57	95
The following processes are prone to error:	Presence of outlier patients on ward	4.55	0.51	100
	Prescription and administration of medication	4.35	0.49	100
	Lack of nurses on ward round	4.4	0.68	90
	Handover between medical teams	4.4	0.50	100
	Documentation – Nurses	4.25	0.72	85
	Documentation- Doctors	4.15	0.59	90
	Handover between nursing teams	4.35	0.49	100
	Communication - clinical and nurses/ allied health professionals	4.25	0.72	85
	Infection control**	3.95	0.89	80
	Communication between staff and patients**	4.4	0.68	90
	Response to deteriorating patient**	4.6	0.60	95
The following organisational factors have a ***negative*** impact on patient safety in ward-based care:	Inadequate nurse staffing levels	4.7	0.47	100
	The use of temporary staff/agency staff	4.15	0.67	85
	Out of hours reduction in services	4.05	0.60	85
	Lack of senior nurses out of hours**	4.45	0.69	90
	Frequent change in ward doctors**	4.1	0.72	80
The following organisational factors have a ***positive*** impact on patient safety in ward-based care:	Good managerial leadership	4.7	0.57	95
	Adequate skill mix of nurses	4.7	0.47	100
	Good access to doctors out of hours	4.6	0.50	100
	Good nursing morale/ working relationships	4.65	0.49	100
	Positive safety culture**	4.75	0.44	100
The following characteristics of how duties are organised can compromise patient safety in ward-based care	Junior doctors cross-covering multiple specialties out-of-hours	4.2	0.70	85
	Access to appropriate clinical equipment	4.25	0.64	90

The following environmental factors can influence patient safety in ward-based surgical care				
	Ward cleanliness	4.25	0.72	85
	General atmosphere of a ward	4.2	0.52	90
Concerning ward layout, the following factors can influence patient safety in ward-based surgical care:	Good visibility between patients and nurses	4.55	0.60	95
	Adequate space for medication preparation	4.2	0.62	90
	Space around patient bed to facilitate clinical needs	4.3	0.57	95
The following facilities maintain patient safety:	Bathrooms with access for those with disability	4.3	0.47	100
	Adequate number of bathrooms	4.2	0.62	90
The following facilities for staff maintain patient safety	Adequate computer facilities located on the ward	4.4	0.75	95
	Adequate access to clinical supplies and equipment	4.6	0.50	100
The following are quality markers of a safe surgical ward	Good leadership- nursing/managerial	4.6	0.94	95
	Staff who are attentive	4.7	0.92	95
	Staff morale/motivation/engagement	4.55	0.94	95
	Nurse station position and visibility of patients	4.6	0.50	100
	Nurse staffing levels	4.6	0.94	95
	Adequate computer access	4.2	0.95	90
	Spacious wards	3.95	0.94	80
	Nursing skill mix	4.6	0.94	95
	Cleanliness of the ward	4.35	0.93	95
	Well stocked and organised wards	4.25	0.91	95
	Access to equipment when required (including out-of-hours)	4.3	0.92	95
	Appropriate equipment in good condition	4.2	0.95	90
	Nursing experience level	4.45	1.00	90
	Clutter-free, well-organised wards	3.95	0.89	80
	Medical team staffing level	4.4	0.99	90
	Availability of rapid response team**	4.35	0.99	90
	Education level/ training of healthcare support workers**	4.2	1.01	85
Safety can be improved by:	Investing in staff training	4.65	0.49	100
	Having nurses accompany ward rounds	4.35	0.67	90
	Higher nurse staffing levels	4.55	0.60	95

	Digital notes and other technology to enhance communication	3.9	0.85	85
	Promoting adherence to policy and procedure	4.1	0.79	85
	Rapid response team**	4.35	0.59	95
The following should be involved in making changes:	Consultants/ Attending Doctors	4.7	0.47	100
	Nurses	4.7	0.47	100
	Patients	4.5	0.51	100
	Junior doctors/ Residents	4.7	0.47	100
	Hospital Managers	4.5	0.61	95
	Allied Health Professionals	4.5	0.51	100
	Hospital Board	4	0.92	85
	Non-Clinical staff	4.15	0.59	90

** items added in second round

4.3.2. Errors in Processes of Care

Within processes of care, participants agreed that lack of nursing presence on the ward round (90%; 4.4 ± 0.68) and the presence of outliers (those patients being cared for on a ward not aligned with the speciality whose care they are under) on the ward (100%, 4.55 ± 0.51) create potential for errors. The process of prescription and administration of medication was also deemed crucial to safety (100%, 4.35 ± 0.49).

Areas that were highlighted as a concern by patients in the interview study, most pertinently concerns about safety in mobilisation, was not identified as a process that was prone to error by our Delphi panel. Additionally, the absence of a consultant during the surgical round was not seen as a variation in this process that could lead to error.

Several elements of process failures in communication were agreed upon: handover between medical teams (100%, 4.4 ± 0.50), handover between nursing teams (100%, 4.35 ± 0.49), communication between clinical teams and nurses or allied health professionals (85%, 4.25 ± 0.72) and communication between staff and patients (90%, 4.4 ± 0.68). In addition, documentation by both doctors (90%, 4.15 ± 0.59) and nurses (85%, 4.25 ± 0.72) and response to the deteriorating patient (95%, 4.6 ± 0.60) were determined to have large potential for errors.

4.3.3.The impact of organisational factors on patient safety on the surgical ward

Participants agreed upon the negative impact of five elements related to the workforce and the arrangement of duties; this included inadequate nurse staffing levels (100%, 4.7 ± 0.47), the use of temporary or agency staff (85%, 4.15 ± 0.67), out-of-hours reduction in services (85%, 4.05 ± 0.60), lack of senior nurses out-of-hours (90%, 4.45 ± 0.69) and the frequent change in ward doctors (80%, 4.1 ± 0.72). The latter statement was introduced at the second round as more than one participant indicated concern regarding inconsistency of team members from day-to-day or week-to-week due to how the clinical team's timetable was arranged.

Positive organisational qualities that achieved consensus included the strength of managerial leadership (95%, 4.7 ± 0.57), appropriate nursing skill-mix (100%, 4.7± 0.47), access to doctors out-of-hours (100%, 4.6± 0.5) and good nursing morale/working relationships (100%; 4.65± 0.49). A statement was included in the second round with regards to the importance of a strong safety culture- this achieved unanimous consensus (100%; 4.75± 0.44).

4.3.4. Environmental Factors and patient safety on the surgical ward

A number of qualities of the environment within which care is delivered achieved consensus. Appropriate visibility of patients to nurses (95%, 4.55 ± 0.60), adequate space for medication preparation (90%, 4.2 ± 0.62) and space around the bed to facilitate clinical needs (95%, 4.3 ± 0.57) were determined to have a positive influence on safety.

In addition, disabled access to bathrooms and adequacy in bathroom numbers were important patient facilities to maintain safety (100%, 4.3 ± 0.47 and 90%, 4.2± 0.62 respectively). With respect to facilities for staff to perform their duties safely, the importance of adequate access to computer terminals (95%, 4.4 ± 0.75) as well as clinical supplies and equipment (100%, 4.6 ± 0.50) was recognised by the panel and achieved consensus.

Questions regarding layout were approached slightly differently in the two rounds, the results of which are conveyed in table 4.3: in round 1, participants were invited to select the configuration that they deemed safest (figure 4.1). The majority of participants (almost three quarters) were almost equally split between a mixture of bays and side rooms (9 out of 23 participants) and a racetrack configuration (8 out of 23 participants).

In order to ascertain if there was any superiority of one over the other, in the second round, participants were invited to rank all 4 possible configurations. This did not differ greatly from the round 1 findings, with highest ranking configuration being the mixture of bays and side rooms followed by the racetrack.

A ward of side rooms was in third place, but the least popular arrangements were nightingale and completely bay-based arrangements; in the case of the latter, this was not selected by any participants in the first round and ranked lowest in the second round.

Table 4.3: In round 1, participants were invited to select the safest layout. In round 2, the layouts were ranked (1-5; 1=safest)

	Round 1		**Round 2**
Layout	**No. selecting this item (/23 participants)**	**%**	**Ranking (mean)**
Mixture of bays and side room	9	39	1.8
Racetrack	8	35	2
Ward of side rooms	5	22	3.1
Nightingale	1	4	3.9
Bay-based	0	0	4.3

Figure 4-1: Representation of ward layouts

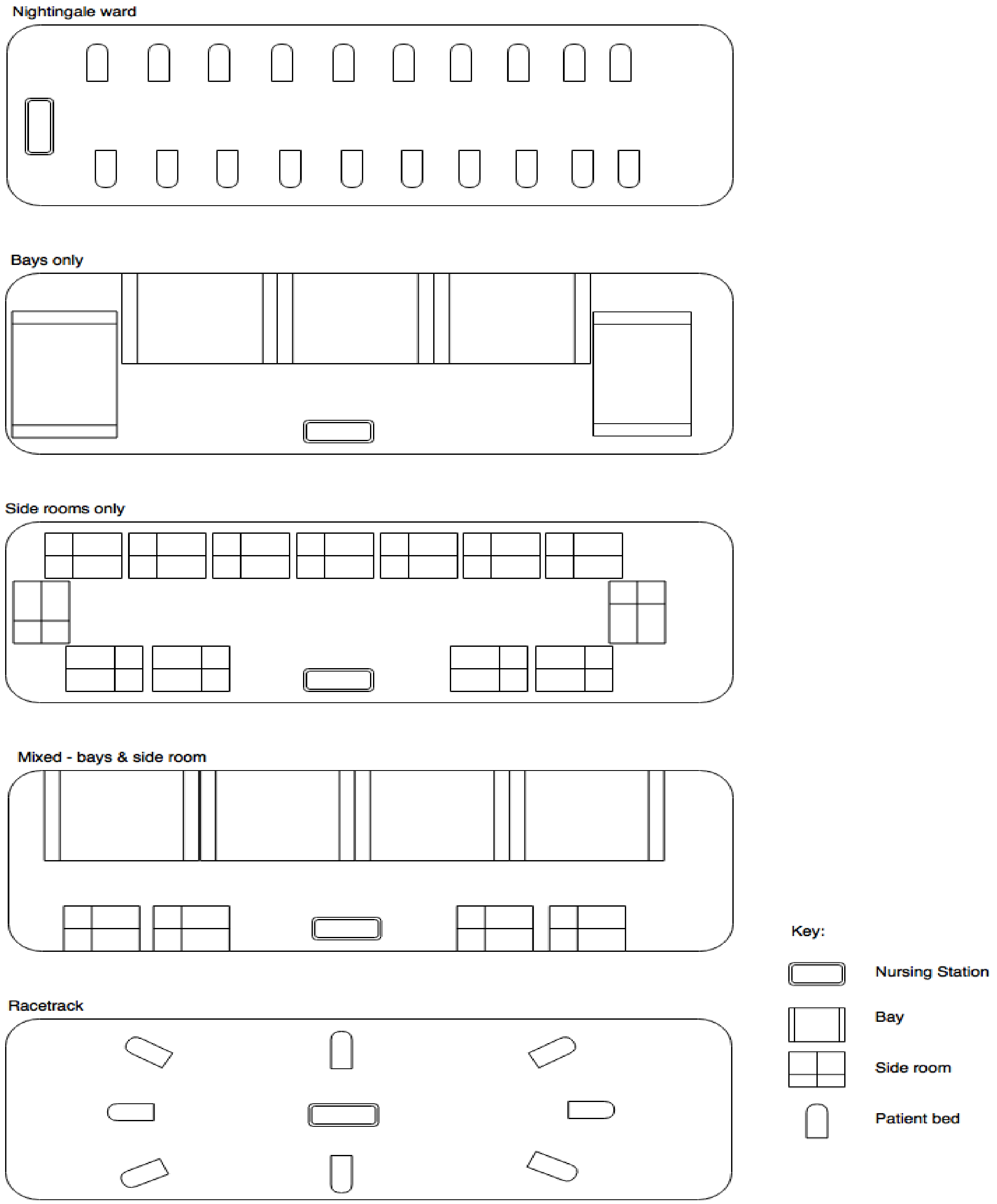


Figure reproduced with permission (Hassen et al., 2019. *Annals of Surgery)*

4.3.5. Quality markers of a safe surgical ward

17 statements detailing potential quality markers of a safe surgical ward achieved consensus by round 2. Two statements had been introduced in the second round and both achieved consensus. These were the availability of rapid response team (90%, 4.35 ±1.0) and education level/ training of health care support workers (85%. 4.2 ± 1.0).

Additionally, in the second round the panel was also invited to select the top ten quality markers in order of importance with 1 being the most important. The results of these are outlined in table 4.4. The highest scoring factors were nurse staffing levels, strong leadership and as well as the morale, motivation and engagement of staff as they were selected by all participants to be included in their top ten.

Table 4.4: A ranking of quality markers in order of importance

	Number of participants who selected item (/20)	Mean rank
Nurse staffing levels	20	1.9
Strong leadership	20	2.3
Morale/motivation/engagement of staff	20	4.6
Medical team staffing levels	19	4.6
Staff who are attentive	17	5.1
Nursing skill mix	17	5.5
Nursing experience level	15	5.5
Cleanliness of the ward	15	8.0
Availability of a rapid response team*	12	7.7
Nurse station position	10	7.6
Education level/training health care support workers*	9	7.4
Adequate computer access	7	8.0
Appropriate equipment in good condition	6	9.5
Access to equipment when required	5	8.4
Clutter-Free	3	8.0
Well stocked organised ward	3	8.7
Spacious ward	1	9.0

*Item introduced in second round.

4.3.6. Improving patient safety on the surgical ward.

A number of proposed improvement measures achieved consensus. With respect to features of the organisation, these included investment in staff training (100%, 4.65 ± 0.49), and the promotion of adherence to policy and procedure (85%, 4.1 ± 0.79) achieved consensus. Additionally, higher nurse staffing levels (95%, 4.55±0.60) as well as nursing representation on the ward round (90%, 4.35±0.67) were agreed upon as improvement measures.

Improved safety through rapid response teams was also introduced as a statement in round 2 to this section of the questionnaire as it was suggested by panel members in round 1. This was also suggested as a quality marker in the previous section. There was consensus that they improve safety. (95%, 4.35 ± 0.59).

4.3.7. Who should be involved in making changes?

By the end of round 2, multiple stakeholders were identified as having a role to play in making changes to promote safety on the surgical ward (table 5). Almost all participants agreed that clinicians of all grades, nurses, patients, allied health professionals and managers have a role to play. Non-clinical staff and the hospital board's role was also deemed to be required.

Table 4.5: Stakeholders who have a role to play in making changes - results at the end of round 2.

Stakeholder	Consensus (% of participants)	Mean Score (Standard deviation)
Senior clinician (i.e., Surgical Consultant)	100	4.7 ± 0.47
Nurses	100	4.7 ± 0.47
Patients	100	4.5 ± 0.51
Junior doctors (below consultant level)	100	4.7 ± 0.47
Hospital managers	95	4.5 ± 0.61
Allied Health Professionals	100	4.5 ± 0.51
Hospital Board	85	4.0 ± 0.92
Non-clinical staff	90	4.2 ± 0.59

4.4. Discussion

Through this validated consensus methodology, a global panel of patient safety experts and advocates reached consensus on the key factors that potentially determine safety and care quality on the surgical ward. Represented in this study are the most critical process-driven and organisational factors in this setting that warrant further investigation in order to understand how they may influence patient outcomes. Additionally, multiple potential markers of care quality as well as improvement measures that merit consideration have also been highlighted.

The first statement was “some wards are safer than others”. Much like staff members who engaged in the interview study, there was near unanimous agreement amongst the expert panel that variation in safety exists amongst surgical wards- reinforcing why this study was necessary in the first instance.

With regards to processes that are prone to error, aspects of the ward round have been highlighted. It is unsurprising that the panel achieved consensus on the vital need for a member of the nursing team to be present for the surgical round. However, more interestingly, the same level of presence for the consultant surgeon was not deemed vital; ward rounds that were not led by consultants were not seen as an element that promotes error. One may speculate, therefore, that the panel may view an appropriately qualified physician as sufficient.

A number of guidelines in the UK have indicated the benefit of consultant-led care, with documents published through the Academy of Medical Royal Colleges (*The Benefits of Consultant-Delivered Care*, 2011(310) and *Seven Day Consultant Present Care*, 2012 (311)) and the Royal College of Surgeons specifically (*Emergency Surgery: Standards for Unscheduled Care*, 2011(312)). The combined reports from the Academy of Medical Royal

Colleges supports a more "consultant-led" role for patient care, manifested by early and direct involvement in patient care from admission, especially in the case of emergency admissions. In the Royal College of Surgeon's recommendation, daily ward rounds are advocated, but can be "*carried out by senior trainees (ST3 or above) or trust doctors with equivalent ability ... and/or consultants, including weekends*" for some specific specialties- thus not placing any definite emphasis on the role of the consultant in leading the ward round in person (312). In the case of general surgery, there is an onus on the level of involvement in acute decision making and intervention but the intensity of involvement in subsequent ward rounds is not explicitly articulated.

There are key advantages to daily consultant involvement in ward rounds, and much of the work has come from a study of medical services. In their prospective observational study, Ahmad et al. demonstrated that twice daily consultant ward rounds, in comparison to twice-weekly rounds, resulted in decreased length of stay by almost a half – from an average of 10.4 days to 5.3 days- as well as almost twice the discharges and a decrease in bed occupancy from 95.3% to 87.5% (313). However, there was no effect on mortality or readmission rates. Reduction in length of stay has also been demonstrated in another single site study with daily consultant ward round (314). Here, a gastroenterology ward introduced daily consultant ward round, provided by a single consultant over a 2 week block and free from other duties, and supported by a multidisciplinary team (315). In addition to a reduction in the average length of stay from 11.5 days to 8.9 days, there was a reduction in mortality from 11-12.6% in the preceding years to 6% in the year after the intervention. Other studies have similarly demonstrated the impact of consultant-led daily rounds in medicine (316, 317). However, apart from Ahmad et al.'s study (313), these studies are based on retrospective data and further analysis of the effect on daily consultant ward rounds will need to be made. Furthermore, these studies that focus on actual inpatient stay are fewer than those that deal with the initial assessment and the level of consultant involvement at that stage e.g. consultants have been shown to produce faster turnaround time, administer more definitive management plans and refer patients to clinics when their presence is increased in the emergency unit (318).

In essence, patient status may evolve in between consultant reviews – which may be mitigated by daily consultant involvement. However, the practicalities are such that it has also been recognised that the level of involvement in patient care does not need to only be practiced through ward rounds but and can take the form of daily discussions with or updates to the consultant by the middle grade doctor performing the round (311). Guidance from NHS England, published since data collection was completed for this study, also recommends daily face-to-face consultant review, but also presents cases where this may be exempted (319). The frequency of consultant review may be tailored in accordance with the acute needs of the patient: medically optimised patients may be reviewed via a daily board round, with the actual face-to-face review delegated to another team member. Also, patients who are medically fit and awaiting discharge may only require review to ensure no further medical issues have arisen in the interim. In this way, consultant involvement is maintained but balanced against wider duties. Therefore, the agreement of the Delphi panel is likely in tandem with the flexible attitude taken to the need for a direct face-to-face consultant review on the ward round.

By contrast to the role of the consultant, nursing presence on the ward round has been deemed vital to improving communication between nursing and clinical teams regarding the management plans of patients and can help avoid omission and other errors. National guidelines and published ward round checklists support the participation and presence of nurses on the ward as an essential requirement (191, 320). However, nursing presence on the surgical ward round remains below expected standards (321, 322). This is an area of potential focus for future research.

In addition, the myriad of statements that achieved consensus highlights that there is an inherent complexity to the surgical ward environment and echoes the sentiments of the interviewees in Chapter 3. Firstly, there are many aspects that can affect the quality of nursing care. Above, it has been highlighted that nursing presence on the ward round is crucial. However, key areas of concerns were highlighted with respect to organisational factors that may affect this workforce – namely nurse staffing levels, skill mix, lack of senior nurses out-of-hours, overall morale and availability of good leadership. These were all agreed upon as determinants of ward safety. Care quality can also be at the mercy of miscommunication – both written and verbal- between teams, another key area of concern. Furthermore, other stressors – again rooted in how care may be organised by the institution – had a bearing on surgical care at the ward level; specifically, the presence of outliers, which was comprehensively presented as an area of concern by interviewees - also reached consensus as a key component to safety by the expert panel. The literature is in support of this, with outlier patients experiencing more emergency calls (208) and a 40% increased risk of in-hospital mortality (206). Thus, it is evident that multiple components of care processes and structures can contribute to any single facet of surgical care. Deeper exploration of the relationship between such variables will allow for targeted long-term, rather than temporary, solutions.

Finally, surrounding all of this is the physical environment. The importance of ward layout in facilitating safe care achieved consensus, with experts selecting a layout that allowed for a mixture of bays and side rooms or a racetrack layout. The arrangement of an inpatient ward has been an area of research -with multiple studies examining the roles of the layout types included in the Delphi (218, 220, 323, 324). There is evidence that although a private room may afford dignity and comfort, it can present challenges in the delivery of safe care. In one study, the impact of a ward designed with single occupancy rooms only on staff and patient experience was assessed (325). Patients admitted that they felt more protected in a bay with other patients around and some expressed that they felt that the level of monitoring they received in a single room was compromised; however, this was offset by advantages such as the privacy single rooms offered. Nurses, however, ultimately cited the advantage that open bays offered, including maintaining visibility with patients, as well as being able to easily see other members of staff and request assistance from within the bay. The move to single rooms also temporarily increased the risk of falls. This was mitigated by change in work patterns and intentional rounding. There is no denying that there is a role for single accommodation rooms within the surgical unit both to meet the patient's need for privacy and dignity - as well as a clinical area that will allow for isolation of patients where needed for infection control purposes. However, given the challenges posed from the wide array of factors already present when it comes to safe care delivery on the surgical ward, a ward design that promotes rather than hinders the nursing team ability to interact with their patients and one another freely becomes indispensable.

There was one aspect of organisational care that was mentioned by interviewees that also gained consensus amongst the expert panel: that the use of agency or temporary staff had a negative impact on safety in ward-based care. In the literature, the association between use of temporary staffing and care quality as measured by certain patient outcomes has been variable (59, 326, 327). Any potential detrimental effect may arise as a result of lack of familiarity with the unit as well as local practice and policy (327). Some studies showed that rates of infection may be higher where temporary staff are being used, as is the case in the study by Alonso-Echanove from 2003 (326). Here, a prospective multi-site observational study across eight intensive care units demonstrated that patients cared for by a temporary or "float" nurse for more than 60% of the time were 2.6 times more likely to develop central line infections. By contrast, Aiken et al. performed an analysis of survey data completed by nurses across four states and compared it to inpatient mortality data amongst surgical patients (59). Initially, before other characteristics were controlled for, there appeared to be an association between the use of temporary nursing staff and FTR and 30-day inpatient mortality rates. However, once the analysis controlled for other factors – namely nurse staffing levels as well as nurse work environment in combination (as measured by the practice environment scale of the nursing work index) – that association ceased to be seen. It is possible that, overall, the use of temporary nurse staffing does pose some potential impracticalities to providing timely and effective care as per local policy. However, underlying organisational shortcomings may be inadvertently overly attributing some of the risk to safe care to the temporary nurses directly; this is supported by Aiken et al.'s earlier 2007 study, which demonstrated that hospitals that required the use of temporary staff already suffered with low staffing and deficiencies (measured as staffing-resource adequacy); when this was adjusted for there was a less significant association between the use of temporary staff and most outcomes (276). This was also supported by Hurst et al., who suggest that work intensive, understaffed wards would benefit from the use of temporary staff (275). Hurst et al. could not be certain on whether there was an adverse effect from the use of temporary staff, but Aiken et al. (276) demonstrated that permanent nurses in hospitals with more temporary staffing did not necessarily express significant job dissatisfaction and were actually significantly less likely to be burned out.

A number of quality markers were also subjected to the Delphi process, with seventeen elements achieving consensus. These will need to be studied further to ascertain if they are indeed potentially measurable in real-time and ascertain their possible association with patient outcome at the unit level. Furthermore, grass roots level quality improvement measures will need to consider elements across process and structure as per the Donabedian model (265);

beyond addressing staffing issues, there are key areas in the environment that need to also be considered such as availability of staff but also in access to resources such as computer terminals, features of the environment such as physical space and stock and equipment availability. Successful implementation of improvement measures will require investment from several stakeholders – ranging from clinicians, nurses and other staff members to patients.

The novelty in this work is that a high-calibre, international panel of experts have considered the surgical ward environment in its totality, identifying the most meaningful quality markers. The statements presented to the panel originated from the experiences of frontline staff and patients. Further value and applicability were added by the fact that the panel also consisted of experts who are active clinicians or registered nurses with relevant experience in the day-to-day care of surgical patients. Many of the factors presented in this Delphi study have been described in the literature, but this is the first study to generate a more complete understanding by addressing all aspects of this care environment at once, thus presenting a montage of factors that span process-related and structural themes which will likely need to be considered in tandem when considering where errors in ward-based care arise. These most pertinent factors will be observed in real-time in the next chapter to ascertain their potential as quality measures.

4.4.1. Strengths & Limitations

One of the limitations of this study is that 70% of respondents were from the UK. Nonetheless, with the consensus threshold set at 80% of respondents scoring statements of 4 and above, the fact that such a volume of statements achieved consensus likely reflects the ubiquitous nature of some of these themes across similar health systems in Europe, North America and Australia.

This study, however, did not have participants who exercise their expertise in health systems within low- to middle- income countries. Therefore, it is difficult to truly extrapolate key findings to these settings, where process-related and structural challenges may differ.

Furthermore, 50% of those invited did not respond to the invitation to participate in this study. This is similar or slightly higher in rate to other studies were similar approaches to invitation were used i.e., email as a first point of contact with link to survey (300, 328). In studies where there was an element of modification to the Delphi with an initial panel interaction or for a niche area with a small pool of experts, the rate of return was understandably higher (293, 301). The number of panel members itself is not a concern (329). However, there is always the possibility that those who did not participate may have brought a different perspective to the exercise. Nonetheless, the heterogeneity with regards to range of expertise and the inherent homogeneity, i.e., focused patient safety backgrounds, do not diminish the overall applicability of these results.

The findings in this study signal that organisational level involvement in addressing certain elements of surgical ward -based care is required. However, the granularity of the findings offers an opportunity for grass roots teams to locally address many of these factors. For example, where staffing is deemed adequate, altering nursing practice in the first hours of the day to accommodate accompanying the ward round could be instigated. Additionally, encouraging clinical teams to produce or introduce established care protocols, such as enhanced recovery programmes, may help maintain uniform care, which may help nursing teams recognise any new issues that arise and facilitate communication.

4.5. Conclusion

Surgical ward- based care, where post-operative care is delivered, has been understood to be particularly vulnerable to error. In this study, an expert panel representing clinical, academic and patient-centric points of view have agreed upon the most important factors contributing to safe care on the surgical ward. These factors span multiple processes and organisational elements. Thus, addressing these care needs will require simultaneous consideration of all of these elements across these domains.

The next chapter details an observational study- to ascertain a potential link with care service delivery and factors that have been identified in this study. It is predicted that a combination of factors will need to be assessed against any specific patient outcomes, in support of the theory that the sum of these parts is greater than the individual components. Attempting to assess any of these in isolation is unlikely to be successful as "confounders" are likely to be other factors that have been suggested as contributors to care quality.

4.6. Acknowledgement of Participants (named with consent)

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Professor Marja Boermeester (Surgeon, Inventor of SURPASS checklist for surgery, Academic Medical Centre, Amsterdam. Netherlands)

Professor Sir Liam Donaldson (at the time Chair of Health Policy at Institute of Global Health Innovation, Imperial College London. England, UK)

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Professor Rhona Flin (Emeritus Professor, School of Psychology, University of Aberdeen. Scotland, UK)

Dr Amir A. Ghaferi (Associate Professor of Surgery and Business, University of Michigan, USA)

Mrs Helen Haskell (Mothers Against Medical Error, USA)

Dr Helen Hogan (Associate Professor in Public Health, London School of Hygiene, London. England, UK)

Emeritus Professor Sir Brian Jarman (Co-director of the Dr Foster Unit, Imperial College, London, UK)

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5. Measuring Variation on the Surgical Ward: An Ethnographic Observational Study

5.1. Introduction

Silber's seminal description of FTR (53), and the ensuing use of this as a way to demonstrate variable care quality between institutions, sharply highlighted that not all surgical units are created equal. Efforts have been made to understand the root of this variation, but thus far this has not led to a narrowing of the gap between the best and worst performing hospitals (100, 330). Given that FTR itself is a hospital-level metric, research has focused on understanding this variation through the interrogation of pre-existing large-scale databases. Factors such as hospital volume, availability of intensive care beds, nursing hours, presence of resident doctors and the level of technological advancement within care settings have been cited as potential reasons for this variation (56, 109).

There is a significant portion of FTR that cannot be explained by institutional variations alone. A recent study by Fry et al. published in *Annals of Surgery* in May 2020 demonstrated that since 2005 there has been an overall reduction in mortality, mainly driven by improved FTR, with a marginal reduction in rates of serious complication (100). However, 30% of improvement in mortality cannot be explained by FTR and reduction in overall mortality alone - with the authors expanding that further consideration of "hospital micro-system factors" is now required. A closer assessment of the post-operative care environment is warranted to assess variation in care quality and safety in the more granular features of ward-based care.

Observational and ethnographic studies allow for the *in-situ* evaluation of care delivery, the environment within which that care is delivered, and the potential impact on outcomes. Existing studies have considered individual areas of practice or clinical care; in a study by Norris and colleagues, a human factors approach was adopted to address functionality of the bedspace (213). The multidisciplinary research team (consisting of clinicians and designers) engaged in a direct observation of current practice as well as interviews to understand the obstacles, then followed this up with a collaborative design of a number of prototypes including equipment, signs and recommendation for handover space to facilitate more effective care delivery. Ultimately this study demonstrates the feasibility of identifying and ameliorating a locally characterised obstacle and engagement with local personnel, although no long-term outcomes are described in follow-up to this work. A further study used observation to map the venepuncture process and identified that re-organisation of equipment in a more user-friendly way reduced the time spent gathering that equipment; a simple intervention that could be implemented locally within existing resources (331). Furthermore, ethnography can help inform future plans for care environments, as was the suggestion by researchers who observed and mapped nurse travel around a unit and identified a number of environmental factors that caused inertia to task performance (332).

The magnitude of variations in local care processes overall, and their potential effects on post-operative care quality and patient outcomes, is yet to be described comprehensively. Quantifying the level of variation at the grassroots level of processes of care, structural factors and care outcomes themselves could serve to identify locally attainable targets for quality and care improvement.

Thus, in follow-up to the interview study (chapter 3) and Delphi study (chapter 4), which identified structures and processes pertinent to safety on the surgical ward, this chapter describes an observational study.

This study aimed to assess the variation present in these previously identified factors, and the feasibility of directly capturing their effects on care delivery, as a means to drive quality improvement and outcomes optimisation.

5.2. Methods

5.2.1. Study Design

Prospective observations of care processes and the structural arrangements within which they were conducted, were performed on three general surgical wards across two centres. These comprised of a tertiary university hospital and a district general hospital. Observations were conducted as continuous 12-hour periods of observation by the author of this thesis. Both day and night shifts were sampled in a purposive fashion to capture a broad representation of practice across days, nights, weekdays, and weekends. Additional ethnographic data was also captured where it contextualised the variations seen.

Observations were performed on non-consecutive days between 28th February and 13th September 2017.

5.2.2. Participant Eligibility

All nursing and medical staff administering care on the observed ward were informed of the study in advance via posters and dissemination of participant leaflets at nurses' stations and doctors' offices. Ward managers and matrons were engaged at the outset to help increase awareness of the study.

Patients were required to speak/read English and have the capacity to provide informed consent. Patients admitted under the care of a general surgical team (emergency, upper gastrointestinal, bariatric or colorectal) and over the age of 18 were considered for inclusion in the study. Patients were identified via the clinical and nursing teams engaged in the observation as meeting this criterion and were approached to be enrolled in the study.

The study was approved by an institutional ethics review board (NHS London REC 16/LO/1937). All participants, both patients and staff, were provided with participant information sheets, and signed consent forms to participate in the study.

5.2.3. Data Collection

The factors observed in this study were determined from the preceding studies; the interview study of surgical ward stakeholders (chapter 3) identified multiple factors across process and structure (271). The subsequent Delphi consensus study considered these and prioritised those that warranted further consideration. As a result, three variable domains were captured in the data collection, reflecting these identified factors. These domains are care processes, care environment and organisational health. (see table 5.1). The aim was to record measurable variation; therefore, the nature of data collection was numerical data for each observed factor e.g., frequency. Ethnographic data was captured through field notes and used to help understand this variation.

Table 5.1: Outline of the domains and variables recorded

Variable	Method	Metric
Processes of Care		
Ward round Characteristics • Clinical team structure • Nurse presence • Interruptions to ward round	Direct Observation	Clinical Team Structure- numbers of each grade on team Nurse presence- proportion of patients seen with a nurse present Interruption counted if caused team member to step away from the ward round or stopped the ward round whilst team attention focused elsewhere
Clinical/ Nursing task for patient care*	Direct Observation/ review of medical notes	Time from order to completion
Medication administration*	Direct Observation/ review of electronic drug chart	Time delay from scheduled to administration
Care Environment		
Footfall	Footfall counter - Total number/2 (to account for entrance/exit)	Person visits
Patient complexity	Direct observation	Percentage of patients requiring nurse-specific care or extra mobility support e.g., IV fluids, IV medication, stoma care, nutritional support etc.
Outliers	Direct Observation	Percentage of patients that are outliers
Physical layout	Direct Observation	Arrangement of ward – e.g., bays, single rooms etc. Facilities available to staff and patients.
Organisation Health		
Patient: nurse ratio	Direct observation	Ratio
Healthcare: Nurse ratio	Direct observation	Ratio
Presence of a ward manager/ matron	Direct observation	Yes/ No
Occupancy	Direct observation	Percentage of beds occupied, and discharges/admissions observed
Agency Nurses	Direct observation	Percentage of nurses
Patient reported safety*∇	PMOS questionnaire	Score
Staff reported safety*∇	SAQ questionnaire	Score

* - Outcome Measures ∇ - Reported in Chapter 6

Variation in care process (e.g., ward round, medication administration, meeting patient care needs) were recorded through direct observation. Any interruptions during a care process or omissions were noted, as well as the timeliness of process completion. In the case of interruptions, this was any stimulus that resulted in an observed individual performing a process having to stop that process and divert their attention elsewhere. Additionally, case records and electronic drug charts were reviewed to assess any further communications or plans that may have been recorded in that given period of observation.

Environmental factors were observed directly; to establish overall patient population complexity, outlier numbers and staffing levels, the observer liaised with the nurse in charge immediately after nursing handover and at the end of the shift to ensure accurate data. This ensured an accurate record of present conditions. In the case of patient complexity – this was recorded through a number of measures such as the need for intravenous medication or assistance with mobilisation. The observer also liaised with clinical teams to establish the team make up and total number of patients under their care for the periods of observation.

To help reflect other aspects of the ward, and to address variables such as the "general atmosphere" of the ward, footfall was identified as a potential marker. In the case of the former, this was achieved using an automated device that was mounted by the main entrance to the ward and employed infra-red technology to capture data. At the beginning of each period of observation the device was reset. At the end of the period of observation, the number was recorded, and halved to account for a signal also being detected when individuals left the ward (see figure 5.1).

Clinical team make-up was observed and recorded directly. The number of patients under the team in total were derived from the clinical team's patient list and verified with team members directly.

Figure 5-1: Infrared people counter used in the course of the study to measure footfall

5.2.4. Outcome Measures

The end points for patient outcome were delays (defined below) or omissions in care administration, both in terms of nursing and clinical tasks, as well as delay in medication administration times compared to scheduled time.

Direct patient- and staff-reported outcomes via validated questionnaires were also captured and are reported separately in chapter 6. Although captured in real-time with the observations described in this chapter, the questionnaire results are explored in depth separately as they represent subjective views of important stakeholders with the shifting nature of the care environment, whereas this chapter will explore the variable nature of the care environment itself through directly observed objective measurements.

Delay/ omission in care definitions

For each patient recruited into the study, planned care as outlined during the ward round was recorded. Any later plans made during the course of the observation period were also recorded. Patients were then observed until the planned care was completed. Plans that were not completed within the 12-hour observation window (i.e., end of the shift) were classed as omitted.

Medication administration scheduled and actual administered times were also recorded along with route of administration. Drug administrations exceeding or preceding the scheduled time by 60 minutes were recorded as errors in line with existing guidance; the institute for Safe Medication Practices recommends that non time-critical medications prescribed more frequently than daily up to every 4 hours should be given within a 1 hour window before or after the scheduled time (333). For the purposes of this study, this recommendation was applied to all medication administrations. To assess daily variation, the proportion of medications that met this criterion were calculated and represented the outcome measure for that period.

Further subgroup analysis was performed (intravenous vs non-intravenous by early 60 minutes vs late 60 minutes) to ascertain if there were specific behaviours with regards to how medication administration was affected. This analysis was undertaken as during the course of the observation, it was noted that there appeared to be a prioritisation of intravenous medication administration, especially the morning administrations. Thus, the analysis seeks to quantify this observed behaviour.

During night shifts, in the absence of a ward round to set out new clinical targets or tasks at the beginning of shifts, outcome measures for this portion of 24-hour cycle focused on medication administration times only.

5.2.5. Data Analysis

Data was collated in Microsoft Excel (Microsoft® Excel for Mac, Version 16.40). Descriptive statistics were calculated and are reported below. Median values and ranges are reported for observed factors.

5.3. Results

5.3.1.Participants

Fifty-four patients were recruited into the study, of which 33 were male. The median age was 55 years (range 21 to 83). Patient demographics are detailed in table 5.2.

Of these patients, 66.7% were under the care of emergency surgery team, and 33% were under elective care. Patients had a broad range of conditions, both malignant and benign, under both services and represent a broad sample of general surgical patients with common presentations, who have undergone common procedures. These patients were observed for a total of 128 patient days over 56 non-consecutive ward days. The median number of days each patient was observed for was 2 (range of 1- 7).

A total of 844 hours (624 daytime and 240 nightshift hours) of direct ward observations were performed. Of the day time hours, 72 hours of observation occurred during weekend shifts. Of the night time hours, 36 hours of observation occurred over the weekend.

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Table 5.2: Demographics and clinical presentations of recruited patients

Gender	
Males	33
Female	21
Ward recruited from	
1	41
2	9
3	3
Speciality team	
Colorectal	12
Upper Gastrointestinal	6
Emergency	36
Age Median (range)	55 (21- 83)
Type of Admission	
Elective	10
Emergency	44
Surgery/intervention during admission	35
Length of stay days Median (Range)	6 (1-433)
Charlson Scores **Median (range)**	2 (0-11)

Admission Diagnosis	n
Elective	
Colorectal:	
Cancer	6
Planned reversal of stoma	3
Other (benign)	3
Upper Gastrointestinal:	
Cancer	3
Other (benign)	2
Emergency	
General:	
Appendicitis	1
Superficial abscess	2
Intra-abdominal collection	3
Incarcerated hernia	2
Small bowel obstruction	2
Biliary/Upper gastrointestinal	
UGI Haemorrhage	1
UGI perforation (duodenal/oesophageal)	3
Biliary colic	1
Cholecystitis/cholangitis	7
Acute Pancreatitis	5
Colorectal	
Stoma blockage	2
Infective colitis	1
Per rectum bleed	1
Trauma	
Penetrating injury	4
Blunt injury	1

Surgical Procedures/Interventions	n
Elective	
Colorectal:	
Hemi- /total colectomy	4
Anterior resection	2
Reversal of stoma	3
Pelvic exenteration	1
Adhesiolysis + enterocutaneous fistula repair	1
Formation of stoma	1
Upper Gastrointestinal:	
Oesphagectomy/ Gastrectomy	2
Hiatus Hernia repair	1
Other Elective	
Incisional hernia repair	1
Emergency	
General	
Appendicectomy	1
Incision and drainage of abscess (superficial)	2
Laparotomy- bowel resection+ abscess drainage	1
CT- guided abscess drainage	1
Emergency hernia repair	1
Adhesiolysis	1
Biliary Upper GI	
Duodenal ulcer repair	2
Repair of perforated oesophagus	1
Cholecystectomy	3
ERCP	1
Colorectal	
Formation of stoma	1
Drainage of diverticular abscess	1
Trauma	
Laparotomy	4

Co-morbidities	n
Cardiac/vascular	
Ischaemic heart disease	5
Arrythmias	5
Hypertension	14
Peripheral vascular disease	3
Other cardiac	2
Respiratory	
COPD	1
Asthma	6
other respiratory	2
Metabolic	
Diabetes Mellitus	9
Hypothyroidism	3
Other metabolic	2
Other	
Musculoskeletal	5
GORD	3

5.3.2. Variation in Processes of care

A total of 70 ward rounds were observed. These were comprised of 55 emergency team ward rounds, and 15 elective ward rounds (11 for colorectal surgery, 4 for upper gastrointestinal surgery).

5.3.3. Clinical team composition

There were variations with regards to composition of the clinical and nursing teams that participated in the ward round. Consultants invariably led the emergency team ward round (96.4%). However, 86.7% of the elective ward rounds were led by registrars. The junior members of the team (i.e., the equivalent of a foundation year doctor or senior house officer), who would conduct the clinical plans outlined during the round, were relatively consistent across days observed. 13/15 (86.7%) elective rounds had 2 foundation year one doctors (remaining comprised of a single registrar only round, and a round with one foundation year 1 doctor). Emergency rounds comprised of a mixture of foundation year 1 doctors and advanced nurse practitioners (ANPs), with 78.2% of emergency rounds involving 3-4 of these team members.

5.3.4. Nursing participation in the ward round

Nursing representation on the ward round varied from no presence on the round, to presence for every patient reviewed on the round (100%). The main source was the nurse in charge, whose role was assigned so that he/she would be freed from looking after a cohort of patients to fulfil a supervisory role. Despite this wide range, there was a high median with a nurse present for 86.3% of the ward round. One of the factors that challenged nurse accompaniment for a round was when a further simultaneous round was being conducted by a second team; on 17/56 days (30.4%), other ward rounds were being conducted at the same time as the observed round. On these occasions, nurses accompanied a median of 70% (range 14.3-100%) of the ward round, compared to 90% (0-100%) when there were no simultaneous rounds.

A further potential obstacle was a clash of the round with the nursing handover; overall, failure to complete the nursing handover at the designated time (of 8 am), was seen in half of the observed days (51.8%, 29/56). There was a clash with 14 ward rounds with a median overlap of 10 minutes (range 5-30 minutes). However, the median accompaniment of nurses on these days was 90.3% (range 14.3-100%). Even when simultaneous rounds were being conducted in addition to overlaps with nursing handover, the rate of nursing presence on the ward round did not diminish (median 95.7%, range 14.3-100%). Although the nurse in charge was occupied in handover, the absence was compensated by other members of the nursing team, such as the night staff who were waiting to be relieved. These team members would accompany the review of patients they had been responsible for overnight. The information from the round then would be passed on to the day nurse after handover. As the round moved from patient to patient, the nursing team arranged their presence for the review of patients they were responsible for until the nurse in charge joined the round.

5.3.5. Timing of the ward round

Despite the intention that ward rounds should lead the day's clinical activity, conflicting commitments meant that this resulted in significant delays or deviations. Timing of the ward round was highly variable; although the median start time was 08:40 in the morning (with clinical handover start times ranging from 07:30 to 08:00 at the observed sites), the range was

07:00 to 10:15. The later end of the range is representative of rounds that were initiated following rounds on other wards i.e., patients on other wards were seen first. In the case of emergency team ward rounds, these were consistently after 8 am as the emergency team attended handover to receive the list and history of new admission from the night team first. By comparison, 9 of the elective ward rounds started before 8 am (constituting 40% of all elective ward rounds). These early rounds were seen where the clinical team was mitigating for competing commitments such as starting the operating lists or attending clinics. All of the rounds conducted before 8 am had a lower median nurse accompaniment of 66.7% (range 0 – 100%).

There was also a clash with other clinical commitments- such as a clash with the MDT meeting. On these occasions, the round was suspended and recommenced at a later point. In addition, on two emergency ward rounds, it was noted that the registrar (who was on call) was also the only available registrar to perform an elective round. With agreement from the emergency consultant, the registrar broke off from the emergency round to see the elective patients, then later re-joined the emergency round.

On another occasion, an elective ward round that was nearing the end was restarted when a consultant joined, so the junior team had to restart the round. However, on this occasion, the registrar who had led the round was also cross covering the emergency theatre list and thus broke off whilst the house officer repeated the round with the consultant.

5.3.6. Interruptions during the ward round

The majority of ward rounds were subject to some form of interruption (45/70; 64.3%) which either served to distract the whole team from conducting the round or caused a member of the ward round team to be distracted from the process. In all, 88 interruptions were recorded (table 5.3). The median number of interruptions during a ward round was 2 (range 1-8).

By far, the leading cause of interruptions were telephone calls, accounting for almost half of all the interruptions (42/88; 47.7%). Most of these calls were made to the consultant leading the emergency round (57.1%, 24/42) and affected 15/70 rounds (21.4%). Some examples of these phone calls were calls from the registrar assigned to emergency theatre (as the emergency consultant was also supervising this area) or from other surgical team members outside of the emergency team. On 5 occasions (7.1% of all rounds), the consultant conducting the ward round left to tend to emergency theatre or was called away to another part of the hospital. The accompanying registrar was left to complete the round. Another source of ward round inertia or interruption came from the patient encounter, when unplanned discussions with family members were instigated by the patient. Where this was initiated by the clinician to ascertain further clinical details, this was not counted as an interruption.

The next most common source of interruptions was paging of the clinical team during the round. These accounted for 20.5% of interruptions (18/88) and required a team member to step away to answer. Thereafter, in person interruptions were the third most common; these consisted of queries from other nurses in the ward or allied teams such as stoma nurses or dieticians. One in-person interruption was from another patient who was already seen on the round, who wanted to clarify their plan.

The remaining interruptions came out of necessity – such as tending to an unwell patient- or out of technical obstacles i.e., computer malfunction so patient notes not accessible.

Table 5.3: Nature of interruption encountered during the clinical ward round.

Nature of interruptions (total observed = 88)	**Number**
Mobile phone calls	42
Pager calls	18
Interruptions in person: Staff Other patient (not one being reviewed at the time)	9 - 8 - 1
Impromptu discussion with relatives (telephone or in person)	5
On-call consultant called away from ward round to theatre	5
Team members performing tasks during the round e.g., referral	4
Clash with a clinical departmental meeting (i.e., MDT)	3
IT/technical failure	1
Unwell patient	1

5.3.7. Care Team Work Burden

With respect to the clinical team, the number of patients they were responsible for in the hospital overall varied, with a higher burden at weekends when only one clinical team was on site. The patient: junior ratio was median 6.0:1 (range 7.5:1 to 14.0:1) for elective teams, 7.7:1 (range of 5.0:1 to 30.0:1) for weekday emergency teams and 12.2:1 (range of 11.7:1- 17.0:1) for weekend emergency teams.

Furthermore, there was variation in how widely dispersed patients under the care of a particular surgical team were within the hospital. The proportion of patients that were actually located on the observed surgical ward were median 38.5% (11.4 – 83.3%).

5.3.8.Variation in the Care Environment

Critical features of the three observed surgical wards are presented in table 5.4. All were modelled on a bays and side rooms arrangement and only varied slightly with regards to dimensions, amenities available and level of visibility of patient beds to nurses from the workstation. An all 3 wards, the nurses' station was based centrally with bays and side rooms radially allocated, and inevitably there were 2-3 bays in each ward that were not visible from the nursing station. This was also the case with side rooms. Two of the three wards had a doctor's office in adjacency. Although not a quantifiable metric, it was observed on occasion that this facilitated communication, as nurses from the ward would approach the office to discuss patient care with clinical teams in person, rather than relying on the paging system. Thus, as ward layout was fixed, variation in other aspects of the care environment were observed.

Table 5.4: The nursing arrangement on observed wards

Ward	**1**	**2**	**3**
Hospital	**Teaching Hospital**	**Teaching Hospital**	**District General**
Bed Number	23	14	30
Layout	Combination of bays and side rooms		
Bays	4	3	6
Bed in each bay	5	4	4-5
Bathroom facilities in bay	Outside of bay/ corridor	Within the bay	Outside of the bay/ corridor
Side Rooms	4	2	5
Bathroom facilities in room	Yes	Yes	Yes
Nursing Numbers: Day Weekend Night	 7 6 5	 3 2 2	 7 7 6
HCA Day Weekend Night	 2 2 2	 1-2 2 1	 3 2-3 1
Intended ratio nurse: bed	Weekday		
	1 bay (HDU model) - 2 nurses (2:1) Remaining bays- 1 nurse: **(5:1)** 1 nurse for side rooms (**4:1)**	1 bay each +/- a side room **(4-5:1)**	1 bay each (4-5:1) and 1 nurse for side rooms (5:1)
	Weekend		
	side rooms divided amongst the non-HDU bay nurses **(6-7:1)**	7:1	As for weekday
	Night		
	HDU as for day (2:1) Remaining bays and side rooms **(6-7:1)**	7:1	6-7:1

5.3.9. Patient Complexity

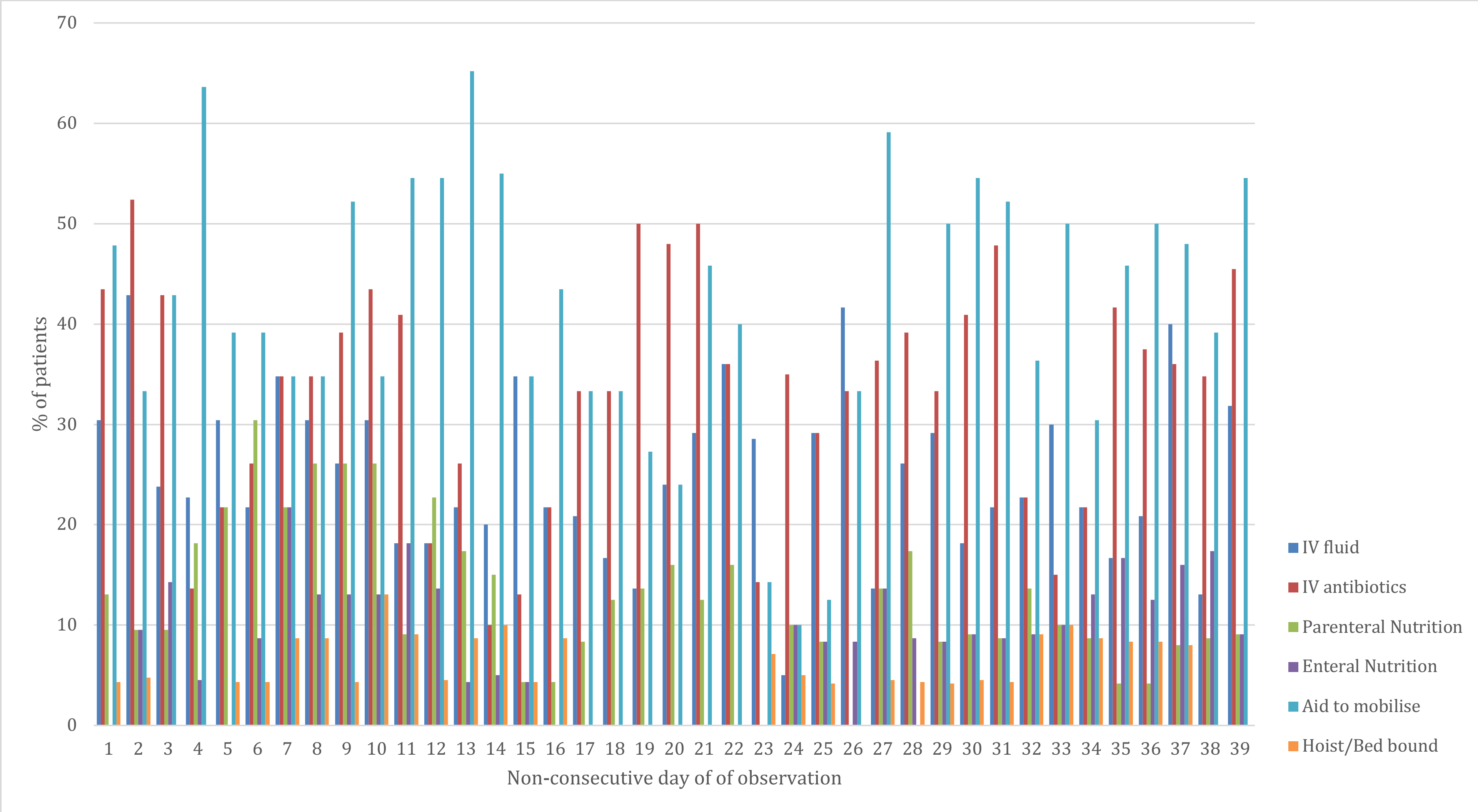
There was daily variation in the care needs of patients- both in specific nursing expertise as well as the physical requirements. This is exemplified in figure 5.2, which shows the degree of variation on a single observed ward on a shift-level basis. These variations highlight the fluctuating patient demands and work volume or intensity for nurses at the unit level on a day-to-day basis.

Overall, a quarter of patients required intravenous fluid therapy, and a third were on intravenous antibiotics. The median daily percentage of patients requiring intravenous fluid was 23.1% (0-50%) and for intravenous antibiotics was 34.8% (10-53.8%). Despite this high load, not every nurse on every shift was trained to administer intravenous therapy. Although the median was 100% (range of 66.7- 100 %), this was not the case a quarter of days (28%).

There was also variation in how much assistance in mobilisation patients required from healthcare staff: the percentage of patients requiring additional physical assistance to mobilise ranged from 0 – 65.2%, with a median of 35.6%. Hoist transfers or bedbound patients were present on 34/56 days (60.7%). The median proportion of the patient population at the instance of observation requiring this was 4.3% (0 – 15.4%).

Some patients were also on enteral or parenteral nutrition, which also required more technical skills and demand from the nursing team. The median proportion was 4.8% (range 0- 21.7%) and 8.7 % (0-30.4%) respectively.

Figure 5-2: Variation in patient complexity at a daily level on a single surgical ward



5.3.10. Footfall

The level of traffic through the ward was measured using footfall. Due to technical problems, only reliable measurement of traffic through one of the three wards could be analysed. On this ward, median footfall overall was 616 person entries per day (355-1008) which reduced to 532 at the weekend (range 435-550) and 228 at night (118-450).

5.3.11. Outlier Patients

The presence of outlier patients, i.e., where primary care was provided by other specialty teams, who were placed on the observed ward for capacity reasons were common. Outliers were present on the observed wards on most days (54/56; 96.4%), representing 3.7- 53.8% of the ward population (median 21.4%) of the ward's total bed capacity.

5.3.12. Variation in Organisational Health

Nurse Staffing

The number of nurses required on a ward was a fixed number – regardless of the level of ward occupancy. These are outlined in Table 5.4.

Staffing failed to achieve these numbers, and thus a ward was understaffed as per local policy, on 28.6% (16/56) of observed days. On these days, nurse staffing ratios ranged from 3.3:1 to 7.0:1, as this was also influenced by the occupancy rates. By comparison, all observed night-time staffing was at the required number i.e., there were no shortages.

Maintenance of staffing numbers with agency nurses was required on 48.2% (27/56) of observed days, and 25% (5/20) of night shifts. On 6 of these day shifts, 2 agency nurses were required, representing 40-50% of the nursing team in that instance.

in 33/50 weekday observations, the ratio of nurses to healthcare assistants was 3.0:1 or less. This was also the median with a range of 1.0:1 to 8.0:1. At the weekend, 3.0:1 was the median, with a range from 2.0:1 to 7.0:1. On nights, the median was a slightly lower at 2.5:1 but with a similarly wide range of 1.7:1- 5.0:1.

Additionally, the presence of nursing leadership was noted to be at certain times; matrons or ward managers were present usually on weekdays from 8am to 5 pm.

Occupancy rates

Ward bed occupancy rates per observed 12-hour period varied from 50-108.7%. 100% occupancy was seen on 25/56 (44.6%) and greater than 100% capacity was seen on 19.6% of days. This occurred where additional escalation beds were placed into bays to meet increased organisational demand on a temporary basis. However, on these occasions, the nursing numbers were not increased i.e., additional nurses were not allocated to cover escalation beds.

5.3.13. Care Outcomes

Observed Care Delivered: Care decided on the ward round or later by the clinical team

A total of 226 discrete care items were recorded during the observation; these were comprised of 157 tasks to be delivered by the clinical team, and 69 tasks to be delivered by the nursing team.

The clinical tasks were planned in 50/56 days and time to completion are demonstrated in table 5.5. Average time to completion of tasks were calculated for each period of observation (table 5.6). The median completion time for all clinical tasks was 02:50 hours (ranging from immediate execution of a task to not being performed by the end of the shift). Nursing tasks occurred over 34/56 days with a median completion time of 02:45 hours, with the range as with clinical tasks. Twenty-one tasks were not completed by the end of the observed shift. These were mainly clinical tasks (19/21 – representing 12.1% of all clinical tasks). By comparison there were only 2 omissions in nursing tasks (2.9% of all nursing tasks). This indicates that at times, conditions were such that care items were missed.

Table 5.5: The range of clinical and nursing tasks observed

Clinical tasks	Time taken to perform task - hours and minutes (median (range)		Nursing Tasks
Total	157	69	Total
Subgroups:			
Blood tests	45 (28.7%)	19 (27.5%)	Removal of drain/ catheter
Making a referral to another specialty	36 (22.9%)	13 (18.8%)	Sit patient out
Prescription Change	35 (22.3%)	8 (11.6%)	Removal/ change of therapeutic agent
Radiology Request	22 (14.0%)	7 (10.1%)	Addressing change in oral intake status
Invasive procedure	7 (4.5%)	6 (8.7%)	Wound attendance
Completion of discharge summary	4 (2.5%)	4 (5.8%)	Specimen collection
Other (including new cannula siting, wound attendance, following up results etc)	8 (5.1%)	4 (5.8%)	Specific monitoring requests
		3 (4.3%)	Patient Training/ Education
		5 (7.2%)	Other- including bedside test, invasive treatment, discharge arrangement

Table 5.6: Overall time delay from request to performance of the main completed clinical and nursing tasks

Clinical tasks	Time taken to perform task - hours and minutes (median (range)		Nursing Tasks
Overall	02:07 (00:00 - 10:24)	01:39 (00:00 -10:04)	Overall
Subgroups:			
Blood tests	03:22 (00:00- 10:24)	01:19 (00:38-08:33)	Removal of drain/ catheter
Making a referral to another specialty	03:51 (00:02 - 08:31)	01:36 (00:00-07:05)	Sit patient out
Prescription Change	00:31 (00:00 – 09:48)	03:45 (00:05-07:05)	Removal/ change of therapeutic agent
Radiology Request	00:03 (0:00-03:20)	00:00 (00:00 – 03:10)	Addressing change in oral intake status
Invasive procedure	01:28 (00:00-05:39)	08:32 (03:45-10:04)	Wound attendance
Completion of discharge summary	00:52 (00:29 – 03:28)	06:30 (00:40-08:05)	Specimen collection
Omissions:			
Radiology requests	2	1	Removal of a drain
Blood tests	6	1	Failure to complete patient training (for self-administration of low molecular weight heparin.)
referrals to other specialties	7		
omissions of a drug chart amendment	2		
provision of a patient information leaflet	1		
wound attendance	1		

Medication Administration

A total of 2017 individual medication administrations were recorded during the study. Of these, 543 (26.9%) were administered in the course of night time shifts. These shifts overall accounted for 27.8% of the total shifts observed.

The median proportion of medication associated with administration error was 33% (range 2 – 70%) during daytime shifts; this was considerably lower at night, median 7% (range 0 - 63%).

Over half of all administered drugs on these wards were either analgesia or antimicrobials (34.8% and 19.9% respectively) with both entailing multiple doses a day. Further subgroup analysis was performed as it was noted during the observation that the morning intravenous antibiotics were given by the night staff before the end of their shift. On the 42 days that 8 am intravenous antibiotics were scheduled- the average administration time on a third of these days was equal to or earlier than 60 minutes before the scheduled time (37.5%, 15/42 days). In contrast only 1 of the 17 days in which oral antibiotics were scheduled at this time were administrations made this early. In fact, the median time for oral antimicrobials was 46 minutes after scheduled time (range of -62 minutes to + 170 minutes) compared to intravenous preparations which had a median of 43 minutes *earlier* than scheduled (range -126 to +101 minutes). This was not reflected at the other time points both during the day and night.

By comparison, regularly prescribed analgesia overall had a less marked swing in the 8 am administration time, with intravenous analgesia given at a median average time of 35 minutes *early* (range -135 to +120 minutes) compared to oral which was given 31 minutes *after* scheduled time (range -200 to +99 minutes).

5.4. Discussion

This study is the first to prospectively capture and characterise the daily variation of multiple factors determining the organisation and delivery of surgical ward-based care. Through this ground-level observation over hundreds of hours, the dynamism of this environment in terms of obstacles, disruptions, and disparities are evident, even within a single unit. This study has highlighted the variable staffing (pre-determined nurse to patient ratios were not achieved on 28.6% of observed shifts), variable patient needs according to complexity as well as the role of organisational pressures, with surgical wards expected to care for outlier patients on almost every observed shift as well as contend with high occupancy rates.

Processes could also vary depending on ward conditions. One of the prime examples of challenging conditions for practice encountered was the variation in the nature and quality of the ward round. Multiple conflicting priorities are evident, such as meeting other clinical commitments, as well as the frequent disruptions to the round. Previous research has demonstrated the link between ward round quality and measurable patient outcomes (266). In a study by Pucher and colleagues, variations in bedside patient assessment during ward rounds were associated with poor outcomes; patients experiencing lower quality wards rounds experienced preventable errors or were managed poorly. A systematic toolkit introduced on the basis of this study demonstrated improved performance in the conduction of ward rounds and detecting and managing complication through a standardised checklist (188). Further interventions to facilitate training of the ward round team have also been developed (334). Such measures may help focus the efforts of the team, despite the external challenges they may face to completing this process safely.

Further potential obstacles to completing a safe round included a clash with at least one other round in 30% of rounds and during 20% of rounds the nursing handover was still ongoing. Additionally, some rounds started earlier than planned and clashed with nursing shift changes (13%). Although overall nurse accompaniment rates exceeded that of a recent audit of surgical rounds in England where only 44% of patients were seen with a nurse (335), these occurrences either diminished nurse presence on the ward round (16% decrease with simultaneous rounds, and almost 20% decrease for the early rounds), or required a "workaround" by the nursing team. This is where the team has employed an alteration in practice to overcome a workflow obstacle, to achieve a final goal- in this case, maintaining nurse involvement on the round (336).

A further example of a workaround in this study was the early administration of 8 am intravenous antibiotics- the final duty of the night team prior to handover. This facilitated a smooth start for the day team, who would have to contend with rounds and other aspects of patient care during the morning, although in a large proportion of patients, this meant an administration outside of the standard 60-minute window of scheduled time.

The relevance of this is two-fold; firstly, the fact that nursing accompaniment is diminished is concerning given the recommendation in place; the Royal College of Physicians (RCP) white paper *Ward rounds in medicine: principles for best practice* recommends that a senior nurse is present for every patient review on the round to facilitate effective communication (320). Secondly, although the workaround culture offers a potentially innovative role, the evidence highlights potential negative consequences. An example is an observation of barcode assisted medication administration – where nurses proceeded to administer medication in the face of obstacles such as missing wristbands or bar-codes from wristbands, or nurses participating in scanning of medications for multiple patients at a time. In administrations involving workarounds, there was an 8.2% error, compared to 0.7% for non-workaround administration (337).

With regards to addressing timings of the round, this is also highlighted in the RCP document, with a recommendation that “scheduling” be attempted to avoid such occurrences where nurse accompaniment may be compromised. The difficulty of scheduling a ward round in such a manner is that, as demonstrated, clinical teams are under pressure to fulfil roles that are often in direct conflict with the ward round. The elective team were usually scheduled for a clinical commitment that could either be a clinic at 9am or an operating list that starts even earlier, requiring consenting and team briefing to be performed. The emergency team had emergency theatre to contend with as well as the multiple communications that they would field in the course of the round from phone calls to bleeps. In addition, the higher patient volume and the spread of patients across the hospital complicates matters further. Given the importance of this process in directing patient care, streamlining focus on this task is required. This may be in the form of protected ward round teams – with a dedicated consultant or suitable deputy- who can execute this duty without external stressors such as conflicts in commitment. This would be akin to other measures taken in safe care provision, such as protection of the nurse during drug rounds – to the extent of wearing a “do not disturb” tabard in some cases (338).

The extensiveness of interruption to the round demonstrated in this study has been shown in a previous 2008 audit of critical care unit processes (339). These interruptions also included multiple calls, pagers and interruptions by other members of staff. The audit surmised that essential interruptions were in the minority, accounting for only 27% of daytime ward round interruptions. However, the potential impact of such interruptions on errors has not been defined for the process of ward rounds. Currently, the effect of interruptions and patient outcomes overall have been limited. In a systematic review from 2010 – only seven studies existed in the literature that attempted to characterise the effect of interruptions on patient outcomes with a mixed set of results (340). In the last year, a further review has demonstrated that there is still a limit in the evidence that supports the role of interruptions in harm, but certainly there is a potential to employ more sophisticated research methodologies where interruptions are studied within the context of the associated co-factors that may promote or prevent error (341). However, the potentially deleterious effect can probably be extrapolated from data that supports the association of interruption to medication administration and errors (270). In one study, over half of drug administrations were observed to be subject to interruptions, with each event in a single process associated with a 12% increase in procedural failures and an almost 13% increase in clinical errors (342). Another study found that almost every medication administration was interrupted, with one-third of these resulting in procedural failures, although there was only a small percentage of clinical errors (less than 4%) (343). Thus, there is merit in pursuing an understanding of the role and measurement of interruptions.

The second domain of variables- the care environment- was characterised in this study by the complexities of care demands e.g., the burden of intravenous medication administration and the degree of assistance required by patients to mobilise. Quantification of work volume or intensity through the terms of patient demands was necessary. Historically, work burden has been described in terms of ratios or nursing hours. However, as early as 2009, the merits of these measurements alone in reflecting the reality of care provision has been questioned (344). In the intervening years, a suitable measurement of patient acuity, and in turn intensity, is yet to be established for use in quality improvement. A recent study, published in 2017, retrospectively assessed the care needs of 400 patients admitted to a single institution with a diagnosis of heart failure (345). The acuity score for patients was calculated using software which utilised a nursing taxonomy to extract relevant nursing documentation from electronic health records, and automatically generate a score. These scores were tempered with nursing judgement, which formed part of the review of the results from the software. Using this method, the authors demonstrated the degree of fluctuation in overall patient acuity in single units. The relevance of this is that the standard nurse: patient ratios that current practice is established upon are unlikely to meet the demands of a dynamic workload. Furthermore, opinions about the ideal patient to nurse ratio is mute, though absolute minimums are required for practical purposes. Although data generated in this study has not been able to establish the relationship between work intensity and patient care, it does demonstrate the daily variation in care requirements of patients on observed wards. Thus, finding ways to better quantify workload is an area that is ripe for further research; in creating such care quality metrics for the surgical ward, a real-time patient acuity scale may help to inform where organisational support for the ward is required.

The last element within the care environment is the phenomenon of outlying patients. This was a very common occurrence – with 96.4% of days demonstrating the presence of this cohort, with the proportion varying from just under 4% to over half of the ward population. Although an association to patient outcomes was not demonstrated in this study, the impact of outlier patients is reflected in the interview study – where outlier patients were seen as an obstacle to safe care delivery by nurses and managers. Secondly, as this study examined the care environment and outcome of general surgery patients, the potential effects on care delivery on outlier patients was not examined. The literature is replete with evidence of the potentially inadequate care outlier patients receive on wards not aligned with their specialty (204, 206, 208). Therefore, this specific cohort of patients should be repatriated to appropriate wards to facilitate their outcomes, as well as to re-balance nursing workload.

The third and final variable domain is organisational health. The reported study demonstrates the wide variation in factors within this domain and thus the pressures experienced by frontline staff. This included staffing levels, staff: patient ratios and skill mix. Nurse understaffing occurred in just under 30% of observed days- affecting pre-determined patient: nurse ratio. The effect of nurse staffing on patient outcomes is established through the works of leading researchers in the field such as Aiken, Needleman and others and is described at length in the narrative review chapter (103-105, 118, 123, 142, 248, 274, 346-348). Increased registered nurse staffing reduced mortality, with a 61% difference between the best and worst quartiles for this factor, as well as reduced adverse events rates such as hospital acquired infections (119). Agency nurses were also highlighted as an area of concern in the interview study but have not shown a negative effect on care delivery. Beyond the financial burden of relying on temporary staffing, this would be in line with the literature (59, 349). In the case of using HCAs, negative effects were seen where these personnel were employed to supplement the team rather than working alongside nurses in specifically defined task-orientated roles, where their presence actually helped deliver timely care (143, 348). Thus, identifying and ear marking routine, structured care items to these team members, that does not require specific expertise, may actually help streamline the nursing workload.

The number of patients per ward-based physician (i.e., foundation year 1 doctors) varied more than threefold. Although not detectable within this observational study, an association between higher doctor staffing levels and reduced patient mortality has been established in at least one previous study (350). Here, hospitals with the lowest mortality rates amongst adult emergency surgery patients exhibited higher numbers of consultant surgeons and junior team members per bed. However, beyond this study there is a paucity of data establishing a ratio of doctors to patients in surgical specialties, with more intense focus on working patterns and the role of fatigue (169, 174, 351).

The other interesting element studied was occupancy rates; in 64.2% of shifts observed, the occupancy rate was 100% or more. Thus far, research has focused on addressing *hospital* occupancy levels, with targets set at 85% in the UK (352). Beyond the challenges of maintaining patient flow (353) and cross-infection (354, 355), there is a concerning association with mortality (356-358). However, the impact at ward levels where the consequences play out, has not been considered in the literature. Potentially, data from this study is unique in its characterisation of the frequency with which high occupancy at the unit level is encountered, and the delays to care associated with it. Boyle and colleagues' study comes the closest to characterising the local effect of occupancy but still measures this at an institutional rather than unit level; probability modelling was employed to calculate the risk of an adverse event on a given day in the context of occupancy levels within a single site (359). Adverse events were reported by staff through a number of mediums including hard copy and electronic forms as well as a hotline. When the occupancy is at 80%, the probability of a single adverse event was calculated as 15%, rising to 28% at 100% occupancy.

Additionally, the literature provides an insight into how local teams may be empowered to address their unit's occupancy. One study documents an implementation for a single older adult psychiatry ward based within an NHS trust with such patients routinely presenting complex discharge issues (360). Combining multiple safety tools such as a pathway checklist, a real time dashboard detailing tasks or barriers for discharge as well as discharge planning huddles, all nurtured by an engaged multidisciplinary team, led to a 34% reduction in bed occupancy on that ward.

Inequalities in patient outcomes between institutions is well established and is quantified through several metrics such as standardised hospital mortality, FTR and complications or PSIs (54, 110, 115, 350, 361). These broad comparisons, made through analysis of administrative databases, pinpoint macrosystem qualities such as hospital case volume, staffing levels and availability of intensive care beds as important protective factors (105, 362, 363). Additionally, a strong safety culture has increasingly been shown to be instrumental (273, 364). However, these features do not account for variation in its entirety, with recent data demonstrating there is an elusive factor, or set of factors, yet to be identified (109). Sheetz et al. employed analysis of Medicare data and found that hospital and patient characteristics only accounted for up to 57% of the variation in FTR between high – and low-performing institutions. At this juncture, the characterisation of unit level practice is necessary. The present study effectively demonstrates this underlying irregularity in ward conditions that may go some way to explain this variation.

Although assessments of the surgical ward are lacking, qualitative assessments of care variability, distractions, and error have been described in a number of other environments at the unit level. Arguably, the most examined of these has been the operating room; Healey and colleagues characterise distractors originating from a range of sources including opening doors, pagers, ringing phones, irrelevant conversations and staff members travelling around the room during a case (365), findings elucidated in subsequent studies (366-368). However, these studies do not assess the impact on care quality and error directly, and utilise endpoints such as rates of interruptions (365, 366), participant -reported measures of team work, workload or stress levels (367) and prolonged theatre time (368). More recently, the ‘black box’ work of Grantcharov and his team utilised video recordings of 132 laparoscopic procedures and identified over 3000 errors (369). Like previous studies, a number of distractors were described (door opening, machine alarms, pagers, telephones, malfunctioning equipment, irrelevant conversations) with a median of 20 errors per case. However, although direct associations were not established, the authors present their study as a first step to examining this further.

In contrast, observations of the intensive care unit (ICU), which possesses an extra layer of complexity with multiple processes and simultaneous tasks, has been able to find some associations. A 1995 study by Donchin et al. employed a direct observation of patient care within a single ICU through continuous 24-hour bedside observations (370). This revealed a high number of errors (554 over a 4-month period) with 29% classified as errors with the potential to lead to significant harm or death. Although accounting for only 2% of activities overall, verbal communication between a clinician and nurse contributed to 37% of error reports. Clinicians had a higher rate of error proportionally to tasks performed, and it was postulated that clinicians were involved in more reactive decision-making, reducing the predictability of outcomes compared to the performance of more repetitive or routine tasks. Additionally, the intermittent nature of patient-physician interactions and additional duties outside of the ICU (such as review of patients on other units) were also identified as potential contributors to error. A more recent study of variation in the ICU demonstrated that unstructured tasks (i.e. where defined steps were not available) were also more vulnerable to errors (371).

5.4.1. Strengths and Limitations

This study has many strengths: it has captured unit- level ward activity with respect to multiple factors in a prospective manner. The routine fluctuations in processes, which are otherwise not recorded in electronic or other contemporaneous records, were quantified through a time-intensive period of direct observation. This has allowed for a detailed understanding of potential ward metrics relevant to day-to-day care- creating a focus for local improvement measures.

There are some limitations. Fifty-four patients were recruited into the study to directly observe care quality, and efforts were made to represent a wide range of demographics and acuity of clinical presentations across general surgery. As a cohort size, this is reasonable in the context of previous observational studies (266, 372). However, as direct consent was required, and patients therefore had to be proficient in English and able to give informed consent, there is an inherent selection bias in this group observed. Therefore, patients who may be very unwell and/ or have lost capacity as well as patients hindered by language barriers are unlikely to have had their experiences or potential vulnerability to error reflected in the data. A 2016 Dutch study showed that there was difficulty in conveying necessary actions when a language barrier exists, such as staying in bed to minimise a falls risk as well as effective communication with the clinical team regarding symptomatology to facilitate management (373).

Secondly, this is a descriptive and qualitative study. Having identified potential factors that influence care delivery, associations between these factors and overall outcomes cannot be determined. further quantitative work with larger data sets needs to be undertaken to ascertain the statistical significance of these effects.

Thirdly – as these were 12-hour periods of observation (i.e., a standard nursing shift), there were rest periods for the observer and potentially specific events that may have been missed. This is compounded further by the presence of a single observer on this study. This was mitigated to an extent by the review of medical notes and medication charts of observed patients, and through informal discourse with the team members on the ward. There is also the potential of fatigue on the part of the observer with such long periods of observations. However, most of the observations occurred on non-consecutive days – allowing for periods of recovery.

Additionally, the use of a single observer always presents the risk of introducing bias. However, as the aim was to identify measures that are objectively measurable (e.g., length of time taken to perform a task, number of interruptions, patient complexity) this was tempered to an extent.

As with all observational studies, there is a potential Hawthorne effect. The observation of ward rounds and clinical and nursing tasks may have led to participants altering how they would normally perform. Thus, some of the observations have the potential to not be a true reflection of the behavioural responses of participants to the fluctuating ward conditions.

5.5. Conclusion

This study effectively demonstrates the degree of variability in ward-based surgical care through three variable domains of processes of care, the care environment and organisational health. There are marked variations in day-to-day ward conditions including the make-up of the clinical and nursing teams, patient complexity and organisational influences leading to higher occupancy rates and the placement of outlier patients. All these may contribute to the quality and safety of patient care that is delivered to surgical patients on surgical wards, as the study also demonstrates the range in time to task completion and medication administration, as well as omissions. This will require further assessment with studies designed to elucidate the association between these daily fluctuation in ward factors and patient outcome measures.

Building on seeking real-time care quality measures, the next chapter details the potential role of patient and nurse reported outcome measures. This data was collated alongside this study.

6. Nurse- and patient- reported outcomes of safety on the surgical ward: Questionnaire-based metrics to measure day-to-day care quality and safety.

6.1. Introduction

Variation in care quality is a well-established phenomenon. Quantitative analyses of administrative datasets have natural advantages– including access to readily available, large and longitudinal datasets (374). However, "top-down" examination of practice and subsequent policy shifts has not resulted in homogenised quality of care across health systems, as disparities in patient outcomes persist (97). The previous chapter in this thesis (Chapter 5) adds a further layer- indicating that such variation does not only exist between institutions, but also at the intra-unit level. It is clear that no two days on even a single unit are the same, and these fluctuations in conditions presents a daily challenge for frontline staff who are attempting to ensure consistent, safe and high-quality care for all patients at all times.

Given the intensity and complexity of delivering ward-based care for the surgical patient, the experiences of those negotiating this system to ensure safe care provides relevant insights into understanding variations in care. Indeed, as Makary and colleagues argue, adhering to the Donabedian model alone to measure care quality is likely to be an incomplete assessment of the true nature of the care environment, as some of these variations in quality may also be rooted in the local safety culture itself (375). The majority of ward-based activity revolves around the care provided to *patients* by *nurses*. Unlike their clinical colleagues, the majority of nurses' shift is confined to the ward. There is an opportunity to explore if nursing and patient experience can be captured in real time and juxtaposed with the existing conditions at that timepoint. Thus, the experiences of nurses and their patients may prove to be a boon of insight into identifying when or where failures of the ward system are occurring.

This premise is supported firstly by a correlation between nurse-reported outcomes (e.g. job satisfaction, burnout) and the stressors within their work environment. Van Bogaert et al. demonstrated that nurses who rated hospital management, organisational support and workload poorly were more likely to score highly for emotional exhaustion on the Maslach Burnout Inventory Human Service Survey (MBI) (253). Additionally, nurses' opinions of the management at the unit level were associated with nurse-assessed quality of care. Similarly, Halbesleben et al. found that higher exhaustion and depersonalisation scores as measured by the MBI were associated with poorer nurse-perceived patient safety grades as well as a significantly reduced rate of near-miss reporting (376).

Secondly, there is also an association with objective patient outcomes; Teng et al., in their study conducted in Taiwan, measured the state of emotional stability of nurses (described as being "free from negative emotion") and examined how this may be associated with patient safety (145). Using five items from the Mini-Marker scale, the investigators found that patient outcomes (including nosocomial infections, medication errors and patient falls) were associated with higher scores on this scale, and that this was independent of other factors such as staffing levels and nursing experience. This echoed findings from earlier work by Aiken and colleagues (61). Using feedback from 40, 000 nurses, it was shown that poorer ratings on the Nursing Work Index, and a concomitant consideration of staffing levels, was associated with higher 30 days mortality and FTR rates in surgical patients. Other work has also noted a strong correlation between nurse-reported experiences and the quality of nursing care, such as screening for delirium or assessment of pain in post-operative patients (377).

Therefore, the role of nurse and patient perceptions of care quality and safety warrants further examination as it relates to the daily variations in care delivery noted on the surgical ward. A number of measurement tools are currently in use to gather feedback from this groups. This chapter details how two of these tools, one for nursing and the other for patient feedback, were employed to assess if there was a discernible variation in opinion at the unit level from day to day.

6.1.1.Measures of Safety Climate

Measurement scales for safety climate are predominantly questionnaire-based and adapted from scales used in other high-reliability organisations. These came out in quick succession from various research groups in the 2000s including the Hospital Safety Climate Scale (HSC, 2000) (378), the Hospital Survey on Patient Safety Culture (HSOPSC, 2004) (379) the Safety Attitudes Questionnaire (SAQ, 2006) (50), and the Patient Safety Climate in Healthcare Organisations (PSCHO, 2007) (380). Though each of these questionnaires' development and validation was detailed in these initial publications, later studies by other researchers attempted to examine associations between measurements of safety climate and practice. A 2005 systematic review demonstrated that most studies were using these tools for comparative studies (i.e. comparing healthcare institutions to high reliability industries or inter-institution comparisons), fewer still were seeking an association with climate and the adoption of safety interventions and only one (using the SAQ) sought the potential correlation with patient outcomes (381). A review performed five years later showed a weak to moderate association with outcomes such as hospital mortality and PSI (382).

In the most recent review, published in 2015, it was determined that the type of patient outcomes that show significant association with safety climate also depend on the level of analysis i.e., hospital versus unit level. For the former, these were more direct measures of safety such as PSI, mortality and readmission rates; at the unit level, significant results were associated measures such as carer and patient satisfaction (364). As ward-level adverse events are more infrequent than hospital level events, the fact that carer and patient satisfaction is associated with safety climate is valuable. At a deeper level- and tied in with the whole premise of this thesis - this finding in itself is an indication that such granular measures of outcomes have a role in understanding the impact of unit level variation. Collectively- the data in these described studies suggests safety climate measurement tools are valuable as endpoints in themselves. i.e., poor scores are enough to indicate that a unit maybe unsafe, and this can be considered alongside objective assessments that are rooted in process, structure and outcome measures.

The Safety Attitudes Questionnaire (SAQ)

The SAQ was designed by Sexton and colleagues in 2006 as a self-reported measure of individual healthcare workers' perception of safety culture within their clinical units (50). The SAQ was adapted from the Intensive Care Unit Management Attitudes Questionnaire, which itself was modelled on the Flight Management Attitudes Questionnaire (FMAQ) taken from commercial aviation (50). As a quarter of the FMAQ statements were directly applicable to healthcare, these formed part of the SAQ. The remaining items were borne out of discussions with safety experts, along with healthcare workers themselves.

The authors of the SAQ also cite Vincent et al.'s framework for analysing risk and safety in medicine (90) in addition to Donabedian's conceptual model (265). Thus, some of the items in the questionnaire are not only attempting to detect the nature of the culture as it pertains to openness regarding errors and event reporting, but also directly probes perceptions on the ability to carry out care processes effectively (e.g. "I get adequate, timely information about events that might affect my work...") and potential structural factors that may be a hindrance (e.g. "the levels of staffing in this clinical area are sufficient to handle the number of patients"). Ultimately, the SAQ examines six important subsets of safety culture: teamwork climate, safety climate, perceptions of management, job satisfaction, working conditions and stress recognition.

The initial validation study by Sexton and colleagues examined 11,000 completed SAQs across 203 clinical areas in three countries (UK, USA and New Zealand), with psychometric rigour demonstrated through composite scale reliability assessments and multi-level factor analysis. However, the value of the SAQ as a measure of the safety climate has been effectively demonstrated both through its widespread adoption- it is recognised as one of the most frequently used tools to measure safety climate (364) as well as one that has been effectively used to measure unit-level variation in attitudes (382)- and further validation in a number of languages. Thus far, validation studies have been conducted in countries including Switzerland, Norway, Denmark, Italy and China (383-387). Content validity has been demonstrated by some of these studies. In particular, the Swiss study engaged a 19-person expert group of physicians and nurses who assessed the relevance of each item to safety climate evaluation (385). All but one of the statements were retained in their version of the tool.

Furthermore, the strength of using the SAQ (in comparison to other tools) is that it has clear associations with defined outcomes such as mortality and length of stay (LOS), even in early studies (382). More recently, Huang et al. found that perceptions of management were negatively associated with hospital mortality, with every 10% reduction in scores for this subscale increasing the odds of death by 24% (388). Further, the safety climate subscale of the SAQ was also inversely associated with LOS, with every 10% decrease in safety climate producing a 15% increase in LOS. A more recent study by Odell et al., published in 2019, administered a modified SAQ to all ICU, theatre and administrative staff involved in providing surgical care across 49 institutions, with responses then aligned with the American College of Surgeons NSQIP data (389). Ultimately, the authors demonstrate that for a 10% increase in SAQ scores, there was a significant association with decreased risk adjusted rates of perioperative complications, mortality or serious morbidity. However, these were small reductions in the order of 0.29 – 0.52%. The authors propose that patient outcomes are determined by a complex milieu of factors, part of which is safety culture.

6.1.2. Patient satisfaction and reported measures

A number of validated staff safety climate questionnaires are available but those for patients are less common. Exploratory patient experience surveys have been the norm. In the UK, the Friends and Family Test (FFT) is used across all NHS trusts and serves as the "biggest source of patient opinion in the world" (390). Prior to its reform this year, the FFT has asked patients a single question at the end of their interaction with healthcare, '*How likely are you to recommend our service to friends and family if they needed similar care or treatment?'* with a further free text area included for further feedback. However, though seemingly simple and user-friendly, the FFT is severely hindered by its application (i.e. focus on mandatory minimum targets), interpretation and use (93) with limited resources to unlock information from the rich qualitative data of the free text boxes (391). Furthermore, the FFT is isolated from other markers of safety or clinical outcomes, making it difficult to contextualise its incorporation into quality improvement strategies (392). Only moderate associations have been shown with other quality metrics such as the summary hospital mortality indicator (237, 393). Other health systems have their versions; in the United States, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) examines key areas through 29 questions, employing a mixture of scoring scales (394). The Press Ganey online patient experience survey uses Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) but offers real-time interpretation of data (395). There are concerns about the validity of this tool in comparative analysis and establishing association with defined quality metrics as well the statistical modelling used by Press Ganey (396).

However, much like the limitations of the FFT, information gained from patient surveys is hardly translated into meaningful safety policy or intervention; a systematic review of studies utilising the data from the National Adult Inpatient Survey conducted in England found that results were utilised for subgroups analysis and to ascertain comparison between staff-reported and patient-reported aspects of care (397). Many of the studies simply established trends but did not demonstrate that feedback was used to implement improvement measures. The authors quite rightly underline that any local improvement measures that may be working are inaccessible through the standard literature review methods if these interventions have not been shared outside of these organisations. If there are interventions that are working at the local level, then a platform needs to be set-up to allow for these to be shared.

In addition to this, a recent NIHR review also conveyed the same problem; both across mental health and acute trusts, over half of institutions were unable to translate locally collated patient survey data with only 27% able to use patient feedback to inform change (398). A potential barrier identified in the review is difficulty in synthesising large amounts of free text data into something digestible. Although data mining software may be of use, the review indicates that large amounts of text may be excluded by this method because of linguistic informality. A further barrier includes failing to present data at the unit level, which then abrogates grassroots improvement measures. However, when it is presented for use at this unit level, data may be presented unfiltered, thus proving unwieldy for local teams to understand and utilise.

Lastly, collection of patient feedback may be driven by external expectations without the local understanding of the power of the data gathered. Indeed, at the hospital executive levels, the motivation seems to be to meet national data collection obligations, then falling short of utilisation of these quality metrics to develop interventions (399).

Although these barriers exist in transferring what patients say into meaningful interventions, there is adequate data from academic work to support that ultimately the pursuit of this warrants ongoing exploration. Beyond being a marker of mere satisfaction, the patient experience may also be closely aligned to how safe a healthcare environment may be. For instance, Isaac et al. used the HCAHPS data of 771 hospitals against 9 PSIs (including 4 surgical indicators: post-operative sepsis, thromboembolism, respiratory failure or haemorrhage) as well as failure to rescue, decubitus ulcers and two further medical PSIs (400). Each of the surgical PSIs had at least some association with one of the parameters of the HCAHPS, with the most pronounced associations for respiratory failure and thromboembolism. Similarly, Wang et al. showed an association with the patient experience of those receiving Medicare across more than 3000 US hospitals and mortality; those hospitals scoring the highest demonstrated a significantly lower 30-day mortality rate than low performing hospitals (401). An association with reduced 30-day readmission in the context of higher satisfaction scores has also been demonstrated (402).

Additionally, the sensitivity of patient-reported safety concerns or incidents has been showed to be comparable to case records review. O'Hara et al. gathered data regarding the experience of safe care from 2471 patients across 33 units in 3 English NHS trusts between May 2013 and

September 2014 (403). One third of incidents reported by patients were determined to be a patient safety incident. These included medication errors, ward management issues, infection risk and health and safety occurrences.

Patient Measure of Observational Safety (PMOS)

Thus far, a handful of patient- reported safety scales (unlike measures of experience) have been designed, with focus on both primary (404) and later secondary care (405). At the time of this study, the *Patient Measure of Observational Safety* (PMOS) was one of the few validated for use in the latter. The PMOS has been developed with a qualitative lens by the Bradford Institute for Health Research (406). The questionnaire items were selected through 33 patient interviews across multiple units in a single institution, meaning that the tool is rooted in real patient experiences (279). These items were then assessed and revised with both a patient panel and researchers. Subsequently, the PMOS was administered to almost 300 individuals across 11 wards and demonstrated a reasonable level of discriminant validity and test-retest reliability (279). The questionnaire consists of 8 subscales: communication and teamwork, organisation and care planning, access to resources, type and layout of ward, information flow, staff roles and responsibilities, staff training and equipment design and functioning.

A study published in 2015 assessed the association between PMOS scores, safety climate scores given by staff (via HSOPSC) and patient outcomes (407). The latter was measured as harm-free care via the NHS patient thermometer, which includes items such as falls, urinary tract infections, pressure ulcers and in-hospital thromboembolism. There was a statistically significant association between staff scores and patient outcomes and patient scores and patient outcomes. This implies that patients are potentially able to detect the level of safe care they are provided, and that this assessment can be performed successfully via the PMOS scale.

6.1.3. Unit-level application of staff safety climate and patient reporting scales

The challenges of adapting user feedback to direct improvement of care quality and safety are outlined earlier. However, potentially, the use of qualitative data to formulate quantitative scale measurements may ease and facilitate aggregation and interpretation of user feedback for local policymakers. Further, a direct comparison of participant opinion can be made for fluctuating conditions, such as ward conditions that may vary on a day-to-day basis. Concomitantly, the feedback itself may act as a metric of how safe conditions on a ward are at a given time, but unlike FFT, with a more granular set of quantitative information. This may more effectively direct local teams or managers to the areas of their service that participants feel are most lacking at any given time. Thus far, though such correlations between safety climate scores and patient outcomes have been demonstrated at macrosystem level, further exploration at the microsystem i.e., unit level is warranted.

The aim of this study is to assess the level of variability in nurse-and patient-reported feedback, through validated questionnaires (SAQ and PMOS respectively) at the unit level on a day-to-day basis. The sensitivity of nursing and patient reported outcomes to the dynamic conditions of a ward will be gauged as responses are contextualised within the variations in ward factors as described in chapter 5.

6.2. Methods

6.2.1. Setting

This study was conducted on two surgical units in a teaching hospital, and a third unit in a district general hospital in London on non-consecutive days between 28th February and 13th September 2017.

6.2.2. Participants and Study Design

Patient- and nurse-reported outcomes of safety were captured in real time alongside the observations detailed in Chapter 5; respondents were instructed to complete their respective questionnaires (i.e., SAQ for nurses and PMOS for patients) with reference to the care experienced or given during the observed shift.

Patients were given a questionnaire at the time of recruitment along with the patient information sheet and consent form. Patients were asked to complete the questionnaire once during their time in the study- for the first shift that their care was observed in the study. Nurses, however, could complete the questionnaire multiple times for multiple observed shifts as they were a smaller pool of participants, who were regularly involved in this environment.

This study uses the short form version of the SAQ, including 36 items. 30 of these items fall into one of the six subscales (Appendix F). The PMOS was modified to remove questions addressing the patient's experience outside of the ward, leaving only 33 questions assessing experience on the ward (Appendix G).

6.2.3. Questionnaire Data and Analysis

Data was collated into spreadsheets using Microsoft Excel (Microsoft Corp, Redmond, WA, USA). Questionnaire data analysis was performed using SPSS (IBM SPSS Statistics for Macintosh, Version 25.0, Armonk, NY: IBM Corp).

Not all assessed shifts achieved multiple responses; therefore, in order to account for respondent bias, inter-rater correlation coefficients (ICC) were calculated for both the SAQ and PMOS for shifts that did return multiple questionnaires. Calculation of concordance in opinion under such variable ward conditions would establish that participants within each target group respond similarly, thus lending additional weight to the reliability of the use of these measurement scales as a quality indicator of safety, beyond their own previously established reliability as rating tools (408).

Associations between variables and questionnaire responses could not be demonstrated given the nature of the dataset. However, descriptive overall results with respect to variations in the ward environment are presented.

6.2.4. Data Presentation

As per the authors, for both the SAQ and PMOS, the subscale score is determined as the mean score for all of the statements included within it (279, 409). Further, the designers of the SAQ offer an algorithm for the conversion of the subscale score to a 100-point scale; however, the principle of interpretation is the same, with a score of 75 equalling 4 and a score of 100 equalling 5. Therefore, for the purposes of this study, results are presented as means and standard deviations of the Likert scale.

With regards to interpreting results to determine the performance in each observed environment, McEchan and colleagues in their validation study of the PMOS presented the total statements that achieved a score of 4 or above for each respondent as well as mean subscale scores (279). Similarly, Sexton and colleagues also presented results by subscale. This has been employed for presenting results in this study.

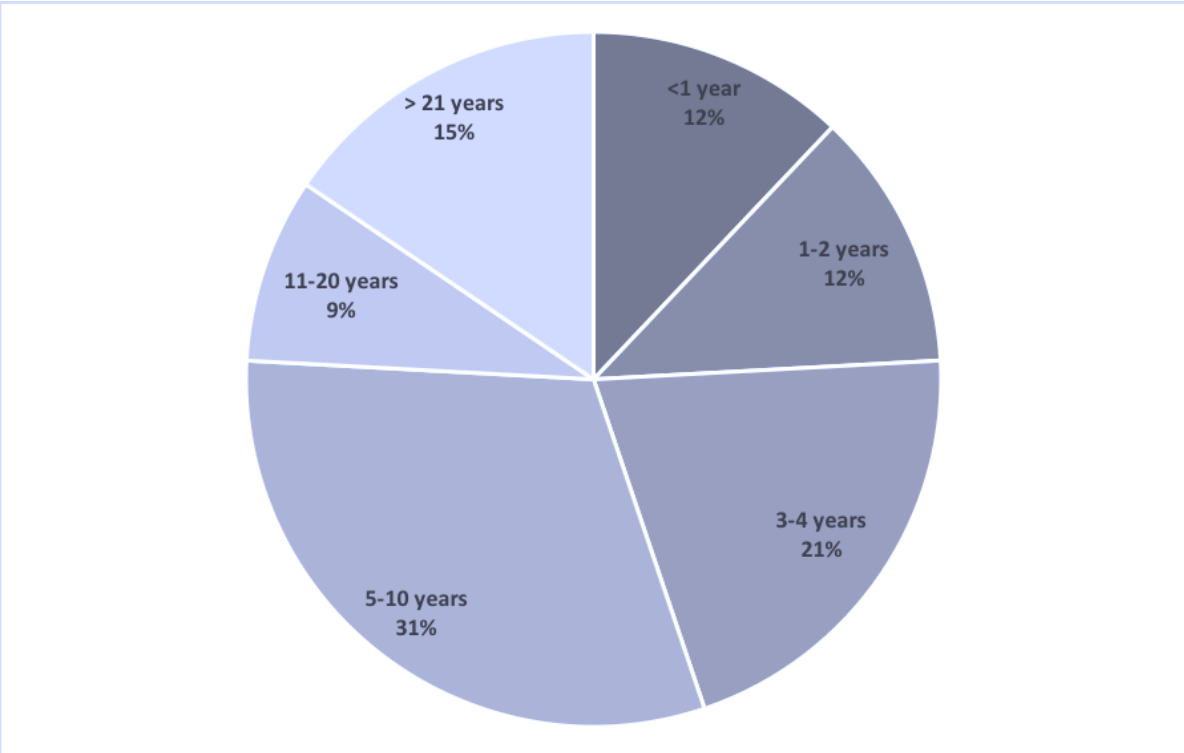
A further additional layer offered by the designers of the SAQ was to detail the proportion of patients ascribing a score of 75 (i.e., 4 on a Likert) or above to a subscale. However, as the unit of examination in this study is observation of a 12-hour shift, respondents were grouped by the time of response and the mean score achieved on that shift for each subscale across all respondents is given for both questionnaires. This method has been used for the PMOS in research both preceding and following this study, where patients were broken down into similar subsets such as by hospital location (410, 411).

6.3. Results

Patient demographics are already outlined in Chapter 5. 60 SAQ and 54 PMOS responses were collected across the 3 wards. SAQ were collected over 33 observed day shifts and PMOS over 30 days shifts.

The years of experience in surgery of participating respondents is mapped out in figure 6.1.

Figure 6-1: Years of experience in surgery of nurses completing the SAQ



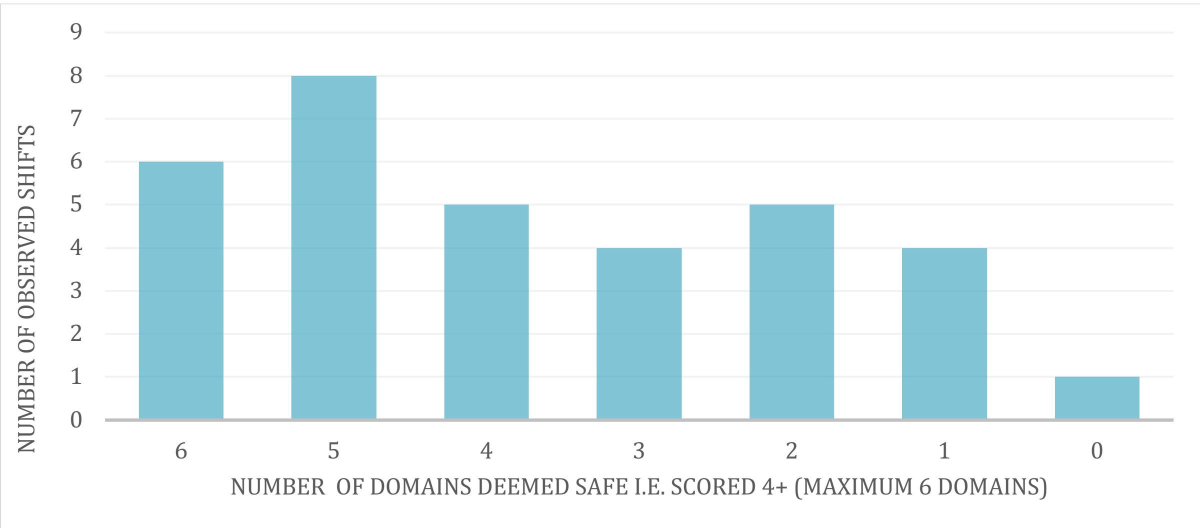
6.3.1. Variation in Nurse -Reported Outcomes

The median rate of return for the SAQ for each observed day was 28.6% (range 14.3-100). ICC was very high at 0.932 (p = 0.004). Cronbach's alpha was 0.907.

Of the 33 observed periods, only 6 achieved a score of 4 and above on all domains, representing 18.2% of all observed periods. Figure 6.2 demonstrates the variation in performance for the number of domains that scored 4 and above.

SAQ scores overall demonstrated wide daily variation as illustrated in figure 6.2. For each subscale of the SAQ, it can be seen that the lowest scores achieved were below the threshold of a satisfactory standard of care (i.e., below 4), and the highest was a perfect score of 5.

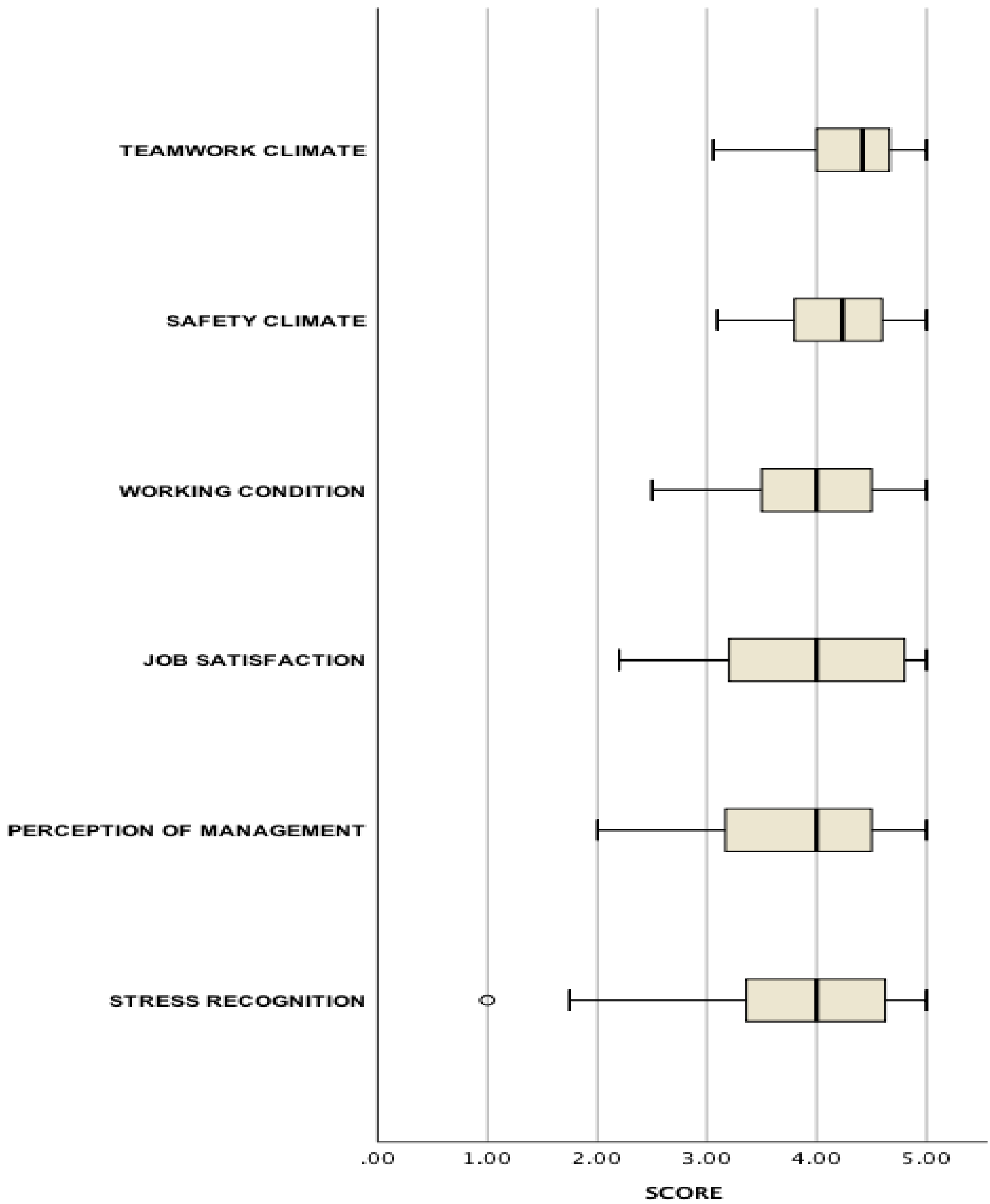
Figure 6-2: Variation in performance: chart demonstrating the number of domains in the SAQ that were scored as safe (4 and above) across observed periods.



There was a wide range of scores for each domain (see figure 6.3).

There was almost consistently high performance for the teamwork climate, with 84.8% of days scoring 4 or above. However, a wider variation is seen for the other subscales, with only 69.7% of days scoring highly for safety climate, 57.6% for stress recognition, 54.5% for working condition and 51.5% for each of the job satisfaction and perception of management subscales.

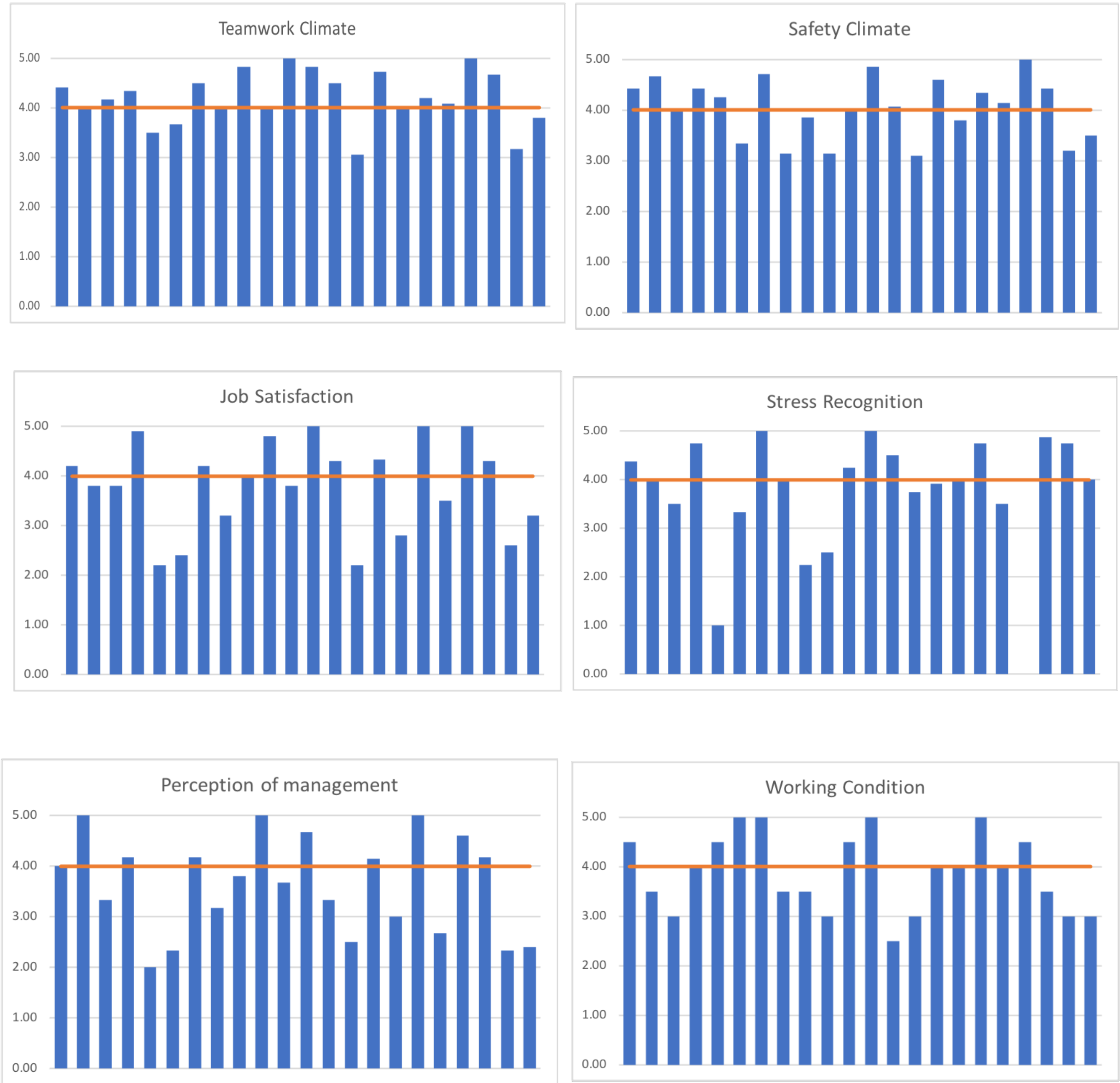
Figure 6-3: Range of scores for each SAQ subscale over observed days



The level of variation identified exists even when the surgical unit is controlled for; in the case of the unit that received the most observations (22 days), the degree of day-to-day variation is illustrated in figure 6.4.

The fluctuation in scores over these days of observations verify that within a single unit, and within a defined team of nurses, the SAQ results fluctuate daily between satisfactory (4 and above) or unsatisfactory levels.

Figure 6-4: The fluctuation in SAQ subscale scores for a single unit (red line indicates the score of 4) across non-sequential daily observations (unit of observation = shift)



There were statements within the SAQ that were not part of any particular subscale but posed important questions. These statements are illustrated in table 6.1.

Table 6.1: SAQ statements outside of a subscale

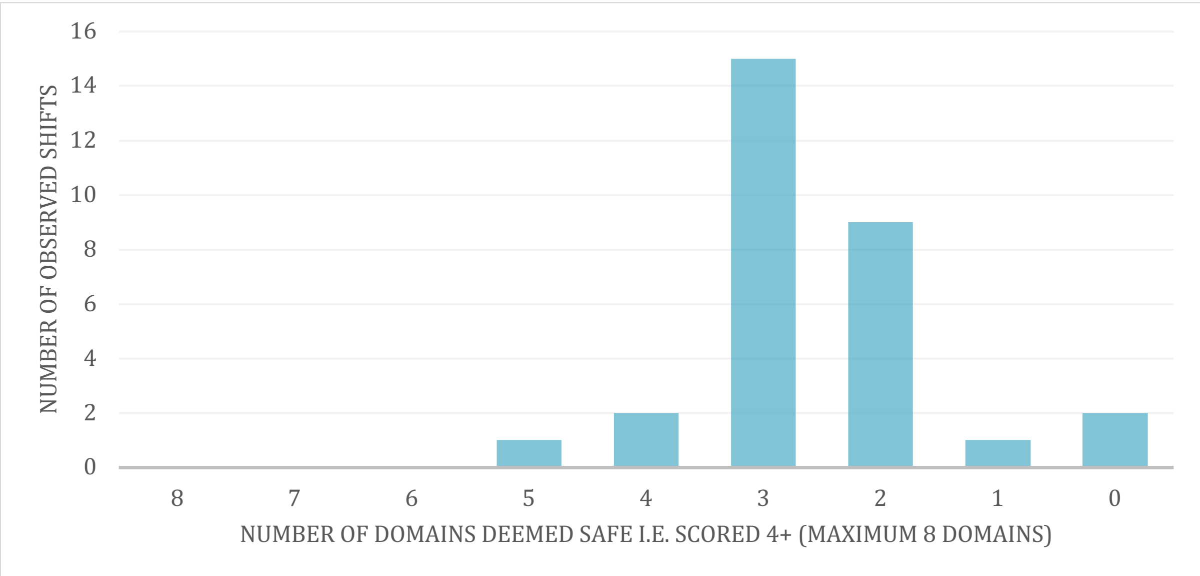
Statements within SAQ but not contributing to defined subscale
My suggestions about safety would be acted upon if I expressed this to management.
Trainees were adequately supervised in this clinical area.
I experienced good collaboration with nurses in this clinical area.
I experienced good collaboration with doctors in this clinical area.
I experienced good collaborations with pharmacists in this clinical area.
Communication breakdowns lead to delays in the delivery of care

There was almost consistently good performance for 4 of these 6 statements; on 81.8% of days, good collaboration between nurses, good collaboration with pharmacists and the absence of communication breakdowns were noted. 78.8% of days performed well for collaboration with doctors and 72.7% of days demonstrate that nurses' suggestions about safety would be heeded by managers. The only marked variation was in how nurses perceived trainee supervision, with this item being rated an average score of 4 or above on 51.5% of days.

6.3.2. Variation in Patient- reported outcomes

Of the 30 observed shifts during which PMOS was recorded, there were no days where all domains were scored as safe, i.e., achieving a score of 4 of above. In fact, there were no days where even 6 or 7 out of the 8 domains scored 4 and above. The highest achieved was 5 out of 8 domains in 1 observed shift. This is demonstrated in figure 6.5.

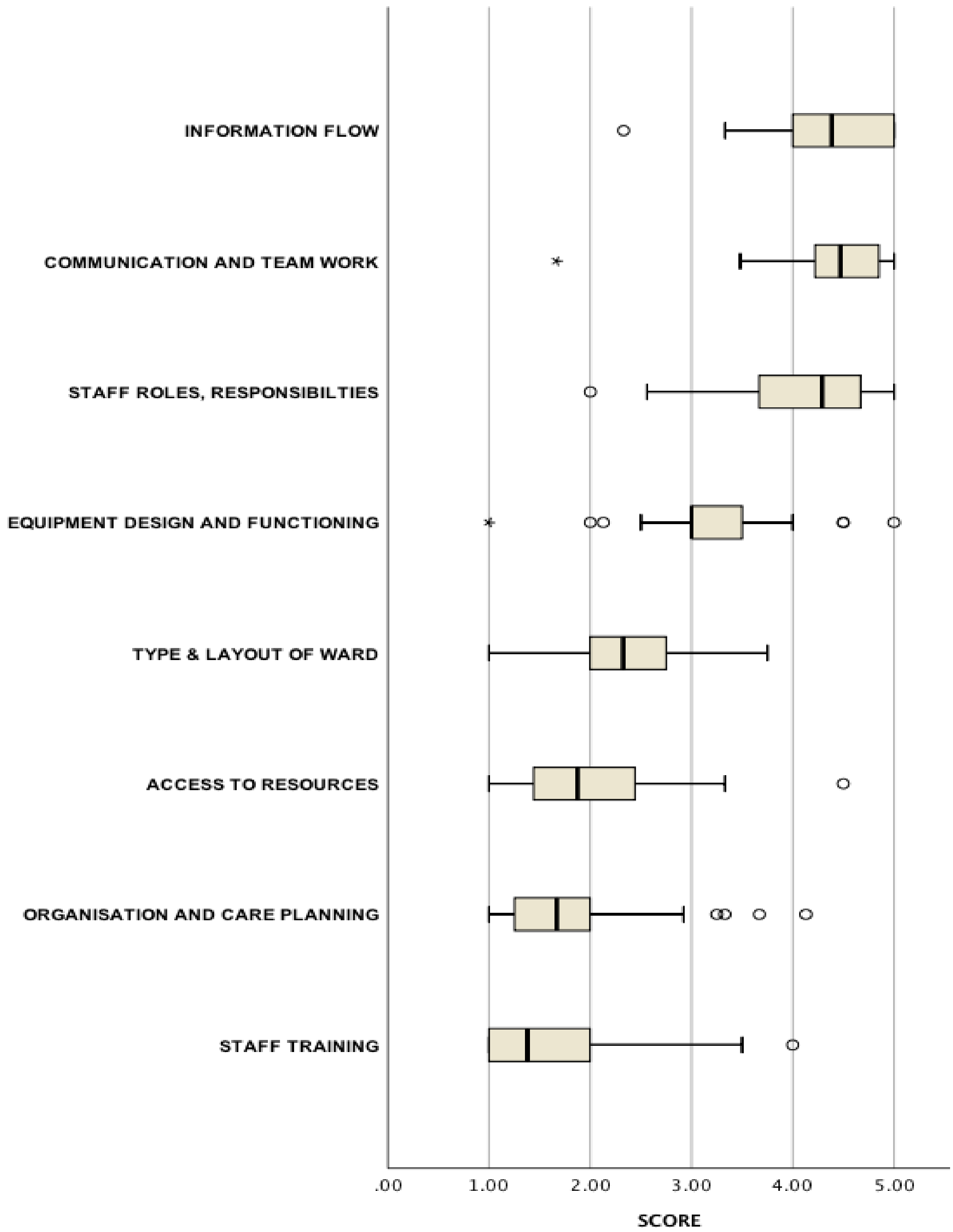
Figure 6-5: Variation in performance: chart demonstrating the number of domains in the PMOS that were scored as safe (4 and above) across observed periods.



The range of scores for each of the PMOS subscales is shown in figure 6.6. Like the SAQ, there was wide variation in PMOS subscale scores, indicating fluctuating daily scores. ICC was moderate to good, at 0.661.

Three of the eight domains scored well; 86.7% of days scored 4 and above for communication and teamwork, 76.7% of days for information flow and 70% for staff roles and responsibilities. There were two subgroups where the satisfactory threshold was not attained for any of the 30 observed days. These were the organisation and care planning (which include statements such as “I didn’t know who to go to if I needed to ask a question”) and type and layout of ward subscales. For the remaining categories, the scores were poor overall: 13.3% of days scored the equipment design and functioning domains well and the access to resources and staff training subscales only scored 4 and above for 3.3% of days each.

Figure 6-6: Range of scores for each PMOS subscale over observed days



Unit level variation was also assessed to account for potential inter-ward variation. 24 observations were made on one of the units and the fluctuations in scores are demonstrated in figure 6.7. Similar to observations seen overall, some areas, such as communication and teamwork, information flow and staff roles and responsibilities scored well.

Within the PMOS, there were 2 further statements that did not contribute to any of the subscales but were stand alone. These questions were “I was treated with dignity and respect” and “I felt that patient safety was a top priority”. Despite the variation in the other subscales- and the overall low scores for particular subscales as outlined above- these statements scored consistently well. On 93% of days, patients felt they were treated with dignity and respect and on 83.3% of days, patients felt safety was a priority.

Figure 6-7: The fluctuation in PMOS subscales on a single unit

6.4. Discussion

This study presents the feasibility of using validated safety questionnaire tools to prospectively capture "real time" safety information from clinical staff and patients. It presents the scale of day-day variation which is present in the perceived safety of care even within a unit. To current knowledge, this is the first study to explore variation in reported outcomes for surgical units in this way. Overall, in the observed settings, the SAQ rating were consistently high for innate qualities of the nursing team, as demonstrated with the teamwork domain, but there was variability in scores with regards to the qualities of the work environment. Similarly, patient ratings for aspects of the care team's qualities (i.e., communication and teamwork, information flow, staff roles and responsibilities) scored higher than those items that pertain to the care environment.

A number of novel angles have been displayed in this study; firstly, alongside an established and validated SAQ for staff, patient feedback has also been gathered via a validated questionnaire. The PMOS offers an effective way to capture patient opinion on a range of issues at the ward level. Secondly, the feedback is administered with an emphasis on reflecting over a defined period of time rather than the condition of the ward in its usual generality, encouraging consideration of existing care conditions. Thirdly, this study also implies a potential relationship between real-time assessments by patients and nurses and contemporaneous ward conditions given the degree of fluctuation in the feedbacks. This possible relationship will need further in-depth data collection and study in future work.

The interrater correlation was high and statistically significant for staff. For patients, although there was reasonable correlation, it was not statistically significant. From a scientific standpoint this may pose an issue with the use of this tool as a care quality metric, but the real-life implications may actually indicate that patients have a far more heterogenous set of viewpoints and interpretation of their environment compared to healthcare workers. The patients involved in this study span from 21 to 83 years old, have undergone a wide variety of interventions or conservative management plans, and span both emergency and elective admissions. Jaipaul and Rosenthal assessed patient ratings of hospital quality and satisfaction with respect to five age groups and found scores increased with age, peaking at 65 years old before scores declined again (412). Furthermore, DeVoe and colleagues demonstrated that younger patients (25-44 years old) were more critical in their evaluation of the quality of healthcare providers' communication (413). External factors such as socioeconomic status (SES), patient demographics or previous encounters with inpatient care were not within the scope of this study. Although the association between SES and health outcomes is well described (414-417), the relationship between patient satisfaction and SES is complex. Alter and colleagues demonstrated improved access to specialised care for myocardial infarction patients with higher socioeconomic status in Canada, but a tendency to display greater dissatisfaction with care. However other studies specifically looking at socioeconomic status and satisfaction, demonstrated that those with lower SES displayed less satisfaction (418) and were more likely to feel that their SES influenced their access to care and interaction with healthcare providers (419). Therefore, this lack of ICC does not negate the merits of PMOS. Rather, clinicians and policymakers more than likely need to recognise that the needs of the patient population are as diverse as their demographics. Additionally, this diversity may prove valuable- offering a comprehensive overall patient perspective.

It is reassuring that almost all patients across all observed days in this study felt they were treated with dignity and respect in the face of unstable ward conditions. However, the PMOS responses reveal that elements of care delivery are falling short on all days. Furthermore, there were subscales where the range of scores were always in the lower end of the scale despite ever- changing ward conditions: the daily score of the organisation and care planning component peaked at 3.67, and for the type and layout of ward component at 3.75. This indicates relative uniformity in opinion that the safe standards for these areas were not met – indicating that there are underlying factors that may be rooted in more macrosystemic qualities.

It is also noteworthy that communication and team work overall showed higher scores compared to other subscales of the PMOS. It is telling that of the 9 statements from the communication and teamwork subscale, 80% of respondents across the study scored 6 statements as a 4 or above, as well as 2 of the 3 information flow statements. This is likely a consequence of the importance placed on communication with patients that has evolved over the last 20 years of research and policymaking, with an emphasis on improving healthcare provider-patient interactions as well as how personnel work with one another (420-423). For example, there has been encouragement for nurses to participate in the ward round (320); it is known that patients feel supported in representing their concerns if a member of staff with which they have a relationship is present (424) or reassured by the present nurses explaining or clarifying management plans after the round (425).

Nursing opinion also demonstrated a wide range of scores across these SAQ subscales. Less than one-fifth of the observed days actually scored 4 and above across all domains. When assessed by subscale, unit level daily job satisfaction and perception of management scores were only at a safe level for approximately 50% of days observed. Interestingly, scores for teamwork climate were higher than the safety climate. This in itself may be a separation of the quality of interpersonal nursing encounters (teamwork climate covers acceptance of nurse input, support of colleagues and inter-team co-operation) from those that directly address management of unsafe practice (i.e., handling of medical errors, patient safety escalation routes, reporting and learning systems). The former is more in the control of local teams, and easier to foster through interpersonal relationship development, with the latter being under the influence of the institutional culture overall. Of the questionnaire items not included in specific subscales of the SAQ, the one item noted to have marked variation response is how nurses perceived trainee supervision. As no specific follow-up was given during the delivery of this questionnaire, the interpretation of trainee may be both nursing and clinical. Nonetheless, it is telling that adequate supervision may not have been immediately available to either of these two groups. This may be a reflection of both organisational factors and potentially, local work conditions that may hinder this.

The variation in these questionnaire responses is most likely the product of multiple aspects of the care environment. The observation of the environment as outlined in chapter 5 demonstrates that there is a lack of consistency in many areas on a day-to-day basis including the performance of processes, staffing qualities and organisational pressures that can result in variable occupancy and patient composition. For example, any aberration in the established parameters for delivering care by the unit– such as increased occupancy through escalation beds or understaffing for a shift that has not been addressed – will result in an abrupt change in factors e.g. patient-to-nurse ratio. These changes may then manifest in how nurses respond in the SAQ, as they detect how their workload has changed.

Indeed, nurses themselves have long expressed their concern regarding their ability to perform their duties under difficult working conditions (145, 376, 426). In a recent RCN employment survey, the pervasive nature of the stresses of an increasing work burden across the country was evident (427). In the last decade, the number of nurses expressing feeling under pressure has increased by 12% to 63%. 61% feel they are too busy to provide the level of care they aspire to. Given that the most recent updated research demonstrates that the actual incidence of adverse events has not changed in the last two decades (428), there is certainly room to characterise the specific aspects of ward-based care that nurses are most concerned about.

The congruity of nurse-reported outcomes and care quality also is established; Aiken and colleagues showed that patient-nurse ratio was associated with high levels of burnout and job satisfaction within hospital units (61). For each additional patient under their care, burnout in nurses increased by 23% and job dissatisfaction by 15%. Once adjustments were made for patient and hospital characteristics, there was an associated increase in mortality and FTR for additional patients. A further international study from 2012 demonstrated a distinct association between challenging work environments and the tendency for nurses to report a hospital as poor or failing to deliver safe care across multiple countries; nurses' perception also correlated with patient outcomes and patient feedback (272).

Additionally, a 2016 systematic review by Hall and colleagues highlighted that a number psychological dimensions such as burnout, depression and stress were linked to near misses and adverse events (429). Moreover, these associations are more pronounced with self-perceived errors compared with objective measures such as patient records or prospective observations. With the latter, either no association or an association with a single dimension was seen. As implied by the authors, the sensitivity of self-report may be superior to objective measures. A more recent study conducted in Norway demonstrated that when nurses perceive their workload to be high, there is a significant association with increased seven-day mortality in patients presenting with acute myocardial infarction, stroke or hip fracture (430). This association was not replicated in physician responses.

By comparison, patient reported outcomes and their association with patient clinical outcomes are just being established. The impetus to involve patients in safety reporting has gained increasing prominence in the last decade and has been by notable reports such as the NHS Next Stage Review of 2008 (431), the 2013 report from the National Advisory Group on the Safety of Patients in England led by Professor Berwick (432) and Sir Bruce Keogh's review of 14 hospitals with the highest mortality rates (433). Indeed, patients have been shown to be able to detect adverse events that are not described in their case notes (278) and a 2013 systematic review determined that there was a respectable level of engagement by patients in safety programmes (434). The potential role of real-time patient feedback is also demonstrated in a 2017 study (435). Here, aggregate scores of patient feedback garnered across multiple platforms including social media were compared to subsequent CQC scores and found a strongly positive correlation. The collated opinions successfully identified struggling hospitals, with the authors determining that this presents a potential tool to prioritise future CQC inspections.

However, there is room for improvement in how patient feedback is promoted and employed for maximum benefits; the first challenge is engaging patients, who may find it difficult to participate in the challenging position encouraged by national safety initiatives - and an active encouragement from ward staff to engage in this may be required (436). Also, patients may not want to appear to be critical of staff if they deem them to be working under difficult conditions; one study employing ethnography and semi structured patient interviews on oncology wards demonstrated this effectively, with overworked nurses eliciting the sympathy of patients they cared for (437). The second challenge is finding the most effective way to translate patient responses to improvement measures (438). Ultimately, it may be a union of nurse-led and patient-centred efforts that will help identify the unstable elements in the surgical environment that are leading to unsafe care.

6.4.1. Strengths and Limitations

There were a number of limitations to this study; firstly, the number of responses was low. The particular challenge was engaging with staff to complete the questionnaires at the end of a busy shift. In particular, a clash with a particular task was encountered – the documentation of nursing notes in the patient records. Although this was not immediately quantifiable (i.e., would one measure the number of nurses who were staying behind to document, or the length of time one was staying behind to document?), the phenomenon in itself is worthy of focused attention. This feeds into the "care left undone" studies, that have demonstrated that nurses exercise their judgement to prioritise items of care that need to be administered, inevitably leaving some care processes incomplete (134, 135). Further attempts to acquire completed SAQ towards the end of the shift rather than waiting until its conclusion did not improve the yield of completed questionnaires. The challenge of acquiring completed questionnaires reflecting on the night shift resulted in a lack of responses to allow for further analysis and comparison with daytime care delivery. In terms of the PMOS, the overall recruitment of patients was challenged by the acute nature of the setting, with patients often being too unwell to be approached. This introduces a selection bias for those who were in the stable phase of their care – e.g., recovering from surgery, receiving other inpatient therapy -and were relatively comfortable engaging with the research. Although a larger number was desirable, once 50 recruits had been exceeded, the study was closed due to time pressures.

Additionally, patients seemed to be deterred by the length of the questionnaire- although for the ward-focused nature of this study, 13 questions that had no relevance to ward-based care were removed. The research group that developed the PMOS questionnaire is currently in the process of testing and validating a shortened versions of the questionnaire, PMOS-30 and PMOS-10, containing 30 and 10 items respectively, and it may be that the 10-item questionnaire would be the most feasible to use (439). Thus far, PMOS has been validated for use in primary care (440) and in the Australian healthcare system (411).

A further issue is the wording of statements on the PMOS, which may have been challenging for patients. Almost half of the statements on the questionnaire were negatively worded. Potentially, this may have contributed to some of the very low scores seen. Since the data collection for this study was completed, the original authors of the PMOS questionnaire have proceeded to identify this as a concern in a recent paper (441). Citing the work of Sonderen et al. (442), Louch and colleagues recognise the part "inattention" and "confusion" may play in patient's being able to provide reliable feedback from this type of statement, and this maybe the effect seen in this study. Although this was recognised at the time of data collection, it was decided to persevere with data collection and highlight to patients that careful reading of questions is required.

Furthermore, engaging with patients may require other methods of feedback; in one study by O'Hara et al., published in BMJ Quality and Safety in 2016, three mechanisms of harvesting patient feedback on safety concerns on their wards were tested- bedside interviews, a written form returned via a drop box or via a patient safety hotline (443). there was a significantly higher rate of reports in the face-to-face interviews, accounting for almost half of all reports. Of the patients recruited to face-to-face interview, 64% reported 1 or more safety concerns compared to 19% for the hotline and 41% for the paper based.

Ultimately, an effective and non-disruptive method of real-time feedback must be designed for both patients and nurses. This must not only be validated, but easily collected at a convenient time point of the day and amenable to repeated completion by potentially the same participants across multiple days. If further studies are able to establish that there is a reasonable association between such feedback and the variable ward conditions and/ or patient outcomes, this would potentially offer a tool to focus safety initiatives for ward-based care. Furthermore, the use of technological assets may allow for responses to be collated on an instant dashboard that can facilitate real-time assessments and evaluations.

6.5. Conclusion

This study demonstrates that nurse- and patient-reported assessments of safety and care quality varies daily at the unit level. A satisfactory score across all domains of the SAQ was only achieved on 18% of observed days, whereas this was not achieved for the PMOS across any of the observed days. Although scores by domain fluctuated on a day-to-day basis, those pertaining to teamwork and communication within teams scored better in both groups in comparison to those related to organisational features (e.g., organisation and care planning and type and layout of ward domains in the PMOS and working conditions and perception of management domains in the SAQ). These responses are likely to be influenced by the dynamic nature of the ward, as demonstrated in the previous study. Further work is required to assess whether there is a direct association between present ward conditions and nursing and patient perception of care quality and safety at that given time. This introduces the possibility of utilising real-time nursing and patient feedback to identify areas that would benefit from timely intervention.

The next chapter is an interrogation of large, administrative datasets to ascertain if the ward independent variables identified are associated with patient outcomes.

7. Building on observation: a study of near real-time clinical care data to assess the association of identified structure and processes-driven factors with patient outcomes on the surgical ward.

7.1. Introduction

Processes performed in the ward-based, post-operative care setting are widely acknowledged to be vulnerable to error; through the intimate observation detailed in chapter 5, the surgical unit has been revealed to be a far more dynamic environment than can be appreciated from macrosystemic evaluation alone. This may then require ad hoc planning of care delivery, allowing human factors to prevail and thus errors to occur. The impact that such variations can have was reflected in patient care by time delays in care delivery or omissions of care, as well as the variation in the feedback obtained through validated questionnaires (SAQ and PMOS) demonstrated in Chapter 6.

However, given the design of these studies, associations between independent variables and recorded outcomes could not be inferred. If an association between the observed ward variables and specific patient outcome measures can be established – this is will be a pathway to understanding the individual and sum total effect of these variations on the ability to deliver safe care on the surgical ward. Furthermore, a statistical model may be formulated to understand the risk of a threat to safety, which may help predict how a particular environment under existing conditions may behave. Many of the factors identified in the observational study are retrievable from existing datasets, specifically electronic health records.

7.1.1. Predictive modelling in healthcare

Electronic health records (EHR)-based research and predictive modelling.

Historically, predictive models in healthcare have used data derived from observational studies, such as cohort studies or randomised control trials as well as administrative datasets. However, EHR-derived data has several advantages compared to these traditional research methodologies including a longitudinal study design employing large sample sizes, and the potential to analyse live data entered into the system in real-time that is reflective of the population to be studied; this combination of statistical power and reduction in selection bias can give more weight to inferences made in comparison to traditional study designs (444). Additionally, once the need for expertise in informatics is met, EHR offers greater cost -effectiveness overall yet can boast similar sensitivity to traditional research study designs with respect to certain outcomes, such as the treatment effects seen in randomised control trials (445).

However, there are a number of challenges to be addressed when embarking on using EHR-derived data to answer research questions. Firstly, the data is not organised with research in mind, rather it is a vast number of granular datapoints stored in a large data warehouse at best, so the skill and expertise of an analyst is necessary to retrieve the desired information (446). The least accessible data is the unstructured entries, such as free text data, which is difficult to utilise in research without employing more complex and time-consuming strategies (e.g., natural language processing) but is likely to be information-rich and useful for future healthcare research (447, 448). In addition, data from EHR may be incomplete or of variable quality which would also need to be addressed in designing a study protocol (449, 450).

Despite these challenges, research driven by big data analytics including EHR-derived data in healthcare has gained momentum (447). A systematic review conducted in 2017 assessed 107 studies and demonstrated more than half of these studies were predicting a clinical end point such as the development of an organ disease (451). The remaining studies looked at a combination of other markers of care quality such as readmission/ reattendance rates, length of stay or mortality. However, the use of EHR to understand patterns of service delivery and monitor safety in specific environments remains an evolving area. Thus far, one group was able to demonstrate how EHR-derived data may be leveraged to develop real-time monitoring of adverse events (452). This study was conducted within a patient safety organisation, Pascal Metrics and its associated hospitals, using a cloud-based platform that firstly, allowed for user entry of adverse events details and secondly allowed for integration of EHR-derived data with electronic versions of the Global Trigger Tool to develop a predictive safety model. Examples of these triggers include lab results (glucose levels, platelet count, haemoglobin) and administration of certain treatments or initiation of investigations (radiological assessment for thromboembolism). The algorithm was shown to predict the risk of an adverse events, with risk scores peaking approximately 3.5 days before the occurrence of an event. In addition, the study was able to demonstrate the significant association of adverse events with inpatient mortality, length of stay and 30-day readmission rates. However, beyond this, suggestions regarding where the risk stems from and the proposal of interventions could not be made.

Another single site study also demonstrated some effectiveness in predicting the risk of complications (surgical site infection, bleeding and ileus) in patients undergoing colorectal surgery using EHR data (453). However, more work is needed to actualise the potential of EHR data for predictive models in patient safety research.

Enhancing research through linkage of EHR with other data sources

A number of research groups have aligned EHR data with other sources to provide a more comprehensive dataset that improves the depth of the associations that may be inferred. EHR has already been linked with genomic databases, as in the case of the Electronic Medical Records and Genomics (eMERGE) network (454). More recently, the feasibility of linking EHR data with administrative data to elucidate social determinants has also been demonstrated (455).

However, beyond research into disease development, there is a paucity of work that utilises EHR data alongside other data sources for health service research specifically. As EHRs record time stamped processes of care, there is an opportunity to perform longitudinal assessments of unit-level service provision if considered alongside available organisational data that has likewise been collated in real-time. In response to the Carter Report of 2016 (456), there has been a growth in the use of electronic duty rostering, especially for allocating nursing shifts. Like EHR, these platforms also generate large, retrievable datasets that detail staffing, skill-mix and fulfilment types (permanent versus temporary) at the shift level. Thus, this presents a readily available granular dataset that can be aligned with EHR-derived data.

7.1.2. Selecting appropriate EHR-derived outcome measures for near real-time unit level assessments

Unit- level daily variation needs to be measured against an appropriately granular outcome. Recognised quality metrics, such as complications or FTR, are useful measures for comparison between institutions or longitudinal comparisons within a single provider. However, as dynamic measurements for daily assessments, these occur too infrequently to be used as daily quality metrics. In Chapter 5, delay to care processes and timing of medication administration in relation to scheduled times were assessed.

A further useful marker of performance is the response to clinical deterioration. It is clear that there is a measurable period of deterioration as measured through vital parameters, such as decrease in oxygen saturation or hypotension, before an adverse events or mortality occurs (457). Confidential enquiries and academic analyses have demonstrated that a delayed response to such deterioration is rooted in a number of factors- including the ability to recognise deterioration, training and supervision of junior team members, and working relationships between team members that empower them to escalate their concerns (62, 458, 459). Overall, nurse staffing levels are shown to be associated with adverse events or missed care (118, 123, 135, 350) in addition to other features such as nursing workload and patient turnover (354, 357, 460, 461). This evidence indicates that there is a role for clinical deterioration as a marker of the overall ward conditions, as its occurrence appears to be associated with many factors rooted in processes of care and variation of structure.

Additionally, two of these measures (drug administration timing and clinical deterioration) are represented as structured data in EHR. Electronic prescribing and automatic/ manual entry of vitals into the patient records leaves a time-stamped data footprint. This means that this is readily retrievable from EHR, a quality that is important when considering future use.

Outcome Measure 1: National Early Warning Scores (NEWS) as a measure of clinical deterioration

NEWS was introduced by the Royal College of Physicians as a standardised method of detecting and initiating a response to a patient that is clinically deteriorating (64). It is an aggregate score of six physiological parameters: respiratory rate, oxygen saturation (score increased if supplemental oxygen in place), temperature, systolic blood pressure, pulse rate and level of consciousness. In an updated version released in 2017 (NEWS2), a separate saturation scale is incorporated for patients with chronic obstructive pulmonary disease (65). The initial NEWS scale is used in this study as this was in use at the time of data extraction.

The threshold for each NEWS parameter is outlined as in figure 7.1. The aggregate score of 5 or more (or 3 in a single parameter) triggers an urgent clinical assessment and an increased frequency of vital parameters monitoring to a minimum of 1 hour (see table 7.1).

Figure 7-1: Parameters and their thresholds that trigger need for clinical response (green- score 1; orange score 2, red score 3)

Score – 0

Respiratory rate (RR)
12-20

Oxygen Saturation (sats)
>96%
(note supplemental oxygen – extra +2)

Temperature (T)
36.1-38.0

Systolic BP (SBP)
111-219

Heart Rate (HR)
51-90

Level of Consiousness
Alert
(Otherwise response to Voice (V), Pain (P) or unresponsive (U))

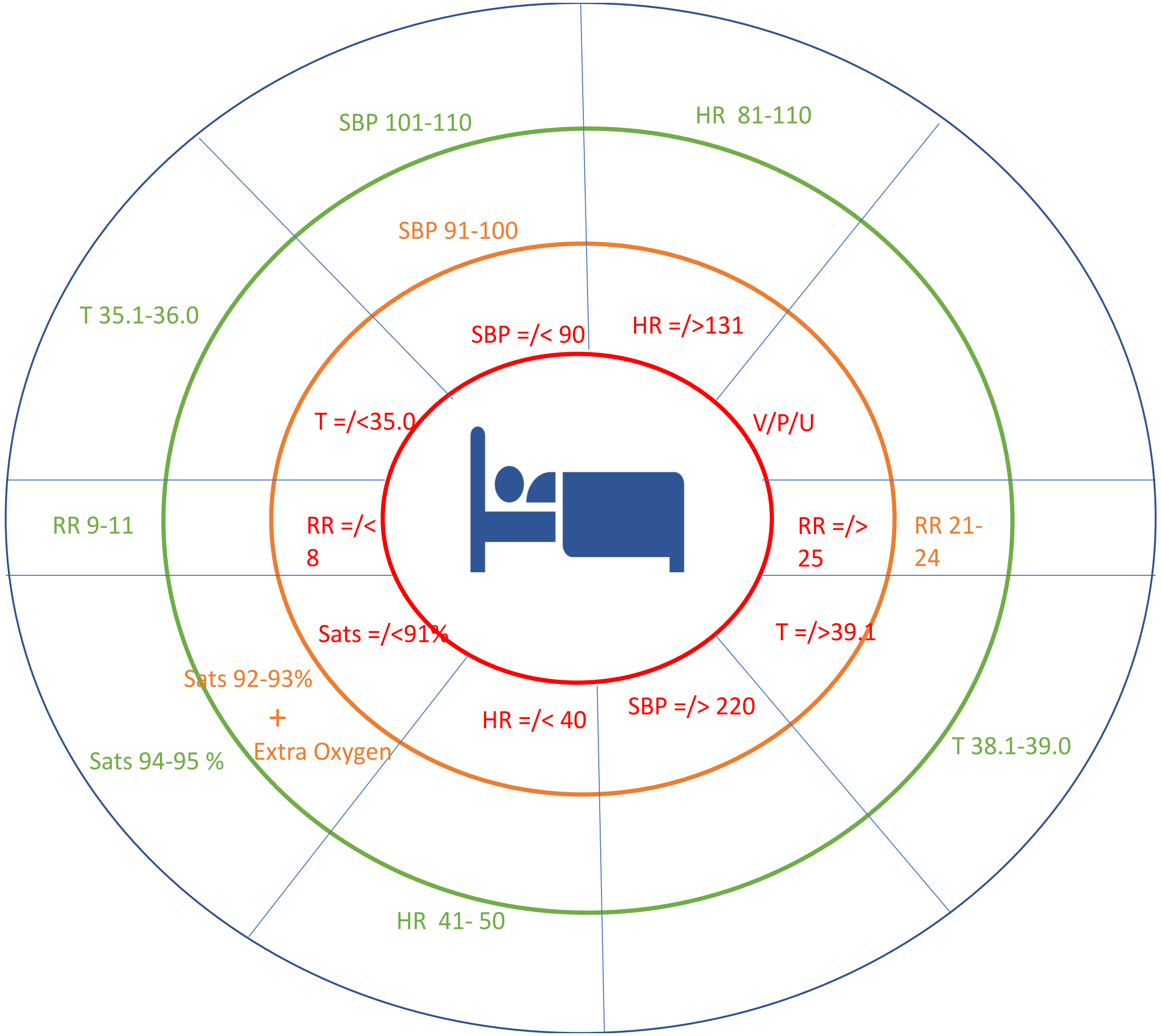


Table 7.1 : The recommended clinical response to NEWS trigger thresholds

NEWS Score	Frequency of Monitoring	Clinical Response
0	Minimum 12 hourly	Continue Routine NEWS monitoring with every set of observations
1-4	Minimum 4-6 hourly	Informed registered nurse who must assess the patient Registered nurse to decide if increasing frequency of monitoring and or escalation of clinical care is required
5+ Or 3+ in one parameter*	Minimum 1 hourly	Registered nurse to urgently inform the medical team caring for patient Urgent assessment by clinician with core competencies to assess acutely ill patients Clinical care in an environment with monitoring facilities
7+	Continuous monitoring of vital signs	Registered nurse to immediately inform the medical team caring for the patient – this should be at least registrar level. Emergency assessment by clinical team with critical care competencies, which also includes a practitioner/s with advances airway skills Consider transfer of clinical care to a level 2 or 3 care facility, such as high dependency or intensive care unit.

***In the NEWS2 version, these 2 conditions are split- 3 in a single parameter triggers a nurse to inform the medical team, who will then decide what escalation of care may be required whereas 5+ triggers an urgent and immediate response from the clinical team.(65)**

Early warning scores in general have been shown to be predictive of patient outcomes- especially where aggregate scores of multiple parameters are used; a 2014 systematic review demonstrates that such systems demonstrate a high sensitivity in predicting cardiac arrests and mortality within 48 hours of a critical measurement (462). The NEWS protocol was developed by a working group reflecting a range of clinical, nursing and academic expertise (64, 65). The scale is based on an early warning system developed previously by Prytherch, Smith and colleagues- the VitalPac EWS or ViEWS- with Smith himself being involved in the NEWS working group (463). The parameters for the ViEWS were isolated through available knowledge regarding the association of vital parameters and patient outcomes. Iterative adjustments were then made to the parameter ranges and their weighting against area under the receiver-operating characteristic (AUROC) curves for in-hospital mortality within 24 hours until the best-performing formula was achieved. Subsequently this was validated against a database of vital signs, and compared with other early warning scores, and was shown to be superior. The derived NEWS scale was similarly validated against a vital signs database and also compared with 33 other early warning scales (464). For validation of NEWS, AUROC curves for a number of possible outcomes occurring within 24 hours were performed; these included cardiac arrest, unexpected ICU admission, death and a fourth parameter that considered the occurrence of any of the 3 events as a combined outcome (464). The AUROC curves were superior to the AUROC curves of the other 33 scales and ranged from 0.722 to 0.894 compared to 0.570 to 0.858.

Thus, appropriate escalation at the pre-determined thresholds, as outlined in table 7.1, is therefore vital in averting these unfavourable patient outcomes. As time stamped NEWS scores are recorded in the EHR, they can be used to identify the frequency, incidence or patterns of deterioration in real-time. Contextualised within the care settings, NEWS may in itself be utilised as an easily retrievable outcome measure from the EHR. Deteriorating NEWS may indicate the contributory effect of structural and organisational factors at play, as well as patient factors themselves. Thus, if patients are crossing into the higher thresholds (e.g., NEWS of 5 or more overall, or 3 or more in a single parameter as outline in table 1 will trigger an urgent medical review), it may potentially indicate that the observable signs of deterioration that may have been noted at NEWS of 1-4 may have been missed, and in part this may be due to the ward dynamics at play on these occasions.

Outcome Measure 2: Wrong Time Medication Errors

Delays in medication administration, along with omissions, is a parameter that has previously been quantified by the National Patient Safety Agency as an important outcome measure: in its February 2010 alert, over 21,000 incidents of omitted or delayed medications were reported, with a resultant 27 deaths and 68 reports of severe harm (465). In its April 2017 update, the NHS Specialist Pharmacy Service released an example of omissions and delays associated adverse outcomes reported through the National Reporting and Learning system (NRLS). This list included anti-infectives in sepsis (death), steroids in adrenal insufficiency (Addisonian crisis/ serious harm) and insulin omission in those at risk of developing ketosis (death) (466).

The institute for Safe Medication Practices recommended that non time-critical medications prescribed more frequently than daily up to every 4 hours should be given within a 1 hour window before or after the scheduled time (333). This 60-minute threshold is a parameter that has been used in previous studies; in one systematic review, 1/3 of the studies (22 out of 66) classified medication error by this threshold (467).

EHR encompasses electronic drug chart where such data would again be readily available. Thus, similarly to NEWS, deviation of drug administration times greater than 60 minutes before or after the scheduled time may be used as an outcome measure of care quality and examine this with respect to the ward factors present.

7.1.3. Study Aims

In Chapter 5, real time observations of the surgical ward demonstrated the considerable degree of variation in processes and structure. These included fluctuations in the level of nursing care, the complexity of the patients present on the ward, and the institution-level pressures placed on the ward such as the need to accommodate outlying patients and opening of escalation beds, raising occupancy rates. Care outcomes in this study- specifically delay to delivery of care and delay/ omissions in medication administration- also varied, but the relationship between observed variables and outcomes needs defining. If this can be demonstrated, then this would be a step towards demonstrating the feasibility of real- time measurements of these independent variables as markers of safety, helping to focus the improvement measures of local teams.

Therefore, the study has the following aims:

1. To assess the relationship between EHR- and electronic staff roster-derived data as real-time measures of pre-defined ward-based factors observed in Chapter 5 and patient outcomes

2. To design a predictive model for patient safety in the post-operative ward environment using these variables

7.2. Methods

7.2.1.Research Setting

The study was conducted using data for three general surgical wards at a tertiary academic hospital in London, UK. These wards accommodated both elective and emergency surgical patients across multiple surgical specialties including vascular, oesphagogastric, bariatric, colorectal and urological surgery. However, each ward had distinct attributes: ward 1 was predominantly an oesphagogastric and colorectal ward, ward 2 was the vascular ward and ward 3 mainly dealt with bariatric as well as short-stay elective cases.

7.2.2. Data sources

Following appropriate ethical approval (REC reference: 16/LO/1937), the research informatics team at the participating institution were engaged to extract data from two sources- the EHR platform (Cerner Corporation, North Kansas City, MO, USA) and the e-rostering system (Allocate Software Group, United Kingdom).

Once the local information governance process was completed and approval for data retrieval granted, data was anonymised at the extraction stage by the institution and then transferred from the institutional data warehouse to the Imperial College Big Data & Analytical Unit. The data extracted is outlined in table 7.2.

From the EHR system, patient demographic data, ward allocation, time stamped NEWS scores, vital signs, and medications prescribed were retrieved. The e-rostering data consisted of time-stamped shift -level staffing information for each ward – with each staff member's seniority level and fulfilment type recorded. The unit of observation was the standard 12-hour nursing shift on each ward.

Data extracted covered a calendar year in the time period from 1 August 2016 to 31 July 2017.

Table 7.2: Outline of the raw data parameters extracted from both health records and duty allocation records.

Electronic Health Records	Electronic Duty Roster
Patient Demographics: • Age • Gender • Ward	**Ward Allocation**
Observations: • Heart Rate • Blood Pressure • Oxygen Saturations • Respiratory Rate • National Early Warning Score (NEWS)	**Duty Hours:** • Start Time • End Time
Medication Administration • Drug item • Route • Scheduled time • Administered Time	**Fulfilment type** • Local • Bank • Agency
	Grade/ Band • 2 (health care assistant) • 5-8 (Registered Nurses)
	Shift Type • Day (8am – 8pm) • Night (8pm- 8am)

7.2.3. Independent variables

The variables to be examined were identified in the preceding chapters of this thesis. The Delphi consensus study (chapter 4) isolated pertinent process-related and structural factors that were then carried forward into the observational study (chapter 5). In the case of the observational study, the variability of these process measures and structural factors were described.

A selection of these variables could be retrieved or calculated through the available data sources (see figure 7.2). Variables pertinent to staffing levels were directly derived from the e-roster database: this included the seniority of each nurse, the presence of healthcare assistants and the fulfilment type (whether permanent, bank or agency staff). Temporality (day versus night, weekday versus weekend) was also recorded, and was retrievable from the data.

Other structural details had to be calculated; for example, EHR data was not only used to extract patient outcomes but also to derive independent factors such as occupancy rates (by measuring the number of unique patient identifiers in the dataset for a given shift against the number of beds on the ward). This was also a reflection of patient flow (i.e., discharges and admissions occurring during the shift). Thus, this figure can exceed 1.0. Further factors, such as the element of work burden, could also be calculated in this manner (e.g., the proportion of medications that are intravenous during a given shift).

Figure 7-2: Retrievability of Pre-defined Quality Metrics (independent variables) demonstrating variation in Observational Study from existing electronic data

Directly observed in Ethnographic study (Chapter 5)

Processes of Care

- Ward round Qualities
  - Timing of the round
  - Lead clinician
  - Team Structure
  - Nurse Presence
  - Interruptions
- Time to completion of clinical or nursing tasks
- Medication administration errors

Care Environment

- Footfall
- Patent Complexity
- Outliers

Organisational Health

- Patient: Nurse ratio
- Healthcare Assistant: Nurse Ratio
- Nurse Skill mix
- Occupancy rates
- Presence of Agency Nurses
- Effect of weekend/ nights
- Patient reported Safety
- Nurse Reported Safety

Data either directly retrievable or translatable from data in existing IT systems (Current study)

Processes of Care

- Ward round Qualities
  - Timing of the round
  - Lead clinician
  - Team Structure
  - Nurse Presence
  - Interruptions
- Time to completion of clinical or nursing tasks
- Medication administration errors

Care Environment

- Footfall
- Patent Complexity
- Outliers

Organisational Health

- Patient: Nurse ratio
- Healthcare Assistant: Nurse Ratio
- Nurse Skill mix
- Occupancy rates
- Presence of Agency Nurses
- Effect of weekend/ nights
- Patient reported Safety
- Nurse Reported Safety

Methods of data extraction/ translation from existing IT systems

Variable	Method of extraction/ translation
Medication administration error	Directly extracted scheduled and administered time stamp comparison
Patient Complexity	This was made up of a number of items in chapter 5 – for this study, EHR data allowed calculation of the proportion of patients on intravenous medications
Patient: Nurse ratio	The number of unique patient identifiers compared against the number of nurses on shift (band 5 and band 6 nurses on e-roster)
Healthcare assistant to nurse ratio	Healthcare assistant (denoted as Band 2 nurse on e-roster data) compared against the number of nurses on the shift (band 5 and band 6)
Nurse Skill Mix	Proportion of nurses that are band 6, the higher of the two ward nurse bands.
Occupancy rates	The number of of unique patient identifiers against which NEWS and medication administrations were recorded, counted per shift .
Presence of agency nurses	Directly extracted from staffing rostering data, recorded as a fulfilment type. The proportion of agency to total nurses on shift calculated.
Effect of weekend/ nights	Directly extracted from time stamps.

7.2.4. Outcome Measures

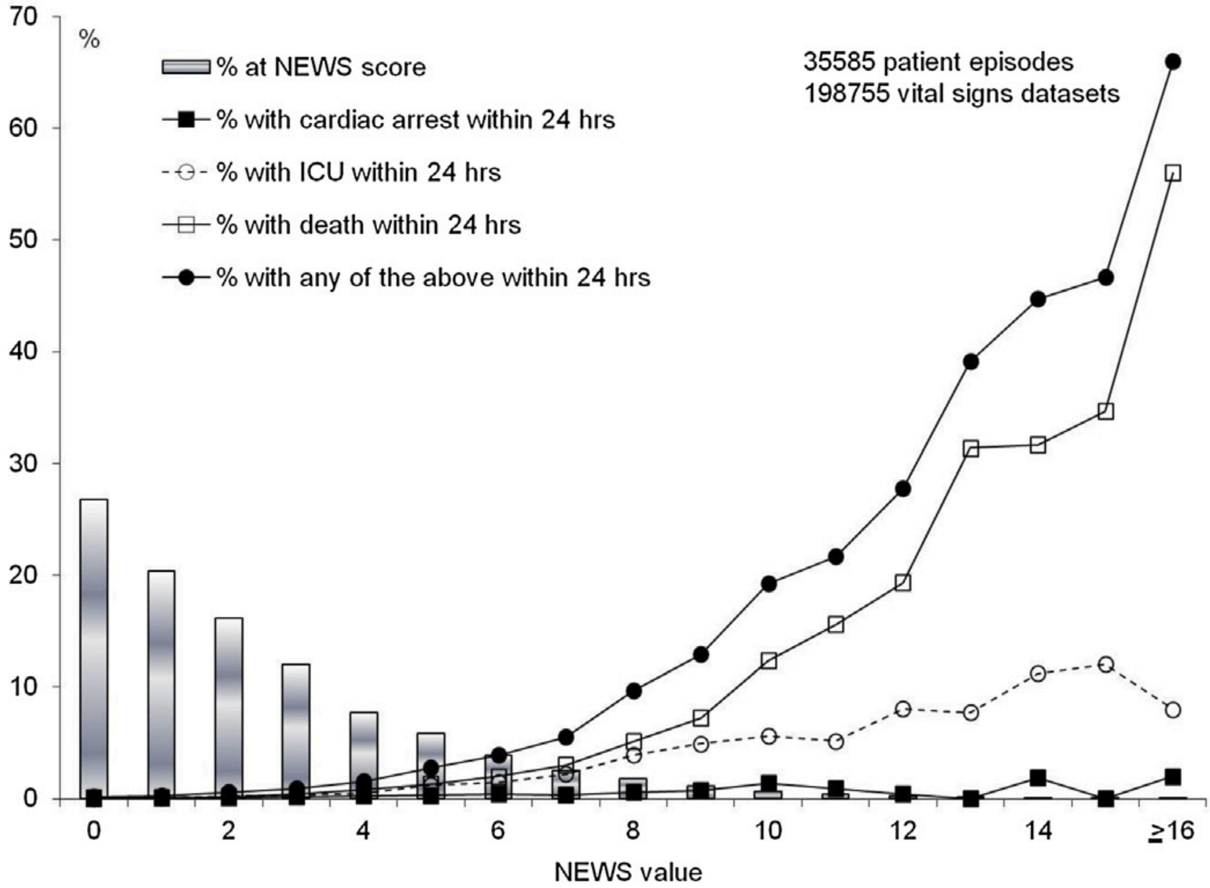
NEWS grading

The purpose of this study is to establish whether the present care conditions are allowing patients to become unwell. For the purposes of this study, a NEWS of 5 has been selected as a threshold that indicates that a patient has deteriorated. The reason for this is that from the NEWS protocol, a threshold of 1-4 prompts a registered nurse to assess the patient and evaluate the reason for the aberrant vital signs contributing to this score. Thus, a patient crossing into the 5+ threshold may have had these early warning signs missed. The relationship between NEWS values and the outcomes outlined in the study by Smith et al. is demonstrated in a figure taken from their study (see figure 7.3). Starting at this pre-defined value of 5, it can be seen that there is an exponential rise in the negative outcomes for patients.

Although the NEWS algorithm requires the same response to a NEWS of 3 in one parameter as it does for a combined score of 5- the data extracted from EHR indicates the aggregate score only, thus this was a clearer threshold to reflect an unequivocal deterioration (see table 7.1).

For the purposes of this study, the dependent variable was thus defined as the proportion of patients who experienced a NEWS of 5 and above in the defined period of observation, i.e., per shift.

Figure 7-3: Figure reproduced from Smith et al. demonstrates the relationship between NEWS values and patient outcomes



Taken from Smith et al., 2013

Wrong-time medication error

For the purposes of this study, a medication delay-related error was defined as 60-minute or greater in keeping with the institute for Safe Medication Practices. Although early administration outside of this window (i.e., 60 minute or more before scheduled) is also deemed an error, it was evident from the observational study that this was a strategy employed by the nursing team to mitigate delays/ omissions when it is anticipated that the scheduled time conflicts with other circumstances (e.g., 8am intravenous antibiotics given at before the shift changeover by night staff). Using a delay of administration as a marker will be a more robust measure of failure to deliver care in a timely fashion.

Thus, the second dependent variable is the proportion of medications that were delayed by 60 minutes or greater in each observed shift.

7.2.5. Data handling and application of integrity thresholds

Data was retrieved as "all medication administrations" and "all NEWS recorded" over the defined period with unique patient identifiers, ward locations and time stamps attached to that value. There were shifts where a very low total number of unique patients were present. The reasons for this may be rooted in data entry or extraction errors.

Reference was made to publicly available data on NHS England website's statistical work areas section to ascertain the average overall general and acute bed overnight occupancy for this institution for the dates observed (468). The range was 80.9% to 85.5%- therefore we took the lowest of these and established the threshold occupancy at 80%. Days where occupancy was calculated to be below this were excluded from the study. Ward-days which recorded fewer than a mean of 1 NEWS score per patient per 12-hour shift were also excluded.

7.2.6. Statistical Analysis

Data extracted from the institutional data warehouse was delivered as comma separated values (csv) files retrieved at individual NEWS or medication level with attached demographic and timing details.

To amalgamate these into shift- level data, computer coding was required. This was performed using Python version 3.6 (Python Software Foundation) in consultation with a researcher proficient in this programme. This generated two final csv files for each outcome measure against the intended variables (outlined in figure 7.2) at shift level.

As the dependent variables were continuous values, linear regression was used to determine associations. Descriptive and multilinear regression analyses were then performed on the final dataset with IBM SPSS Statistics for Macintosh, Version 25.0 (Armonk, NY: IBM Corp.).

For multilinear regression analysis, key statistical assumptions need to be met (469). Firstly, the absence of co-linearity between variables must be demonstrated. This was assessed through a Pearson's correlation test. If a Pearson's correlation between variables falls below 0.7 then co-linearity was determined to not be present. Additionally, tolerance values are generated on SPSS during the test for co-linearity; this value must exceed 0.1 to meet the required condition. Finally, outliers were tested through the leverage and Cook's values; if the leverage value is less than 0.2 and Cook's less than 1, then there are no significant outliers that may unduly influence the results.

Univariate linear regression analysis was performed for each independent variable before running the multivariate regression. A threshold of $p < 0.1$ was selected to determine which variables from the univariate regression were to be included in the regression model.

7.2.7. Ethical Considerations

NHS research ethics committee approval was obtained for this study (amendment to 16/LO/1937)

7.3. Results

7.3.1. Shift-level data extraction from EHR

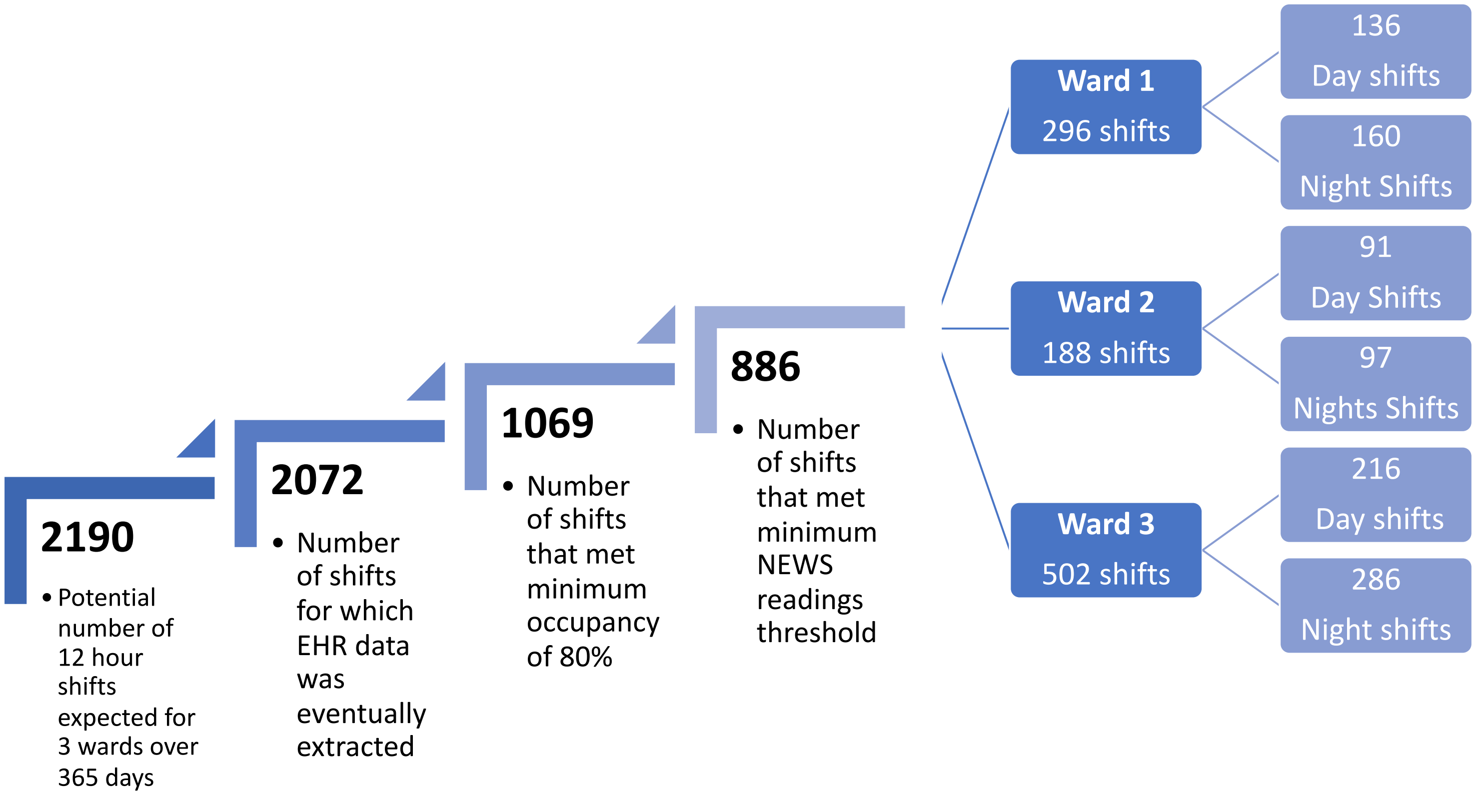
The observed time period covers a full year; thus over 365 days, 730 shifts would be expected for each ward resulting in a total of 2190 shifts. The extracted data covered 2072 shifts (94.6% of expected). Once data integrity thresholds were applied, the final number of shifts included in the analysis were 886 shifts (42.8% of all eligible extracted shifts). Data cleaning is outlined in figure 7.4.

21, 088 NEWS were recorded during these shifts. 1383 unique patient identifiers were noted to have a NEWS recorded.

376/1383 (27.2%) of patients had a NEWS of 5 or more recorded on at least one occasion.

Alongside NEWS data, 356, 826 scheduled medications were also extracted in this dataset.

Figure 7-4: Flow chart outlining data cleaning prior to analysis



7.3.2. Nursing Data Extraction from e-rostering database

Nurse staffing data was extracted for all 3 wards for all shifts in the desired date range. Therefore, staffing data was matched to all 886 shifts included in the study.

There was variation in staffing with regards to time of day and time of week; firstly, for example, all senior nursing management presence (either matron or a band 7 ward manager) was during weekday daytime shifts. Even then, out of the 350 weekday daytime shifts, nursing leadership (manager or matron as presented by a designation of band 7 or 8 respectively) was present on 235 (67.1%) only. Given the defined shifts that these managers were present for, the absence/ presence of these team members was not measured as a variable due to its collinearity with timing of the shift (daytime and weekday).

The use of agency nurses was also noted. Overall, this ranged from no agency nurses in a shift to 100% - although in the case of the latter this was for one daytime weekday shift, when a ward manager was also present, and two night shifts. These shifts all occurred on the same ward.

Of the 886 shifts, 384 shifts (43.3%) required supplementation with agency nurses. These shifts comprised of 265 day shifts (69.0%). 6.4% of day shifts needed 50% or more of their workforce to be supplemented by agency nurses, as well as 13.5% of night shifts.

In terms of work burden for team members, the median occupancy rate was 0.9 (0.8-1.8), patient: nurse ratio was 3.8:1.0 (range 1.9:1.0 – 11.5:1.0) and the proportion of intravenous medications on a given shift was 24.3% (2.8 – 65.2).

7.3.3.Patients reaching and exceeding a NEWS of 5

Descriptive Statistics

NEWS that equalled or exceeded 5 accounted for 5.1% of all scores (1085 out of 21 088). There were 370 shifts (41.8%) where not a single reading of 5 or above was recorded. The maximum proportion of ward patients scoring 5 or above on a given shift was 33%. The median proportion was 5%.

In the 516 shifts where NEWS >=5 was recorded, 400 (77.5%) occurred during a weekday (accounting for 59.9% of all weekday shifts) and 322 (62.4%) in the daytime (accounting for 68.5% of all daytime shifts). 48.5% of deteriorations occurred during daytime shifts on a weekday.

The range of values observed for the independent variables in this study are demonstrated in table 7.3.

Table 7.3: Descriptive Data for Independent Variables

Independent variable	**Median (range)**
Nurse to HCA ratio	**2.0:1 (0 – 7.0:1)**
Patient to Nurse ratio	**3.8: 1 (1.9:1 – 11.5:1)**
Percentage (%) of nurses that are Agency Nurses	**0 (0- 100)**
Percentage (%) of nurses that are Band 6	**16.67 (0 – 75.00)**
Occupancy rate	**0.93 (0.80 – 1.79)**
Proportion of Medications that were intravenous	**24.32 (2.78 – 65.22)**

Regression Analysis

All statistical assumptions for multivariate regression were met; firstly, none of the VIF values were below 0.1 (ranging from 1.085-2.708) and none of the Tolerance values were above 10 (ranging from 0.369 to 0.921), thus there was no multicollinearity. The Durbin-Watson statistic fell within an expected range (2.058), indicating that autocorrelation of residuals was not present. Finally, the scatterplot of standardised residual on standardised predicted value did not funnel out or curve, and thus the assumptions of linearity and homoscedasticity have also been met as well. Leverage values (all less than 0.2) and Cook's (less than 1) did not reveal any data points causing biased influence on the outcome.

In univariate analysis, the proportion of patients crossing the NEWS of 5 threshold (have become unwell) was significantly associated with increased occupancy rate, patient: nurse ratio, increased proportion of intravenous medications, daytime shifts and weekday shifts.

These 5 significant variables were incorporated into the multivariate model (table 7.4)

Table 7.4: Regression results for the outcome of proportion of patients scoring a NEWS of 5 and above

Univariate Regression					
	Coefficient	**Standard Error**	**95% Confidence Interval**		**p-value**
			Lower Bound	**Upper Bound**	
Nurse to HCA ratio	-0.291	0.216	-0.714	0.132	0.177
Patient to Nurse ratio	-0.225	0.104	-0.428	-0.021	0.031
Percentage of nurses that are Agency Nurses	-0.001	0.013	-0.026	0.024	0.942
Percentage of nurses that are Band 6	0.000	0.012	-0.024	0.024	0.982
Occupancy rate	4.635	1.205	2.270	7.001	<0.001
Percentage of Medications that are intravenous	0.072	0.021	0.031	0.113	<0.001
Daytime shift	3.415	0.400	2.630	4.199	<0.001
Weekday shift	1.263	0.480	0.321	2.205	0.009
Multivariate Regression Coefficients					
Patient to Nurse ratio	-0.302	0.137	-0.570	-0.033	0.028
Occupancy rate	4.591	1.477	1.692	7.491	0.002
Percentage of Medications that are intravenous	0.125	0.021	0.084	0.165	<0.001
Daytime shift	3.590	0.444	2.719	4.460	<0.001
Weekday shift	0.907	0.475	-0.025	1.839	0.056
Constant	**-3.204**	**1.241**	-5.639	-0.768	0.010

R^2 of 0.132, p <0.001

The analysis demonstrates an R^2 of 0.132, with a p value of <0.001.

7.3.4. Wrong time error in medication administration

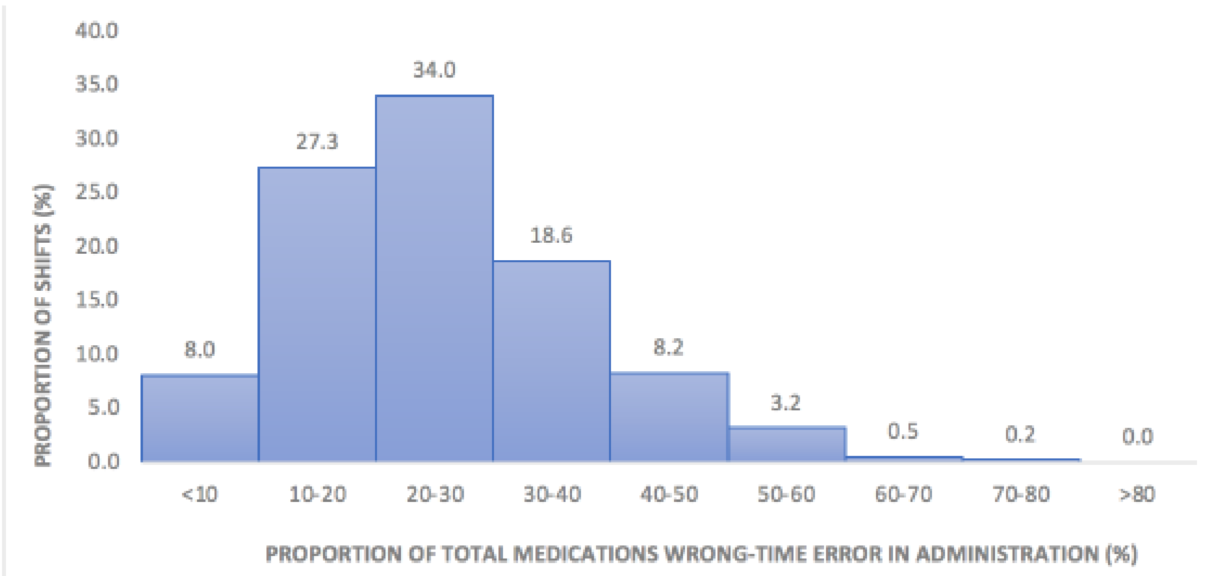
Descriptive Results

The median proportion of medications that were administered with a 60-minute or more delay was 24.2%, with a range of 1.8% to 73.8%.

The frequency of delays is demonstrated in figure 7.5. Two-thirds of shifts demonstrated drug administration delays affecting up to 30% of due medications. However, more than one quarter of all shifts had up to 50% of medications affected (30-40% of medications delayed- 18.6% of shifts; 40-50% - 8.2% of shifts). Though rare, there were shifts were more than half of all medication administrations were given more than 60 minutes late (just under 4%).

Median medication delay was similar across all 3 wards: Ward 1 was 25% (2-49%), Ward 2 was 29.5% (2 - 66%) and Ward 3 was 22% (2 -74%).

Figure 7-5: Frequency of each decile of wrong-time errors in administration



Regression Analysis

Initial univariate regression of the 8 independent variables was performed as demonstrated proceeding to multivariate regression (table 7.5).

There was no evidence of multicollinearity (Tolerance values were less than 10, and VIF values exceeded 0.1). Leverage values (all less than 0.2) and Cook's (less than 1) did not reveal any data points causing influence on the outcome.

Table 7.5: Regression results for the outcome of proportion of medication delay beyond of 60 mins

	Coefficient	Standard Error	95% Confidence Interval		p-value
			Lower Bound	Upper Bound	
Univariate Regression					
Nurse to HCA ratio	0.001	0.004	-0.007	0.010	0.771
Patient to Nurse ratio	-0.013	0.002	-0.017	-0.009	<0.001
Percentage of nurses that are Agency Nurses	0.002	0.000	0.002	0.003	<0.001
Percentage of nurses that are Band 6	0.000	0.000	0.000	0.001	0.703
Occupancy rate	-0.052	0.024	-0.099	-0.006	0.028
Percentage of Medications that are intravenous	-0.004	0.000	-0.004	-0.003	<0.001
Daytime shift	0.101	0.007	0.086	0.116	<0.001
Weekday shift	-0.009	0.009	-0.028	0.009	0.330
Multivariate Regression Coefficients					
Patient to Nurse ratio	0.002	0.002	-0.002	0.007	0.341
Percentage of nurses that are Agency Nurses	0.001	0.000	0.001	0.002	<0.001
Occupancy rate	-0.082	0.027	-0.134	-0.030	0.002
Percentage of Medications that are intravenous	-0.002	0.000	-0.003	-0.001	<0.001
Daytime shift	0.086	0.008	0.070	0.102	<0.001
Constant	0.371	0.022	0.273	0.361	<0.001

R^2 of 0.249, p <0.001

Univariate regression demonstrated that 5 of the 8 independent variables demonstrated statistical significance with delay in medication administration of 60 minutes or more. Delay was significantly associated with increased presence of agency nurses and occurred more during daytime shifts. However, delays decreased with increased patient numbers- as demonstrated by a negative association with patient: nurse ratio and occupancy rate as well as an increased proportion of intravenous medication.

These 5 variables were incorporated into the model outlined in table 7.5. This model has an R^2 of 0.249 (adjusted R^2 of 0.245).

This model was statistically significant at predicting medication delay with these independent variables, $p<0.001$.

7.4. Discussion

This study presents the feasibility of developing predictive models of care quality and safety for the surgical ward that are based on locally measurable factors that are already routinely collected via health record and organisational data. This novel approach represents a potential first proof of concept towards the vision of harnessing the information in routinely collected data in real-time, to guide local teams in their policy design.

This study builds upon the observational study, an exhaustive examination of the surgical ward though direct observation of care processes and the structural circumstances within which that care is delivered. At the heart of this thesis is the aim to identify locally measurable factors that have an immediate relevance to healthcare providers, administrators and policymakers at the unit level, while appreciating that focusing on one area alone is unlikely to be unsuccessful due to how these various factors interact with one another. For this, ground-level frontline enquiry has demonstrated the degree of variability which exists but demonstration of associations between these metrics and patient care outcomes at the unit level required characterisation with larger datasets. This was a need that could not be met through available traditional data sources such as administrative databases but with the increased uptake of EHR and e-rostering which allows for this level of granularity, this has now become feasible.

There are a number of findings from the two models – the first using an end point of proportion of patients attaining a NEWS >=5 and the second is the proportion of medication error– which would be in line with existing literature and lend some real-world applicability of these preliminary models.

Firstly, with respect to the model predicting the likelihood of patients becoming unwell i.e., NEWS >=5, there were clinically significant positive co-efficient slopes for patient occupancy rate and volume of intravenous medication. This implies that as both these variables increase, the proportion of unwell patients also increases.

These findings are in keeping with what is understood about the effects of such pressures on nursing performance. In the instance of occupancy rates, or in similar phenomenon such as patient turnover, the effect on care outcomes is a recognised; as noted in a 2016 literature review, these characteristics of the ward are described in various manners (churn, patient thorough put, census variability etc) and measured in various ways (including as the inverse of the length of stay, a readily available metric in most administrative datasets) and overall, there is clear evidence that this needs to be taken into consideration with respect to the effect on nursing workload (470). Specifically, patient occupancy/ volume/ turnover is not only likely to increase nursing activities related to care but produces an increased burden of administrative duties on nurses in relation to admission and discharge processes.

In their study, Park and colleagues assessed turnover (the sum of admission, discharges, transfers and observational period of stay) represented this as a ratio of the midnight census at the unit level (471). Results, however, were aggregated at the hospital level due to the nature of the outcome measure (FTR- a value available at hospital level only from administrative data). Examining the relationship between FTR and registered nurse staffing levels to corroborate the known protective effects of higher nurse staffing levels on this outcome, they demonstrated the corrosive effect of patient turnover on this. In this case, a direct association between turnover and FTR was not established; however, when patient turnover increased from 48.6% to 60.7%, the protective effect of the nurse staffing on FTR diminished by 11.5%. Needleman and colleagues had previously demonstrated a similar effect; ensuring that their study design allowed for unit level assessment, they found that high turnover was associated with mortality, with a 30-day exposure odds ratio of 1.04, increasing to 1.07 when limited to the initial 5 days (103). The implication from this study is that patient turnover does have an effect on patient care that can be measured at the unit level on a shift-shift basis.

The other measure of work burden used in this study alongside patient turnover was the proportion of intravenous medications administered in a shift, presenting a potentially novel and readily retrievable marker from existing datasets. Although there are other known markers of patient complexity, e.g., Charlson scores, the nature of the EHR-derived data meant that structured patient information detailing active co-morbidities or physical care needs at time of admission could not be derived to reflect shift-level variation. There were also some ethical limitations which are discussed later. Furthermore, there are numerous surrogate markers of work burden; one review published earlier this year identified eleven measures with reported psychometric properties, however all were scale-based (472). Additionally, many of the of these work burden measures are subjective measures, as indicated in a recent scoping review by Griffiths et al. (473).

In comparison, the use of directly and objectively measured markers such as proportion of IV medications allows for a real-time quantification of an element of work burden, acting as an indicator of nursing needs. It is a task that needs to be undertaken by trained nurses and cannot be delegated to other team members. The evidence around errors in their administration reflects this burden that comes with the inherent complexity of IV medication administration. Errors are more likely to occur with IV medications than non-intravenous; one systematic review of quantitative observational studies found through a metanalysis that medication administration errors associated with intravenous medications were five time more likely than non-intravenous (474). In a further systematic review by another group, the sources of error were investigated; using Reason's model of accident causation, a thematic analysis of 54 studies was conducted and found several process and structure related contributors (475). Some themes were reflective of the effect of the environment on nurses' ability to complete this process- these included being distracted in a busy environment, staff workload and multi-tasking.

Furthermore, the interventions that have been introduced to mitigate errors with IV medication administration may inadvertently increase workload; 'double-checking' has become a routine practice, requiring two nurses to perform safety checks before administration. However, nurses recognise that there are issues around having enough staff available to perform this task appropriately (476) and in a survey study amongst Swiss oncology nurses, one third reported that it was disruptive to workflow, with 28% recognising that the due attention to it was not paid even when performed (477). However, caution may need to be exercised in interpretation of the relationship between the burden of intravenous medication as it may be that increasingly unwell patients require more intravenous medications such as antibiotics or fluids.

There were some unexpected results: for instance, these same variables (occupancy rates and IV medication proportion) do not show the same association in the second model predicting medication error. Rather, both of these factors have an inverse relationship with the outcome indicating that as work burden decreases, medication delays increase. In addition to unappreciated confounding factors as a result of the limitations of the source data, there may be clinical reasons for the inverse relationship in the medication delay model with increased occupation rates and IV burden. Firstly, it is recognised that in particularly busy environments, nurses prioritise workload and perform “workarounds”, which are discussed in chapter 5’s discussion. This is essentially where nurses may deviate from a protocol or expected processes to mitigate perceived impediments to workflow (336). Previous qualitative investigation has demonstrates that missed nursing care is least likely to affect treatments and pain management, as these are prioritised when work pressures increase (137). In a recent scoping review, Suhonen and colleagues amalgamated studies seeking insight into how nurses prioritise their tasks (478). They found that nurses prioritise with respect to “essential” e.g., vital needs such as medication, and the administrative demands placed upon them. Thus, the results in this study, though seemingly counterintuitive, may be a reflection of a culture of prioritisation, and it may be that with more difficult working conditions, nurses may prioritise tasks such as medication administration.

Combining this information with the finding that there is a positive association with the NEWS of 5 threshold model and occupancy rate and proportion of IV medication, it may indicate that this increase in work burden is shifting focus to more procedural tasks, i.e., thus failing to react to the low-level NEWS scores that may have heralded the high NEWS of 5 and above. Work arounds and nurse prioritisation is inextricably linked to the themes that have emerged through this thesis, of a dynamic and unpredictable environment requiring on-the-ground adaptation. However, this is an area that needs further investigation and examination to ascertain the extent of this phenomenon, quantify it and thus measure it using existing data. Potentially, this may require frequent direct engagement with staff on the ground, possibly through validated short-from questionnaires akin to the methods of chapter 6, that would be performed in real-time alongside EHR and duty rostering data that is collated in real-time.

Other unexpected results were demonstrated with respect to some well-established variables such as patient: nurse ratio. It is well- established that increasing patient: nurse ratio impacts safe care, and this has been reiterated in the literature over the last 20 years, with improved nurse staffing levels consistently being associated with reduced FTR when other factors are controlled for (57, 61, 109, 123). However, for the NEWS threshold model, increasing patient: nurse ratio was inversely associated with higher proportion of unwell patients and in the final model for medication error, there was a very modest positive co-efficient which was not significant in the final model. All in all, this is likely to mean there are other factors missing from these model that will need further research and incorporation into future models, as well as potential effect from the quality of the raw data extracted for this study.

Similarly, the use of agency nurses also featured as a variable in the medication delay model, which although statistically significant, had an extremely modest coefficient.

Although concerns of fractured communication have been raised both in the interview study in the initial stages of the thesis (271) and other qualitative data (276), the association with patient outcomes through quantitative measures is yet to be demonstrated. Aiken and colleagues linked survey data with mortality data and found that there was no negative impact on 30-day hospital mortality or FTR (59). Their initial analysis demonstrated some association, but once work environment was adjusted for there was no association. Bae et al., using an endpoint of rate of nosocomial infections on intensive care units, also could not demonstrate any association with the use of temporary nurse staffing (479). This is also the case for patient satisfaction, with no effect demonstrated by Lasater and colleagues (349). In the context of this study, the small association with medication delay seen in this study may be for one obvious reason: a reflection of temporary staff being unfamiliar with local systems- e.g., electronic drug chart on the EHR system- resulting in delay. It may also reflect other issues underlying the work environment and due to the level of interest it raised in the qualitative research chapters of this thesis, further assessment of the role of agency nurses in safe care- whether as a protective or deleterious factor - is warranted.

The timing of shifts was also a variable in both models: with respect to daytime shifts, there was a positive association in both models. This indicated that medication delays and failure to detect patients becoming unwell is more likely during the day. There was an additional effect on the NEWS threshold model from a further timing of shift variable – weekday shifts- with a suggestion that weekdays pose a greater risk. However, in line with the lack of association of patient: nurse ratio and the outcomes of interest, the weekdays were actually more well-staffed (median patient: nurse ratio 3.43 vs 4.2-4.6 at other times). This would therefore indicate other factors at play.

Specifically, the observational study highlighted a marked difference between weekday and weekend such with respect to how busy the ward environment can be; a weekday is the busier time, with multiple team rounds, a multitude of elective and emergency post-operative cases and investigations which increase the stress on the ward. However, these features are not easily captured using EHR datasets in the current study and thus the effect of such factors have not been accounted for.

Overall, the slope coefficients for predicting patients becoming unwell were of a greater magnitude than then those of the model predicting medication administration delay. This suggests that opportunities to recognise unwell patients before they deteriorate to the point where urgent clinic review is required is being compromised at the local level under these variable conditions. Research suggests that nursing concerns correlate with patient deterioration, even before triggering of an early warning score (480). However, this liberty in care cannot be exercised at times of elevated work burden. The effects on medication delay are variable and appear to be overall more modest. Further work is necessary to discern how these outcomes (medication delay and failure to recognise a patient becoming unwell) should be combined when predicting care quality at the unit level.

7.4.1. Strengths and Limitations

There are a number of limitations to this study; firstly, this study was centred around a single institution with a well-established EHR system. This study needs to be replicated across other institutions to ascertain if the impact of these pre-defined factors on patient outcome is reproducible and thus can claim to be generalisable. Furthermore, such studies will allow for assessment of a wider variation in these factors than seen in this study, especially those that do not have a nationally established threshold (e.g., patient: nurse ratio).

Secondly, this study was not able to characterise the patient population through available data - such as clinical acuity, proportion of outliers, surgical procedures performed, morbidities- thus there is limited understanding of the complexity of the patient population.

Thirdly, and probably the limitation that may have had the most significant impact on the quality of these models, there were issues with the quality of data from the health records. The degree of data cleaning required meant that only 43% of the available 12 hours shifts were included in the regression analysis. This significant diminishment may have affected the quality of the results, and potentially even the direction of co-efficients and the extent of the associations demonstrated. There could be a number of reasons for this degradation in data quality – either at data entry into the EHR point of view or at the point of data extractions, such as the complexity of coding required to achieve this. At present, the limitations of EHR data are well-established; in particular, given the primary purpose, certain clinical information required by researchers may be incomplete, inaccurate or altogether missing (481). One of the key findings during the data cleansing was that if a vital sign was missing, whether not performed or not recorded, then the NEWS algorithm could not be completed and the cell for this would be empty. Other factors that were desired for this study also had to be omitted due to the quality of the data: for example - one of the key values assessed in the thesis that could not be explored on this study was the presence of outliers. The named consultant attached to each identifier could be retrieved as this would be a way to match patients to the specialty team. However, at the time of data extraction, it was highlighted by the analysts assisting with extraction that this was often wrong (e.g., the Emergency Department consultant's name still attached to episode) so was not deemed reliable data. Strategies to improve the quality and integrity of information pertaining to patient episodes must be developed, both for clinical governance as well as audit and research purposes.

Fourth, data mining of EHR poses ethical concerns (482, 483). Vulnerability to deanonymisation by use of contiguous data that is collected for individual patients as part of the research exercise is a concern in EHR-based research (484). The protocol had to be crafted to balance that enough information is gained to inform the research into the environment and care provided without compromising anonymity and so, some limits to data extraction are posed. Future endeavours will need to address this, as the use of EHR data in clinical and health services research becomes more sophisticated.

However, despite the many limitations of using EHR data for care quality analysis, it holds enough promise to warrant ongoing research, especially where it can be aligned and integrated with other data sources that reflect the working conditions of a unit. Like this study, another published in 2020 mined rostering data and combined this with EHR data to understand the effect of working conditions on patient outcomes; here nurse staffing data was aligned with vital sign observations and additional calculations of occupancy and staffing levels (485). With an end point of "failure to respond" (i.e., patients remaining at a high acuity vital sign score over an extended period without an indication of either being moved to an intensive care unit or placed on end-of-life pathway), a significant correlation with registered nurses hours-per-patient day was shown.

Furthermore, there is a potentially prospective role that datasets used in this research my offer at the local level. There is an opportunity for an institution to use information contained on its own servers to characterise its own ward environments- detecting areas of organisation, structure, and potentially process that are influencing safe delivery- and use that information to change practice at the coalface. As predictive modelling offers an opportunity to project future behaviours, aligned with the real-time nature of monitoring of the ward environment under a set of conditions, there may be a future where a clinical dashboard evaluating the environment and processes of a ward can be designed.

Recently, machine learning has gained increasing popularity in the design of prediction models, circumventing the weakness of traditional linear models (486-488). The analysis of high volume, often dense and heterogenous datasets (including free text data) may uncover previously uncharacterised variables related to patient outcomes.

Future work is required with the current study; firstly, a way must be found to automatically measure other metrics identified in the observational studies (Chapter 5) that are not yet readily available through EHR data. Secondly, further validation studies must also be run on these models.

7.5. Conclusion

This study demonstrates the feasibility of integration of EHR and staffing data to propose prediction models of care outcomes on a surgical ward, in the light of inherent instability and variability in that environment. Furthermore, EHR data can be used to infer workload and environmental pressures that may be influencing these outcomes. Specific process-driven and structural metrics can thus be employed to monitor care quality- and even anticipate the conditions under which suboptimal care and potential adverse events may develop through predictive modelling of this routinely collected data.

8. Conclusions, Recommendations and Future Work

8.1. Outline of Chapter

In this concluding chapter, the overall findings from this body of work will be discussed. To facilitate the discussion, the background upon which this work was conducted will be summarised. Thereafter, the thesis aims will be outlined, followed by how these have been addressed through the studies conducted. The key finding of this research and its implications for how we perceive, potentially measure and hope to improve surgical ward-based care quality and safety will be considered in depth. Future directions for research will also be explored.

8.2. Summary of background- why was this work needed?

When considering the delivery of safe care to the surgical patient, immense resources have been allocated to defining this within the peri-operative period. This is unsurprising as errors in the operating room account for as much as 41% of all adverse events (96). Subsequent policy and interventions have seen a marked decline in the rates of errors and perioperative mortality in relation to procedures performed in this area (489-492). However, despite more than two decades of patient safety research and innovation, adverse events are still occurring at a troubling rate (493). However, much of this is inflicted upon the surgical patient in the post-operative period, during the ward-based care episode (494, 495).

Beyond the fact that errors within the operating room can be immediately devastating to both the patient and those involved in any incident, quality improvement with respect to ward-based care likely lags behind due to its more complex nature (table 8.1).

Table 8.1: Contrasting the Operating Room and the Surgical Ward.

	Operating Room	Surgical Ward
Patients	Single patient within environment	Multiple patients of variable clinical presentations
Personnel		
Nursing	Defined and rarely non-familiar	Varied and can include temporary staff
Medical	Single clinical team responsible in environment	Multiple clinical teams, frequently across specialties
Processes	Happen in succession – e.g., team brief, patient checked, anaesthetised, safety checklist before knife to skin, prep and drape, procedure start, procedure ends, sign out checklist, patient awake, moves to recovery. Documentation occurs in real-time Procedure specific environments e.g., general surgery, orthopaedics, gynaecology	Multiple processes often occurring simultaneously e.g., ward round, drug round, administering care, assisting patients, accompanying patients to other diagnostic and therapeutic areas of the hospital. Frequent delayed documentation (nursing in particular) Variable processes depending on patient need and clinical presentation
Structure	Standardised environment Purpose built Standardised equipment	Variable environment Variable layout Variable Equipment
Outcome	Immediately obvious outcomes e.g., failure or successes Complications can be managed – e.g., bleeding, iatrogenic injuries Omissions unlikely due to processes being performed in succession and checklists	Delayed e.g., complications such as DVT/PE, chest infection, urinary tract infection, FTR, escalation of care. Omissions detected late. Sometimes difficult to trace back where errors occurred

Operating rooms are relatively controlled environments undertaking a small collection of defined processes. This work system is conducive to adopting strategies and protocols that are successful in high-reliability high-stakes situations. Furthermore, given its cocooned nature, the operating theatre has been considered in its totality - hence the quality improvements interventions have spanned all aspects of care delivery – ranging from how processes are conducted (e.g. checklists) (28, 490), how the team is structured and communicates with one another (e.g. team briefings, development of non-technical skills) (44, 496) and resources available (e.g. equipment) (497).

By contrast, the ward remains a relatively nebulous area when it comes to fully understanding why errors occur. A holistic overview of a surgical procedure in the operating theatre is more easily achieved than the entire ward-based care episode, with the inherent increase in the time taken and number of people involved. Ward-based care has been studied predominantly with respect to patient outcomes. Although it is necessary to include this as part of a measure of care quality, developing a map of where issues arise and how they can be tackled has gradually introduced specific structural and process measures that may help identify issues before they can affect patient outcome.

However, many of these newer measures have been derived through the assessment of large datasets, and the analysis is often performed in a remote fashion from the daily experience of ward teams. This potentially is a missed opportunity to directly observe and thus, better understand and improve ward-based care.

This thesis fills the gap between published research which details the sources of variation in care quality and safety and daily surgical ward life. Although many studies have used qualitative methodology such as questionnaires, interviews and observations to study this area, the focus has been predominately on a single or group of processes- e.g., medication administration, ward round, handover- with a focus on how they may be addressed. Such strategies are important, and represent the cornerstone of QI projects locally, but when a potentially two-dimensional approach is taken for multi-dimensional issues, the success of the designed intervention may fail due to the other unaccounted-for areas within the environment and organisation in which that process is being delivered.

Through an intimate and extensive examination of post-operative ward-based care, this thesis presents a novel collection of process-driven and structural quality metrics, that are amenable to direct daily measurement. The minutiae of life on the surgical ward have been characterised and salient elements that may have evaded study through a broader approach have been identified.

8.3. Review of Aims

The aims of this thesis were:

1. To identify, prioritise and aggregate the key contributors to error in ward -based care of the surgical patient, by assessing the processes of care and the organisational constructs within which that care is delivered.

2. To observe the surgical ward in real-time, assess sources of variation and derive measurable metrics rooted in ward-level processes and structural factors.

3. To develop a statistical model of risk of harm using these real-time quality metrics through a proof-of-concept study using routinely collected administrative data.

8.4. Development of Thesis Aims

At the outset of thesis, it was important to understand what was known with respect to what determines safe care for patients admitted to a surgical ward. Therefore, this enquiry began with a thorough review of the literature. As there is a vast volume of literature concerning patient safety in the inpatient setting (the initial search of databases detailed in Chapter 2 yielded more than 70,000 articles across the three databases), the information available was almost unwieldy for the primary line of enquiry – what are the key factors that determine care quality on the surgical ward?

Therefore, an exploratory approach was taken to account for all aspects of ward-based care culminating in a narrative review. However, the data needed to be structured and organised in a way that most logically addressed this topic. A framework was required. Given that the Institute of Medicine's *To Err is Human* (4), The UK's an organisation with a memory (6) and James Reason's seminal publications (15, 16, 18) have emphasised the systematic, multi-layered contributors to error, a framework that reflects this was needed. In 1999, Sally Taylor-Adams and Charles Vincent developed the London Protocol to systematically analyse clinical incidents (90). This was re-purposed for the literature review- and the evidence was organised with respect to individual staff factors, team factors, task and technology factors, work and environmental factors, organisational and management factors and finally institutional factors. As it was not something that could be altered or improved upon, patient factors were not considered directly.

The lion's share of data with regards to post-operative, ward-based care was dedicated to qualities pertaining to nursing care – with a large focus on aspects of nursing care which span several domains of the London Protocol. There was focus on the level of experience of nurses, with studies based in the United States demonstrating the protective effect of registered nurses with appropriate qualifications (i.e., individual staff factors) on patient outcomes, especially failure to rescue. Also, there was focus on the composition of the nursing team (team factors), the hours or level of patient staffing scheduled for patient care (organisational and management factors) as well as governmental and executive level discussion about what an appropriate nurse staffing looks like (institutional context factors).

However, despite these deep, fundamental patterns being widely recognised, change has been slow. At the point in time that this thesis was conceived, the concerns around nursing care were still very much front and centre in both academia and politics. In 2015, The Royal College of Nurses released their labour market review, *A Workforce* *in Crisis*, and noted that the market review of the year before '*painted a dismal picture of nursing shortages, recruitment drives in Europe, increased use of agency staff, the degradation of specialist and senior nursing as well as worsening workload, morale and stress level'* and that this latest review *'shows a further deterioration in the key factors necessary for planning a sustainable workforce'* (498). Problems such as short-sighted high-level plans, pay cuts and failure to address reasons for workforce attrition were cited. Thus, although the importance of maintaining a robust nursing workforce has been recognised as imperative for safe care, interventions and subsequent successes have been limited. A closer analysis of the machinations that impact on this workforce at the unit level was thus essential in this thesis.

In addition to qualities of the nursing team, the clinical team was also scrutinised in the literature to an extent, although the focus of patient safety from this perspective was heavily skewed towards perioperative safety. Nonetheless, there was evidence that work patterns and extended working hours were producing error prone behaviour. Furthermore, interactions both within the clinical team (e.g., team hierarchy and the impediments to escalation of care it poses) and between the clinical team and nursing teams were also highlighted as compromising safety. These are areas that again span multiple aspects of the London Protocol.

However, it was also evident that teams were likely working within complex conditions. Safety culture has been an evolving concept since to *Err is Human* (4). Comparisons with high-reliability industries e.g., aviation and nuclear industries, and how these were succeeding at running complex simultaneous processes with limited errors, starkly highlighted the inadequacies in healthcare. A culture that is open and promotes learning was encouraged, and a number of systems were introduced at the national level to globally promote this. Furthermore, standardisation of care became a key area, with protocols and pathways introduced into healthcare. Additionally, and to a lesser extent, examination of the structures within which care was delivered also revealed areas that may be contributing to error. The physical constraints of the ward environment and the organisational pressures placed on the unit also became key considerations.

The literature review essentially highlighted that this was a hugely complex problem, with contributory factors scattered across a range of domains. Furthermore, many of these factors originate several layers above the front-line team. However, the chronic issues present in the system were culminating into a sharp apex at the patient- healthcare provider interface, where the realities of error were being lived by these care workers and their patients. Thus, the aims were developed to understand what was happening at the ward level, to derive useful metrics- a currency that local team can then use to interact with the managerial and executive level of their organisation- that were locally measurable and locally modifiable to improve safety on the surgical ward.

8.5. Addressing Aims

Aim 1: To identify, prioritise and aggregate the key contributors to error in ward - based care of the surgical patient, by assessing the processes of care and the organisational constructs within which that care is delivered.

In Chapter 3, using the revelations of the literature review, a probing semi structured interview protocol was developed. Furthermore, the involvement of patients reflects the increasing focus on patient and public involvement in health services and safety research, and the novel and useful perspective they present. This theme runs through other studies in the thesis. As well as patients, a purposive sampling of doctors, nurses and managers across all grades of experience was also undertaken across three institutions in London.

The interview study revealed a prevalent sentiment amongst staff, that there was variation in safety between surgical wards (97% of staff). It is likely a testament to staff that only 13% of patient were aware of any variation, and 93% of patients felt safe on their current ward at the time of interview. Participants were able to clearly identify error-prone processes and the point at which these errors were occurring. These included key processes such as wards rounds and the prescribing and administering of medication as well as how communications are undertaken across the environment between different key players.

Structural impediments were also considered; well-known areas of concern identified in the literature persisted in present settings (e.g., staffing shortages, use of temporary staff), indicating that these issues were yet to be resolved. However, more nuanced aspects of the surgical ward were also revealed; for example, in discussing the challenges of caring for outlying patients, nurses identified that beyond challenges with the clinical presentations- which at times were unfamiliar- there was often difficulty in interacting with the clinical team of outlying patients as there was a lack of familiarity in comparison to their usual clinical teams covering their ward. Clinicians also expressed their ability to deliver safe care was compromised when simultaneous responsibilities were placed upon them. This showed a clear clash between organisational demands (available beds vs. patient allocation, clinical team availability vs. service provision) and the ability of personnel to discharge their duties adequately. Furthermore, nurses appeared to be more acutely mindful of the environmental constraints of the ward such as space and cleanliness in comparison to managers and clinicians, a reflection of their constant presence on the ward, versus the nomadic nature of clinical and managerial duties. Unsurprisingly, patients also identified these environmental features.

In comparison, patients could identify issues that immediately affected them, such as potential medication errors (one patient reported that a nurse attempted to administer medication that was already given to them, which the patient flagged up independently) and having access to aid when they were at their most vulnerable. Patients desired comfort and reassurance- those were markers of safety for them.

Ultimately, all stakeholders saw the potential for the involvement of frontline personnel and patients in contributing to changes to the surgical ward, and a number of processes and structure-based quality markers were identified. Ultimately, the Delphi consensus study (Chapter 4) allowed for a systematic evaluation of the process and structural factors identified in Chapter 3 by not only a national, but international endeavour, to seek what the patient safety academic community, seasoned clinicians and nurses, and patients advocates thought were the priorities with regards to safety on the surgical ward. The global nature of this panel widened the applicability of the concepts sought from this exercise. This process did to an extent narrow down the areas of focus, but ultimately still demonstrated the complexity of this environment with almost unanimous agreement on many of the process-related concerns, structural and environmental factors raised in the interview study. There were 17 quality markers that achieved consensus (as detailed in Table 4.4) across these themes. These were carried forward into an observational study to assess how these factors behave at the ward level, and how they may affect patient outcomes.

Aim 2: To observe the surgical ward in real-time, assessing sources of variation and derive measurable metrics rooted in ward-level processes and structural factors.

This was the most challenging, labour intensive yet enjoyable part of this thesis. The priority in this study was to elucidate which of the factors identified and prioritised through the interview and Delphi studies were amenable to measurement. In addition to some traditional ethnographic methodology, there was an intention to quantify observations rather than just describe. This allowed for the demonstration of a most surprising finding - the sharp degree of variability in care delivery on the surgical ward. Even more surprising was the relatively low rates of omissions and delays in nursing care (2.9% of care items were missed) in response to the variability seen in process and structure. This most probably highlights the degree of cushioning of patient outcomes that occurs when the system compensates for these strains – i.e., a critical mass of variation at the deprivation end of the scale needs to occur before you see it affecting care in a measurable way.

However, wrong time medication showed a wide variation, from as low as 2% and peaking at errors affecting 70% of medication administration. The median proportion of medication error was 33%. The sensitivity of this, in comparison to complete omission of care, is likely to be rooted in the influence that pressures on the ward environment have on how nurses prioritise the care they administer. For example, it was noted that nurses had developed a practice of administering 8am intravenous medication, especially antimicrobials, by the night team as the last care item of their shift. This was to facilitate a smooth transition for the day staff, who can carry on with other duties of daytime care. Just under 40% of these were administered more than 60 minutes before the scheduled time.

By comparison, the rate of omission was higher for clinical teams, 12.1%. However, the causes of this are multifactorial and likely to be a reflection of the overall burden these teams were under rather than factors related to the nature of the ward environment alone. On every observed day, clinical teams were responsible for patients residing in multiple locations within the hospital, and the senior clinicians were negotiating commitments outside of the ward- whether they were providing emergency or elective services.

A more telling outcome measure of the pressures of the surgical ward was the nurse and patient-reported outcomes. These showed marked dissatisfaction overall with present conditions. Nurses were burdened at times by these conditions, and patients were also sensitive to it. Although there were well established high scoring domains, overall, the scores were low most days. Beyond the measurable elements, there were observations made that implied a system under pressure. Frequently, nurses were observed working beyond their scheduled hours to ensure documentations were complete. This was a task that they delayed in favour of providing direct care. In addition, nursing managers (band 7 or 8 on the ward) put aside their administrative duties to pick up clinical ones. Furthermore, on occasion, curtailment of break times was also observed. Frustrations with technology were also noted; in a system that was wholly reliant on online systems, this was an inertia to care delivery.

Nonetheless, the observational study revealed a number of measurable elements for ward based surgical care: direct measures of process measures (in what manner the ward round is conducted with respect to timing, clashes with other activities) and structural measures (staffing level, patient complexity, the number of occupied beds, turnover and presence of outliers) was possible. Furthermore, the granularity of these measures meant that the outcomes against which they were monitored need to be equally granular. Long-term outcomes, such as FTR and length of stay would still have an important role in giving an overall impression of care quality at a higher level but measuring the effect on day-to-day care is necessary. This would be met by, as demonstrated in this study, through measures of delayed care administration.

Finding a way to introduce these measures into practice would need some innovation, and thus the final study in this thesis aimed to fashion available data collection methods for this unit level enquiry and define associations for a statistical model.

Aim 3: To develop a statistical model of risk of harm using these real-time quality metrics through a proof-of-concept study using routinely collected administrative data.

Many of the factors identified in the observational study were readily quantifiable. Furthermore, they demonstrated a degree of variability. This may indicate that fluctuation in these factors can result in variation in care safety and quality observed. However, this would only be of value in the real world if there was a way to routinely measure these factors through existing systems.

Thus, it was theorised that many of the variables can be derived by mining EHR data and can be combined with electronic roster data detailing nursing levels- including absolute numbers, seniority and fulfilment type. Medication errors were retrievable; however, omitted care could not be measured. It was determined that delayed care can be measured by rates of patients becoming unwell i.e., the warning signs were not detected at the early stages. As a proof of concept, this study demonstrated many elements. Firstly, data pertaining to shift level characteristics of the ward across process and structure were readily retrievable through existing data sets, collected in real-time. Secondly, some association to outcome could be demonstrated. This means that building upon this premise, there is an opportunity develop a predictive model of patient care using the metrics isolated throughout the thesis. Work will be needed to refine this model, and eventually develop it into a usable dashboard of care quality and safety on the surgical ward.

8.6. Limitations

The specific limitations to each study are detailed in the respective discussions; here the methodological limitations contained within this thesis are discussed.

8.6.1. Performing a literature review

Selecting to perform a narrative, rather than a systematic, review can often leave authors open to criticism with regards to being selective (and biased) with the studies they choose to include and the lack of transparency with regards to search methods (499). However, the topic of this thesis pertains to markers of a safe surgical ward, which spans the gamut of process related and structural themes that contribute to how safety may be determined in that environment. This is a review that was necessary – to bring together the multiple themes that culminate in error in the surgical ward. This could not be captured through a systematic enquiry. For this purpose, the narrative review would be more appropriate, and indeed there have been calls for this approach to be recognised as a necessary adjunct to systematic reviews, with its ability to provide breadth in addition to depth (500). Additionally, to focus this chapter, a theoretical framework of clinical error helped organise these findings.

8.6.2. Employing Qualitative Methodologies

The use of qualitative research methodologies is now well established in health services research. It helps to mine the experiences of healthcare providers and patients, providing a richer portrayal of a service than can be assessed through administrative data alone. As the grassroots level experience was being explored in this thesis, this was the ideal initial methodology. Both the interview study (chapter 3), the observational study (Chapter 5) and the questionnaire study (chapter 6) represent this methodology. Some of the limitations are that given the open-ended nature of these studies, it can be difficult to verify whether the data pertains to all similar groups, e.g., all surgical wards. To minimise this effect, these studies were conducted in diverse setting- involving participants across different wards and hospitals. Additionally, sample size can be a key issue with these studies; however, the interview study recruited a relatively large number for this type of study (51 in total) and provided a diverse perspective on this topic.

The labour-intensive nature of this line of research is also evident, with several months taken for data collection alone. The hundreds of hours of observation conducted for chapters 5 and 6 revealed relatively few omissions of care; if this was the primary focus of a study – then a much longer period of observation, and more observers, would have been required.

Finally, qualitative work does not lend itself to defining associations. The intention was to identify key areas that may be more measurable that are novel and not derived in previous work to this level of granularity. Once this was achieved quantitively, further qualitative work was required.

Overall, I value the skills in qualitative research that I have developed over the course of this thesis. The deeply probing nature of these methods allowed me to tap into the realities of delivering care in a modern NHS surgical ward and allowed me to understand why human factors were poorly controlled for in this environment compared to the perioperative period.

8.6.3. Limitations of use of routinely collected data

The limitations pertaining to this are discussed extensively in chapter 7. Issues of data quality were central to this exercise. However, the other crucial limit is that not all of the derived quality markers from Chapters 5 could be derived through this method. e.g., there were no routinely collected items to reflect nursing presence on ward round, clashing of the rounds with other events, volume of outliers. Nonetheless, the associations seen demonstrate the feasibility of developing a model of ward safety based on locally modifiable factors.

8.7. Implications of this work

The research in this PhD thesis represents the first characterisation of the daily variation in processes and care structures in the surgical ward. This environment is often unpredictable, and unfortunately presents a challenging set of circumstances under which healthcare providers are expected to discharge their duties. The complexity of this environment is that the traditionally well-recognised factors, such as those relating to staffing for example, are not occurring in isolation. All the deficits seen with respect to how processes are conducted, how they are impacted by organisational shortcomings, and the subsequent impact on the well-being of staff and ultimately the safety of patients co-exist in a perpetually dynamic soup.

Therefore, quality metrics rooted in process and structure, directly relevant to safe care at the patient: healthcare worker interface are presented. These metrics encapsulate some of the areas of most concern for stakeholders and demonstrate some association with delays in care and potential for deterioration of patients. The implications for the direction of future policy are significant; essentially, the ward must be managed in its totality rather than focusing on one area only. The successes seen in perioperative care take this approach. Secondly, the concerns of local teams about the safety of their day-to-day activities must be heeded. This thesis goes some way to advocating for local teams to have more control and pushback with the organisational demands placed upon them.

8.8. Future Research

Post-operative care on the surgical ward remains in critical need of change. Even areas that have received intensive consideration over the last two decades- that of the level and quality nurse staffing levels- remains an intractable healthcare issue. The CQC report detailing their first inspections that occurred between 2014 and 2016, in the wake of the Francis report, describes an NHS with frontline staff who are demonstrating '*high levels of compassionate care in virtually every hospital*', with 95% of non-specialist acute trusts being rated as good or outstanding for 'Caring', one of the five key areas of the inspection template (501). However, 'Safe', another key area, has been rated as inadequate or requires improvement in 11% and 70% respectively, meaning 81% of acute non-specialist trusts are not rated as completely safe. The recent CQC adult inpatient survey, covering responses from 2019, demonstrates there are still issues: 42% of patients raised concerned about the level of nurses staffing to meet their care (of which 12% felt there were rarely or never enough) and 41% reported that it was not always possible to get help in a reasonable amount of time (8% reported they were not able to get help) (502).

The findings of this thesis are relevant to our times, and the changes proposed – to consider the totality of the care environment through metrics derived from many key areas of the surgical inpatient unit- are a necessary step to move forward with patient safety at the ward level. Such granular metrics may also allow teams to feel empowered enough to effect local change by recognising what are the pertinent issues in their local setting. Ultimately, it also provides local teams with a common language that can be used to exchange with managerial, organisational and executive level teams to highlight the deficiencies in the unit, by these higher levels with a definable metrics that helps them understands why things are going wrong. This would be a valuable asset alongside the hospital level metrics that most are accustomed to using alone.

The research in this body of work has been purposefully focused on local issues affecting patients and local teams and ascertaining what can be achieved through existing resources. There has been a gradual decline in NHS funding in the face of increasing demand. A peak of 66% of NHS trusts and foundation trusts were in a budget deficit in 2015-2016, although this is steadily improving following the five-year funding plan outlined by the Government for the NHS and now stands at 27% (503). The impact of these financial constraints on the organisation of services has been measured at the national level, e.g., restriction of access to certain services or longer waiting times etc, but it is likely that it also felt at the local level, restricting the changes that can be made at the ground level.

The direction for future work will be to seek ways that the metrics identified in this study can be measured most effectively and least intrusively. Some of these are readily available or can be derived via routinely collected data, but other areas of the ward-based care, such as the timing of processes and how they are configured need to be assessed. A way of incorporating an environmental evaluation is also needed.

Furthermore, ultimately, the granularity of this data, and the real-time nature of this recording, makes this amenable to a real-time dashboard presenting predictive analytical data to local teams. Once effective methods of measurement of these metrics are established, a further iteration of the predictive model will be needed incorporating more elements from the observational study. Thereafter, once data extraction of variables and model suitability is determined, the next step would be a "bolt-on" to existing technology- a programme that can pull that data automatically and feed it into the algorithm, presenting a statistical model of harm in real time.

In addition, future work will also need to consider how patient and nurse-reported feedback is being used. The current design of snapshots of care at specific intervals gives us ideas on what the priorities for these groups are, but it does not marry this up to present ward conditions necessarily. It is acknowledged that the free text data provided in the FFT is rich and varied but it is not practical. A set of targeted and validated questions collected in real time alongside the routine collection of ward variables can offer more information about the experience of these groups. Further work is needed to ascertain how they relate to outcome and which questionnaire are best – indeed new ones may need to be devised specific to the surgical ward environment. These will need to be acceptable for daily use, both in length and available resources.

8.9. Personal Reflection

This thesis has been a challenging but ultimately rewarding experience. At the outset I wondered whether this question, “what makes a surgical ward safe?” was a fundamental question that had been answered many times before. However, much to my surprise, I realised that the issue of patient care in this environment had been dealt with extensively but compartmentalised by a structure or processes in question. Multiple pathways, policies and educational programmes have been introduced over the years to improve care, but successful integration of improvement measures has been rare. We may have VTE proformas for every patient, early warning scores to tell us when to ask for help and safe staffing levels outlined- but errors are still rife.

It became obvious that in order to absolve the post-operative care period of any error, the whole nature of this environment needed to be responded to and modulating one area but not dealing with another can only lead to limited results. However, as I progressed through the early chapters and arrived at the most intensive part as a researcher, the observational study, I quickly understood why few have tried to integrate these areas into a unified concept. Indeed, I was anxious about how I would bring everything together. Essentially, I wanted my work to be relevant to practice and easily translatable, and thus I focused on the ward-level variables and teased out those that are measurable.

The experiences of those who participated in this study has left an indelible mark on me. As a higher surgical trainee, I was very familiar with many of the concerns that clinicians- and to an extent, managers- raised. The patient view was also extremely valuable. However, I was struck by the experiences of my nursing colleagues.

Like many clinicians, I have had occasions where I wondered why my patient had not received the treatment I advised in a timely fashion or why was the drain not removed as per the plan yesterday? Why was a nurse not present on the ward round, again? This is the first time in my career that I have spent time on a surgical ward, in the presence of surgical nurses, for prolonged, unbroken periods and observed how they work. Surgical nurses are resourceful, know how to manage their time and are attentive to the needs of their patients- despite the daily challenges of understaffing, high occupancy, erratic clinical interactions, cumbersome environment and complex patients. Furthermore, it has made me reflect on my practice as a clinician, where my priorities may not necessarily completely align with those of the nursing team, and their ability to effectively carry out their duties.

Lastly, nurses and patients can clearly identify what needs are not being met on their ward – yet their views and comments are not effectively absorbed into quality improvement exercises. I developed the inevitable familiarity with nurses in the observational study. Many times, these encounters culminated in informal chats in the ward break room and this therapeutic venting sessions painted a picture of motivated individuals working under enormously challenging circumstances. Feelings of exhaustion and frustration were expressed. Explanations of where issues are were given to organisational levels – but from beyond the ward, there was a struggle to understand and thus resolve these issues.

With this research, I hope that I have put down the building blocks for ward-based metrics. In healthcare, we like to measure and quantify everything. Empowering local teams with a number that they can wield and focus themselves and others upon may help in the journey of improving safety on the surgical ward in a meaningful and timely fashion.

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10. Appendix

10.1. Appendix A: Author Permission from *Surgery*


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SURGERY

Identifying quality markers of a safe surgical ward: An interview study of patients, clinical staff, and administrators

Author: Yasmin Hassen,Pritam Singh,Philip H. Pucher,Maximilian J. Johnston,Ara Darzi

Publication: Surgery

Publisher: Elsevier

Date: June 2018

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BACK | CLOSE WINDOW

10.2. Appendix B: Chapter 3 - Interview Protocol

1. Demographics and Introduction	*"We are conducting research into factors that make a safe ward. We want to explore the area broadly. We hope that your experience will help identify novel areas that can help us target future improvements"* In this interview we aim to: 1. Define what factors contribute to a safe ward 2. Identify how we can measure or classify the factors that make a ward safe 3. See how we could improve ward safety in the future using these measurements I would like to confirm your role: Patient or Staff Member If Staff Member- • Title & training level • Length of experience – on this ward/ in this trust/ overall in career *"I would like to confirm that this interview is being recorded with your consent"*
2. Identify the problem	*"To begin with I would like to ask about your experience on surgical wards – do you think there are differences between wards in terms of safety?"* *"What is it that made that ward safer/or less safe?"*
3. Define processes	"*What activities do you see on a ward that you think may be prone to errors?"* Prompts for tasks: • Ward rounds/ medical reviews/ outliers • Prescribing and administration of drugs • Patient transfer • Personal assistance of patients • Documentation and handover
4. Define structural/ organisational factors	*"How is care organized in your trust – do you think this affects safety of ward-based care?"* *"How are your duties organized in your trust – do you think this affects the safety of ward based care?"* Prompts: • Staffing levels for both doctors and nurses • Shift work for both doctors and nurses • Out of hours care (nights and weekend)

5. Define environmental factors	*"In your opinion – does the ward environment affect how safe a ward is?"* *"Have you been on wards where the layout has made it safer – could you describe wards that you have been on that you thought were safe?"* Prompts: • Visibility of patient • Places for nurses/ doctors to document • Places for nurses to draw up and check meds • Lighting • Noise/ disturbance *"What do you think about facilities for patients?"* *"What facilities do you think should be available for staff to make the ward a safer place?"* Prompts for facilities: • Where equipment is kept and availability • Space to prepare medication • Space to document in notes • Transfer between departments
6. Identify Quality markers	*Taking all the factors that we explored into consideration – what elements do you look for on a ward to tell you whether it is safe or not?"* *"Which of these factors in your opinion have the greatest effect on overall outcome?"* *"Do you think some are easier to address than others?"* Prompts: • Seniority/ experience level of staff • Medical team factors • Environmental factors
7. How to improve practice	*"I would like to move on to how we could improve safety based on the factors identified- how do you think we can attempt to make all wards safe?* Draw on previous answers: *"So for the quality markers you mentioned, can you think of ways to improve these?"* *"Can you suggest who would need to be involved in making this change"* *Prompts:* *Which members of staff? Patient involvement?*
8. Final Points	"*Thank you for your time. Before we conclude the interview- is there anything else you would like to add?"*

10.3.Appendix C: Chapter 4- Author Permission from *Annals of Surgery*

Wolters Kluwer

Key Components of the Safe Surgical Ward: International Delphi Consensus Study to Identify Factors for Quality Assessment and Service Improvement

Author: Yasmin A. Hassen, Maximilian Johnston, Pritam Singh, et al

Publication: Annals of Surgery

Publisher: Wolters Kluwer Health, Inc.

Date: Jun 1, 2019

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BACK CLOSE WINDOW

10.4. Appendix D: Chapter 4- Delphi Questionnaires sent to Participants

Questionnaire: Round 1

Thank you for participating in this Delphi Questionnaire - we appreciate your input into this study.

Please complete all questions. This process should take no longer than 10 minutes.

If you have any further opinions to add regarding any of the questions - please enter these items in the free text box provided at the end of each section.

Many thanks,

Yasmin Hassen

Clinical Research Fellow
Department of Surgery & Cancer
Imperial College London

y.hassen@imperial.ac.uk

Please enter your name:

Please enter your email address:

Please enter a brief summary of your experience in patient safety:

IDENTIFYING THE PROBLEM

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Some wards are safer than others with regards to errors and preventable adverse events:

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
○	○	○	○	○

Block 1

DEFINE PROCESSES THAT ARE PRONE TO ERROR

The following processes are prone to error (error defined as a preventable adverse effect of care regardless of whether harm has occurred to the patient):

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Ward rounds not led by consultant/ attending surgeon	○	○	○	○	○
Lack of nursing team presence on clinical ward rounds (for communication of management plans)	○	○	○	○	○
Presence of outlier patients on the ward (i.e. patient placed on a ward not associated with their specialty care team)	○	○	○	○	○
Prescription and administration of medication	○	○	○	○	○
Patient mobilisation	○	○	○	○	○
Documentation - doctors (e.g. accuracy/ legibility)	○	○	○	○	○
Documentation - nurses (e.g. observations/ drain & urine outputs etc)	○	○	○	○	○
Handover/ hand-off of patient care between medical teams	○	○	○	○	○
Handover/ hand-off of patient care between nursing teams	○	○	○	○	○
Communication between clinical and nursing/ allied healthcare staff	○	○	○	○	○

Are there any other processes that are prone to error (not mentioned above) that need to considered?

Block 3

DEFINE ORGANISATIONAL FACTORS THAT AFFECT SAFETY OF WARD-BASED CARE

The following organisational factors have a negative impact on patient safety in ward-based care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Inadequate nurse staffing levels	○	○	○	○	○
The use of temporary/agency staff	○	○	○	○	○
Out-of-hours reduction in services and increased waiting times (e.g. portering, radiology, laboratory)	○	○	○	○	○
Multi-site duties for doctors (e.g. clinic at one hospital but inpatient population in another)	○	○	○	○	○
Multi-site services requiring patient transfer (i.e. for investigation/ treatment)	○	○	○	○	○

Block 4

The following organisational factors have a positive impact on patient safety in ward-based care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Good nursing morale and working relationships	○	○	○	○	○
Adequate skill-mix of nurses (i.e. presence of experienced staff among team)	○	○	○	○	○
Good managerial leadership	○	○	○	○	○
Good access to doctors during out-of-hours care (nights/ weekends)	○	○	○	○	○

Please add any factors not mentioned above that you would like considered further:

Block 5

DEFINE HOW THE ORGANISATION OF DUTIES CAN IMPACT WARD SAFETY

The following characteristics of how duties are organised within a healthcare system can compromise patient safety in ward-based surgical care

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Inadequate rest for nurses within/ between shifts	○	○	○	○	○
Altered junior doctor hours (i.e. effect on continuity of patient care)	○	○	○	○	○
Junior doctors cross-covering multiple surgical specialties out-of- hours	○	○	○	○	○

Please add any information pertaining to the this question not mentioned above that you would like considered further:

Block 7

DEFINE ENVIRONMENTAL FACTORS THAT CAN INFLUENCE SURGICAL WARD SAFETY

The following environmental factors can influence patient safety in ward-based surgical care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Elevated noise level	○	○	○	○	○
Cluttered corridors (e.g. with equipment)	○	○	○	○	○
Ward cleanliness	○	○	○	○	○
Ward organisation (location of stock room and equipment, bay/bed space etc)	○	○	○	○	○
Adequate ventilation	○	○	○	○	○
Access to appropriate clinical equipment	○	○	○	○	○
Location of ward in relation to the rest of the hospital e.g. intensive care, operating rooms	○	○	○	○	○
The general atmosphere of a					

ward (busy/ stressful vs. calm)	○	○	○	○	○

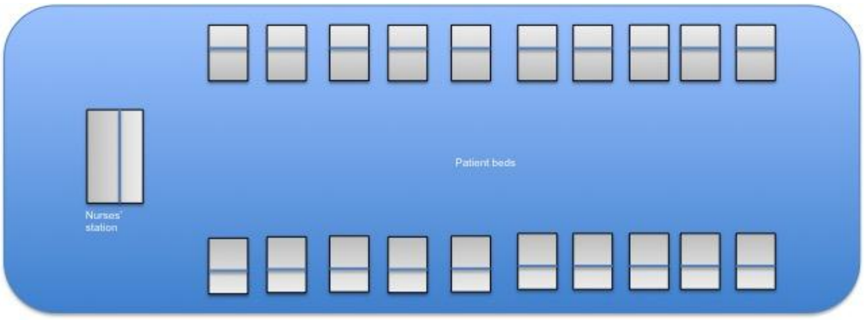
Please add any information you would like considered under this section:

Block 7

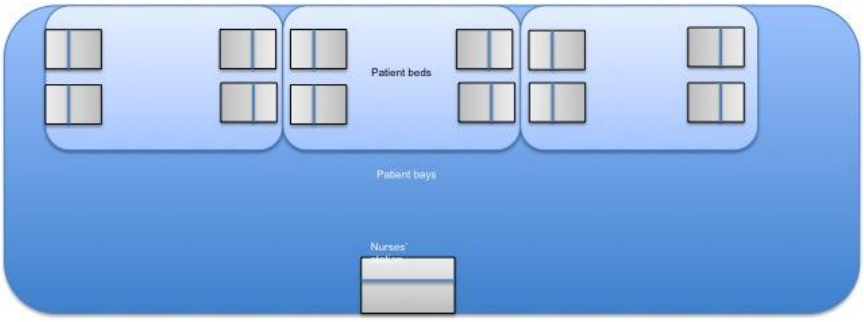
DEFINE THE EFFECT OF LAYOUT ON SURGICAL WARD SAFETY

The layout most conducive to patient safety is:

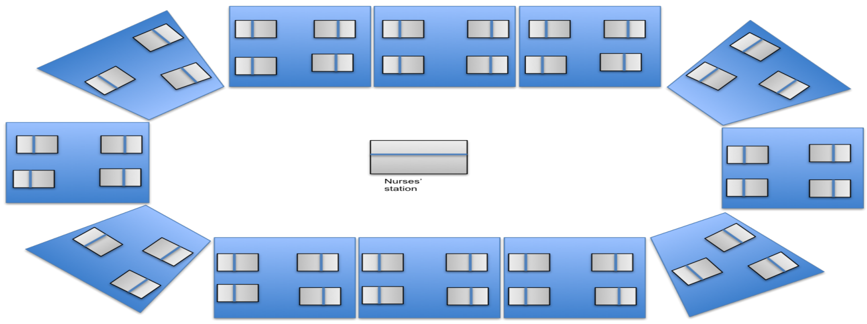
○ Nightingale ward - defined as a single bay ward with beds arranged in one communal space.



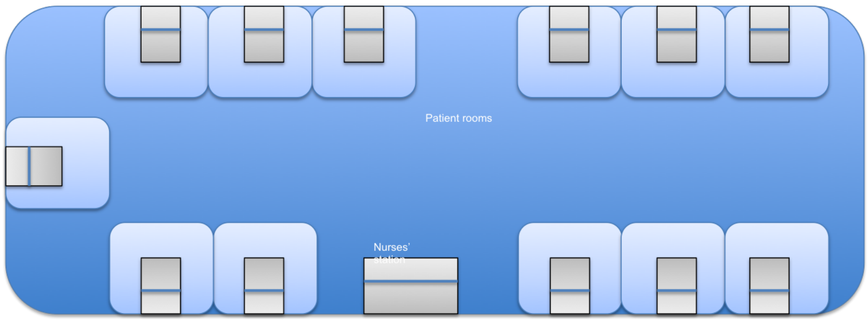
○ Bay based wards- defined as individual bays which can hold 4-6 beds.



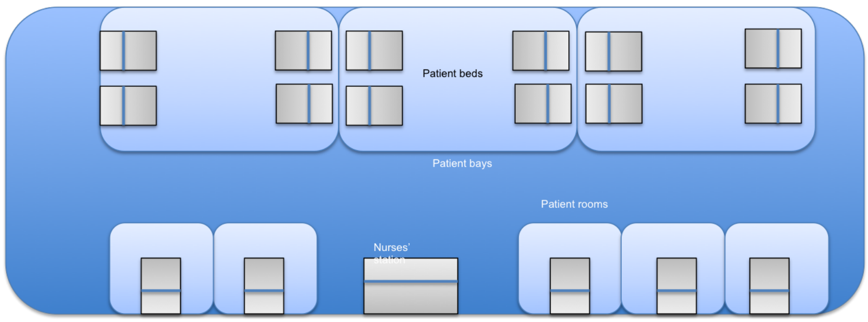
○ Racetrack- beds/ bays arranged around periphery of ward with nurses' station and other facilities located centrally:



◯ A ward of side rooms- where each patient is isolated in their own room



◯ A mixture of bays and side rooms



Concerning ward layout, the following factors can influence patient safety in ward-based surgical care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Good visibility between patients	◯	◯	◯	◯	◯

The following facilities for staff maintain patient safety:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Adequate rest space located on the ward	○	○	○	○	○
Adequate computer facilities located on the ward	○	○	○	○	○
Adequate access to clinical supplies and equipment	○	○	○	○	○

Please add any factors you would like considered under this section not mentioned above:

Block 10

DEFINING QUALITY MARKERS OF SURGICAL WARD SAFETY

The following are quality makers of a safe surgical ward:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Good leadership-nursing/managerial	○	○	○	○	○
Staff morale/ motivation/ engagement	○	○	○	○	○
Staff who are attentive	○	○	○	○	○
Nurse staffing levels	○	○	○	○	○
Nursing skill-mix	○	○	○	○	○
Nursing experience level	○	○	○	○	○
Medical team staffing levels	○	○	○	○	○
Nurse station position and visibility of patients	○	○	○	○	○
Cleanliness of the ward	○	○	○	○	○
Clutter-free, well-organised wards	○	○	○	○	○
Spacious wards	○	○	○	○	○
Appropriate equipment in good condition	○	○	○	○	○
Well-stocked and organised wards	○	○	○	○	○
Adequate computer access	○	○	○	○	○

Access to equipment when required (including out of hours)	○	○	○	○	○

Which quality marker has the greatest effect on safety:

Please add any quality markers that you would like to be considered:

Block 11

HOW TO IMPROVE PRACTICE

Safety can be improved by:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Higher nurse staffing levels (including out-of-hours)	○	○	○	○	○
Standardising processes	○	○	○	○	○
Promoting adherence to policy and procedure	○	○	○	○	○
Having nurses accompany ward rounds	○	○	○	○	○
Investing in staff training e.g. regular opportunities to improve knowledge/ skills	○	○	○	○	○
Designate someone to assess environment/ supplies daily	○	○	○	○	○
Digital notes/ other technology to enhance communication	○	○	○	○	○
Electronic prescriptions	○	○	○	○	○
Single specialty wards	○	○	○	○	○

Please add any other suggestions for how surgical ward safety may be improved:

The following should be involved in making changes:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Doctors (Juniors/ Residents)	◯	◯	◯	◯	◯
Doctors (Consultants/ Attending)	◯	◯	◯	◯	◯
Nurses	◯	◯	◯	◯	◯
Hospital Managers	◯	◯	◯	◯	◯
Hospital Board	◯	◯	◯	◯	◯
Patients	◯	◯	◯	◯	◯
Allied healthcare professionals	◯	◯	◯	◯	◯
Non-clinical staff	◯	◯	◯	◯	◯

Please add any information you would like considered under this section:

END OF QUESTIONNAIRE

Thank you for your time.

Questionnaire: Round 2

Block 2

Thank you for participating in the second round of this Delphi Questionnaire - we appreciate your input into this study.

Results from the first round are presented alongside each statement.We have considered the expert feedback from the previous round and have added items to this second round questionnaire in response.

Please complete all questions.

This survey should take no longer than 10 minutes.

Many thanks,

Yasmin Hassen

Clinical Research Fellow
Department of Surgery & Cancer
Imperial College London

y.hassen@imperial.ac.uk

Please enter your name:

Please enter your email address:

Please enter a brief summary of your experience in patient safety (if not completed in round 1)

IDENTIFYING THE PROBLEM

Some wards are safer than others with regards to errors and preventable adverse events **(mean 4.48 +/- 0.59)**:

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
○	○	○	○	○

Block 1

DEFINE PROCESSES THAT ARE PRONE TO ERROR

The following processes are prone to error (error defined as a preventable adverse effect of care regardless of whether harm has occurred to the patient):

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Presence of outlier patients on the ward (i.e. patient placed on a ward not associated with their specialty care team) **4.65 +/- 0.57**	○	○	○	○	○
Prescription and administration of medication **4.43 +/- 0.51**	○	○	○	○	○
Lack of nursing team presence on clinical ward rounds (for communication of management plans) **4.39 +/- 0.58**	○	○	○	○	○
Handover/ hand-off of patient care between medical teams **4.35 +/- 0.57**	○	○	○	○	○
Documentation - nurses (e.g. observations/ drain & urine outputs etc) **4.17 +/- 0.58**	○	○	○	○	○
Documentation - doctors (e.g. accuracy/ legibility) **4.13 +/ -0.46**	○	○	○	○	○
Handover/ hand-off of patient care between nursing teams **4.09 +/- 0.60**	○	○	○	○	○
Communication between clinical and nursing/ allied healthcare staff **4.09 +/- 0.67**	○	○	○	○	○
Ward rounds not led by consultant/ attending surgeon **3.87 +/- 0.69**	○	○	○	○	○
Patient mobilisation **3.52 +/- 0.73**	○	○	○	○	○
Response to deteriorating patient (new item)	○	○	○	○	○

Communication between staff and patients (new item)	◯	◯	◯	◯	◯
Infection Control (new item)	◯	◯	◯	◯	◯

Are there any other processes that are prone to error (not mentioned above) that need to considered?

Block 3

DEFINE ORGANISATIONAL FACTORS THAT AFFECT SAFETY OF WARD-BASED CARE

The following organisational factors have a negative impact on patient safety in ward-based care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Inadequate nurse staffing levels **4.61 +/- 0.50**	◯	◯	◯	◯	◯
The use of temporary/agency staff **4.13 +/- 0.69**	◯	◯	◯	◯	◯
Out-of-hours reduction in services and increased waiting times (e.g. portering, radiology, laboratory) **4.09 +/- 0.60**	◯	◯	◯	◯	◯
Multi-site services requiring patient transfer (i.e. for investigation/ treatment) **3.78 +/- 0.60**	◯	◯	◯	◯	◯
Multi-site duties for doctors (e.g. clinic at one hospital but inpatient population in another) **3.52 +/- 0.85**	◯	◯	◯	◯	◯
Lack of senior nurses out-of-hours (new item)	◯	◯	◯	◯	◯
Frequent change in ward doctors (new item)	◯	◯	◯	◯	◯

Block 4

The following organisational factors have a positive impact on patient safety in ward-based care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Good managerial leadership					

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
4.57 +/- 0.59	○	○	○	○	○
Adequate skill-mix of nurses (i.e. presence of experienced staff among team) **4.52 +/- 0.73**	○	○	○	○	○
Good access to doctors during out-of-hours care (nights/ weekends) **4.48 +/- 0.51**	○	○	○	○	○
Good nursing morale and working relationships **4.39 +/- 0.66**	○	○	○	○	○
Positive safety culture (new item)	○	○	○	○	○

Please add any factors not mentioned above that you would like considered further:

Block 5

DEFINE HOW THE ORGANISATION OF DUTIES CAN IMPACT WARD SAFETY

The following characteristics of how duties are organised within a healthcare system can compromise patient safety in ward-based surgical care

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Junior doctors cross-covering multiple surgical specialties out-of-hours **4.09 +/- 0.73**	○	○	○	○	○
Altered junior doctor hours (i.e. effect on continuity of patient care) **3.91 +/- 0.60**	○	○	○	○	○
Inadequate rest for nurses within/ between shifts **3.87 +/- 0.69**	○	○	○	○	○
Doctors working long shifts e.g. >12 hrs (new item)	○	○	○	○	○

Please add any information pertaining to the this question not mentioned above that you would like considered further:

Block 7

DEFINE ENVIRONMENTAL FACTORS THAT CAN INFLUENCE SURGICAL WARD SAFETY

The following environmental factors can influence patient safety in ward-based surgical care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Access to appropriate clinical equipment **4.35 +/- 0.57**	○	○	○	○	○
Ward cleanliness **4.22 +/- 0.80**	○	○	○	○	○
The general atmosphere of a ward (busy/ stressful vs. calm) **4.04 +/- 0.71**	○	○	○	○	○
Ward organisation (location of stock room and equipment, bay/bed space etc) **3.91 +/- 0.73**	○	○	○	○	○
Elevated noise level **3.78 +/- 0.67**	○	○	○	○	○
Cluttered corridors (e.g. with equipment) **3.74 +/- 0.69**	○	○	○	○	○
Adequate ventilation **3.70 +/- 0.63**	○	○	○	○	○
Location of ward in relation to the rest of the hospital e.g. intensive care, operating rooms **3.65 +/- 0.71**	○	○	○	○	○
Distance between beds (new item)	○	○	○	○	○

Please add any information you would like considered under this section:

Block 7

DEFINE THE EFFECT OF LAYOUT ON SURGICAL WARD SAFETY

The layout most conducive to patient safety is (please rank):

A mixture of bays and side rooms **(39%)**

Racetrack- beds/ bays arranged around periphery of ward with nurses' station and other facilities located centrally **(35%)**

A ward of side rooms- where each patient is isolated in their own room **(22%)**
Nightingale ward - defined as a single bay ward with beds arranged in one communal space **(4%)**
Bay based wards- defined as individual bays which can hold 4-6 beds **(0%)**

Concerning ward layout, the following factors can influence patient safety in ward-based surgical care:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Adequate storage space for supplies **4.26 +/- 0.45**	○	○	○	○	○
Good visibility between patients and nurses **4.22 +/- 0.42**	○	○	○	○	○
Adequate space for medication preparation **4.04 +/- 0.47**	○	○	○	○	○
Space around patient bed to facilitate clinical needs **3.87 +/- 0.46**	○	○	○	○	○
Personal space for patients around the bed **3.87+/-0.55**	○	○	○	○	○

Please add any factors you would like considered under this section not mentioned above:

Block 8

DEFINE FACILITIES FOR PATIENTS TO MAINTAIN SURGICAL WARD SAFETY

The following facilities maintain patient safety:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Bathrooms with access for those with disability i.e. needing frame/ extra support etc. **4.22 +/- 0.52**	○	○	○	○	○
Adequate number of bathrooms **4.04 +/- 0.47**	○	○	○	○	○
The presence of a patient day room where patients can relax/ interact with one another **3.22 +/- 0.67**	○	○	○	○	○

Please add any factors you would like considered under this section not mentioned above:

Block 9

DEFINE FACILITIES FOR STAFF TO MAINTAIN SURGICAL WARD SAFETY

The following facilities for staff maintain patient safety:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Adequate computer facilities located on the ward **4.43 +/- 0.66**	○	○	○	○	○
Adequate access to clinical supplies and equipment **4.43 +/- 0.66**	○	○	○	○	○
Adequate rest space located on the ward **3.57 +/- 0.84**	○	○	○	○	○

Please add any factors you would like considered under this section not mentioned above:

Block 10

DEFINING QUALITY MARKERS OF SURGICAL WARD SAFETY

The following are quality makers of a safe surgical ward:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Good leadership-nursing/managerial **4.7 +/- 0.47**	○	○	○	○	○
Staff morale/ motivation/ engagement **4.7 +/- 0.47**	○	○	○	○	○
Nurse station position and visibility of patients **4.65 +/-**	○	○	○	○	○

0.57					
Nurse staffing levels **4.57 +/- 0.51**	○	○	○	○	○
Adequate computer access **4.52 +/- 0.59**	○	○	○	○	○
Spacious wards **4.52 +/- 0.51**	○	○	○	○	○
Staff who are attentive **4.48 +/- 0.59**	○	○	○	○	○
Nursing skill-mix **4.48 +/- 0.67**	○	○	○	○	○
Cleanliness of the ward **4.43 +/- 0.51**	○	○	○	○	○
Well-stocked and organised wards **4.43 +/- 0.59**	○	○	○	○	○
Access to equipment when required (including out of hours) **4.39 +/- 0.66**	○	○	○	○	○
Appropriate equipment in good condition **4.26 +/- 0.62**	○	○	○	○	○
Nursing experience level **4.13 +/- 0.63**	○	○	○	○	○
Clutter-free, well-organised wards **4.13 +/- 0.63**	○	○	○	○	○
Medical team staffing levels **3.74 +/- 0.69**	○	○	○	○	○
Availability of rapid response team **(new item)**	○	○	○	○	○
Education level/ training of healthcare support workers **(new item)**	○	○	○	○	○

Which quality marker has the greatest effect on safety (please rank top 10- with the most important as 1):

- ☐ Good leadership- matron/manager **(35%)**
- ☐ Nurse staffing levels **(26%)**
- ☐ Staff morale/ motivation/ engagement **(22%)**
- ☐ Staff who are attentive **(13%)**
- ☐ Medical team staffing levels **(4%)**
- ☐ Nursing skill-mix
- ☐ Nursing experience level
- ☐ Nurse station position and visibility of patients
- ☐ Cleanliness of the ward
- ☐ Clutter-free, well-organised wards
- ☐ Spacious wards
- ☐ Appropriate equipment in good condition
- ☐ Well-stocked and organised wards

- [ ] Adequate computer access
- [ ] Access to equipment when required (including out of hours)
- [ ] Availability of rapid response team
- [ ] Education level/ training of healthcare support workers

Please add any quality markers that you would like to be considered:

Block 11

HOW TO IMPROVE PRACTICE

Safety can be improved by:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Investing in staff training e.g. regular opportunities to improve knowledge/ skills **4.30 +/- 0.63**	○	○	○	○	○
Having nurses accompany ward rounds **4.22 +/- 0.60**	○	○	○	○	○
Standardising processes **4.17 +/- 0.65**	○	○	○	○	○
Single specialty wards **4.09 +/- 0.85**	○	○	○	○	○
Higher nurse staffing levels (including out-of-hours) **4.22 +/- 0.80**	○	○	○	○	○
Promoting adherence to policy and procedure **4.00 +/- 0.85**	○	○	○	○	○
Digital notes/ other technology to enhance communication **3.91 +/- 0.73**	○	○	○	○	○
Electronic prescriptions **3.83 +/- 0.72**	○	○	○	○	○
Designate someone to assess environment/ supplies daily **3.70 +/- 0.56**	○	○	○	○	○
Rapid response team **(new item)**	○	○	○	○	○

Please add any other suggestions for how surgical ward safety may be improved:

The following should be involved in making changes:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Doctors (Consultants/ Attending) **4.43 +/- 0.51**	○	○	○	○	○
Nurses **4.43 +/- 0.51**	○	○	○	○	○
Patients **4.39 +/- 0.50**	○	○	○	○	○
Doctors (Juniors/ Residents) **4.30 +/- 0.63**	○	○	○	○	○
Hospital Managers **4.30 +/- 0.56**	○	○	○	○	○
Allied healthcare professionals **4.17 +/- 0.78**	○	○	○	○	○
Hospital Board **4.09 +/- 0.85**	○	○	○	○	○
Non-clinical staff **4.04 +/- 0.82**	○	○	○	○	○

Please add any information you would like considered under this section:

END OF QUESTIONNAIRE

Thank you for your time.

10.5. Appendix E: Chapter 4 -Delphi Study Statements that did not achieve consensus

Stem	Statement	Mean Score	Standard Deviation	Score 4-5 (%)
The following processes are prone to error:	Ward rounds not led by consultant	3.55	0.69	55
	Patient mobilisation	3.35	0.59	30
The following organisational factors have a ***negative*** impact on patient safety in ward-based care:	Multi-site services requiring patient transfer	3.90	0.64	75
	Multi-site duties for doctors	3.75	0.55	70
The following characteristics of how duties are organised can compromise patient safety in ward-based care	altered junior doctor hours (effect on continuity)	3.60	0.88	70
	Inadequate rest for nurse within/between shifts	3.85	0.59	75
The following environmental factors can influence patient safety in ward-based surgical care	Ward Organisation	3.90	0.72	70
	Elevated noise level	3.85	0.67	70
	Cluttered corridors	3.65	0.59	60
	Adequate ventilation	3.70	0.66	60
	Location of ward in relation rest of hospital	3.55	0.60	50
Concerning ward layout, the following factors can influence patient safety in ward-based surgical care:	Personal space for patients	3.85	0.59	75
The following facilities maintain patient safety:	Presence of patient day rooms	3.15	0.75	25
The following facilities for staff maintain patient safety:	Adequate rest space located on the ward	3.7	0.73	65
Safety can be improved by:	Electronic Prescriptions	3.95	0.83	75
	Designate someone to assess environment/ supplies	3.4	0.60	45

10.6. Appendix F: Chapter 6 – Safety Attitudes Questionnaire

Version 1
10/08/2016

Modified Safety Attitudes Questionnaire

Please complete the following items ***with respect to the clinical environment you have worked in today*** and with ***respect to the conditions today.***

Choose your responses as per the scale:

A	B	C	D	E	X
Disagree strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not applicable

	A	B	C	D	E	X
1. Nurse input was well received in this clinical area.						
2. It was difficult to speak up when I perceived a problem with patient care.						
3. Disagreements were resolved appropriately (not *who* is right, but *what* is best for patient).						
4. I had the support I needed from other personnel to care for patients.						
5. It was easy for personnel to ask questions if they didn't understand something.						
6. The doctors and nurses work together as a well-coordinated team.						
7. I would feel safe being treated here as a patient.						
8. Medical errors were handled appropriately in this area.						
9. I know the proper channels to direct questions regarding patient safety in this clinical area.						
10. I received appropriate feedback about my performance.						
11. It was difficult to discuss errors.						
12. I was encouraged by my colleagues to report any patient safety concerns I may have had.						
13. The culture in this clinical area makes it easy to learn from the errors of others.						
14. My suggestions about safety would be acted upon if I expressed this to management.						
15. I liked my job today.						
16. Working here is like being art of a large family.						
17. This is a good place to work.						
18. I am proud to work in this clinical area.						
19. Morale in this clinical area is high.						
20. Where my workload was excessive, my performance was impaired.						
21. I am less effective at work when fatigued.						
22. I am more likely to make errors in tense or hostile situations.						
23. Fatigue impairs my performance during emergency procedures.						
24. Management supports my daily efforts.						
25. Ward manager doesn't knowingly compromise patient safety.						
26. Ward Manager is doing a good job.						
27. The ward manager dealt with personnel problems constructively.						
28. I received adequate timely info about events that might affect my work.						
29. The levels of staffing in this area were sufficient to handle the number of patients.						
30. This hospital does a good job f training new personnel						
31. All the necessary information for diagnostic/ therapeutic decisions is routinely available						
32. Trainees were adequately supervised in this clinical area.						
33. I experienced good collaboration with nurses in this clinical area.						
34. I experienced good collaboration with doctors in this clinical area.						
35. I experienced good collaborations with pharmacists in this clinical area.						
36. Communication breakdowns lead to delays in the delivery of care						

Background Information							
Occupation (include banding/ grade)							
Experience in Surgery	< 6 mo.	6- 11 mo.	1-2 yrs	3-4 yrs	5-10 yrs	11-20 yrs	> 21 yrs

Thank you for your time.

10.7. Appendix G: Chapter 6 – PMOS questionnaire

Version 1
10/08/2016

<u>Modified Patient Measure of Safety (PMOS) Questionnaire</u>

Please complete the following items ***with respect to the conditions of the ward you are currently on and with respect to your care over the last 24 hours.***

Choose your responses as per the scale:

A	B	C	D	E	X
Disagree strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not applicable

	A	B	C	D	E	X
1. I was treated with dignity and respect						
2. After a shift change staff knew important information about my care.						
3. Staff caring for me were always able to get advice from other specialities/ areas when needed.						
4. A doctor changed my plan of care and other staff didn't know about it.						
5. I got answers to all the questions I had regarding my care.						
6. I knew what the different roles of the people caring for me were.						
7. On at least one occasion a member of staff was not able to use the necessary equipment.						
8. My treatment/ procedure/ operation did not happen on time						
9. When staff talked about my care with others, the information they shared was correct.						
10. The physical environment made it difficult for staff to do their jobs, e.g. lighting, temperature, position of nurses' desk						
11. I always had to wait too long after pressing my buzzer for a staff member to arrive						
12. It was clear who was in charge of staff						
13. There was not enough space on the ward						
14. There was always a member of staff available with the knowledge/ skills to perform specific tasks						
15. I noticed staff have different ways of doing the same thing, e.g. tasks, prescribing						
16. The ward was clean						
17. I **didn't** know who to go to if I needed to ask a question						
18. On at least one occasion, a member of staff was not able to carry out a task that they should have been able to do.						
19. The physical environment of the ward was comfortable for patients, e.g. lighting, noise, temperature and cleanliness.						
20. I felt that the attitude of staff towards me was good.						
21. I knew which person/ team was responsible for my treatment						
22. Staff seemed to know what they were doing.						
23. I felt that staff listened to what I had to say about my illness/ symptoms / treatment						
24. Too few staff meant that things didn't get done on time e.g. attending call bells, removing bodily fluids, toileting, feeding etc.						
25. Staff gave me different information about my treatment/ care						
26. Information about me that my healthcare team needs was always available						
27. Staff worked together as a team on this ward.						
28. There was equipment that staff/ patients found difficult to use e.g. call bells, beds, hoists, monitoring equipment						
29. My tests were always available when required e.g. scans, blood tests etc.						
30. Staff always knew everything they needed to know to care for me, e.g. allergies, medical history, medications, other conditions						
31. I was always given enough information						
32. Nurses were sometimes unable to get help from other staff when they asked for it						
33. Equipment needed for my care was always available.						

Version 1
10/08/2016

34. I have overheard private/ personal conversations about myself or other patients						
35. Inexperienced staff seemed to find it hard when they were left to do things on their own						
36. Equipment and supplies were not always available when needed e.g. hoists, bed pans, drugs						
37. Staff always agreed about my treatment or care						
38. I felt that staff listened to me about my concerns.						
39. Medication I was prescribed was not always available						
40. I felt that patient safety was a top priority.						

Thank you for taking the time to complete this questionnaire.

Items 8, 15, 16, 23, 30, 31, 34 not validated by original authors so omitted from final analysis – leaving 33 items

10.8. Appendix H: Ethics Approvals

Chapter 3: Interview Study

NRES Committees - North of Scotland
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558458
Facsimile: 01224 558609
Email: nosres@nhs.net

NHS Grampian

12 March 2015

Miss Yasmin Hassen
Department of Surgery & Cancer
St Mary's Campus (10th Floor QEQM Building)
Praed Street
LONDON
W2 1NY

Dear Miss Hassen

Study title:	**The factors that contribute to a safe ward**
REC reference:	**15/NS/0014**
IRAS project ID:	**173204**

Thank you for your letter of 9 March 2015, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the Lead Reviewer.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Carol Irvine, nosres@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Chapter 4: Delphi Study (sponsorship letter by Imperial)

Imperial College London

Imperial College Healthcare NHS
NHS Trust

Joint Research Compliance Office
Academic Health Science Centre
Imperial College London and
Imperial College Healthcare NHS Trust
Room 221, Medical School Building
St Mary`s Hospital
Pread Street
London W2 1NY
Tel: +44 (0)20 759 41862
r.nicholson@imperial.ac.uk
www.ic.ac.uk/clinicalresearchgovernanceoffice

Ruth Nicholson
Research Governance Manager

11/02/2016

Miss Yasmin Hassen
Imperial College London
St Mary's Campus
Praed Street
London
W2 1NY

Dear Miss Hassen

RE: An international Delphi consensus study to define key quality markers of care on the surgical ward.

Joint Research Compliance Office Reference number: 16IC3177

This is to confirm that the above named research project utilises human participants, their organs, tissue and/or data as defined under the sponsorship requirements of the Research Governance Framework for Health and Social Care 2005, incorporating the Medicines for Human Use (Clinical Trials) Regulations 2004.

On behalf of Imperial College of Science, Technology and Medicine, we undertake to act as the identified Research Sponsor for this project.

This letter confirms:

- The research proposal has been discussed, assessed and registered with the Joint Research Compliance Office, Imperial College Academic Health Science Centre, Imperial College London and provisional sponsor approval granted.
- The Chief Investigator has undergone a process of scientific critique commensurate with the scale of the project.
- Indemnity and insurance arrangements have been put in place to cover the project.
- Resources and support are available to the research team to aid delivery of the research as proposed.
- Management, monitoring and reporting responsibilities for the research have been approved.
- Imperial College will undertake and enforce those sponsor duties set out in the NHS Research Governance Framework for Health and Social Care.

Imperial College Sponsorship is conditional on the project receiving applicable ethical and regulatory approval for all research related aspects of its conduct. It is also conditional on successful contract and agreement negotiations and sign off via the Joint Research Office, where relevant, and before the study commences.

A copy of the ethics approval letter **must** be sent to the Research Governance Manager prior to the study commencing. Sponsorship is dependant on obtaining R&D Office approval for all NHS sites where the research is being conducted.

Imperial College London

Imperial College Healthcare NHS
NHS Trust

Yours sincerely

Ruth Nicholson
Research Governance Manager

Chapters 5 and 6: Observational Study

NHS
Health Research Authority

London - Bloomsbury Research Ethics Committee
HRA RES Centre Manchester
Barlow House 3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8002

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

12 December 2016

Miss Yasmin Hassen
Clinical Research Fellow
Imperial College London
Department of Surgery & Cancer
St Mary's Campus (10th Floor QEQM Building)
Praed Street
W2 1NY

Dear Miss Hassen

Study title:	**Observational study of Surgical Patients in the Post-operative environment: A study to identify key modifiable factors in patient safety on the surgical ward.**
REC reference:	**16/LO/1937**
IRAS project ID:	**213425**

Thank you for your letter of 29 November 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Assistant, Miss Ewa Grzegorska, nrescommittee.london-bloomsbury@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting

A Research Ethics Committee established by the Health Research Authority

Chapter 7: Amendment confirmation to collect administrative data

From: BLOOMSBURY, NRESCommittee.London- (HEALTH RESEARCH AUTHORITY)
Sent: 16 January 2018 10:33
To: 'y.hassen@imperial.ac.uk'
Cc: r.nicholson@imperial.ac.uk
Subject: Re: 16/LO/1937 (IRAS ID: 213425). Amendment confirmation of REC Validation, categorisation and implementation information

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Yasmin,

Thank you for submitting an amendment to your project. Please find attached a copy of the REC validation letter for the submitted amendment.

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.

What Happens Next?

When available, please forward any other regulatory approvals that are expected for this amendment to hra.amendments@nhs.net. However, you do not need to forward the REC favourable opinion as we will be able to access this through our systems.

Information Specific to Participating NHS Organisations in England

1. You should now share your notice of amendment and, if applicable, amended documents, together with this email, with all participating NHS organisations in England. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team. A template email to notify participating NHS organisations in England is provided on the HRA website.
2. The participating NHS organisations in England should prepare to implement this amendment.
3. Your amendment will be reviewed by the REC, as per the attached letter. In parallel to this, an assessment against HRA standards will take place.
4. Once the REC Favourable Opinion is issued, any other regulatory approvals are in place and the HRA assessment has been successfully completed, you will receive an email confirming that your amendment has HRA Approval.
5. You may implement your amendment at all participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this email and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner), so long as you have HRA Approval for your amendment by this date. **NHS organisations do not have to confirm they are happy with the amendment.** If HRA Approval is issued subsequent to this date, you may implement following HRA Approval.
6. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
7. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

RAS Project ID:	**213425**
Short Study Title:	**Observational Study: Safety factors on a surgical ward**
Date complete amendment submission received:	**09 January 2018**
Sponsor Amendment Reference Number:	**Substantial Amendment – Protocol V3**
Sponsor Amendment Date:	**09 January 2018**
Amendment Type	Substantial
Outcome of HRA Assessment	**HRA Approval for the amendment is pending.** The HRA will separately confirm HRA Approval for the amendment by email.
mplementation date in NHS organisations n England	35 days from date amendment information together with this email, is supplied to participating organisations **(provided HRA Approval for the amendment is in place and conditions above are met)**
For NHS/HSC R&D Office information	
Amendment Category	**A**

f you have any questions about the ethical review of this amendment, please do not hesitate to contact me.

f you have any questions relating to the wider HRA approval process, please direct these to ra.approval@nhs.net

f you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.