Contemporary Patient Safety and the Challenges for New Zealand

Peter James Beaver

A thesis submitted in fulfilment of the requirements of the degree of Doctor of Philosophy in Sociology, the University of Auckland, 2015.

Abstract

In this thesis I explore the challenges for staff working to reduce harm and implement safety improvement in New Zealand (NZ) hospitals. Their views are contextualised in four stages. First, medical harm is outlined as a persistent and expensive threat to public health. While new practices make decisive action possible, implementation remains problematic. Second, policy in America, England, and NZ is analysed through Light's (1995, 2010) theory of countervailing powers, and a shift from medical to managerial dominance. In NZ safety entered policy rhetoric around 2000, but it was compromised by resource shortages, a lack of evaluation, insufficient centralised support and coordination, and disengagement between managers and clinicians. While efforts intensified post-2008, resourcing remained problematic. Third, theories of organisational accidents (Reason 1990, 2000, 2001, 2004), normal accidents (Perrow 1984), sensemaking (Weick and Sutcliffe 2007), and the empirical literature about in-hospital risks, are reviewed. The review follows Vaughan's (1999) discussion of organisational failure as emergent from the complex interconnection of organisational environments, organisations, and cognition and action. Pressure, organisational systems, hierarchy, communication, and organisational culture are identified as key risks. Fourth, the safety improvement literature is reviewed, implementation challenges are identified, and safety is theorised as emergent from unique organisational solutions to universal challenges of structure, culture, politics, learning, motivation, and infrastructure (Bate, Mendel et al. 2008). Staff perspectives from NZ are provided by n=37 qualitative interviews with doctors, nurses, and managers in three departments in two hospitals. Interviews explored the challenges of risk control and safety improvement, and are theorised as naturalistic accounts of real experiences. The dominant generalised risk was short staffing, which drove pressure, and contributed to poor communication and breakdowns in teamwork. These and other factors meant that some clinical risks were poorly controlled. Some denial of generalised and clinical risks was also evident. Improvement activities showed a number of gains, but many processes were failing from insufficient time, a lack of expertise in using systemic data and sensing problems, staff disengagement, poor ownership of processes, and inadequate IT infrastructure. In conclusion, tensions between productivity and safety pressured clinical work and contributed to ongoing harm. These failures drive up costs and threaten the fiscal sustainability of healthcare in NZ.

To Bill and Eileen

Acknowledgements

This thesis was made possible with the support of two doctoral scholarships that were very generously provided by the University of Auckland and the Health Research Council of New Zealand. I was assisted by many people in the process of completion. Thanks are due first of all to my supervisors Associate Professor Steve Matthewman and Doctor Manuel Vallee. Reading and commenting on all of those drafts must have been quite an experience! Thanks for the time, the suggestions, the insights, and the support. Thanks most of all for the encouragement. Thanks also to those who supervised the early stages of this work, Professor Peter Davis, and Professor Maureen Baker. Thanks to my examiners, Professor Charles Bosk, Professor Kevin Dew, and Doctor Robert Webb. Thanks to current and past Sociology staff and students at the University of Auckland, for enriching sociology, and for the unconditional support. Thanks to the scholars from many disciplines with many interests who provided the ideas and the inspiration that drove this research. Thanks to the hospital staff who helped locate participants, and gave their time to share their experiences of working at the sharp end of hospital care. I hope that this thesis reflects your views truthfully. Thanks to my family and friends, and to Merita for her love and her faith, and for supporting me through this process, which sometimes seemed overwhelming.

Contents

List of tables

Chapter 1

Introduction

This is a thesis about the risks of medical harm to patients in New Zealand (NZ) hospitals and the challenges of improving their safety. It addresses a problem with a history as long as the practice of medicine. For most of that history this problem has largely been either unknown, or ignored. Safety has only recently become a widespread concern amongst clinicians, managers, researchers, and policy writers. One and half decades before now the extent of harm from healthcare was only well known by a relatively small group of clinicians and researchers in the field of healthcare. Today, hospitals are expected to publicly announce their commitment to patient safety. Safety can be a professional calling, an academic discipline, a passion, a worry, and a cliché. For those in hospital, safety may or may not be a physical reality. Occasionally safety also becomes a topic of public anxiety, but mostly, I think, people have great faith in hospitals.

Adverse events during hospitalisation affect patients in advanced healthcare systems throughout the world. The status and the technological sophistication of the hospital is no protection (Kenny 2008). A systematic review covering more than 74,000 medical records from the USA, UK, Canada, Australia, and NZ found that 9.2% of patients were harmed, and 7.4% of events were lethal (de Vries, Ramrattan et al. 2008). In NZ the cost of medical harm has been estimated to be as much as 30% of the hospital budget, with preventable harm (due to errors that could have been avoided) accounting for 20% of the total budget (Brown, McArthur et al. 2002). This problem has been very resilient to dedicated efforts over the last decade and a half.

Progress has been “frustratingly slow” (Leape, Berwick et al. 2009). Patient safety is a complex “wicked problem” without easy solutions (Braithwaite, Runciman et al. 2009).

Contemporary patient safety research offers a diversity of approaches and areas of focus. The literatures that I have found particularly interesting are those concerned with the relationships between people and systems inside hospitals, and the analysis of policies which determine the strategic directions of healthcare. I have also been drawn to wondering about risk and safety in hospitals in NZ. There is some research about the NZ context, but so far there is very little information from inside NZ hospitals about how safety is affected by distinct organisational changes, and what may be more or less unique social processes of risk control and safety improvement. There is also very little analysis of policy in NZ and its effects on safety. There is room for a thesis that explores the challenges for staff in NZ hospitals as they try to control risk and improve safety. This aspect of this topic has not been researched previously in NZ. It matters because while patient safety is a technical endeavour, it is also a necessarily social activity (Bate, Mendel et al. 2008). Moreover, patient safety is also “a site of organisational and professional politics” (Dixon-Woods 2010: 11). But while these social and political challenges are universal to this field of action, the dynamics of failure, and effective safety improvement, are to some extent unique in different contexts (Bate, Mendel et al. 2008). This makes the NZ case interesting. It is both relatively unexplored, and potentially unique.

The analysis in this thesis draws upon a number of theoretical perspectives and frameworks to select, organise, and understand the information provided. A theme throughout is the notorious organisational complexities that are inherent in the provision of modern healthcare. But while insights into the dynamics of organisational systems may, if acted on appropriately, enhance safety, simplistic understandings can equally drive diminished outcomes (Zuiderent-Jerak and Berg 2010). Complexity theory, and the view that healthcare organisations are complex adaptive systems, provides one perspective on this challenge of the unexpected. According to this view, hospitals are systems made from collections of individual agents, whose actions are interconnected, and affected by processes of change that emerge from both within and outside the organisation. Because new actions change the system, and set additional and possibly unexpected processes in motion, outcomes are often not easily controllable or predictable in advance (Plsek and Greenhalgh 2001). Theories of organisational accidents

(Reason 1990, 2000, 2001, 2004), normal accidents (Perrow 1984), and sensemaking (Weick and Sutcliffe 2007) reflect similar concerns with complexity and unpredictability. They also emphasise the necessity of working to secure safety through good design and a ceaseless state of mindfulness about what could go wrong. At a whole-of-system level, comprehending the complex dynamics of the dark side of healthcare, and its capacity to routinely generate harm, makes it necessary to comprehensively investigate organisational environments, organisations, and individual cognition and action (Vaughan 1999). This makes it possible to understand outcomes, both good and bad, as emergent from processes that are generated by the interconnections between factors arising from each of these components of the system of healthcare. A fully contextualised understanding of organisations shows that both risk and safety emerge through the ordered chaos of human actions in a context of unique localised cultures, differing organisational imperatives, and external forces (Bate, Mendel et al. 2008). Understanding these processes in depth brings the possibility of effective change.

An appreciation of the complexity of patient safety, the need for contextual understanding, and the possibility of generating a number of comparative perspectives for reflecting upon the NZ case, means that the investigation in this thesis draws upon four general categories of information. First, an overview of the international patient safety movement provides context about the extent of medical harm and the strategies for reducing it. Second, a comparative analysis of the policy environment in American, English, and NZ healthcare identifies the challenges and the consequences of policy in each of these contexts. Third, the literatures about risk and safety improvement are investigated to provide an understanding of how healthcare organisations generate risk, and how staff may work to improve safety. This analysis provides an interpretive context for the fourth information source, which a qualitative analysis of the perspectives of clinical staff in NZ hospitals about the challenges of controlling risks and improving safety. Their views and experiences are central to this thesis. While their comments need to be interpreted and contextualised, the perspective that I develop here about patient safety in NZ public hospitals is very strongly driven by what they have said. The moment of truth for patient safety as a social and an organisational process is revealed by the challenges of clinical work at the ‘sharp end’ of hospital care.

Harm, preventability, errors, and systems

At the centre of this thesis is a concern with medical harm, sometimes called adverse events or iatrogenesis. Medical harm is caused by medical management rather than the underlying disease process. While medical harm is not confined to hospitals, in this investigation the focus is just on that context. Importantly, the chains of events that create medical harm in hospitals do not simply involve the work of doctors.[1] Nurses, managers, policy makers, politicians, and more, are also implicated in the systems that generate harm.

The specific form of medical harm that this thesis investigates is preventable harm, which involves errors of performing the right action in the wrong way, or performing the wrong action, including inaction (Kohn, Corrigan et al. 2000: 28). While agreement about the precise definition of preventable harm remains elusive, as a general guide harm can be considered preventable when it could have been detected prior to the event, and an intervention of proven effectiveness was possible (Nabhan, Elraiyah et al. 2012: 3). As implied earlier, this focus on errors and harms that could have been prevented does not mean that the analysis presented here works ultimately to identify individual mistakes. Throughout, there is emphasises on the systemic context. Knowledge of systems provides the richest insights into how and why mistakes occur, and become harmful, and how they may be prevented (Reason 1990).

Knowledge with implications for policy

This thesis contributes to both academic knowledge and policy discussion. Its academic contribution is to the literature about the social and organisational processes of patient safety. This literature is well developed internationally, but it is very brief in the NZ context. The thesis is also relevant to policy in NZ. It demonstrates that while policy talks about safety, NZ has failed to create the conditions that are necessary to support a truly safe system of healthcare.

[1] The terms doctor and doctors are used throughout this thesis in a generic sense to refer to both physicians and surgeons. In places where the latter distinction is important, the appropriate terminology is used.

In the next part of this chapter I provide an overview of the thesis. Following that the remainder of *Chapter 1* introduces the patient safety movement, the problems it addresses, and its strategic priorities.

Outline of the thesis

This thesis is a journey in stages. It begins immediately after this outline with a broad overview of the history, emergence, necessity, challenges, and strategies of the patient safety movement. I argue in this chapter that the discovery of medical harm was delayed by institutional intransigence, a lack of measurement, and an inability to conceptualise safety. When numbers and knowledge clarified, action was motivated by the shocking rhetorical communication of numerical data about the rate of preventable death, and the identification of how change could be achieved. The report *To Err is Human* (Kohn, Corrigan et al. 2000) in America was a watershed moment that created a will for change. In my analysis of the patient safety movement I review its challenges and strategic priorities, and position my thesis within the strategies of understanding harm and implementing safe practices. Considering the movement as a whole I identify a challenge and a success. The accurate measurement of safety is currently challenging. Without accurate measurement safety is easily eclipsed by economic objectives. A successes is the emergence of scientific knowledge about practices that reduce harm. How these practices are implemented matters, which is the focus of *Chapter 4*.

In *Chapter 2* I discuss healthcare policies and consequences in the USA, the English NHS, and NZ. Donald Light's (1995) analysis of countervailing powers contextualises a transition in healthcare from medical to managerial dominance. Safety is compromised when either group is too powerful. The analysis in *Chapter 2* of how policies have effected safety in America and England shows that policy can either contribute to safety, or reduce it. In the discussion about NZ I draw upon existing research to argue that while there has been some progress over about the last half dozen years safety as a whole is not well supported. While there is a clear interest in safety improvement, there is a reluctance to invest in and support strong action. This is

evident in research with hospital staff, which shows that they do not feel supported to implement change.

Chapter 3 is a review of the literature about the risks of hospitalisation. I explain theoretically and empirically how risks emerge in hospitals and manifest as patient harm. Following Diane Vaughan (1999) the discussion shows how the organisational environment (institutional and economic) and the organisation (structure, processes, and tasks) influence individual cognition and action. Risks to safety are complex and emerge from combinations of factors. Through a consideration of the causal dynamics of risks and commonalities between risks I argue that a strategy for risk control should have three focal points. These are a reduction in pressure, improved communication through a levelling of the status hierarchy, and general support for a culture of safety. The emphasis on culture as a generalised characteristic of hospitals is last. Cultural change is an important component of risk reduction, but cultural solutions cannot be effective when economic forces pressurise complex systems, and communication is distorted by the impact of structurally determined power dynamics on intersubjective relations.

In *Chapter 4* the focus is on safety improvement. This chapter is about how systems and processes inside hospitals can become safer. I review the literatures about quality assurance, medical audit, evidence-based medicine, human factors and ergonomics, and industrial quality improvement. The role and the effectiveness of these methodologies are discussed, and there is an analysis of how they may be implemented into everyday practice. In the conclusion of *Chapter 4* I argue that these activities are socially demanding, technically complex, and must be fully integrated into everyday organisational activity. This requires the full support of the organisation, dedicated work to build support amongst staff, and the commitment of resources. Successful improvement can be expected to provide a return on investment. However these process cannot be assumed to be necessarily effective. There are risks at every stage of the way. Organisations must honestly their evaluate processes and outcomes, and avoid the temptation of settling for the appearance that they have all of the necessary systems in place.

Chapter 5 describes the methodology of the original research that I conducted for this thesis. My research objectives were to understand the challenges of risk control and safety

improvement from the perspective of staff in NZ hospitals. I used qualitative research as the best means of meeting these objectives, and understanding the experiences, perceptions and motives of staff in depth. Through a naturalistic method I emphasised the need to understand the social world of participants' work in its own terms, as composed of distinctive realities and socially shared meanings. The qualitative approach enabled me to work with participants to actively explore and build these meanings, which may have remained hidden if a less personally engaging method was chosen. At the same time however, the quality of the data collected was dependent upon my capacity to build trust and rapport, and it may also have been affected by processes of impression management and institutionalised norms, that staff may not have been fully aware of. These potential gaps in the data were controllable by careful comparison between interviews, and reference to the wider literature about patient safety. The final sample was n=37 interviews with mostly nursing and medical, and some managerial staff, across three departments in two hospitals.

In *Chapter 6* I describe and analyse the risks to patients identified by clinical staff. I argue that clinical risks can be understood as driven by generalised risks of short-staffing, pressure, communication, and a breakdown of teamwork. Short-staffing drove pressure, and it contributed to poor communication amongst all staff, and a breakdown of teamwork amongst nurses. After discussing these risks in depth I describe the dynamics of nine specific clinical risks, and show how these were driven by the four generalised risks. I argue that many risks in the departments that I studied were are not being subject to effective control. In the conclusion I argue that effective risk control might not be possible without better staffing, although more effective clinical systems may help in some cases. Patient safety was compromised by excessive pressure, and staff were highly aware of this.

Chapter 7 is about staff perspectives on the challenges of safety improvement. The discussion covers performance targets, incident reporting, evidence-based medicine and quality improvement projects. I argue that while there was considerable individual dedication to excellence, and improvement processes were sometimes very effective, there were substantial weaknesses in relation to the structural, cultural, political, emotional, and infrastructural supports for improvement. These challenges revealed the impact of short-staffing and pressure that was also affecting risk control. While some staff were very motivated to do improvement

work they did not always feel sufficiently resourced to make this possible. There was frustration about performance targets being treated as an improvement measure and incident reports not receiving appropriate attention. Staff felt little ownership of improvement processes and they experience insufficient passion for it because they were overwhelmed with the demands of clinical tasks. I argue that these challenges show that the improvement process was facing substantial difficulties which were not being overcome.

In the conclusion to this thesis in C*hapter 8* I argue that while patient safety continues to be a problem internationally, the recent growth of knowledge about safe practices and implementation makes real improvement possible. However I argue that in the NZ context, despite an increase in support in recent years, there is inadequate resourcing in support of safety. This is most evident in the struggles inside hospitals as staff work to control risk and implement systems based improvements. There is an opportunity for NZ to more fully commit to safety, not simply in rhetorical terms, but through appropriate investments that are guided by evidence of effectiveness.

The patient safety problem and the policy movement to address it

Having reviewed the purpose of this thesis and the territory it covers, I now introduce the patient safety movement. This outline in four stages provides a context for the thesis. First, I describe the historical emergence of an interest in patient safety. Second, I identify how a patient safety movement was created. Third, I review some measures of the rate of overall medical harm, discuss the accuracy of measurement, and examine some findings about changes in the rate of overall harm. Fourth, I discuss the strategies of the patient safety movement, and situate this thesis accordingly.

Early starts, stops, delays – and progress

The Hippocratic Oath of Greek antiquity and the promise to "refrain from doing any injury" has set a demanding standard for more than two thousand years of medical practice (Copeland 1825: 258). But even in the nineteenth century, and through into the twentieth, medical tradition constrained patient safety. Eventually however the accumulation of evidence about medical harm could not be ignored. Data about death prompted public shock, and this, in combination with the conceptual apparatus of human factors, allowed the dynamics of harmful mistakes to be understood. A patient safety movement entered the landscape of healthcare policy.

Good character

Medical harm was traditionally a matter of individual conscience. The character of the doctor was the primary defence against error. In his 1803 treatise on medical ethics Thomas Percival recommended the self-evaluation of error in private. There was no reference to empirical standards (Sharpe and Faden 1998). When mistakes did happen, there should be "calm reflection … performed with the most scrupulous impartiality" (Percival 1803: 48). If intentions were good the doctor would find forgiveness, and their skills would be perfected. Failure would then be "conscientiously subservient to future wisdom and rectitude in personal conduct" (Percival 1803: 48-9). This view was reflected in the opening declaration of the American Medical Association's first Code of Ethics. It was stated that the "obligations" of the physician are "deep and enduring … there is no tribunal, other than his own conscience, to adjudge penalties for carelessness or neglect." This model of accountability through individual self-evaluation has been central to the long silence in medicine over illness induced by treatment and harm caused by mistakes (Sharpe 2000: 29-30). Its limits were apparent in the reception of three notable innovators in clinical practice.

Innovation delayed

In 1847 the Hungarian physician Ignaz Semmelweis developed an observation based hypothesis about the effects of 'cadaverous particles,' and instructed doctors in one of his clinics to wash their hands in chlorinated lime before attending birthing women. However a 90% reduction in mortality was not convincing to local doctors, who avoided hand washing and considered themselves incapable of spreading infections (Neale, Vincent et al. 2007). Four decades later Semmelweis' work was revisited, and he was credited with proving the effectiveness of hand washing (Best and Neuhauser 2004). Nonetheless, even after 1900, many surgeons still operated with their hands uncovered (Grol and Wensing 2013: 5).

Florence Nightingale also addressed the issue of hygiene. Nineteenth century hospitals concentrated disease and spread infections so badly that they were known as places to go to die (Neuhauser 1999). In an effort to abide by the principle that a hospital "should do the sick no harm", Nightingale (1863: iii) pioneered medical statistics to identify the effects of hygiene improvement, and showed how outcomes measurement could contribute to improved healthcare (Mundinger 1999: ix). After six months of sanitary reforms in Crimean troop hospitals mortality was reduced from 43% to just over 2% (Mundinger 1999). Nightingale (1863) applied similar practices to troop barracks and hospitals in India. Through statistical analysis of hospital mortality she made recommendations for patient numbers, hospital design, and sanitary conditions. But her 1860s proposal for English hospitals to collect basic statistical information to guide improvement was not adopted (Cohen 1984).

Ernest Codman described early twentieth century surgery as a series of unstudied experiments. Codman's End Result System (ERS), a scientific method for the analysis of surgical outcomes and the basis of modern medical audit, was the first attempt to reduce complications by systematically linking outcomes to treatment. Information about patient demographics, diagnosis, treatment, and outcome was used to determine if fault related to the surgeon, the disease, or the patient (Donabedian 1989). Codman wished to assess individual surgeons and entire hospitals in therapeutic instead of financial terms (Sharpe 2000). But the practice was resisted (Reverby 1981) and deliberately excluded from the 1918 minimum standard for US hospitals (Sharpe 2000).

Codman blamed a lack of enthusiasm for the ERS on the medical profession, and hospitals that prioritised finances over surgical outcomes (Loeb 2004). He accused the profession of granting appointments through nepotism, promotion through seniority not competence, and allocating operations according to the schedule rather than the suitability of the surgeon (Donabedian 1989). Susan Reverby (1981: 170) has argued that the ERS "broke the unwritten rules for tolerance and no open criticism considered necessary in the surgical world." It may also have undermined the entire medical system, which was probably insufficiently developed to survive scientific scrutiny.

Risky medicine

As science rapidly increased the potency of medical therapies in the years following WWII there was a growing perception that the risk of harm was an unavoidable consequence of medical treatment (Sharpe and Faden 1998). Two analyses from the mid-1950s made this point well. David Barr (1955: 1453) argued that advances in diagnostic and therapeutic procedures had "enormously increased" the "hazards of medical management." While medical science had eliminated a host of ineffective and dangerous practices, it failed to banish risk, and medicine had grown riskier over time. In the field of medication, "no drug has been found with a single action, and no human body with a single reaction." Robert Moser (1956: 606) referred to these and other emerging iatrogenic hazards as the "diseases of medical progress." While improved surgical techniques and more efficient equipment bought countless benefits, the issue of safety was forced into a place of "unprecedented prominence" because medical conditions could arise from the *correct* deployment of drug therapies. Both men considered harm an unavoidable cost of therapeutic advances (Sharpe and Faden 1998).

During the 1960s medical harm was still considered to be largely unavoidable. While there were studies of medication errors dating from 1962 at least, the relationship between error and harm was not investigated (Folli, Poole et al. 1987). As a result, preventability was poorly understood. When Elihu Schimmel (1964: 109) reported that 20% of patients admitted to the Yale University Medical Service experienced medical complications, these were understood as due to "acceptable medical care in diagnosis and therapy." In the Boston Collaborative Drug Program of 1966, which monitored the effects of drugs in hospitals, adverse events were treated as

indicative of the riskiness of therapies, not the potential for human error in prescription and use (Jick, Miettinen et al. 1970). While errors were acknowledged in a study of adverse drug reactions in Canada, the only mistakes classified were those that involved the work of nurses (Hoddinott, Gowdey et al. 1967).

By the mid-1970s non-investigation of the relationship between error and harm was problematic. In a major review of adverse drug events stimulated by the "numbers game" (Ballin 1975) of counting medication harms, which seemingly affected anywhere from 1.5% to 35% of hospitalised patients, it was acknowledged that no published studies had "addressed the question of what drug reactions are preventable." There was a lack of clarity about the contribution of ineptitude and ignorance in prescribing, and analysis was needed to understand the extent of improper use (Karch and Lasagna 1975: 1239-1240). This call for a better understanding was first answered in the field of anaesthesia in the late 1970s, and new thinking and practices were rapidly integrated into that discipline. Similar solutions did not appear in the rest of medicine until the mid-1990s, and the spread was much slower.

The new safety agenda – anaesthesia

Modern patient safety research was pioneered in anaesthesiology (Weingart, Wilson et al. 2000). The profession was shocked when the world's leading anaesthetist (Keats 1979) argued that deaths from anaesthesia were entirely due to preventable error (Macintosh 1948). The profession was further unsettled when a study of almost 600,000 cases identified anaesthesia-associated death as a significant public health concern (Beecher and Todd 1954). A raft of mortality studies followed (Keats 1979), and a death rate of 1 to 12 per 10,000 anaesthetics was established (Pierce 1996). Meanwhile the problem of accelerating mortality in operating theatres was blamed on anaesthetic agents (Natof and Sadove 1958). By the early 1960s anaesthesia was considered to be the primary cause of perioperative death. But the claim was controversial and investigation was stimulated (Minuck 1967).

Until the mid-1970s research into harm in anaesthesia largely quantified death as a single measure of failure, and determined the rate at which it was caused by error. Occasionally there were analyses of the technical characteristics of risk, its association with operative procedures,

and the characteristics of deceased patients (Cooper, Newbower et al. 1978). This agenda was substantially altered by the critical incident technique, an import from the US Aviation Psychology Programme (Flanagan 1954), which shifted the emphasis to human factors, and the aetiology of error. Causality, processes, circumstances, and their association with procedures and devices, were bought into view. An understanding emerged not only of what the anaesthetist did wrong, but how and why they were led into error. Factors identified included inexperience, unfamiliarity with equipment, poor communication, haste, and inattention (Cooper, Newbower et al. 1978).

The change of thinking in anaesthesia was profound in two ways. First, it was clear that human error was a significant source of medical harm, and the dynamics that caused it could be investigated. Second, errors were placed in a systemic context as an organisational event. The most fundamental problem for safety became the complexity of the systems that were to achieve it. For some patients, especially the critically ill with multiple complicated needs, this problem was truly "staggering" (Gaba 2000: 87). Nonetheless, that was the new focus. Safety was no longer about the private examination of individual conscience. It was not because of dangerous medical technologies, although these were nonetheless problematic. Harm was to be explained as primarily due to human failings in complex systems, and safety was "to be achieved by the *system* of care" (Gaba 2000: 87-88). While this new way of thinking spread only very slowly beyond anaesthesia, the improvements within that field were dramatic. By the turn of the century, anaesthesia, alone amongst all of the disciplines of medicine, had developed an "outstanding" reputation for safety (Leape, Berwick et al. 2002: 505).

The new safety agenda – medicine

Throughout the 1980s most research for improving safety in medicine was focussed on measuring the rate of adverse events (Battles 2005: 226). Very little attention was given to causes, systemic ones especially, and preventability was poorly understood (Bates, Cullen et al. 1995: 29-30). According to those who eventually succeeded in turning the attention to systemic issues, this lack of insight was not simply because research looked in the wrong places. It was an outcome of the entire culture of medicine. The real problem was that doctors were individualistic. They were socialised to expect perfection, mistakes were unacceptable, and

infallibility was expected. These pressures made error the equivalent of personal failure and culpable negligence (Leape 1994: 1851).

Just as in anaesthesia, a systems perspective from human factors was also imported into medical practice, and a new research agenda was born. Adverse drug events were no longer to be considered blameworthy. The focus was shifted to the problem of constructing systems that promoted fewer errors, and provided "effective mechanisms for catching those that do occur" (Bates, Cullen et al. 1995: 30). But complexity was a notable challenge in the way of building these systems. The potential for errors to cause medication harms, because patients were given pills or doses that were different to those that the doctor had intended to prescribe, was almost overwhelming. In the 1980s the average US hospital patient received about ten different drugs while hospitalised (Jick 1984). The following decade a study in a range of wards found 38 drug orders per patient per day (Bates, Leape et al. 1993: 292).

The influence of systems thinking as a response to seemingly continuous error and harm was evident in the analysis and recommendations of a series of chart reviews conducted in eleven units (including five intensive care) of Brigham Women's and Massachusetts General Hospitals in the mid-1990s. Adverse drug events were present in 6.5% of admissions. One percent of harms were fatal, 12% were life threatening, and 30% were serious. Forty-two percent of life threatening and serious harms were preventable (Bates, Cullen et al. 1995). Adverse events and errors were due to sixteen categories of systemic failure. The most common were the poor dissemination of drug knowledge (29%), and the inadequate availability of patient information (18%). The seven systems failures that accounted for 78% of errors were all improvable by better information systems (Leape, Bates et al. 1995). There were preventive opportunities in the computerisation of drug orders, and the centralisation, standardisation, and simplification of administering processes (Bates, Cullen et al. 1995).

The patient safety movement

The insipient patient safety movement was concerned with measuring and understanding harm in order to prevent it. However it lacked political momentum. The epidemiological measurement of all medical harm and its rhetorical communication was instrumental in creating a policy movement that drew upon numbers as a measure of failure, and found a solution in the blame-free systemic analysis of error.

Measuring all harm

The professional liability market in California in the late 1970s was "in a crisis, with skyrocketing premium costs and limited availability of insurance" (Mills 1978: 360). The Medical Insurance Feasibility Study (California Medical Association 1977) was the first comprehensive epidemiological analysis of the impact of all medical harm in hospitals. Reviewers scanning medical records found that 4.6% of patients in California in 1974[2] were harmed by a 'potentially compensable event', and 0.5% of all patients died as a result. A Clinical Professor who led the investigation noted that most harms were not due to legal fault, and under the circumstances the rate of harm was "remarkably low" (Mills 1978: 365).

During the following quarter century two similar studies of harm were conducted in America. In the Harvard Medical Practice Study 3.7% of patients in New York hospitals in 1984 were affected by at least one adverse event, and 0.5% of deaths were 'associated' with an adverse event (Brennan, Leape et al. 1991). In a study of Colorado and Utah hospitals in 1992 there was a 2.9% rate of adverse events, and a 0.2% rate of death associated with adverse events. In comparing these findings with the New York study, the authors were unable to explain the reduction. Because of an increase in the severity of illness amongst hospitalised patients and fewer nurses there probably should have been more harm (Thomas, Studdert et al. 2000: 267-8). This difficulty in explaining the rate of harm, differences between sites, and changes over time, is ongoing and persistent.

[2] As with subsequent epidemiological research historical rather than current records were sampled.

The call to action

In 1999 the Institute of Medicine (IOM) published *To Err is Human: Building a Safer Healthcare System*. The report quoted multiple studies of medical harm, but made particular reference to the epidemiological studies from New York, Colorado, and Utah. Extrapolation from those cases suggested that the annual toll of death in America from preventable adverse events was in the order of 44,000 to 98,000 people. Even if the lower of these estimates were true, medical error was the seventh leading cause of death, worse than motor vehicle accidents. The annual cost of preventable harm to the US economy in lost income and productivity, disability, and healthcare costs (over half of the total), was estimated at between US$17 billion and US$29 billion (Kohn, Corrigan et al. 2000: 1-2).

The committee that produced the IOM report sought to end the "silence" surrounding medical harm, and "break the cycle of inaction." Their recommendations, informed by human factors theories of organisational risk and safety, sought "high reliability" for healthcare. Hospitals were imagined to be capable of achieving similar outcomes to industries such as commercial aviation, which were notably safe, despite the risky contexts of their operations. Considering the seriousness of the problem, and the available knowledge about how to design safety into complex systems, the IOM were both prescriptive and confident. "It would be irresponsible to expect anything less than a 50 percent reduction in errors over five years" (Kohn, Corrigan et al. 2000, 1999: 3-5).

To Err is Human offered a four-tiered approach to designing safety into the "non-system" of American healthcare. First, research needed to be commissioned to build a knowledge base of methods for identifying and preventing harm. Second, a reporting system should be created to gather information and learn from errors. Third, standards and expectations should be increased through oversight by regulators, purchaser incentives, and professional expectations. Fourth, and the ultimate target of all recommendations, organisations should implement safe practices for healthcare delivery (Kohn, Corrigan et al. 2000: 3,6-14).

Shortly after *To Err is Human,* in *Crossing the Quality Chasm*, the IOM expanded the new agenda for healthcare by identifying quality defects as even more widespread than the lack of safety.

Six improvement aims were identified: care should be safe, effective, patient-centred, timely, efficient, and equitable. Achieving these outcomes was suggested to be possible through the adoption and use of information technology, the development of knowledge about evidence-based care processes, and *significant* resource investment. Organisations would need to overcome challenges involving the redesign of processes, the use of information technologies, the management of knowledge, the co-ordination of care, and the improvement of team effectiveness (Committee on Quality of Health Care in America 2001: 1-11). The outcome of efforts to achieve these comprehensive changes in contemporary healthcare is that safety is just one of many new priorities for action (Shojania 2012: 709).

An international movement

To Err is Human was a watershed moment for patient safety. Its impact was greatly assisted by one of the authors of the New York study, who argued that there were about 180,000 deaths annually in the US partly because of iatrogenic injury, "the equivalent of three jumbo-jet crashes every 2 days" (Leape 1994: 1851). When *To Err is Human* was published the media ran with this metaphor, and public attention was captured. Within two weeks the US President ordered a feasibility study for implementing the recommendations (Leape 2000: 95), and go ahead was subsequently given (Leape, Berwick et al. 2002). The impact was significant. By 2005 three changes were evident in the US. First, qualitatively, "the conversation truly changed" (Leape and Berwick 2005: 2384). Errors were seen in a new light and the focus shifted from individuals to systems and how these could be improved to provide safe and high quality care. Second, stakeholder support was mobilised. In 2001 the US Congress approved $50 million annually for patient safety research,[3] a Centre for Quality Improvement and Safety was established, and numerous existing organisations emerged to support safety. Third, either voluntarily or through legislation, a range of aspects of medical practice changed to improve safety. Collectively these were significant developments. Prior to the report there was commitment to safety in "a few pioneering places … most of healthcare was unaffected." By 2005 the majority of US healthcare institutions had some involvement with the new agenda. (Leape and Berwick 2005: 2387).

[3] While US$50 million was tiny compared with the US$28 billion medical research budget of the National Institutes of Health, it enlisted hundreds of new investigators, and build an academic base for an emerging discipline.

To Err is Human was also internationally significant. It has "set the agenda for thinking about patient safety in the US and much of the western world" (Jensen 2008: 311). In the UK the Chief Medical Officer highlighted safety in *An Organisation with a Memory* (Department of Health 2000) as a fundamental concern in healthcare, and a National Patient Safety Agency was created. In NZ the Ministry of Health published *Toward Clinical Excellence: Learning from Experience* (Ministry of Health 2001), and a Sentinel Events Committee was established to try to improve safety by investigating and learning from errors. In 2004 the World Health Organisation launched the World Alliance for Patient Safety.

The measurement problem

The measurement of all harm was foundational to putting patient safety on the policy agenda. Measurement is also essential to safety improvement, because it provides feedback about the outcomes of interventions. However measurement is also problematic. The discussion here critically reviews a variety of knowledge about the rate of harm. It is clear that harm is an ongoing challenge, but it is very difficult to be sure about its extent, and whether or not overall improvements are being achieved. It is also evident that some research probably overstates the frequency of adverse events in general, and preventable death in particular.

How much harm?

The first systematic review of the epidemiological research on all medical harms covered eight studies of hospitals at various points in time from 1984 to 2004 in the USA, UK, Canada, Australia, and NZ (de Vries, Ramrattan et al. 2008). There was a 9.2% median rate of adverse events, and a 43.5% median rate of preventability. Most harms were due to operations (39.6%) and medications (15.1%). Medical procedures (7.8%), diagnosis (7.5%), and therapy (7%) were further less common causes. But these findings must be interpreted with caution. There were huge variations in adverse events ranging from 3.2% in Colorado and Utah (unweighted), to 16.6% in Australia. Investigation has shown that while the quality of care may have been a factor which can be used to explain these differences, most variation was explicable in other

ways. Differences were due to the threshold of causation, the severity of included events, whether events outside hospitals were counted or not, the quality of documentation, and if the research was motived primarily by medico-legal concerns, or efforts to assist quality improvement (de Vries, Ramrattan et al. 2008: 222).

Jumbo-jet loads of death?

Death is a fearful event. Media publicity in America that drew upon the metaphor of jumbo-jet crashes was critically important in motivating political action to support safety improvement. There has recently been media driven outrage in the UK after reports of an annual toll of 13,000 needless deaths in the fourteen worst NHS trusts (Spiegelhalter 2013). It has been argued that there may be more than 440,000 premature deaths annually in America in association with preventable harm (James 2013). Are hospitals really this dangerous?

The careful measurement and the contextualisation of in-hospital deaths shows that the problem of preventable death is not nearly as bad as some have suggested. Two studies in particular that have addressed the rate of death have made this very clear. First, in response to the claim that as many as 98,000 people die annually in America from preventable harm, and that possibly 180,000 deaths were associated with medical treatment each year, a review of 111 in-hospital deaths in Veterans Affairs hospitals in the US showed that only 6% were probably or definitely preventable. Moreover, “only 0.5% of patients who died would have lived 3 months or more in good cognitive health if care had been optimal, representing roughly 1 patient per 10,000 admissions” (Hayward and Hofer 2001: 415). The second study is from the English NHS, where it has been speculated that as many as 255,000 patients may suffer serious disability or death each year. Against his view, a comprehensive sample of 1000 deaths in English hospitals in 2009 found that 5.2% were preventable, amounting to 11,859 deaths across all of England. The major causes of deaths were poor clinical monitoring, diagnostic errors, and inadequate drug or fluid management. Importantly, “most preventable deaths (60%) occurred in elderly, frail patients with multiple comorbidities judged to have had less than 1 year of life left to live” (Hogan, Healey et al. 2012: 737).

Is harm increasing?

Contemporary safety outcomes are driven by contradictory forces. While safety may benefit from the implementation of new practices and improvement programmes and campaigns, hospitals also face mounting performance pressures, which in combination with escalating technical complexities, and the generally worsening health of people being admitted into hospitals, can increase the risks that patients are confronted with. But because of a shortage of evidence, the overall effects of these changes on safety are difficult to know. What evidence there is in this regard is mixed and inconclusive.

In some locations at least outcomes appear to be either static or improving. In hospitals in North Carolina that were highly engaged in safety initiatives patients suffered a very high rate of adverse events, 25.1% overall, with only a non-significant decrease during the six years to December 2007 (Landrigan, Parry et al. 2010). In the Netherlands, a series of three studies found that adverse events in hospitals increased and then declined, with the latter possibly caused by a national safety programme. The initial increase in standardised adverse events, from 4.0% in 2004 to 6.0% in 2008 (Baines, Langelaan et al. 2015), may have been because of a trend of treating simpler cases in day care, which meant that admissions were of growing age and complexity (Baines, Langelaan et al. 2013). In a statement directed at the much higher rate of harm identified in the North Carolina study just mentioned, the authors noted that they used "an extensive decision framework" which made their method "more specific and strict in only scoring adverse events that are caused by the healthcare" (Baines, Langelaan et al. 2013: 296). In their most recent study, of outcomes during 2011/2012, the Dutch investigators found that while standardised adverse events were "relatively stable" after 2008 (a change from 6.0% to 5.7%), standardised preventable adverse events declined by 30% (from 2.0% to 1.4%) during the same period. However, because of the statistical challenges of measuring changes in a multilevel analysis of clusters of departments and hospitals, this seemingly impressive improvement could not be rated as significant (Baines, Langelaan et al. 2015).

A characteristic of relatively recent evidence from America is that safety outcomes appear to be worsening relative to the 9.2% median rate of adverse events established in a systematic review of outcomes until 2004 (de Vries, Ramrattan et al. 2008). Three studies illustrate this

tendency. First, the research from North Carolina mentioned above, where there was a 25.1% rate of adverse events (Landrigan, Parry et al. 2010). Second, the Office of the Inspector General (2010) in America has reported that 13.5% of Medicare beneficiaries in 2008 experienced adverse events in hospital which extended their period of stay, and a further 13.5% experienced temporary harm that did not extend hospitalisation. Third, in three large American hospitals in 2004, with established safety programs and a complex caseload that would have been challenging for safety, one-third (33.2%) of patients experienced at least one adverse event. (Classen, Resar et al. 2011).

There are a number of reasons to be cautious of the rates of harms identified in the three studies described. The report by the Office of the Inspector General did not mention that the age of Medicare beneficiaries, 65 and older, made them particularly vulnerable. In the study in which a third of patients were harmed, 227/393 or 58% of harms were temporary, and did not extend hospitalisation. More generally, as argued by Peter Pronovost and Robert Wachter (2013), all three of these studies employed the global trigger tool (GTT), and there are three reasons to be cautious about that methodology. First, while the GTT is very sensitive in detecting potential harms, it does not require validated evidence. Second, it does not account for differences in risks between patients, which means that there is no adjustment to moderate for the impact of risks increasing through complexity. Third, it relies upon hospital records, which are of variable quality. Hospitals with more rigorous systems of surveillance and staff that record harms more conscientiously will appear less safe. While not invalidating the point that the level of harm is too high, and ongoing, these criticisms and those mentioned earlier suggest the need for caution in the face of reports about extremely high rates of harm.

Contemporary strategies

The emergence of the safety issue and its possible dimensions have been described. Discussion now shifts in overview to what is being done. *To Err is Human* described a four-tiered approach to safety involving the development of knowledge about safe practices, understanding the

causes of harm, improving standards, and implementing safe delivery systems. These strategies are outlined here and their relevance to the thesis is discussed.

Safe practices

Following the call in *To Err is Human* for research to identify ways of improving safety, the Agency for Healthcare Research and Quality (AHRQ) in America sponsored a review of practices which classified 73 interventions according to their impact and strength of evidence. Eleven were identified with the "greatest strength of evidence" (Shojania, Duncan et al. 2001). However as a guide for hospitals pursuing improvement this finding was problematic in at least five ways. First, most practices were biomedical interventions that improved safety, but did nothing for errors. Second, implementation was ignored. Third, there was no reference to systems level interventions that are central to safety in human factors research. Fourth, many practices were omitted not for being necessarily ineffective, but because they had not been tested by randomised trials. Fifth, there was little to address the major causes of harm because most practices targeted numerically minor risks (Leape, Berwick et al. 2002). These objections signalled a split within the patient safety movement. Should hospitals only implement proven practices, and be free to choose whichever unproven interventions suited their capabilities (Shojania and Grimshaw 2005)? Or was it better to act immediately on the basis of what worked in other industries and seemed intuitive in a healthcare context (Leape, Berwick et al. 2002)? While this debate continues, it has probably been settled on the side of evidence (Shekelle, Pronovost et al. 2011).

A second review of patient safety practices sponsored by the AHRQ has shown considerable progress. The first review exposed an immature science (Wachter, Pronovost et al. 2013). Then, and immediately following, insufficient attention to research created "an enormous gap between what is known and what needed to be known." The new report identified ten "strongly encouraged" strategies and "encouraged" another twelve (Shekelle, Pronovost et al. 2013: 365-6). "Although substantial gaps in the evidence base remain, more than enough evidence exists to prompt decisive action" (Wachter, Pronovost et al. 2013: 350). Importantly, these interventions addressed common harms with low to high severity. Risks in relation to surgery, medication, infection, bed ulcers, and falls, were addressed, although not all of their

causal mechanisms were covered (Shekelle, Wachter et al. 2013: 499-503). Implementation was identified as in need of further understanding (Shekelle, Pronovost et al. 2013: 366). The challenges of implementing safe practices is a direct concern of this thesis.

Improving standards

Improving standards requires accurate measurement. But reliable data (Vincent, Aylin et al. 2008), robust measurement, and nationally agreed methods of gathering information have all been in short supply (Jha and Classen 2011: 1756). Moreover the measurement of all harm, which provided momentum to the patient safety movement, has limited value for improvement. Global measures are too imprecise to provide feedback about the diverse causes of harm, and the strategies for addressing it. There are also harms that general measures often fail to identify, including many surgical site infections, diagnostic delays, and adverse drug events (Shojania and Thomas 2013: 274-5).

Local measurement is more useful for improvement, but doing it well is challenging. An emphasis from the centre on measurement that is "good enough" has often been resisted by clinicians as neither valid nor useful (Pronovost and Lilford 2011: 570). The quality of local measurement can also be variable because of inconsistencies in the interpretation of what is to be measured (Dixon-Woods, Leslie et al. 2012). Standardisation is important, but not easily achieved.

Contemporary improvement can involve three kinds of measurement. First, process measures that hospitals report to regulators to show the application of safe practices (Chassin, Loeb et al. 2010). Second, the targeted surveillance of specified adverse events to provide feedback about the outcomes of interventions (Shojania and Thomas 2013: 275). Third, the investigation of clinical or systemic problems to break them into finer categories that interventions may address (Shojania 2012: 711). All of these measurements have their complexities. Reducing that complexity requires that resources are shifted to make systematic measurement possible (Vincent, Aylin et al. 2008: 1207). When this is not done quality and safety can become secondary priorities and hospitals may focus instead on costs and throughput, which are always measured (Donaldson and Darzi 2012).

This thesis is not directly about measurement, but measurement is important to it. Numbers have contextual relevance because the amount of harm matters, they are the basis of financial calculations that determine the value of safety improvement, they can motivate action, and they are essential to planning and doing improvement.

Understanding harm

The IOM envisioned that systems for reporting errors and harm would provide the intelligence necessary to understand the dynamics of clinical risk. But whether voluntary or compulsory, reported data is "grossly incomplete and highly selective" (Brown, Hofer et al. 2008: 173). Understanding therefore needs to be constructed in other ways. Research with staff, especially through interviews and observing work in progress, provides a means of developing this knowledge. The individual cognition and choices that drive outcomes can then be elaborated and explained through the influence of environmental and organisational contexts (Vaughan 1999). This knowledge becomes even more powerful when it is interpreted through sociological and social-psychological theories of risk and safety. Insight into the dynamics of harm is a direct concern of this thesis, and it provides a basis for knowledge about how to reduce harm.

Implementation

The implementation of safety improvement by changing the systems through which care is delivered was the "ultimate target" of the recommendations of *To Err is Human* (Kohn, Corrigan et al. 2000: 6). The IOM did not imagine any particular challenges with implementation. Their strategy was to import safe practices, such as standardisation, from other industries, more widely implement practices already known to be effective in healthcare, build a culture of safety, and hold hospital boards and executive managers accountable. However in practice implementation (Bate, Mendel et al. 2008) and the associated challenges of spread and sustainability have been problematic (Greenhalgh, Robert et al. 2004). Changing systems and practices is difficult, as is spreading them across hospitals and health systems, and sustaining them over time (Grol and Wensing 2013). These challenges are particularly relevant now because of the accumulation of knowledge about safe practices. Such practices can only have an impact if implementation is effective.

There have been calls for evidence-based quality improvement to be central to the safety agenda. Often however efforts have proceeded through intuition and anecdote about which strategies are most likely to be successful (Shojania and Grimshaw 2005). While this work has provided a useful alternative to managerial and regulatory approaches to change, it has also restricted progress and under emphasised the need for robust outcomes assessment. A true science of improvement needs to involve practitioners and academics in cooperative work that combines the practical wisdom and methodological rigour. This approach holds the promise of explaining the contents of 'black box' inside of which interventions either succeed or fail (Marshall, Pronovost et al. 2013). Improvement needs to become a science of action grounded in detailed know-how and theoretical understanding (Dixon-Woods, Bosk et al. 2011). Contributing to this knowledge base is a direct concern of this thesis.

Overview of the patient safety movement

The 'patient safety movement' is a recognisable entity. Its emergence was historically delayed by the silence surrounding medical error, an emphasis on individual responsibility, and the belief that harm was an unavoidable consequence of the power of medical technologies. Contemporary patient safety was made possible by the combination of human factors research, which allowed errors and harm to be understood as systemic events, and the political impact of communication about the extent of harm and iatrogenic death. But while counting harm and death had political impact many issues with measurement have not been overcome. It is not clear just how much harm there is because of variations between health systems, and variations and imperfections in the methods of quantification. It is also unclear, because of a lack of research, if any changes are being achieved in the overall rate of death and harm. What remains clear however is that rate of adverse events is unacceptably high. While contemporary strategies for addressing this problem are compromised by ongoing challenges with measurement, the growth of evidence about practices that can improve safety means that decisive action is now possible. This action may be assisted by knowledge of the dynamics of

harm and the implementation of improvement. The latter is particularly significant to better safety. It highlights the fact that improvement work is necessarily a social activity.

Chapter 2

Policies and Consequences

In the introduction I outlined how patient safety became a focus of healthcare policy through knowledge about the extent of iatrogenic injury and death, and the possibility of a solution in the systems approach to safety improvement. The systems approach suggests that the safety of healthcare organisations is a product of the interaction of factors involving healthcare organisations and their external environment. External factors are significant because they influence the availability of knowledge and tools, the characteristics of professional leadership, legislative and regulatory initiatives, and other actions that influence safety (Kohn, Corrigan et al. 2000: 5,6).

This chapter is about the external policy environment and how it has influenced the quality and the safety of care inside hospitals. To understand that environment it is necessary to discuss the policies that have affected safety, and analyse their consequences. The understanding of policies and consequences in this chapter builds upon the analysis of harm in the previous chapter, which showed that in the last decade or so the fundamental goal of the patient safety movement, reducing all harm, has been elusive. The evidence presented in this chapter cannot offer any new measures of changes in safety outcomes, but it can suggest whether or not the policy environment is helping to improve safety. By evaluating policies and consequences it becomes possible to outline the context of safety work inside hospitals. What methods and practices are being promoted? What resources are being mobilised? How are managers and professionals responding to changes in policy? Answers to these sorts of questions will be

sought through a comparative analysis of the USA, the English NHS, and NZ. By developing a comparative perspective on these systems it becomes possible to identify a range of policy and practice issues, the effects they have had, evaluate the progress of the patient safety movement as a whole, and judge NZ relative to two other systems that have been influential in shaping policy and practice. In making these comparisons and judgments this chapter provides a generalised outline of the safety of hospitals in NZ. The picture constructed here is developed in finer detail later through an analysis of the challenges of safety work for staff inside NZ hospitals.

The analysis of polices and consequences proceeds as follows. First, there is an overview of Donald Light's (1995, 2010) theory of countervailing powers, which provides a way of understanding the changing balance of power between professionals and managers in healthcare, and identifies the dangers of either group gaining excessive power. Second, there are three separate discussions of quality and safety policies and outcomes in the USA, the English NHS, and NZ. The US and the English cases are selected because they have substantially influenced NZ. For each system, policies and practices over time, and the responses of healthcare professionals, are outlined. In the conclusion I return to the theory of countervailing powers as a way of understanding the changing policy agenda, and suggest some priorities for successful improvement.

Countervailing powers

The theory of countervailing powers, applied to healthcare by Donald Light (1995, 2010), provides a useful framework for understanding the changing balance of institutional power. This shift in the environment in which hospitals work has notable implications for patient safety. The theory analyses the medical profession on the one hand, and entities such as the state, economic interests, and the public, on the other, as powerful and interdependent actors struggling for control over the domain of healthcare. When one group achieves dominance, others are harmed and countermoves are elicited to redress the balance of power (Light 1995).

Light has applied the analysis of countervailing powers to America and the NHS. He argued that America in the early 1970s was the purest form of professional dominance. The market structure, the institutional framework, and the entire legal and administrative apparatus protected the profession and reflected its priorities. As a consequence the profession enjoyed great wealth and status. With the approval of the public, medical treatment expanded to provide as many services as possible, regardless of necessity or safety. The cost of healthcare grew. When costs become a problem after about 1970 the lack of a budgetary framework meant they could not be controlled as they were elsewhere in the West (Light 1995: 33). Patients, governments, and other payers were confronted with an expanded and expensive market for medical services with numerous inefficiencies and the risk of overtreatment and iatrogenesis (Light 1995). In the process a tacit social contract of unquestioned trust in doctors to apply the best scientific and technical information and skills to the needs of patients was violated (Light 2010: 270).

In discussing the NHS, Light (2010) emphasises that it is notably different from America because while there was clinical dominance, the medical profession never developed corporate economic control. Nonetheless, institutional control alone was sufficient to damage the quality of clinical work in the NHS, just as it did in America. Doctors overlooked ineptitude on the part of colleagues, assumed they were fit to practice without having to prove it, and denied the importance of scientifically founded clinical standards in favour of individual autonomy (Light 2010: 280-283).

Light's (2010) perspective on the NHS since around 2000 is that the countervailing powers of managerialism have made considerable progress in reigning in the excesses of clinical autonomy. There has been a new emphasis on clinical guidelines and protocols, National Service Frameworks, regulatory controls on the competence of individual doctors, and public regulation of professional practices and outcomes (Light 2010: 278-282). The result is a new kind of medical professionalism where doctors surrender traditional powers, adopt new responsibilities, and ultimately construct a new social contract between profession and society. This "professionalism based upon accountability" rescues the health-care professions from the destructive pursuit of their own economic self-interests, and embodies a higher morality of service to patients and society (Light 2010: 278,285).

The transition that Light describes however is not without risk. There are a number of "potential excesses and dislocations." These include under-treatment, cuts in services, obstructed access, reduced quality, excess bureaucracy and paperwork, and the thoughtless application of protocols. Because of these consequences Light emphasises the need for controlled professional power, so expertise can be employed according to a competency and performance based model of care (Light 2010: 278).

Overall, the theory of countervailing powers suggests the need to very carefully balance medical and managerial priorities in the interests of safety.

The United States of America

The United States is the only major Western industrialised nation without a universal system of government funded healthcare (Navarro 1989: 53). There is however government provision through Medicare for people who are either over the age of 65, or suffer a few specified conditions, and Medicaid provides for some people on low-incomes. There is also government provision for defence personnel, American Indians, and Alaskan natives. The Patient Protection and Affordable Care Act 2010 requires most other Americans without health insurance to purchase subsidised care, while limiting the rates that insurers can charge.

Foundations

Hospital standardisation

Eighteenth and the nineteenth century hospitals were organisationally backward. The advent of standardisation as a way of improving hospital care began in America, and it continues to inform improvement to the present day (Timmermans and Berg 2003). There were a number

of drivers to standardisation in early twentieth century America. Hospitals were increasingly complex (Timmermans and Berg 2003). They competed to be at the forefront of advances in medical practice (Neale, Vincent et al. 2007). Wealthy patients were coming into hospitals because the equipment needed to treat them was no longer transportable to their homes (Roberts, Coale et al. 1987). Patient care was shifting from individual doctors to teams of consulting and referring specialists (Timmermans and Berg 2003). Senior professionals were embarrassed by the lack of organisation and equipment, the many poorly trained staff, and medical records that were useless because patient histories and diagnosis were seldom recorded (Roberts, Coale et al. 1987: 936).

The standardisation of American healthcare initially targeted medical training and hospital structure. The Flexner Report of 1910 identified poor training and grossly inadequate standards in many US medical schools (Lembcke 1967). Subsequently over half were closed and a fundamental upgrade in standards was initiated (Brennan and Berwick 1996). Medical training was also exclusively focussed upon science, and alternative healing practices were excluded (Wolinsky 1993).

The next phase of standardisation followed shortly after through the Hospital Standardisation Programme of 1918, which specified the minimum standards for American hospitals of staff qualifications, rules and policies, medical records, and technical facilities. Most hospitals were so poorly organised that they failed the initial accreditation in 1919 (Lembcke 1967: 546). Despite this setback, the Hospital Standardisation Program was nonetheless “an unusually impressive example of a medical discipline actually taking responsibility for the assessment of its own work” (Brennan and Berwick 1996: 99). But there were however some notable blind spots in the practices encouraged. While doctors were required to regularly review their work (Roberts, Coale et al. 1987), they were not expected to systematically analyse or report their outcomes (Sharpe 2000). For many decades “the direct and sometimes painful approach” of medical audit was practiced superficially (Lembcke 1967: 545-6). While there was rhetorical commitment to increasing therapeutic efficiency, direct performance comparison was feared (Reverby 1981). Even as the minimum standard substantially expanded in subsequent decades, and auditing increased, for most doctors quality assessment consisted of only the periodic and highly subjective practice of peer review (Sanazaro and Mills 1991). In effect, the power of

standardisation was compromised by medical capture of the regulatory process, and the low status of quality limited the development of effective methods of measurement and comparison. Until the mid-1970s US hospitals were largely self-regulated, and needed to only demonstrate formal compliance. There was no need to provide substantial proof of any measureable differences in quality (Brennan and Berwick 1996).

Compulsory audit

By the late 1960s expenditure on healthcare in the US through facilities, physicians, science, and technology had rapidly grown for two consecutive decades (Wyszewianski 1988). Costs further expanded in 1966 when Medicare and Medicaid extended federal and private insurance to cover 85% of the population. By that time healthcare consumed 4% of GNP (Relman 1988), and payers, who worried about costs, wanted to know if patients were receiving good value or not (Wyszewianski 1988).

Medicare and Medicaid gave the US government a direct interest in healthcare. Participating hospitals were inspected by the Joint Commission on the Accreditation of Hospitals (Brennan and Berwick 1996), and physician run and federal government supported Professional Standards Review Organisations (PSROs) (Roberts, Coale et al. 1987). In an effort to lift standards in 1972 the PSROs and the Joint Commission made medical auditing compulsory (Sanazaro and Mills 1991).

Audit involved systematic review procedures with written and objective standards (Roberts, Coale et al. 1987). Continuing medical education or changes in administrative policies and procedures were called for when quality was unacceptable. Concurrent or utilization review was conducted to reduce costs by ensuring that only medically necessary treatment was provided. Medical care evaluation studies audited care processes, patient outcomes, and the use of some procedures. Comparative profile analysis sought to identify hospitals, care processes (Goran, Roberts et al. 1975), and physicians, that needed to improve (Goran 1979).

The PSROs were not supported by the American Medical Association. The profession feared government control over the details of medical work, the gathering of information that

supported malpractice suits, and 'cookbook' medicine that stifled innovation and progress (Donabedian 1978: 862-863). The PSROs were especially resented because while physician designers emphasised quality, the US Congress and evaluators were mostly concerned with cost control (Lohr and Brook 1984a). There were also problems with funding, expertise, data, inconsistent approaches, and disagreements over measures. In addition there were worries about a lack of commitment within the medical profession to changing behaviours (Goran 1979). Meanwhile excessive diagnostic testing was increasing the risk of iatrogenesis (Dershewitz and Gross 1980).

While the PSRO programme did show some gains because of a growing acceptance in some quarters that the conduct of peer review was essential to good medical practice (Lohr and Brook 1984b: vii), relative to initial ambitions it was nonetheless and for the most part a medical (Sanazaro and Mills 1991) and political failure (Bindman, Lee et al. 1994). By the late 1970s auditing degenerated into a "paper exercise" of fulfilling legal obligations (Roberts, Coale et al. 1987: 940). Costs rose, and a 'revolt of the payers' saw businesses, unions, and government collectively try to deny payments (Relman 1988). Medical professionals responded to the aggressive cost focus by deliberately subverting regulatory processes. The ineffective self-regulation of previous years become external and antagonistic (Brennan and Berwick 1996).

Quality assurance

In 1979 the federal government relaxed its auditing regulations and required hospitals to establish organised programmes of quality assurance (QA) (Sanazaro and Mills 1991). A Utilisation and Quality Control Peer Review Organisation (PRO) programme was created to retrospectively review random medical records to confirm diagnosis, reduce unnecessary admissions and operations, and lower the rate of death and complications through screening conditions (Bindman, Lee et al. 1994) that were major contributors to mortality and morbidity (Bhatia, Blackstock et al. 2000). To respect localised differences written and objective quality criteria were substituted by the less rigorous process of implicit peer review (Rubin, Rogers et al. 1992).

The PRO system was accompanied in 1984 by the introduction into Medicare of a system of prospective payments (Bhatia, Blackstock et al. 2000). Patients were allocated to a Diagnostic Related Group (DRG) on admission, which meant that the hospitals could only be reimbursed for providing them with the treatments that were specified for that condition (Wyszewianski 1988). While this reduced the risk of iatrogenesis through over-treatment, QA was essential because of the risk of under-treatment.

A perverse outcome of the DRG categories was that Medicare used them to deny payments for treatments that were not initially recognised as necessary. The struggles that emerged from this complication were sometimes quite intense, and they reinforced the adversarial regulatory relationship of the earlier regime of compulsory audit (Bhatia, Blackstock et al. 2000). Consequently a large part of the efforts that should have gone to quality remained fixed upon costs (Lohr and Schroeder 1990), compliance continued to dominate quality (Cooper 2004), physicians generally failed to learn from negative feedback (Jencks and Wilensky 1992), and monitoring often had little impact on performance (Cooper 2004). At the same time there was a continuing lack of data about the effectiveness of interventions, and for many diagnoses it was difficult to know how to improve outcomes (Chassin and Loeb 2011).

The failings of QA created a significant problem (O'Leary 1988). While costs rose to 11% of GNP in 1986 (up from 4% in 1966), quality was not improving (Relman 1988). Moreover the emphasis on cost containment triggered public anxiety about the potential for quality to decline (Brook and Lohr 1981). The US Congress and the media responded by pressing for more monitoring to reassure the public that quality was not being sacrificed (Wyszewianski 1988). One outcome of this monitoring was the publication of data on hospital mortality and other measures that the profession justifiable slated as “standardless” (O'Leary 1988: 1760). Another negative consequence of QA, supported by the worries about failure, and the tendency to focus on outliers that most needed to improve (Kritchevsky and Simmons 1991), was a growing emphasis on systems of inspection and surveillance looking for “bad apples” to punish. The dominance of this mentality and the defensiveness it created made QA a particularly ineffective method of improving quality (Berwick 1989: 53).

The outcomes movement

US healthcare in the 1980s was like an organism "desperately in need of a central nervous system that can help it cope with the complexities of modern medicine" (Ellwood 1988: 1550). The outcomes movement responded to this crisis by promising to resolve complexity through computerised intelligence in the form the Indicator Management System, and the Patient Care Algorithm System (Brennan and Berwick 1996). Both were databases of treatment information that could be statistically analysed to understand the relationship between diagnoses, interventions, outcomes, and costs (Ellwood 1988). Regulators could then provide targeted and practical feedback (Jencks and Wilensky 1992), and treatment could be focussed on techniques with proven effectiveness (Tanenbaum 1993).

While the use of outcomes data during the mid-1990s involved some effort to achieve more responsive regulation. But the available systems were not always employed very effectively. An unavoidable complication was the necessity for case-mix adjustment (Chassin, Loeb et al. 2010). But this was difficult. The data was complex to use, it required sophisticated computerisation, and some hospitals, supported by The American Hospitals Association, resisted the necessary cost of their time (Brennan and Berwick 1996). Consequently regulators often continued to employ the same kind of "narrow inspection focus and punitive authority" that had plagued the previous system of QA (Brennan and Berwick 1996: 178).

Evidence-based medicine

Evidence-based medicine promotes scientific evidence from statistically driven randomised controlled trials as the correct basis for medical decision making (Chassin and Loeb 2011). It rejects the assumptions that what most doctors do is correct; that expert pronouncements are reliable; and that practice automatically converges upon the best treatment (Eddy 1990).

Evidence-based medicine entered mainstream health policy in America in the 1990s through the Agency for Health Care Policy and Research. Physicians were offered more and better access to systematic reviews and meta-analyses to support critical appraisal, and professional associations and hospitals encouraged them to act upon guidelines. Support was provided by a

national register of research, and the Agency established a series of evidence-based centres to provide evidence reports, and a national clearinghouse to develop clinical guidelines (Walshe and Rundall 2001). While the guidelines approach ran into difficulty in the mid-1990s for a number of reasons, including resistance from the American Medical Association, which labelled it "cookbook medicine", it remains central to contemporary policy (Harrison, Moran et al. 2002: 8).

Industrial quality improvement

Continuous quality improvement (CQI) was the first of several methods of industrial improvement to be introduced into the US and other healthcare systems. CQI gained widespread support through the 1992 launch of the Health Care Quality Improvement Initiative. Attention was shifted from individual problem cases, to helping every provider (Jencks and Wilensky 1992). Where QA sought to "inspect errors out" CQI emphasised "designing quality in" (Coster and Buetow 2001: 28). This was to be achieved in three ways. First, subjective local care criteria were replaced by explicit national standards. Second, the focus shifted from periodic to persistent differences. Third, the role of the PROs was limited to identifying problems and offering solutions. Providers then became responsible for issues of who and why (Jencks and Wilensky 1992: 900). This work continued throughout the 1990s in the form of thousands of cooperative projects. But while improvements were reported in two thirds of these projects, the Health Care Financing Administration were unable to demonstrate any overall impact on quality (Bhatia, Blackstock et al. 2000: 72). The essential difficulty behind this outcome was that most of the projects were non-strategic. Although leaders in healthcare talked about improvement, the system remained dominated by the mentality of inspection (Brennan and Berwick 1996: 136-137).

Contemporary outcomes

By the beginning of the current century many systems and methods had been developed in the US for improving healthcare quality. But implementation was problematic, safety

improvements were negligible, and with the US was ranked 37th globally for system performance by the WHO. American hospitals were consistently failing to meet expected standards. Quite simply, efforts were weak. There was no sustained response from policy makers to information on failures, and efforts were uncommonly directed at improvement (McGlynn and Brook 2001: 82). Even until the mid-2000s safety largely relied upon hospitals meeting the demands of regulators, and being shamed into improvement by negative publicity (Wachter and Pronovost 2006a: 621).

Although their impact took time, two notable reports around 2000 helped to turn the tide on quality and safety in the US. In *To Err is Human* (Kohn, Corrigan et al. 2000) the Institute of Medicine drew upon existing research to suggest that there were between 44,000 and 98,000 preventable deaths annually in American hospitals. *Crossing the Quality Chasm* (Committee on Quality of Health Care in America 2001) identified quality defects as even more widespread than problems with safety. Shortly after an overview of quality standards in US hospitals during 1998-2000 showed that compliance with guidelines was so poor that Americans were receiving only 54.9% of "recommended processes for basic care" (McGlynn, Asch et al. 2003: 2635). With largely similar results for preventive, acute, and chronic care, the overall deficits posed "serious threats to the health and well-being of the US public" (McGlynn, Asch et al. 2003: 2644).

More recent events in America suggest that the prominence of quality and safety has shifted, although both remain elusive. Robert Wachter (2010a) has graded progress by 2009 in safety improvement in the US as B- overall. Gains were most evident in incident reporting and leadership. Hospital leaders were beginning to see a business case for improvement, and engagement was increasing through the impact of national safety campaigns. The regulatory process had also become more robust, although its effectiveness as a method of change was limited. The implementation of IT had been slow and difficult but was expected to improve with better funding.

Process regulation

From 1998 the ORYX initiative made process measurement central to accreditation. The system was relatively simple, but it required some audit expenditure. Its basis was a rapidly expanding

set of measures of care processes that were correlated with better clinical outcomes, and could be proven to have happened or not through administrative data or audits of compliance. In a decade the ORYX initiative achieved "breathtaking" results (Chassin, Loeb et al. 2010). Data from 2013 showed that hospitals achieved a 97.6% composite accountability performance on 17.5 million care opportunities. This was significantly better than the 81.8% result achieved on less than a million opportunities in 2002 (The Joint Commission 2014: 6).

National improvement campaigns

Over the last decade American hospitals have been increasingly engaged in national improvement campaigns that extend the earlier Health Care Quality Improvement Initiative. The first two such campaigns were initiated by the Institute for Healthcare Improvement (IHI). The 100,000 Lives campaign voluntarily enrolled hospitals to work simultaneously on six best practice interventions to try to save 100,000 lives in 18 months (Hackbarth, McCannon et al. 2006). A 'life saved' was defined as "a patient who survived a hospital stay during the Campaign period (January 2005 – June 2006) who would have died had he or she received that hospital's pre-Campaign year (2004) level of care" (Hackbarth, McCannon et al. 2006: 2). With the support of the American Medical Association 3100 hospitals were enrolled, covering 75% of all patient beds (Sinkowitz-Cochran, Garcia-Williams et al. 2012). When the campaign ended the official IHI evaluation claimed that 122,300 lives had been saved (Wachter and Pronovost 2006a). Some caution was expressed however because inpatient mortality had been improving for a number of years, and the results may have been due to a mix of existing change processes, and campaign initiatives (Hackbarth, McCannon et al. 2006).

The actual outcome of the 100,000 Lives campaign is unclear. Robert Wachter and Peter Pronovost (2006a) contested the figure of 122,300 lives saved on two grounds. First, non-standard counting practices were used to collate the results. Second, case-mix adjustment, "an inexact science at best … accounted for nearly three out of four 'lives saved'" (Wachter and Pronovost 2006a: 623). While the IHI claimed three independent assessments of the adjustment (Berwick, Hackbarth et al. 2006), Wachter and Pronovost were not reassured:

> The difference between the unadjusted (33,000) and adjusted (122,300) 'lives saved' reflects a change in patient severity of illness and case mix during a short period of time that would, to our knowledge, be unprecedented in health services research. In the absence of a new product line (such as a surgical or cardiac service) that recruits new groups of patients, severity of illness in hospitals tends to change very gradually—certainly not to this degree during an 18-month period. As such, an adjustment resulting in 89,000 additional saved lives continues to strain credibility (Wachter and Pronovost 2006b: 632).

There was also a conflict of interest because the campaign was designed and evaluated by a private organisation (Wachter and Pronovost 2006a: 626).

Shortly after 100,000 Lives a second national campaign was implemented by the IHI to try to prevent five million incidents of harm over the two years ending December 2008 (there were an estimated 15 million incidents of harm annually). The reduction was to be achieved through replicating the interventions of 100,000 Lives, and adding five others (McCannon, Hackbarth et al. 2007). A total of 4,050 hospitals were enrolled (well up on the previous 3,100) and the campaign was again supported by the American Hospital Association (IHI 2015). This was an unprecedented achievement in involving hospitals in an endeavour they had traditionally resisted (Kenny 2008). However the outcome of Five Million Lives, like its predecessor, is unclear. According to the IHI "there is no formal evaluation available" (IHI 2013). The website provides selective evidence of success, but "we don't know yet" if harms were reduced by five million incidents (IHI 2015).

The third national campaign was conducted by the federal government Centers for Medicare and Medicaid Services. The Partnership for Patients, lasting from 2011 through to the end of 2015, sought to reduce 30-day hospital readmissions by 20%, and ten categories of preventable harm by 40% (Clarkwest, Chen et al. 2014). Federal government invested $1 billion to support these outcomes, which had the potential to save $15 billion in costs (McCannon and Berwick 2011). A progress report to February 2014 identified significant reductions in readmissions and in four categories of harm. Deaths were reduced by 15,500. Cost savings amounted to between $3.1 and $4 billion. The causes of these outcomes however could not be solely attributed to campaign interventions. Hospitals may have had other harm reduction process in place, and a

change in payment policy limited reimbursement for treating preventable harms (Clarkwest, Chen et al. 2014: 1-2).

Contemporary challenges

While patient safety continues to be problematic in the US there are strong signs of progress and momentum. Recent commentary has identified the depth of the progress made, and the vast complexities of the challenges that remain.

Peter Pronovost and Robert Wachter (2013: 3) have found many signs of change. These include growing economic incentives and social pressures towards safer care, the increasing implementation of safe practices and safe culture, greater engagement by hospital boards, increasing accountability, public reporting of compliance with safe practices, and an "explosion" in the implementation of evidence-based safe practices.

There are ongoing challenges involving research, measurement, and systems engineering. Safe practices have not been identified for all harms. Better research is needed to identify interventions that could make a difference, and valid measures of safety for reliably tracking the outcomes of interventions (Pronovost and Wachter 2013). The systems engineering challenge, identified by Peter Pronovost and George Bo-Linn (2012) highlights the growing complexity of modern medicine. By targeting nine categories of harm the Partnership for Patients worked at prevention in silos because it is "too burdensome to attempt to reduce multiple harms at the same time." Controlling all of the risks patients are exposed to is "challenging, if not impossible" (Pronovost and Bo-Linn 2012: 769). The only way this complexity could be overcome is through a systems engineering approach with "a machine-human interface, requiring data transparency, actionable feedback, teamwork, and continuous learning" (Pronovost and Bo-Linn 2012: 770). Developing and implementing such a system would be challenging but pilots indicate it is possible.

Overview

America initiated a global progressive movement in the early twentieth century to the standardisation of hospital care. This established the legitimacy of scientific medicine and overcame competition from non-scientific treatments. But once competition was eliminated organised medicine captured and controlled the regulatory process, and quality and safety was compromised for the rest of the century. Throughout the twentieth century quality and safety improvement were low status activities (Brennan and Berwick 1996). The profession was concerned primarily with introducing new facilities and treatments that expanded the market, escalated costs, and increased the status of doctors and the profitability of treatment. This drove the federal government and other payers to intervene, primarily to control costs, but also because of concerns about quality. Both efforts failed because the organised profession was too powerful. It was not until after the turn of the century that growing evidence of the fiscal and human costs of quality and safety failures, funding in support of patient safety as an academic discipline, the development of more effective methods of regulation and improvement, and normative pressure, combined to create a powerful constellation of methods and motives for change. These pressures slowly transformed the views of professionals, and forced hospitals to either participate in increasingly rigorous forms of regulation and national safety campaigns, or lose business. As a result, the safety of clinical practices has been substantially improved by integrating evidence-based medicine into clinical work through the mechanisms of process regulation and national improvement campaigns. Accordingly, in 2013 the ORYX initiative achieved a 97.6% composite accountability performance on 17.5 million care opportunities, and the recent Partnership for Patients saved (by providing safer care and reducing the need for additional treatment) up to four times its cost of US$1 billion. But while these outcomes were impressive, they did not cover all of the ways in which patients may be harmed. Moreover, the Partnership for Patients achieved only about a quarter of what was targeted as possible. So while many gains are in evidence, there is still a long road for American hospitals to provide care that is truly safe. Increasingly, the new challenges involve issues of complexity and culture. While top-down processes have delivered results, safety is also, as will become apparent as this thesis develops, the outcome of processes in the clinical realm that cannot be legislated into being.

The English National Health Service

Created in 1948, the National Health Service (NHS) is a publicly funded service providing free hospital care and GP visits for all UK citizens. It has three independent parts, each accountable to their respective government: the English, Scottish, and Welsh NHS. The discussion here is about the English NHS.

Until the 1980s management teams in the NHS were primarily composed of medical staff (Harrison and Ahmad 2000). This meant that there were few constraints on medical autonomy. Because of rapid cost inflation during the 1950s the state was very quickly confronted with the problem of controlling costs (Dent 1993, Dent 1995). One of the first strategies in response, in the mid-1960s, was to encourage medical audit. Although the British Medical Association and the Royal Colleges were initially disinterested, they eventually supported audit because it might protect professional autonomy. Their memberships were unconvinced until 1981 (Dent 1995). In the meanwhile government began its second strategy, of administrative reorganisation, in 1974. But the introduction of consensus based teams did not significantly alter medical dominance because doctors held a power of veto over team decisions. The government's third strategy in 1976 was to cease underwriting all costs through a policy of cash limits (Marnoch 1996). This controlled total costs to some extent, but it politicised decisions about resource allocation and service provision.

Foundations of the current system

Managerialism

The first real challenge to the managerial authority of NHS doctors began in the early 1980s in a context of ongoing dissatisfaction with the failure of cost containment (Dopson 2009). Through the 1983 Griffiths Inquiry a managerial revolution was unleased through a conservative agenda of "rolling back the state" (Flynn 1999: 28). The *Griffiths Report* sought

cultural change and greater cost efficiency (Hunter 2006). General managers, modelled on the ideal of the CEO (Harrison 2004), replaced consensus teams, and began reorganising clinical workloads, and introducing systems of budgets and performance indicators (Harrison and Ahmad 2000).

Doctors in the 1980s generally accepted the growing power of managers (Harrison and Ahmad 2000) over clinical budgeting, allocation, and the need for financial limits on treatment. They retained their traditional autonomy over most clinical decisions (Dent 1995) and their lack of accountability for quality (Bevan 2008), which did not improve (Marnoch 1996). But as general managers centralised their power and increased bureaucracy, objectives proliferated, and provision for local populations declined. While some peripheral logistic activities improved, patterns of health care delivery remained relatively unaffected because managers could not challenge clinical power (Dopson 2009).

The internal market

Efforts to increase managerial power were renewed in 1989 through the report *Working for Patients* (Department of Health 1989). The outcome was a 'purchaser-provider split' that created a quasi- or internal-market in 1991 (Exworthy and Halford 1999). Health Authorities purchased services from hospitals remodelled as NHS trusts (Harrison and Ahmad 2000) with financial responsibility for their own survival. Trusts provided the services that Health Authorities deemed necessary, but made their own decisions about the performance of work (Exworthy and Halford 1999). To survive, trusts needed to allocate and use resources effectively, and both managers and doctors held a stake in the outcome (Harrison and Ahmad 2000). It was imagined that doctors would become more accountable for clinical decisions, and there would be a reduction in expensive behaviours, and improvement in quality and innovation (Marnoch 1996).

The reforms of the 1990s significantly advanced managerial power. Some senior consultants were appointed to the roles of Medical Director, with a seat on the board, and Clinical Director, with managerial responsibility for budgets and quality. The latter were typically supported by a nurse manager and a business manager, and occasionally an information manager, an

accountant and a resource manager (Marnoch 1996). Across all managerial categories, managers were expected to become entrepreneurial change agents, and they faced demanding performance targets (Dopson 2009). Managers had more direct control over doctors, and internal mechanisms were developed for calculating and controlling costs (Harrison and Ahmad 2000), while quality assurance (Gabe, Kelleher et al. 2006) and compulsory audit targeted quality (Hunter 2006). Specialist institutions were created to support evidence-based medicine and increase the clinical and cost-effectiveness of decision making (Harrison and Checkland 2009).

Despite the elaborate controls they created, the market reforms failed. They lacked the sophisticated measures needed to convert price data, though an analysis of quality, into information on value, and price competition was the result. Throughput dominated and quality was largely ignored (Quam 1989). Evidence-based medicine received little promotion, and was not widely implemented (Harrison and Checkland 2009). Audit, as a measure of quality that could have introduced other priorities into managerial accounting, was controlled by doctors and taken on trust as eliminating quality differences (Neale, Vincent et al. 2007). Doctors used it only selectively (Marnoch 1996). Over the course of the decade there were multiple audit failures, including a very high death rate amongst babies at the Bristol Royal Infirmary, botched operations on over 100 women by a gynaecologist who headed medical audit in his department, and the murder of possibly more than 200 patients by GP Harold Shipman (Bevan 2008).

By the end of the 1990s the NHS was in a crisis. Audit was expensive and ineffective (Neale, Vincent et al. 2007). Doctors were unhappy with the dominance of finances and targets. The competitive ethos had made quality and professionalism subservient to price and quantity (Scally and Donaldson 1998: 61-2).

Clinical governance

In 1997 an incoming Labour government introduced a ten year program of modernisation to "place quality at the heart of healthcare" (Department of Health 1998: 2). The new NHS explicitly opposed the excessive cost focus of the previous administration (Scally and Donaldson 1998), which "ignored the real needs of patients" (Department of Health 1998: 2). In its efforts to secure these goals through a "fundamental shift in the relationship between the state and the medical (and other health care) professions" (Flynn 2002: 155), clinical governance was intended to be "the most ambitious quality initiative that will ever have been implemented in the NHS" (Scally and Donaldson 1998: 62).

The ambitions of clinical governance were outlined in *A First Class Service: Quality in the new NHS* (Department of Health 1998). Clinical governance was defined as a means of making healthcare organisations "accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (Department of Health 1998). The locus of accountability for the performance of individual hospitals (NHS trusts) rested ultimately with the chief executive (Bevan 2008). But quality was not divorced from economic criteria. Clinical governance sought to fully integrate financial control with performance and quality (Scally and Donaldson 1998). "High quality and cost-effectiveness" were "two sides of the same coin" (Department of Health 1998: 2).

Clinical governance was initially imagined as being implemented while the internal market was dismantled so the system could become more collaborative (Scally and Donaldson 1998). Scaling back the market was intended to reduce transaction costs and free up resources to reduce waiting lists. But waiting times worsened (Bevan 2008: 90), and in 2002 the internal market was reintroduced (Ham 2010a), and competition intensified (Hunter 2006).

Clinical governance has been described as "a framework upon which to hang different quality initiatives" (Swage 2004: 53) The NHS Clinical Governance Support Team proposed 'seven pillars' of clinical effectiveness, risk management, patient experience, communication,

resource use, organisational strategy, and learning effectiveness (Haxby, Hunter et al. 2010). They later added systems awareness, teamwork, staff ownership and responsibility, and leadership (Haxby, Hunter et al. 2010). Others have included clinical audit, quality assurance, staff development, research and development (Degeling, Maxwell et al. 2004), evidence-based medicine, clinical supervision, learning from complaints, incident reporting, adverse event management, performance management, and the use of data to monitor clinical care (Swage 2000).

The implementation of clinical governance required substantial investment. In 1997 the NHS received £35 Billion, but it was chronically underfunded. Capacity was lacking and the average wait time from referral to treatment was 18 months. By 2010 funding had grown to £110 Billion, and waiting times were reduced to just a few weeks (Darzi 2009). As a percentage of GDP costs grew from just over 6% in 1997 to 9.6% in 2010 (The Commonwealth Fund Commission on a High Performance Health System 2011).

Regulation of the new quality strategy

The regulation of hospitals and treatment was critically important to the quality agenda. While there was no shortage of regulatory agencies in the NHS, with at least seventeen in 1999 (not counting new bodies introduced as a part of clinical governance) (Walshe 1999), their scope was too limited. Although organisations complained of "inspectoral overload" (Day and Klein, quoted in Walshe 2002a: 968), individual regulators with their strictly limited concerns were ill-equipped to identify organisational failure (Walshe 2002a: 968). Standards were inconsistent, and individual clinical discretion (Scally and Donaldson 1998) meant that proven treatments were sometimes introduced too slowly, while unproven ones could be taken up too rapidly (Department of Health 1998).

Two new organisations were central to bringing hospitals into line with clinical governance. The National Institute of Clinical Excellence (NICE) was briefed to make recommendations about the cost-effectiveness and affordability of treatments; to provide evidence-based guidelines; and to approve models of clinical audit for compulsory use (Salter 2007). The NICE also developed National Service Frameworks to provide equal access to standardised care (Swage

2004). These were later identified as some of the most successful of all clinical governance initiatives (Leatherman and Sutherland 2008: 25).

The Commission for Health Improvement (CHI) was given statutory authority to monitor the uptake of NICE recommendations and National Service Frameworks through a rolling programme of Clinical Governance Reviews. The process was expanded in 2001 by a system of star ratings that ranked organisational performance (Bevan 2008: 90), and become especially significant after 2002, when government sought to make a political return on ambitious funding increases to reign in the growth of waiting lists (Salter 2007: 270). Hospitals that performed poorly were named and shamed, and the CEO's job was at risk. In the first set of acute hospital ratings in 2001, twelve zero-rated trusts were described by the Secretary of State for Health as the "Dirty Dozen" (Bevan 2010a: 38).

The politically driven expansion of the star ratings overloaded the CHI (Salter 2007: 270). It was unable to visit all trusts, and clinical governance implementation could not be reviewed effectively because it was only possible to focus on the less important elements of the process that could easily be scored (Bevan 2008: 90). The CHI also faced a variety of other challenges including the need to invent an inspection methodology from scratch, the difficulties of measuring quality, inconsistencies between review teams, and trusts that complained about having to provide data and the way it was interpreted (Day and Klein 2004: 1-4).

In 2006 the star ratings system was replaced by an Annual Health Check from the Healthcare Commission (which replaced the CHI in 2004). The Annual Health Check added resource use to the inspection of quality and clinical governance implementation. Providers received a performance rating against national targets, and there was periodic inspection to ensure the accuracy of declarations (Haxby, Hunter et al. 2010: 5). The new approach, involving a light touch and 'smart information', saved the need for a comprehensive programme of visits (Bevan 2008: 85). But it was unsafe. The lack of visits opened an audit hole that restricted the regulator's capacity to identify gaming practices with data (Bevan and Hood 2006a: 421). A "tick box culture" emerged (McKee 2013: 1), and unsafe hospitals went unidentified.

The institutionalisation of quality and safety improvement

Alongside the promotion of best practice and quality regulation clinical governance also sought to improve safety through quality improvement projects and the reporting and analysis of safety incidents. Quality improvement often drew upon industrial improvement methodologies with varying degrees of centralised support and coordination.

The Modernisation Agency (MA) and the National Patient Safety Agency (NPSA) were initially central to safety. The Modernisation Agency (MA) was tasked with assisting the implementation of clinical governance, improving infrastructure, and supporting leadership, workforce development, and collaborative projects for implementing best practices (NHS Modernisation Board 2002, MA 2009). It sought to involve all NHS staff in building "long-term capacity, capability, and networks for continuous improvement" (NHS Modernisation Board 2002: 4). By the time of its incorporation into the NHS Institute for Innovation and Improvement (NHS III) during 2006 to 2007 the MA had developed a comprehensive set of programmes for redesigning clinical systems. At any one time there were thousands of projects in place. The core programmes involved booking systems, critical care, cancer services, coronary heart disease, emergency services, and other services with high demand and long waiting times. The goals were faster delivery, and improved patient experience, clinical processes, and outcomes. There were also programmes to tackle key performance issues in day surgery, diagnosis and treatment, operating theatres, preoperative assessment, and endoscopy (MA 2009). During 2002 to 2008 a small number of trusts were supported to "transcend current standards and expectations" by participating in the US Institute for Healthcare Improvement's Pursuing Perfection programme (NHS III 2013a).

The NPSA was created to provide a central repository for learning from multiple sources of information and to produce solutions for reducing harmful errors (Department of Health 2001: 4). Its 'Seven Steps to Patient Safety' advocated the need for a safety culture, support for staff, integrated risk management, reporting, patient involvement, learning and sharing safety lessons, and implementing solutions (NPSA 2004a: 1). The NPSA's core work was implementing the National Reporting and Learning System (NRLS), which encouraged clinicians to report risks

and harms so managers could investigate causes, and identify preventive possibilities (Waring 2007).

The number of incident reports received by the NRLS increased steadily from 2003 through to mid-2014 (Thorlby and Maybin 2010: 27, Illingworth 2015). In the second quarter of 2014 about 400,000 incidents were reported across all areas of healthcare (Illingworth 2015). But while the continuous increase in reporting indicated an improving safety culture, reporting until 2009 at least was dominated by patient accidents such as falls, and there was significant underreporting of many harms, including medication incidents, serious incidents, and anything involving doctors (Thorlby and Maybin 2010: 27,32). In 2013/14 93.5% of reports involved no harm or low harm. The outcome was a lack of actionable learning (Department of Health 2006: 6). In 2009 only about a third of staff felt that they were informed about incidents in their trust, and provided with feedback about changes for improving safety (Thorlby and Maybin 2010: 31).

The NPSA also coordinated national safety campaigns. The first, Cleanyourhands, began under central coordination in 2005 before moving to a localised model in late 2010 (NPSA 2011a). An evaluation of the pilot suggested that full implementation could produce annual savings of about £140 million pounds and 450 lives (NPSA 2004b). The campaign evaluation to June 2008 found that the combined procurement of alcohol hand rub and soap almost tripled; MRSA infections fell by about half; *C difficile* infections declined; and MSSA infections rose slightly (possibly from community sources) (Stone, Fuller et al. 2012: 3-5).

By 2006 there appeared to be a considerable volume of safety improvement activity in the NHS. But according to the *Safety First* review (Department of Health 2006: 6-7), while actions had driven significant awareness, and some progress, there had been insufficient real improvements 'on the ground', and an inspirational and motivational environment had not been created. Moreover safety was often secondary to waiting times and financial balance. The planned fix, involving the NPSA in collaboration with the NHS Institute for Improvement and Innovation, and The Health Foundation, was the 2008-2010 Patient Safety First Campaign, which sought "to make patient safety a top priority and to create a mindset of 'no avoidable death and no avoidable harm'" (NPSA 2011b: 5). As a programme of culture change it targeted the behaviour of frontline staff and senior managers, and following social movement theory

improvement was to be locally owned and motivated by a campaign style of information provision. This broke the tradition of top down directives and monitoring to measure compliance. There was one compulsory intervention, of engaging leaders in safety culture improvement, and a requirement to implement one or more of four other clinical interventions (NPSA 2011b: 4-6).

The cost of the Patient Safety First campaign was just over £3 million (not including design). It sought to reach as many people as possible with the least resource possible. Ninety-six percent of acute hospitals enrolled voluntarily. There was no independent evaluation of outcomes, but an official review found that many processes improved, and qualitative feedback "suggests that NHS organisations gained value." The campaign "was cited as one of several influential initiatives that were thought to have created the space for a shift in organisational patient safety culture" (NPSA 2011b: 5,7,11,61).

Launched prior to the Patient Safety First campaign, the Safer Patient's Initiative (SPI) of 2004-2008 was the first programme to comprehensively address patient safety in England by implementing several clinical and cultural interventions at the same time. Funded by an independent charity, The Health Foundation, and supported by the US Institute for Healthcare Improvement, the SPI involved two phases of top-down (it engaged senior management) and bottom-up (it engaged clinicians and front line managers) improvement. In Phase 1 four hospitals received £750,000 each, and sought to reduce adverse events by half (The Health Foundation 2011a: xiii, xiv). In Phase 2 twenty hospitals received £270,000 each, and sought a 30% reduction in adverse events (The Health Foundation 2011b: iv, xiv). There were generic interventions around safety culture, leadership, risk identification and control, and safe practice; and specific interventions for deteriorating patients, medication errors, communication, and infection control (The Health Foundation 2011a: 3).

An independent evaluation of the SPI showed significant improvements on some measures but no better than control sites (The Health Foundation 2011b: xv). Three factors may explain this outcome. First, implementation was problematic. Managers were enthusiastic but most initiatives did not penetrate hospital wards (The Health Foundation 2011a: v, xiv). Second, investment, at only 0.01% to 0.1% of hospital budgets, was possibly insufficient (The Health

Foundation 2011a: xiv-xv). Third, a "rising tide" of safety in the NHS meant that many measures of evidence based care were good at baseline, with little room for improvement (The Health Foundation 2011b: iv,v,xv).

After completion, the SPI influenced the NHS in two ways. First, a Safer Patients Network was created for developing, testing, and exporting quality and safety improvement (The Health Foundation 2015). Second, the NHS Institute for Innovation and Improvement was inspired to develop a Leading Improvement in Patient Safety programme for implementation in other hospitals (Butterworth, Jones et al. 2011: 246). The modules provided training in quality improvement, leadership, clinician engagement, human factors, communication, and teamwork (Haxby, Hunter et al. 2010: 7).

Improvement troubles

By 2008 the NHS had an institutional apparatus for improving safety. In some regards policy was effective. As the SPI evaluation identified some clinical measures were improving across the NHS and others showed little room for improvement. However in four other ways safety were still very challenging. First, staff were generally difficult to engage in safety improvement (Vincent, Aylin et al. 2008: 1206-1207). While this problem was acknowledged and there were efforts to balance top down and bottom up improvement, in practice top down dominated. Second, the reporting system was not providing the necessary intelligence. Third, the cost of improvement was substantial and investment often seemed to be insufficient to achieve the dramatic improvements hoped for. Forth, with few reliable indices and solid measurements of safety outcomes, long term trends were impossible to know (Vincent, Aylin et al. 2008).

Clinical governance implementation was similarly challenging. A crucial between-hospital difference was cooperative leadership. When this was missing implementation could fail. Many doctors felt that their workload was increasing without compensating support from government (Smith 2001). Resources that could have supported clinical governance locally were often shifted to meet national directive and targets (Som 2009). Doctors faced increasing accountability, but there was less emphasis on personal care, and less professional autonomy (Edwards, Kornacki et al. 2002). There was also a growth of bureaucracy which required

clinicians to complete a growing number of forms to monitor and evaluate their decisions. The change agenda was typically dominated by managerial edict and poorly communicated by senior hospital managers, which sowed confusion and disagreement, and made it difficult to develop consistent approaches to clinical care (Som 2009).

The new processes of compliance were also problematic because they distorted clinical work. Centrally determined and generic performance indicators led managers to view clinical work as a series of silos composed of the various conceptual categories of clinical governance. These silos were viewed as an abstraction, and subsequent planning and organisation failed to account for the clinical, organisational, and interpersonal processes of meeting patients' needs. Clinical governance was divorced from the practical concerns of clinical staff (Degeling, Maxwell et al. 2004).

Clinical governance as a whole often created conflict between managers and doctors over accountability, guidelines, targets, and finances (Edwards and Marshall 2003). Clinical staff resented the lack of consultation, they had minimal input into service redesign, and little ownership of the change process overall (Som 2009). The subsequent crisis in trust led doctors to reject improvement and default to traditional patterns of work (Degeling, Maxwell et al. 2003). In disengaging from quality they treated it with anything from apathy to outright resistance (Davies, Powell et al. 2007a).

The *Next Stage Review*

The *Next Stage Review* (Department of Health 2008) was notably unique for including the views of 2000 frontline staff. Three US organisations (RAND Health, the Joint Commission International, and the Institute for Healthcare Improvement) were also commissioned to report on quality in the NHS.

The review found that there was better use of technology and staffing, more immediate treatment, and more choice for patients. But while volumes had increased the focus needed to shift to improvements in the provision of care that was "clinically effective, personal, and safe" (Department of Health 2008: 8-9). There were also significant variations in quality, staff were

tired of top-down imposed change, and information for improving quality was ambiguous and difficult to access.

The American reports were all highly critical of how clinicians, doctors especially, were not engaged in improvement (Ham 2010b). Six other themes were evident. First, management were driven by a culture of fear, a shame and blame attitude was pervasive, and "virtually everyone" was looking up to satisfy an inspector or manager. Second, and despite pervasive top-down control, inspections by the regulator were light handed and ineffectual. Few trusts were visited each year, and when they were findings often differed from self-evaluations. Third, the regulator was failing to adopt an educational role to assist improvement. Fourth, data provided to the Department of Health was of poor quality and had little clinical relevance. Useful data on procedure specific mortality, patient outcomes, and patient experience was not routinely collected. Fifth, patient needs were sidelined while managerial directives gained attention. Sixth, continuous change and restructuring was creating chaos, institutional knowledge was being lost, and staff were generally disengaged from change processes (Jarman 2010). The chief executive of the NHS described these reports as "caricatures" (Jarman 2012) when they finally became public two years after completion through a request under the Freedom of Information Act (Ham 2010b).

The recommendations of the *Next Stage* were to reduce top down control, and encourage greater initiative and leadership by clinicians in planning and delivering services. There was to be more freedom, accountability, and empowerment, and a new professionalism and transparency would make quality improvement the real concern of clinical teams. A national quality framework with internationally comparable measures would be reported annually and trusts would publish quality accounts. A new regulator, the Care Quality Commission, would make regulation intelligent and tough with robust minimum standards (Department of Health 2008).

Crisis stage one – tragedy

From 2005 to 2008 the Standardised Mortality Ratio at Mid Staffordshire NHS Foundation Trust was unusually high across a range of conditions (Healthcare Commission 2009: 4). During this time numerous patients and members of the public tried to bring the trust to official attention (Cure the NHS 2015). While the trust was aware that its mortality outcomes were seemingly worse than average, it sought to explain them as an anomaly caused by inaccuracies in the recording and the analysis of data. The hospital board claimed its top priority was patient safety (Healthcare Commission 2009: 3, 9).

It was not until 2008 that the Healthcare Commission finally conducted a thorough investigation of Mid Staffordshire. The investigation concluded that care was "appalling." There were "deficiencies at virtually every stage of the pathway of emergency care." There was an atmosphere of chaos, shortages of staff, equipment, and expertise, and deficiencies in communication, teamwork, and learning. Care "looked good on paper", which allowed the hospital to escape detection for years, but there was a lack of effective systems of clinical governance, audit, and outcomes monitoring. The HCC explained these failures as due to an excessive emphasis on performance targets and financial criteria in order to achieve and maintain Foundation Trust status (Healthcare Commission 2009: 8-9, 134-135).

The findings of the Healthcare Commission investigation into Mid Staffordshire were confirmed by an independent inquiry (Francis 2010). The crisis of confidence in the NHS that followed was sufficient to stimulate a further series of investigations into the system of governance (Francis 2013), other hospitals with high mortality (Keogh 2013), NHS bureaucracy and data management (The NHS Confederation 2013), complaints management (Clwyd and Hart 2013), and the role of healthcare assistants (who spend more time at the bedside than nurses) in the provision of care (Cavendish 2013).

The public inquiry into governance was briefed to understand how poor care flourished in the NHS when "a plethora of agencies, scrutiny groups, commissioners, regulators and professional bodies" should have acted (Francis 2013: 3-4). Their inaction was explained by multiple factors. The culture was interested in the system's business, not patients; there was a preference for

positive information, standards and measures lacked patient focus; poor standards and risk were tolerated; agencies did not communicate and share concerns; it was assumed that someone else would monitor and intervene; professional cultures were not built; and corporate memory was lost from repeated restructuring (Francis 2013: 4). The recommendations suggested that fundamental cultural change rather than systemic reform should be a first priority (Francis 2013: 83).

The Keogh review investigated clinical effectiveness, patient experience, and safety in fourteen trusts with high mortality (Keogh 2013: 3). Each was a further potentially hidden disaster. Previously undisclosed problems uncovered in all of them included: a lack of genuine listening to patients and staff and engaging them in improvement; a limited capacity to use data to drive quality, made worse by complexities in the system as a whole; difficulties with using and interpreting aggregate measures of mortality; recruitment difficulties creating excessive reliance upon locums and agency staff; insufficient support for front line clinicians, especially juniors; and a tendency for the transparency agenda to support blame. Keogh recommended that inspections should not be triggered by mortality data alone. Clinical effectiveness, patient experience, and safety all needed consideration (Keogh 2013: 4-6). “Intensive visits to hospitals by experienced, multi-disciplinary teams; talking in-depth to patients and staff … should inform … all hospital reviews and inspections” (Keogh 2013: 34).

The Mid Staffordshire tragedy has provided the NHS with an opportunity to reprioritise safety. Two critically important lessons are on offer. First, regulation must improve. As Carl Macrae (2014) has argued, organisations and regulators must learn to accurately interpret the early warnings of disaster. Second, argued by a National Advisory Group (2013: 7,11), while a new approach to regulation is needed, it cannot be a singular answer. “Culture will trump rules, standards and control strategies every single time … a vastly safer NHS will depend far more on major cultural change.” But even as culture is important, and safety must become the first priority for all leaders and staff, staffing must also be appropriate to the needs of safety (National Advisory Group 2013: 14-35). Considering the latter fiscal reality Sidney Dekker and Thomas Hugh (2014: 358) have argued that a national conversation is necessary about the risk of failure, which is an “inevitable byproduct of pursuing success in a resource-constrained, goal-conflicted world.”

The Health and Social Care Act

The strategy of the current Conservative government, outlined in the white paper *Equity and Excellence* (Department of Health 2010), built on the ideal in the *Next Stage Review* of increasing quality by empowering clinical teams from the bottom up. There was to be a reduction in top down control, less process measurement, and more emphasis on outcomes. Improvement was to be motivated by increasing the transparency of hospitals to the public. This emphasis on market mechanisms was supported by radical structural and fiscal changes. Control over hospital services purchasing was to be transferred from Strategic Health Authorities to GP commissioners, and management costs were to be cut by more than 45%. While increased spending in real terms was promised each year, £20 Billion in savings (against an annual budget of just over £100 Billion (Klein 2013: 854)) was sought during 2010-2015 through increased efficiency and administrative cut-backs, with savings reinvested in frontline care.

Equity and Excellence was legislated as the Health and Social Care Act 2012. In the reorganisation that followed NHS England and NHS Improving Quality were created in 2013 to support the implementation of improvement. A number of new programmes were also developed, including the Harm Free Care programme to reduce harm from pressure ulcers, falls, urinary infection, and venous thromboembolism. Data from this programme currently assists local improvement, and provides a trackable 'safety thermometer' measuring the proportion of patients free of four common harms. A similar system is planned for medication harm (Harmfreecare 2015). The Sign up to Safety programme was launched in 2014 with a three year objective of reducing avoidable harm by 50%, and saving 6,000 lives (NHS England 2015a). There are plans to recruit 5,000 safety fellows (NHS England 2015b) and a Patient Safety Collaborative Programme was announced in 2014 to tackle the leading causes of harm, and become the most comprehensive programme of its kind in the world (NHS Improving Quality 2014).

While change under the Health and Social Care Act supported improvement programmes, it also presented significant organisational and fiscal risks. It was at least the 15th identifiable major structural change since 1980 (Walshe 2010), and the most complex attempted in the

history of the NHS (Klein 2013: 849). As another episode in the programme of seemingly endless reorganisation it was precisely what some previous reports had identified as problematic. The extent of reorganisation risked distraction from the need for rapid efficiency savings (Nuffield Trust 2010), and presented substantial opportunity costs for the continuity of improvement (Dixon and Ham 2010: 9). While managerial expertise would be required for implementation, managerial capacity was to be reduced (Nuffield Trust 2010: 5). Evidence from the wider governmental sector rejected these ambitions. A study by the National Audit Office of 90 reorganisations showed that benefits were often unclear, processes were often poorly managed, and the impact on performance was often adverse (in Walshe 2010).

The evidence in support of marketisation was similarly negative. The leading British health economist Peter Smith has argued that "in no sector of the economy can the departure from the neoclassical economist's assumptions underlying a competitive market be more pronounced than in the field of healthcare" (quoted in Gilbert, Clarke et al. 2014: 372). A review of literature on market reform in the NHS found increased transaction costs and failure to deliver improvement (Brereton and Vasoodaven 2010). While public behaviour was expected to drive the market, and thus improvement, people had very little interest in choosing healthcare providers (Roland and Rosen 2011: 1365).

Crisis stage two – austerity

The Health and Social Care Act was opposed by the British Medical Association, the Royal Colleges of Nurses and Midwives, and the Chartered Physiotherapists. The NHS Confederation, and the Royal Colleges of Physicians and Surgeons sought to achieve some influence by working with it. The *British Medical Journal* described the structural changes and calls for "unprecedented savings" as a cause of "deep distress" amongst staff who had no confidence in the plans they were expected to implement (McLellan, Middleton et al. 2012: 1). In 2013 an additional £30 Billion savings target for 2015-2021 was added to the £20 Billion target of 2010-2015 (Appleby, Galea et al. 2014: 40).

A number of measures suggest the impact of the Health and Social Care Act. While currently available data is insufficient to determine if safety is improving overall (Vincent, Burnett et al.

2013), information about waiting times, staff affect, reporting, safety outcomes, senior management perception, and financial performance, all indicate the effects of reform.

Waiting times have implications for patient outcomes. In the quarter to December 2014 there was increased waiting in A&E (a 47% increase on the previous quarter and the worst since 2003/4); and increased waiting for inpatients (the worst since the target was introduced in 2010/11), outpatients (the worst since 2008), and cancer treatment (the worst since records began in 2008/9). Delays in transfers of care were the worst since 2010/11 (The King's Fund 2015).

The mood and the wellbeing of staff is a useful safety barometer. For the second consecutive quarter to December 2014 a survey of finance directors found that nearly half identified staff morale as one of their biggest concerns (The King's Fund 2015). During 2010-2014 the proportion of staff feeling unwell because of stress increased from 29% to 38% (Illingworth 2015). While the proportion of staff who felt that their trust acted on incident reports increased during 2009-2014, from 55% to 63%, there was also an increase in the number of staff who felt that those involved in incidents were punished, from 10% to 13% (Illingworth 2015: 4).

Some clinical indicators of safety have improved. MRSA and *C difficile* infections declined during 2007 to 2014, but MSSA and *E Coli* stayed around the same. From July 2012 to February 2015 the proportion of patients free of four common harms (pressure ulcers, falls, urinary infection, and venous thromboembolism) increased, from 91% to 93.7%. However there was considerable variation in rates between trusts, from one in a hundred, to one in six (Illingworth 2015: 4-6).

The views of senior management on quality suggest that while there has been progress on productivity, maintaining safety is increasingly difficult. According to 26 chief executives, finance directors, medical directors, and productivity leads, staff at all levels were motivated, innovative, increasingly united, and effective in their efforts to implement cost-cutting solutions that did not compromise patient care. These gains were achieved despite the managerial and coordination vacuum created by the abolition of Primary Care Trusts and Strategic Health Authorities. However there was growing conflict between the need for cost

savings, and the quality recommendations of the reports that followed Mid Staffordshire (Appleby, Galea et al. 2014: 38-56).

The demand for hospitals to meet ambitious financial goals without sacrificing quality and safety is a potential contradiction in the current reforms. According to monitoring by the King's Fund 42% of trusts expect to be in deficit by the end of the 2015 financial year (The King's Fund 2015). Even organisations with a history of good performance were struggling. There is "every prospect that problems that have so far been found in a small number of providers will become much more common" (Appleby, Galea et al. 2014: 73). As the fiscal squeeze tightens in 2015/16, it is increasingly unlikely that a crisis of overspending, or reduced quality, or both, can be avoided. Without new investment, "on its current trajectory, the health and social care system in England is rapidly heading towards a major crisis" (Appleby, Galea et al. 2014: 67-68).

A financial crisis in the NHS would risk patient safety. Broadly, this could manifest in either of two ways. First, some trusts could fall below acceptable standards. While clinical indicators continue to improve on average, there is huge variation between the best and the worst providers (Illingworth 2015: 4-5). During its 2014 inspections the Care Quality Commission found widespread variations in overall safety. Of 38 trusts visited (mostly because they were identified as higher risk), four out of five were rated 'inadequate' or 'requires improvement' for safety. "Too many providers have not got to grips with the basics of safety" (Care Quality Commission 2014: 4-5). Historically this finding is not unique, but it suggests that the lessons of Mid Staffordshire have not been broadly integrated across the NHS. The second possibility is a generalised decline in safety. The growing conflict between productivity and safety, morale problems, stress, blame culture, and the generalised exhaustion of improvement indicate the harms of austerity and reorganisation. Whilst gains in targeted clinical indicators suggest otherwise, these are a fraction of the risks that patients are exposed to. Moreover, financial and cultural problems must not be trivialised because of their potential to very badly impact safety outcomes.

Overview

For more than thirty years after its creation in 1948 the medical profession controlled the NHS and costs became increasingly problematic for government. Medical audit, administrative reorganisation, and cash limits did not significantly improve either costs or quality. The general management reforms of the 1980s emphasised costs but did little for quality. The internal market of the 1990s further expanded managerialism, and compulsory medical auditing, quality assurance and evidence-based medicine were introduced. But audit was haphazard and there was little promotion of evidence-based medicine. Meanwhile an aggressive emphasis on costs was detrimental to quality and drove disharmony between doctors and managers.

Clinical governance was introduced in England in the late 1990s as a comprehensive programme of modernisation to end the dominance of costs and make quality central to the NHS. There was an ongoing commitment to increased funding that lasted about a decade. There was greater support for evidence-based medicine and clinician leadership in the improvement of local services. A monitoring programme reviewed the implementation of clinical governance and hospital performance was measured against specified targets.

Clinical governance and associated changes in England have been both successful and problematic. Successes included reduced waiting and the implementation of improvements that created a 'rising tide' of safety in some aspects of care. But alongside these gains cases of poor quality and safety were not eliminated, and there was ongoing tension between occupational groups which meant that the gains achieved were less than what was possible.

There are many reasons that English healthcare did not produce better outcomes on average and eliminate cases of unsafe care. Primarily, there was a culture of fear and blame driven by top down directives and economic objectives. There was a lack of cooperative leadership, managers dominated processes, and the clash between medical and managerial cultures disempowered clinicians and turned them against improvement. There were also problems with collecting, accessing, and using data; ineffective inspections; and continuous restructuring disrupted cohesion. The worst manifestation of these failures was the tragedy at Mid

Staffordshire, where the financial priorities of the system eclipsed safety, and the regulator took years to identify and correct the problem.

While many of the failings of the NHS were identified in the *Next Stage Review,* the repression of American reports on quality demonstrated a will to denial at the ministerial level. The many inquiries that followed Mid Staffordshire provided the NHS with a further opportunity to learn, and there were expressions of renewed commitment to empowering clinical teams. The forces of austerity now challenge this resolve. In 2012 the NHS began the largest reorganisation in its history, managerial staff are to be cut by 45%, and £50 billion in savings has been targeted for the period 2010-2021.

The current reforms in English healthcare are placing severe financial pressure on providers. Implementation of the latest improvement programmes, the most ambitious yet, could be difficult when hospitals are turning in their worst performance against throughput targets in several years. Moreover, observations by the Care Quality Commission, that widespread and unacceptable variations in safety remain, suggest the lessons of Mid Staffordshire have not been widely implemented. While the NHS has created an impressive organisational apparatus for improving quality and safety, the work of these organisations has been undermined by constant reform, an ongoing obsession with short-term finances, and a failure to support clinicians and gain their buy-in to drive local improvements. These failures mean that the goal of clinical governance, to make quality central to the NHS, is yet to be fully realised.

New Zealand

The legislative and institutional framework of the NZ health system, based around tax-financed health care with free hospital access for all citizens, was created between 1938 and 1941 (Fougere 1993). Not long after, and amplified by new patterns of disease and the post-war baby boom, public hospitals faced an increasing demand for new and costly services and technology. From around 1950 government was both unwilling and unable to satisfy the demand for

funding, and the system was unable to keep pace with the public need for hospital access and new treatments. The outcome was long waiting lists for non-urgent treatments, and, from the early 1970s, a growing political interest in reform and performance improvement. Reform was however politically complicated because of multiple challenges including a parochial and entrenched healthcare administration and hospital boards, inequitable funding systems, the failure of preventive medicine, and poor linkages between primary care and hospitals. There were also risks of antagonising the public, the medical profession, and other interest groups in the health sector (Gauld 2009a).

Foundations and deviations

Managerialism

Following the traditional model, leadership in NZ hospitals was initially differentiated into separate medical, nursing, and administrative hierarchies (Malcolm, Wright et al. 2002). The first major reform started in 1983, when the implementation of Area Health Boards (AHB) began on a limited basis (Gauld 2009a). A population based funding formula was introduced and costs were controlled, both as a share of government spending, and GDP. This success was however political challenging when providers blamed government for their inability to meet the needs of the public (Fougere 2001).

Full implementation of the AHB system occurred through the State Sector Act of 1988, which introduced general managers into the executive and service levels of hospital management. Clinician involvement in management was promoted through the Health Services Development Management Unit (Malcolm, Wright et al. 2002). By 1989 the AHBs combined notions of "local democracy, service integration and planning ... with an agenda of management, accountability and efficiency" (Gauld 2009a: 74). The managerialist and regionalised AHBs (Davis, Lay-Yee et al. 2007) copied developments in the NHS, where general management was intended to improve efficiency. Managers introduced comprehensive management information systems and provider performance was increased monitoring by central government (Fougere 1993).

Market experimentation

In 1991 during an acute fiscal crisis an incoming right wing administration announced plans to reform the AHB system (Fougere 2001). Subsequently in 1993, in deference to market oriented theories of government, a purchaser-provider split was introduced into healthcare and a degree of marketisation was achieved that has not been attained in any other country where state provision dominates (Gauld 2009a). In the new competitive system public hospital corporations knows as Crown Health Enterprises (CHEs) provided services for four government-funded Regional Health Authorities (RHAs) (Davis, Lay-Yee et al. 2007). The RHAs purchased these services through a competitive contracting process that held the CHEs 'at arm's length.' The intention was to reduce costs, with some estimates suggesting up to 30% more services for the same expenditure (Fougere 2001). Consistent with a new attitude to healthcare management, the Health Services Development Management Unit was disbanded, and clinician involvement in management declined (Malcolm, Wright et al. 2002). Chief executives were appointed from the business sector despite their negligible understanding of health (Malcolm, Wright et al. 2002).

The performance of this strongly market oriented system (Davis, Lay-Yee et al. 2007) was a lot worse than expected. Waiting lists remained, ad hoc expenditure grew, and hospitals began to request budgetary bailouts. There were also fights between the RHAs and providers, and significant public discontent (Fougere 2001). Collaboration between the CHEs diminished because of concerns over commercial sensitivity. Clinical leadership was also sidelined, and there was a clash of cultures between managers, who fought to improve efficiency, and clinicians, who emphasised patient outcomes (Malcolm, Wright et al. 2002).

The failings of the RHAs led to their amalgamation into a single Health Funding Authority in 1996. The CHEs were renamed Hospital and Health Services. The intention was to give greater control to government (Fougere 2001), and increase cooperation within the sector (Gauld 2009a). The contracting process remained, but competitive tendering was eliminated (Gauld 2009a). While the previous purchaser-provider split and the emphasis on efficiency was retained, such that the new system was of modified market orientation, there was a more explicit emphasis upon quality (Davis, Lay-Yee et al. 2007). While this was successful in part,

there was still significant conflict between clinicians, and the more commercially driven boards. The funding arrangements of both systems failed to incentivise managers to maximise resource use, and encourage clinician involvement in managing clinical activity. When clinicians did adopt managerial duties they were perceived by their colleagues as taking a soft line (Malcolm, Wright et al. 2002).

The District Health Boards

The health reforms of the 1990s diminished public and professional confidence in the NZ health system and became central to the election of 1999 (Gauld 2009a). After the election a new centre-left government eliminated competition (Gauld 2009a) through a system of regionalised District Health Boards (DHBs) directly funded by government (Davis, Lay-Yee et al. 2007). The role of the DHBs under the National Health Strategy was "improved health, reduced inequalities and higher quality care" (Minister of Health 2000: iii). A National Strategy for Quality Improvement was planned to provide services that were people-cantered, safe, and subject to continuous improvement (Minister of Health 2003: 13). The Minister of Health began to promote clinical governance in her annual 'Letter of Expectations' to the DHBs (Powell 2013a: 5).

The National Strategy for Quality Improvement sought to encourage widespread adoption of the culture of quality. No additional regulatory or legislative requirements were imposed beyond the existing need to develop, use, and monitor nationally consistent standards and quality assurance programmes (Minister of Health 2003: ix). These included systems of accreditation, the use of audit, a quality assurance advisory committee, a mortality review committee, a complaints investigation commissioner, and an emergent system for reporting medical errors. New areas of focus included the need for a supportive culture and infrastructure, effective leadership and teamwork, and the right balance between professional autonomy and systemic control. Quality improvement was described cautiously because international evidence was unclear about the most effective approach, funds would need to be

diverted to support it, and cost benefits could not be expected immediately. “Decisions have to be balanced within the resources that are available” (Minister of Health 2003: 6).

Clinical governance and quality

The early implementation of quality improvement has been reported on by the Clinical Leaders Association of NZ (CLANZ) (Wright, Malcolm et al. 2001, Malcolm, Wright et al. 2002). After researching the views of senior hospital management the CLANZ were optimistic about the kinds of changes that were in progress. They acknowledged however that clinicians may have a different perspective. Managerialism and new forms of collective professional accountability were argued to have swept aside tribalism and encouraged quality and clinical leadership (Malcolm, Wright et al. 2002). Clinical governance, “a process largely driven by clinical values and aspirations, with clinical leadership playing a strong part” (Malcolm, Wright et al. 2002: 33) emerged from the combination of both (Wright, Malcolm et al. 2001). Support for clinical governance was provided by the National Health Strategy of 2000, which required an unambiguous commitment to better health outcomes. The new quality culture emphasised collaboration, and management and boards sought to devolve quality and cost decisions to clinical groupings (Malcolm, Wright et al. 2002). There was a reduction in the managerial control of finances that had characterised the market-driven system of the 1990s (Wright, Malcolm et al. 2001).

Clinical governance was identified by the CLANZ as different from existing quality activities because it involved integrating quality into an organisation wide strategy and overcoming the problem of multiple poorly coordinated actions. However clinical governance in NZ was notably different from the UK model which was driven by government, implemented ‘top-down’ through a ten year strategic plan, supported by numerous interlocking organisations, and comprehensively funded and evaluated. The central role of managers in the UK reduced the power of clinicians, who were only marginally accountable for quality and cost, and generated adversarial relationships. In NZ on the other hand clinical governance was driven primarily by clinicians, who were also responsible for the financial governance of their work. Clinicians carried greater accountability for quality and cost, and they shared it with managers (Wright, Malcolm et al. 2001). The outcome was a convergence of the two cultures, a growing sense of

partnership which meant that quality was not seen in strictly business terms, and an absence of conflict (Malcolm, Wright et al. 2002).

There were however four significant challenges for clinical governance in NZ. First, it developed independently in the different DHBs, with little information sharing about how to structure, organise and manage quality processes, and little support from government (Malcolm, Wright et al. 2002). Second, there were constraints of limited resources, limited time for clinician participation, a shortage of leadership skills, and the effects of past conflict which created mistrust between clinicians and managers. A particular problem was the disempowerment of clinical staff through funding shortages (Wright, Malcolm et al. 2001). Third, there was a lack of evaluation which was a characteristic problem of the NZ Health culture. Fourth, nurses were potentially becoming subservient to managerial and medical domination (Malcolm, Wright et al. 2002).

While the evidence presented by the CLANZ of an emergent clinical leadership culture in the DHBs had positive implications for quality and safety, issues with planning, resourcing, evaluating, and inter-professional domination did not. The seriousness of these challenges were reinforced by Robin Gauld's (2009a) analysis of DHB structure and performance, quality and safety, use of information technology, and workforce development to around 2008. A notable concern for Gauld was the failure of the DHBs to build quality focused services. While quality was central to the NZ Health Strategy it was not supported by central government, which "shunned responsibility for quality and safety" (Gauld 2009a: 226). Quality was not at the centre of all policy and service work, it had no national infrastructure, and the DHBs were not required to provide evidence of implementing best practice. While a Quality Improvement Committee was created "belatedly" in 2007, they had limited scope for influencing government policy and provider activities. Similarly the quarterly DHB Hospital Benchmark Information reports set performance targets that had "implications for quality," but they were not designed to monitor clinical quality performance or build a culture of quality (Gauld 2009a: 226-7).

There was a similar lack of government involvement in workforce planning and development, leading to shortages of doctors and nurses, and problems with pay negotiations. While nursing pay eventually increased, DHBs were often unable to meet medical demands for more pay,

with subsequent strikes by doctors and damage to organisational cultures. As Gauld (2009a: 229) argued, “health professionals will always struggle to perform at the highest levels if they feel undervalued and overworked.” Information and communications technology (ICT) was similarly neglected. The DHBs introduced systems with flawed architecture, they did not easily interconnect, data collection and transfer was problematic, and there were issues with security and privacy. While some DHBs announced a joint plan in late 2008 for an “integrated, person centred information management system,” government seemed “content to act as a mediator rather than a leader in ICT debates, policy and systems development” (Gauld 2009a: 230).

Unsustainability and strategic refinement

Although the DHBs were expected to implement clinical leadership it was not well supported by the Ministry of Health until the *Time for Quality* (2008) agreement provided for the creation of formal clinical leadership positons within hospitals (Powell 2013a). Policy support for clinical leadership was further advanced shortly after the general election of 2008 through a new centre-right government also concerned with issues of costs, bureaucracy, and waiting lists. The latter were topical for the public as well, who worried about waiting times for emergencies, elective surgery, and cancer treatment (Ministerial Review Group 2009: 11). The new government was keen to “open the books on the true state of hospital waiting lists and the crisis in services” (Ministry of Health 2008: 5).

The cost issue was highlighted but not created by the global financial crisis. A very immediate problem in the context of a decline in government revenue was that the DHBs were running deficits of around $150 million for the 2008/09 year, and faced up to $636 million in unfunded capital requests (Ministerial Review Group 2009: 3). A more substantive long term difficulty was that spending on healthcare in NZ relative to the OECD was high as a proportion of GDP (10.3% versus an OECD average of 9.6%), but low on a per capita basis (US$2,983 versus an OECD average of US$3,233) (Gauld 2012: 110). The growth of spending on healthcare in NZ since 1995 had exceeded national income growth by 30%, compared to an OECD average of 18%. The system was approaching unsustainability (Ministerial Review Group 2009: 10).

A question of critical importance is whether or not quality and safety in NZ could survive an economic squeeze. A Treasury report (2005: 2) which found, with very limited data, that hospital efficiency *appeared* to have fallen by 2.6% during 2000-2004, implied at least some opportunity to improve. But a report to the incoming minister, which identified the average cost per hospital discharge in NZ as only US$4,900, compared to an OECD average of US$6,400 (Ministry of Health 2008: 2), demonstrated that NZ hospitals were already remarkably efficient. Nonetheless there were some areas across the system where efficiency was below international standards, including administrative costs, test results, and unnecessary visits to emergency departments (Gauld, Al-wahaibi et al. 2011: 204). But against these and other possible opportunities NZ's limited capacity to pay had created a substantial weakness in the foundations of quality and safety. Its reliance upon overseas trained doctors and nurses was the worst in the OECD (Ministerial Review Group 2009: 42). After years of failing to compete strongly in the international market for medical personnel the proportion of specialists per head of population in NZ in 2007 was the lowest in the OECD, with only 0.8 per 1000 against an average of 1.8 (Powell 2010). With international shortages in the healthcare workforce projected to worsen, NZ's capacity to compete on pay was likely to diminish (Ministerial Review Group 2009: 11-12).

The government's immediate plan post-election was to try to save costs by reducing bureaucracy and investigating efficiency opportunities (Ministry of Health 2008: 5). Over the long term funding increases were tied to the rate of inflation (Gauld 2012: 110). The opportunities for improved efficiency were explored in two reports that both highlighted concerns about the growing problem of clinical disengagement. The first, *In Good Hands,* published by a Ministerial Task Group on Clinical Leadership (2009), was directly concerned with the increasing disengagement between clinicians and managers in hospitals. Clinicians were withdrawing from managerial responsibilities because they felt unable to influence decisions about healthcare delivery. Managers were feeling unable to influence clinical decisions that impacted quality, safety, and costs. To counter these failings the Task Group recommend stronger steps to establish clinical leadership and governance in the health system (Ministerial Task Group on Clinical Leadership 2009). The Minister of Health supported this recommendation and announced implementation with immediate priority (Gauld, Horsburgh et al. 2011). Intended changes included the development of governance structures in the DHBs

that would ensure clinical-corporate partnership, the promotion of clinical leadership by CEOs and Boards, improved management of the patient journey, appropriately devolved decision making, and the identification and support of clinical leaders (Gauld, Horsburgh et al. 2011). An essential component of change was the explicit focus on *distributive* clinical leadership, which shifted the quality improvement focus from those in formal clinical leadership positions to require the involvement of all senior medical staff (Powell 2011). For many DHBs this shift in policy initiated their efforts to implement clinical governance (Gauld and Horsburgh 2012b: 70). In other words the better part of a decade had expired before one of the fundamental expectations of the DHBs began to become reality.

The second report was prepared by a Ministerial Review Group chaired by a private sector banker but otherwise dominated by clinicians (Gauld 2012: 111). The group was briefed to improve performance, quality, and capacity, and to move resources to support front-line care. A concern throughout was economic sustainability. While New Zealanders "like to consume health services like other OECD countries … we are less able to afford to." Funding increases were unsustainable and likely to "crowd out other social spending" (Ministerial Review Group 2009: 9-12).

The Group argued that productivity was the key to sustainability. It could be achieved by developing new models of care, strengthening clinical-managerial relations, improving quality and safety, and introducing structural changes for better investment, planning, provision, and performance (Ministerial Review Group 2009: 4-5). The new models of care were a system wide endeavour encompassing prevention and treatment in the home and community, and the work of primary, secondary, and tertiary providers. Culture change was needed to encourage cooperation and integrate care across boundaries. Achieving this outcome through better teamwork would improve the economic performance of the system, outcomes generally, and quality and safety in particular (Ministerial Review Group 2009: 10,13). The poor state of clinical-managerial relations described in the *In Good Hands* report (Ministerial Task Group on Clinical Leadership 2009) was identified as requiring the provision of credible evidence about the benefits of cooperation, incentives that rewarded clinicians for driving improvement, increased flexibility in return for added responsibilities, and support for developing leaders. An

identified risk was the “tick-box compliance” of titles and committees that lacked substance (Ministerial Review Group 2009: 19-21).

One of several structural changes planned was the creation of a National Health Board (NHB) that would monitor performance, and plan and fund national services, workforce development, information technology, and facilities (Ministerial Review Group 2009: 6). The NHB would also assist productivity by managing common back office services across the DHBs, and it would work with the DHBs to build clinical networks (Ministerial Review Group 2009: 15,44-45). There were also plans to strengthen the Pharmaceutical Management Agency (or Pharmac, the crown purchasing agent), and the National Health Committee, to better ensure the safety of new technologies and procedures (Ministerial Review Group 2009: 8).

Quality and safety was identified as particularly promising for productivity because of the opportunity for substantial savings that could be reinvested in healthcare. The potential reinvestment if all preventable harm was ended amounted to as much as $800 million, or about 20% of the cost of care in public institutions (Ministerial Review Group 2009: 22). In some cases initiatives such as the new models of care, which offered to save costs directly through productivity gains, could also improve safety by reducing fragmentation and poor handover between providers and within institutions (Ministerial Review Group 2009: 10-11). But safety would also need direct attention if performance was to be lifted in a constrained budgetary environment (Ministerial Review Group 2009: 22-23). This was to be achieved by creating an independent national quality agency from the existing Quality Improvement Committee. Its purpose would be to support clinicians through certified programmes, standards, and guidelines, by benchmarking and gathering data on what worked and why, and providing workshops and publishing reports on national quality indicators (Ministerial Review Group 2009: 26).

Robin Gauld’s (2012) analysis of the current reforms suggests that while these have largely been perceived as progressive by managers and professionals in the health sector, there are nonetheless some inherent weakness in these arrangements due to some new administrative complications, and the failure to tackle an existing weakness. The difficulty that was ignored was the sheer number of DHBs in NZ:

> For a small country of 4.3 million, 21 DHBs[4] and 80 PHOs[5] seemed excessive, with high transaction costs, considerable duplication of planning, purchasing and administrative activities and wide-ranging concerns about variation in size, efficiency and service access (Gauld 2012: 111).

Further administrative complications were added by the duplication of functions between organisations (such as the quality agency and the National Health Board, which both addressed quality and IT); and the National Health Board's brief to drive performance improvement by negotiating individually with each DHB. These double ups and the capacity for resistance from the DHBs meant that transaction costs within the system as a whole could remain problematic.

Contemporary challenges

Two surveys led by Robin Gauld in late 2010 (Gauld, Horsburgh et al. 2011) and mid-2012 (Gauld and Horsburgh 2012a, Gauld and Horsburgh 2015) measuring the 'Clinical Governance Development Index' (CGDI) of the DHBs offer some perspective on how intentions translated into reality. The first survey of consultants sought to establish the extent to which DHBs were "working to facilitate clinical leadership and partner with clinicians." Results included the findings that only 20% of consultants felt they had time to participate in clinical governance activities, 49% were unfamiliar with the concept, and 51% either felt that a partnership structure had not been established, or did not know either way. A CGDI score of 47% was calculated, with individual DHBs ranging from 38% to 55%. NZ, like the UK, was delivering a "mediocre performance" and "considerable effort is required" to implement robust clinical governance systems (Gauld, Horsburgh et al. 2011: 950-1).

The second survey expanded the sample from senior doctors to include hospital leadership, junior doctors, nurses, and allied health professionals. There were also site visits to DHBs for qualitative discussion, and an open ended question about clinical leadership in the DHB. The mean CGDI score was 57%, with individual DHBs ranging from 49% to 61%. Considerable progress appeared to have been made between 2010 (CGDI score 47%) and 2012 (CGDI score 57%). DHBs were performing especially well in making quality and safety a goal of: every clinical

[4] In 2012 the DHBs was reduced to 20.
[5] The PHOs, or Primary Health Organisations, support General Practitioner services.

initiative (90% agreed this was happening); and every resourcing and support initiative (83%). Other areas of high performance were: enabling strong clinical leadership and decision making (78%); and health professionals being highly involved in partnerships with management (71%). The area of worst performance was that only 36% of participants felt that health professionals were sufficiently supported to engage in clinical leadership (Gauld and Horsburgh 2012a: 24-37). Three themes from the qualitative discussions were revealing. First, there was a lack of cooperation and support between DHBs (Gauld and Horsburgh 2012a: 69-70). Second, access to training was variable. It often depended on the size and resourcing of the DHB, and while there were regional initiatives, these were strong in some cases and non-existent in others (Gauld and Horsburgh 2012a: 78-79). Third, it was difficult to engage senior doctors. There was a lack of time, poor support for those who did adopt clinical governance duties, and (according to staff with overseas experience), NZ doctors were very traditional in their prioritisation of clinical work over clinical leadership (Gauld and Horsburgh 2012a: 76-77).

Responses to the open ended question about clinical leadership in the DHB shed further light on why only 36% of participants felt there was support for clinical leadership. Ninety percent of the open-ended responses were negative, implying "limited, if any, progress … on clinical governance." Partnership was weak, relationships were strained, and managerial commitment frequently involved "lip service only." Across the range of comments five themes dominated. First, clinical managerial relations involved an "us and them" mentality with managers controlling decisions and resources. Second, some clinicians were unwilling to adopt clinical governance activities because they were too busy in the private sector, or felt that that clinical governance should not be a universal responsibility. Third, partnering across clinical occupational boundaries was difficult because of tensions driven by the traditional seniority of the medical profession. Fourth, there was a shortage of training for leadership and quality improvement, and fifth, a lack of time for implementation (Gauld and Horsburgh 2015).

Recent surveys by the Association of Salaried Medical Specialists (ASMS) have reinforced the sense of ongoing struggle. In 2013 only 37% of specialists felt they had time to participate in clinical leadership activities (Powell 2013b), and only 30% felt their DHB was genuinely committed to distributive clinical leadership (Powell 2014). The executive director of the ASMS

argued that a "resurgent managerialism" (Powell 2013a: 6) has seen some CEO's treat clinical leadership as a threat to their "right to manage" (Powell 2011: 3).

The ASMS has also traced the poor state of clinical governance implementation to a failure by government to invest in growing the specialist workforce. This has created a lack of senior doctors, who have insufficient time for non-clinical duties (Powell 2014). Specialist undersupply has become "the 'norm' for many public hospital departments" (ASMS 2014: 6), with immediate consequences for safety because senior medical staffing is well short of what is needed, and what the DHBs have agreed is necessary to enable safety (ASMS 2013: 9). The shortage also creates long term costs and service issues as hospitals attempt to plug staffing gaps with expensive locums, and increase their reliance upon international medical graduates. More international doctors brings increasing turnover, recruitment costs, a growing demand on the supervisory requirements of existing specialists, reduces the cohesion of services generally, and limits the capacity to develop clinical leadership, networks, and innovation (ASMS 2014: 6-9).

Safety in New Zealand hospitals

Hospital systems and culture

There are few published studies on safety culture and processes in NZ hospitals. Mary Seddon (2007) has reported on safety systems and culture in the DHBs. She noted that while some DHBs "understood what a safety culture was and demonstrated systems thinking," others did not and only made superficial use of the language of quality and safety (Seddon 2007: 5). A further group had not moved on from an individual blame culture, as was evident in the suggestion from senior management that systems could not prevent poor outcomes due to staff negligence. Seddon also noted that almost all DHBs had produced a "plethora of policies" for quality and safety, but in many cases these were having little or no effect because compliance was rarely audited. Some DHBs appeared to think that written policies were an end in themselves (Seddon 2007: 5-6).

The safety culture of the Counties Manukau (CMDHB) has been measured by Gillian Robb and Mary Seddon (2010). A useful context for interpreting the results is that the Clinical Governance Development Index of CMDHB was rated around the same time as 51%, or third equal amongst 21 DHBs in NZ for facilitating clinical leadership and partnership with clinicians (Gauld, Horsburgh et al. 2011). Robb and Seddon's (2010) findings on the safety culture of CMDHB found "room for improvement" relative to benchmark indicators from 622 US hospitals on all twelve dimensions of patient safety culture (Robb and Seddon 2010: 70). The differences across the twelve indicators were on average almost fourteen percentage points below the benchmark. Areas that were especially problematic included 'hospital management support for patient safety' (52% agreed or strongly agreed versus a benchmark of 70%); and 'overall perceptions of safety' (43% versus a benchmark of 64%).

The Health Quality and Safety Commission

The Health Quality and Safety Commission was established in 2010. As in independent agency it was intended to maintain professional confidence through its separation from the regulatory and performance monitoring functions of the health system. A Clinical Reference Group, which advised the Minister once a decision had been made to establish the Commission, "indicated that an annual 1 – 2% reduction in the rate of adverse events is achievable with good quality improvement techniques and training" (Ministry of Health 2010). The Commission has subsequently developed a range of projects involving medication safety, infection prevention and control, reducing harm from falls, adverse events, health quality evaluation, consumer engagement, and mortality review (Health Quality and Safety Commission 2015). The adverse event programme requires hospitals to report all serious (significant additional treatment required) and sentinel (major loss of function or death) events. The number of such reports received by the Commission increased from 182 in 2006/07 to 454 in 2013/14. The major categories of events reported in 2013/14 were falls (55%), clinical management (35%), and medication (7%) (Health Quality and Safety Commission 2014). These numbers indicate similar difficulties to comparable systems in other countries. A fraction of events are reported and the categories of harm do not represent the major risks of treatment. The Commission's annual reports and website emphasise that hospital staff are enthusiastic and willing to involve themselves in the many initiatives it is currently promoting.

Overview

The NZ public health system ran into difficulties with costs from around the 1950s, driving a search for efficiency through managerial reform in the 1980s, and market reform in the 1990s. The period of market experimentation was relatively brief, and in 2000 a regional and managerialist system of DHBs was established, with an emphasis on quality improvement through clinical governance.

While some early studies of the DHBs found a good level of cooperation between managers and clinicians, and improvements relative to the previous market based system, there were a lack of planning, resourcing, and evaluation, which continued throughout most of the 2000s. Attempts in NZ to follow the UK model of clinical governance were hamstrung by a lack of central support for quality, and it was apparent by the middle of the decade that economic pressures and other forces made clinical-managerial cooperation problematic in NZ healthcare. Clinicians were not leading improvement as expected and managers were not supporting it.

From around 2008 two agendas emerged to address different underlying problems, while holding the potential to both support or contradict one another. One addressed economic sustainability, by advancing cost reduction through tying funding increases to the rate of inflation, and the other, also intended to deliver economic gains, sought to improve systemic efficiency, provide support for clinical governance, and advance quality and safety. While the latter agenda indicated an acceptance by government that quality improvement was not happening, the needs of the former threatened safety because of the potential for insufficient investment in support of systemic change. An additional and related threat to quality and safety improvement in NZ currently is the weak capacity of the state to pay the healthcare workforce. The entrenched shortage of specialist doctors makes it difficult for them to set clinical tasks aside and lead improvement activities. The effects of this shortage of time are evident in research with senior doctors and hospital staff in general, who claim they are too busy and lack the support necessary to work at systemic change.

Real progress in safety improvement in NZ is likely to be difficult if economic pressures continue to drive hospitals to pay lip service to quality and safety. While NZ now has a dedicated and independent quality improvement organisation in the Health Quality and Safety Commission, and a range of programmes are supported by the Commission, it remains to be seen if these can be comprehensively advanced while day to day pressures inside hospitals prioritise throughput. This presents a real challenge to the Commission. Policy makers need to consider not only the quality and safety losses that accompany workforce shortages, but also the economic losses that are inherent in poor quality. At this stage more investment in the workforce appears to be key for NZ to advance the safety agenda and the benefits it may provide.

Conclusion

In this discussion about polices and consequence I have described three very difficult struggles to implement safety improvement. None could be described as ideal, but there are signs that the process can work. The challenges confronted in America, the English NHS, and NZ have been both very similar and very different. In this conclusion I compare events in these systems, and draw some lessons about safety improvement.

This discussion is guided by Donald Light's analysis of countervailing powers. Context is critically important. As Light (2010: 274) argued, "we cannot expect professionals to act too differently from the market structure and institutional framework in which they practice." The initial contextual challenge was medical dominance, which peaked around 1970, and harmed quality and safety because professional autonomy supported overtreatment and non-scientific practice. Since then policy has challenged professional power to control costs and to make quality and safety more central to the provision of care. Light (2010) has argued that this process occurred faster in the centrally controlled NHS.

American healthcare has been described as a “non-system” (Light 2008: 210) of disconnected pieces without a rational structure (Berwick 2008: 213). In the domain of safety improvement this incoherence has started to shift. Over about the last decade American hospitals have been subject to pressures that they have not previously experienced in relation to accreditation, regulation, public reporting of quality and safety metrics, pay for performance initiatives, and pressure from outside stakeholders (Driver and Wachter 2012: 60). Considering the environment of safety in US healthcare Bob Wachter (2010a) suggests that while some (more than expected) progress has been made, healthcare is still not safe enough and overall outcomes are “disappointing” for patients (Wachter 2010b: 1). However Wachter also suggests that in the specific domain of safety improvement there has been considerable change though support from external organisations, the dissemination of tools and training, and the promotion of improvement project and campaigns (Wachter 2010a: 170). The most recent major initiative, the Partnership for Patients, was supported by US1$ billion. Many hospitals have also implemented interventions to improve safety culture and teamwork (Pronovost and Wachter 2013: 3).

While some challenges in US healthcare are of little relevance to other health systems, a clear message for improvement is that consistent pressure from many different sources can assist the process. Another lesson is that resourcing makes a difference for both safety and economic efficiency. The $1 billion invested in the Partnership for Patients improved safety and delivered $3.1 to $4 billion savings (Clarkwest, Chen et al. 2014).

While cost control has also been a problem for healthcare in England and NZ, universal budgets made the dimensions of this challenge considerably smaller than in the US (Light 1995). England and NZ have also pursued policies of clinical governance, although implementation has been notably divergent. Over the last decade and a half English hospitals have been substantially involved in quality and safety improvement activities, and there have been gains. However the NHS has also been subject to multiple expensive process of “redisorganisation” and politicised change, which had driven organisational turbulence and frequently resulting in new policies that contradicted the old ones (Light 2008: 210). This has wasted what could have been a key strength of the NHS. Where it could have been an integrated system that supported improvement, there has been a lack of overall coherence and coordination (Berwick 2008: 337).

Moreover, an emphasis on measuring financial performance rather than quality and safety meant that throughput was often the real agenda (Donaldson and Darzi 2012: 970). This caused continuous conflict between managers and professionals, and contributed to doctors disengaging from the leadership of clinical quality. Managerial control has driven a top down culture of fear (Jarman 2012). This process, which seems to pull in many directions, forwards with improvement programmes, and backwards with financial directives, had delivered huge variability. The Care Quality Commission (2014: 4-5) found that many providers had not grasped "the basics of safety." A comprehensive study of culture found considerable variability within and between organisations (Dixon-Woods, Baker et al. 2014: 110). While there were many instances of excellent care, there was little confidence that it could be relied upon at all times, and in all parts of these organisations (Dixon-Woods, Baker et al. 2014: 113).

The lessons from clinical governance in England show the materialisation of Light's (1995) warnings about countervailing powers. When the pendulum swings too far in any direction quality and safety can be compromised. Excessive managerial power, overemphasis on costs, and political redisorganisation, are not helpful for quality and safety. While the NHS offers many improvement resources hospitals sometimes struggle to use them. There have also been failures in important basics, such as data quality (Jarman 2010), and regulation which overlooked unsafe hospitals (Francis 2013). Oversights of chronically unsafe care have been identified in America as well (Wachter 2010a: 166).

Healthcare in NZ is different from England because it has seen a long period of relative stability since the market reforms ended around 2000. However NZ has also been notably inactive in working to implement clinical governance, and it was not until 2010 that a dedicated organisation was created to support quality and safety improvement. The view from inside hospitals since then suggests that while the importance of the quality and safety agenda is growing, staff are poorly supported to implement change. This reflects a risk that has become evident in England. Providing organisations and programmes in support of safety is not sufficient when the dynamics inside hospitals contradict using them. NZ is confronted with the challenge of employing only 0.8 specialists per 1000 head of population, about half that of the US (1.5) and England (1.8) (Powell 2010: 1). In addition managerial and clinical agendas have diverged (Ministerial Task Group on Clinical Leadership 2009), and continue to do so (Gauld and

Horsburgh 2015). While there is insufficient volume and variety of research to suggest that NZ hospitals have become managerially dominated, there are signs that this outcome is emergent. Against it, hospitals in NZ are not pressured as strongly by narrow performance metrics as has been the case in England.

In this analysis of polices and consequences I have attempted to compare safety improvement in hospitals in the USA, England, and NZ. Differences due to private provision in America, versus central control in England and NZ, and differences in the information available must make this comparison somewhat tentative. However it appears that while US healthcare continues to be medically dominated (Light 2010), concerted pressure for change and resourcing have begun to deliver safer outcomes. Improvement is also evident in the English NHS, but it has been slowed by managerial dominance prioritising finances, and politicisation leading to continuous redisorganisation. The latest austerity driven attacks upon the NHS have very sinister implications for safety. In NZ the safety agenda is at a relatively early stage of development, but it is challenged by the underfunding of busy hospitals, which is increasing the pressures upon staff.

These comparisons suggest some lessons for safety improvement. Both managerial and medical dominance present risk. Safety requires comprehensive support for hospitals and consistent strategy over the long term. Regulatory processes must identify and change unsafe hospitals. There needs to be systems that support managers and professionals to work cooperatively towards safety so hospitals do not become distracted by short term financial considerations. The institutionalisation of safety demands investment and time so expertise and capacity can be developed.

Chapter 3

The Risks of Hospitalisation

In previous chapters covering the patient safety movement and the consequences of policy I have provided an overview of the discovery and the measurement of medical harm, and an analysis of how policies in the American, English, and New Zealand healthcare systems have affected safety. I argued that while there is a lack of evidence, it appears that over the last decade and a half the patient safety movement may not have substantially reduced the amount of medical harm. I also argued that while there is evidence of progress in safety policy, there are continuing difficulties with bringing safety to the forefront of healthcare.

This chapter builds an understanding of risk and harm, and makes some suggestions about how to achieve safety. It does this in two ways. First, by showing in depth how risk processes emerge in hospitals and manifest as adverse events, it allows a detailed understanding of what needs to change for safety to improve. Second, through an analysis of relationships and commonalities between risks it identifies a set of strategic priorities for risk control. These priorities acknowledge that while all risks matter, some are more powerful than others, and they must receive the bulk of the attention.

The chapter begins with a theoretical discussion about how risks emerge and cause harm in complex organisations, and how organisations may protect themselves against risk. Following this the discussion reviews multiple dynamic risk processes that affect the safety of hospital care. These risks are categorised as emergent from the organisational environment

(institutional, economic), and the organisation (structure, processes, tasks). The discussion shows how these factors combine to generate risks by influencing the cognition and actions of hospital staff. Harm involves the collective working of generalised (institutional, economic, structural, processual) risk factors, and specific (task) risks. In the conclusion the relationships between risks described in this review are used to identify and rank three strategic priorities for risk control.

Theories of organisational risk and safety

Two theories of risk and one about safety are drawn upon here to understand organisational action. The risk theories provide a way of identifying how organisations become unsafe. The safety theory, from organisations that have achieved high reliability, offers a standard for evaluating behaviours in healthcare.

The organisational accident

James Reason's (1990, 2000, 2001, 2004) human factors model of organisational accidents is grounded in the distinction between active and latent failures. Active failures occur at the sharp end of the organisation (the clinical environment in a hospital), where doctors and nurses appear to directly harm patients. The active failures that produce harm include errors in the form of slips and lapses, mistaken decisions, and violations of correct procedure. These kinds of failures are due to normal human weaknesses, and they cannot be eliminated. In healthcare however an emphasis on individual failure is common, and the result is blame, which is emotionally satisfying but necessarily superficial as an understanding of organisational action.

Unsafe outcomes in hospitals involve many workers, and not simply those at the sharp end. Clinical work is shaped by an accumulation of design decisions affecting organisational

structure, processes, procedures, technologies, and more. These are all determined at the blunt end of the organisation, by designers, senior managers, regulators, policy makers, and manufacturers. When these groups fail patients are not immediately harmed, but latent failures are generated and the preconditions for active failures are set into place.

Latent failures can be of many kinds. There may be shortages of staff, excessive workload, and insufficient training. Systems, procedures, and technologies may be badly designed leading to problems with planning, communication, regulation, maintenance, and so on. Latent failures may also increase the risk that active failures will harm someone by compromising an organisation's defences against error. An unworkable procedure or an unreliable process may reduce the possibility of detecting and controlling failure somewhere else in the system.

Because latent failures create the local conditions and the psychological precursors that support errors, mistakes, and violations, they constitute the real or the 'root cause' of harm. However the process of harm may involve combinations of events that are not normally damaging. When several latent and active failures are temporarily aligned they present a gap in an organisations' defences against error, and an event that would not normally have any harmful consequences can come into direct contact with a patient.

The significance of latent failures as the greatest threat to organisational safety is not a denial of the potential for non-systemic harm. Individuals have varying abilities, and all are subject to the sway of normal human fallibility. This is particularly problematic in medicine, where it can be very difficult to provide mechanical defences against wrong actions. Healthcare has an

> enormous diversity of its operations and equipment, the frequency of emergencies, the degree of uncertainty, and the vulnerability of patients. But perhaps the most important distinction lies in the way its products are delivered ... It would, for example, require some ingenuity on the part of an individual pilot to engineer the crash of a modern airliner. But in many healthcare activities serious harm is but a few unguarded moments away (Reason 2004: ii28).

It is also very difficult to prevent latent failures from accumulating within a system. Decision makers may fail to recognise their existence, and some failures have an insidious capacity to go

undetected for years before manifesting in a harmful event. As Charles Vincent and James Reason (1999) have argued, not all latent failures can be removed from a system:

> The final note is a rather pessimistic one. Engineered safety devices are proof against most single failures, both human and mechanical. As yet, however, there are no guaranteed technological defences against either the insidious build-up of latent failures within the organizational and managerial spheres or their adverse (and often unforeseeable) conjunction with various local triggers. While cognitive psychology can tell us something about an individual's potential for error, it has very little to say about how these individual tendencies interact within complex groupings of people working in high-risk systems. And it is these collective failures that represent the major residual hazard (Reason 1990: xii).

Normal accident theory

In Charles Perrow's (1984) normal accident theory (NAT) normal or systems accidents arise in organisations through incidents that generate unexpected or uncontrollable interactions between the design of systems, equipment, procedures, operators, supplies and materials, and the environment.

Accidents in complex systems through interacting failures may involve combinations of seemingly trivial incidents. These become disastrous through the effects of complexity, which is especially risky when it applies to the interactiveness of a system and the coupling of its components.

System interactiveness is due to the technical and social processes through which tasks are achieved. These may be either linear or complex. Linear interactions are simple and sequential, with one event leading to another in a predictable path. Complex interactions are more difficult to predict because of branching paths, feedback loops, and jumps between sequences in close proximity.

System coupling is a product of the time and distance between components. In loosely coupled systems separation is plentiful, which allows incidents to be controlled before they spread to affect other parts of the system. Tightly coupled systems have less of a gap between

components, leaving little space for error. They run the risk of cascading sequences of failure as incidents affecting one component quickly spread and damage other parts of the system.

Complexly interactive and tightly coupled systems create the most risk. They are especially problematic for operators because when things go wrong it can be very difficult to understand the cause of the failure and to know what to do once the process is in motion. A number of commentators have identified healthcare in this way. The Institute of Medicine have argued that while not all hospital care is complexly interactive and tightly coupled, some elements of the system are, including emergency rooms, surgical suites, and intensive care units (Kohn, Corrigan et al. 2000). Grant Savage and Eric Williams (2007) however have taken this perspective further by arguing that complex interactivity is widely implicated in the care process, and that hospitals involve many sub-systems which are tightly coupled and must be smoothly coordinated. One such sub-system is the emergency department, imaging department, and laboratory. Doctors making a diagnosis need images and test results on time, which means that the failure of either can contribute to a diagnostic mistake. Similarly Mary Dixon-Woods (2010) has noted that the unavailability of a porter to shift a patient to an operating theatre may trigger a cascading sequence of events that ultimately leads to a patient being harmed.

Collective mindfulness

Karl Weick and Kathleen Sutcliffe's (2007) theory of collective mindfulness reflects patterns of action in organisations that are highly reliable despite working in circumstances that are filled with risk.

Collective mindfulness involves three principles for anticipating failure, and two for containing it. The principles of anticipation are ways of sensing the unexpected. The first is preoccupation with failure. Any failure, no matter how small, should be taken seriously because it may be a symptom of a systemic weakness that could escalate into a larger problem. To 'see' these 'weak signals' organisations must be wary of success, which can narrow perceptions and cause a drift

into complacency. The second principle of anticipation is reluctance to simplify. Because early warning signs are often buried in details staff need to be wary of the simplifying power of concepts. Building diversity into a team helps resistance against simplification because diversity can enhance scepticism towards received wisdom, and with more perceptions more is seen. The third principle of anticipation, sensitivity to operations, requires front line workers to be aware of the messiness of organisational reality. Routines must not prevent the monitoring of unexpected events and possible changes to practice. Quantitative and qualitative information must be gathered from many sources, in real time, and widely communicated. Near misses should be treated not as evidence of safety or the capacity to rescue, but as warnings to be understood.

The two principles of containment apply when unexpected events persevere. The first is commitment to resilience, which means maintaining dynamic stability in the midst of the stress of mistakes and the unexpected. Managers must be wary of the fallibility of formal procedures, and develop resources for coping with the unexpected. Significant time spent 'putting out fires' is evidence of resilience, not a distraction from more important tasks. The learning it creates enhances capabilities. The second principle of containment, deference to expertise, means being wary of allowing decision making to be at the top of the hierarchy. Those near the top may lack detailed understanding and practical experience, and feel falsely secure because they are insulated from bad news for political reasons. When unexpected surprises happen decisions must be driven by expertise, not hierarchy, rules, and edict. Expertise is both technical and social. Solutions arise from networks of people. Interlocking contributions make better outcomes.

Lessons from theory

Organisational accident theory and normal accident theory share two concerns that are useful for the analysis of risks in hospitals. First, attention is focussed on the need to think about risk as the property of a system. The root cause of harm is the design of the system. Understanding how systems shape perception, action, and social processes is the key to the analysis of risk.

Second, small risks have power. An accumulation of minor failures can lead to unexpected harms because of combinations and conjunctions of events that by themselves are tolerated as normal, innocuous, and usually non-damaging.

The theory of collective mindfulness draws attention to whether or not weak signals of failure are seen, if there is deep interest in complexity, if operations matter more than routines, if dynamic stability is maintained under pressure, and if solutions draw upon cooperative expertise rather than managerial edict. Institutions and organisations may either encourage or discourage these behaviours, and the systems they implement may make them more or less possible.

The organisational environment and risk

An interest in the organisational environment is a defining characteristic of the open systems perspective on organisations (Scott 1992). This is a general view derived from the application of systems theory to organisational analysis which emphasises the interconnectedness of the organisation and its environment. From this perspective organisations cannot be understood in isolation from their wider political, economic, and social context. They "are embedded in – dependent on continuing exchanges with and constituted by – the environments in which they operate" (Scott 1992: 25).

Two aspects of the environment that are particularly significant for understanding safety are the institutional environment and the economic environment.

The institutional environment

The institutional environment provides a set of culturally prescribed rules through which different occupational groups determine and pursue their interests (Scott 1992: 140). These rules construct and constrain the purpose and the activities of the organisation (Greenwood 2007). They provide the regulative and normative systems that staff and organisations conform with to secure social legitimacy, and the cognitive and symbolic systems that social actors use to construct the interpretations of meaning and reality that drive their actions (Scott 2004).

There is a considerable volume of research about the institutionalised norms and perceptions of the medical profession, and how these shape the ways in which doctors experience risk and harm.

A culture of denial

Eliot Freidson (1970a) was the first sociologist to discuss medical harm. His observation that ambiguity was an important component of doctors' explanations of harm, set the agenda for much subsequent theorising about medical mistakes. Freidson recognised that ambiguity was sometimes unavoidable in practice because of a contradiction between scientific medical research, which builds knowledge on statistical generalisations, and clinical medicine, where scientific knowledge is applied to unique individuals. This uncertainty not only made clinical judgment necessary, it also opened the door to legitimate differences of clinical opinion, and the potential for doctors to pursue incorrect courses of action. When this happened however doctors would typically defend themselves on the basis that uncertainty makes errors unavoidable.

Freidson (1970a) did not however see ambiguity as the only reason for mistakes. Pointing to the "precision of much modern medical knowledge" and "the trivial routine of much everyday medical practice" (Freidson 1970a: 163), he argued that medical harm was often the result of violating "very clear rights and wrongs." These could include simple rules and precautions, routine tests, scientific recommendations, and the need to be cautious with medications. In

effect, doctors overemphasised ambiguity and used it as an excuse. They would "express a characteristic *subjective sense* of uncertainty and vulnerability, whatever the objective foundation" (Freidson 1970a: 163). The outcome was denial, and a refusal of responsibility.

Freidson (1970a) identified multiple consequences of medical denial. Individual and collective learning was compromised. The entire profession shunned formal discipline, collective accountability, the institutionalisation of collegial controls for assuring adequate performance, and the development of systems for learning from error. These failings were reinforced by complex psychological responses. There was ambivalence because of the vulnerability that uncertainty creates, and pride due to the status of the profession. There was sensitivity to criticism, and defensiveness because mistakes were perceived to be the product of luck. With the exception of self-criticism, which was expected to be met with reassurance, doctors could feel that criticism was only acceptable in private, and could not justify the supervision of performance.

The work of Marcia Millman (1977) reflected similar concerns. Millman (1977) invoked the notion of fake uncertainty, which could be expressed artistically and scientifically. When the art of clinical judgment failed, doctors provided the excuse that cases are unique and several courses of action were possible. When scientifically recommended treatments failed doctors defended themselves with statistics about the potential for error. Behind these rationalisations however Millman (1977: 116) found that the experience of being responsible for harm was "profoundly upsetting". It cost doctors disturbing memories of failure that lasted a lifetime, doubt in their professional judgment, and a permanent stain on their reputation with colleagues. Because mistakes could compromise a doctor's status in the hospital hierarchy, errors were kept quiet, and there was no criticism of other doctors. Criticism compromised the cooperative relationships that were necessary to getting work done and gaining professional advancement. In a profession that put its faith in science, objectivity, and rationality, the feelings associated with mistakes threatened professional identity. Denial created a collected self-deception, in which doctors viewing themselves as altruistic and responsible while "ignoring and condoning each other's errors and incompetence" (Millman 1977: 98).

The moral order of medicine

The work of Charles Bosk (2003; originally 1979) on surgical training departed in two ways from the analysis of Freidson (1970a) and Millman (1977). First, Bosk gave greater emphasis to uncertainty as a pervasive experience that made decisions probabilistic, and errors "essentially contested" (Bosk 2003: 24). Contingency was thus a thoroughgoing component of medical work. Second, Bosk (2003) argued that there were informal-internal controls over surgical work that Freidson had ignored. The lack of formal-external regulatory controls did not equate to an absence of control. On the contrary, surgical training was a highly principled moral training.

Bosk's (2003) argument about the moral order of surgery was founded on a distinction between technical and normative errors. Technical errors involved failures of technique or judgment due to insufficient skill, lapses of attention, an incorrect strategy of treatment, or a sound decision that subsequently proved faulty. These errors were treated as forgivable and honest mistakes that could happen to anyone. They were rare, and their frequency was expected to decline as learning advanced. A critical fact about technical errors was that they occurred within the correct surgical role, characterised by sincerity. As Bosk (2003) observed, doctors cannot promise to cure patients or demonstrate technical perfection. They can only promise to be completely dedicated to the wellbeing of the patient.

Normative errors however broke the rules of "orderly surgical activity" and "no surprises" (Bosk 2003: 36, 51). Normative errors included failing to update superiors about unexpected changes in the patient, an inability to get along with nurses, patients, and patient's families, lack of attentiveness, inappropriate affect, and lack of resourcefulness in getting things done. They created the appearance of insufficient dedication. They invoked a verbal shaming and the suspension of informal social bonds, which could be permanently severed if there was no repentance and dedication to the correct role.

Bosk (2003) argued that the normative rules of surgery showed an internal-informal moral order in which errors were controlled by the surgical hierarchy. Nonetheless, Bosk (2003) was cautious about this finding. Derived from an elite institution training academic surgeons, it might not be widely representative. Moreover, the norms of training could be different to those

of everyday practice. A "strong, structured silence marks those settings where colleagues are assumed to have learned the lessons of training" (Bosk 2003: xviii). In addition, the categorisation of errors was also highly subjective and influenced by multiple contextual factors (Bosk 2003: xx).

Bosk's (2003) doubts suggest that the strength of the moral order of surgical training is questionable. While in some hospitals at least there is an intense informal disciplinary process during the formative years the strength of this order may be different according to hospital. At the same time Bosk (2003) agreed with Freidson (1970a) that there was a vacuum of formal and external controls. Qualified surgeons could commit mistakes over and again without being investigated. In view of this Bosk (2003: 192) argued that the "collectivity needs to promote the structural changes that will build stronger accounting mechanisms into everyday practice."

Calamities without accountability

Terry Mizrahi (1984) investigated postgraduate training in internal medicine. She emphasised even more than Millman (1977) the social and emotional complications that harm created for the doctor. Like Bosk (2003), Mizrahi also invoked uncertainty as real and pervasive. In combination, emotions and uncertainty were devastating. Uncertainty in Mizrahi's (1984: 136) analysis was a visceral, ever-present, "harrowing and frustrating" problem that housestaff were unable to avoid. Without black and white rules for clinical practice they were left striving "to define and develop a level of confidence and competence in the midst of, and often in spite of, the myriad calamities that accrue" (Mizrahi 1984: 136). They learned from superiors, colleagues, and their own experience that there was no uncontradicted way of behaving, only differences of opinion. Luck became central to the relationship between harm and error.

The emotional pressure on houseofficers drove three defensive strategies that rationalised errors and allowed responsibility to be avoided. The first was denial, which included the negation of errors by defining medicine as an art with grey areas, the repression of mistakes by forgetting them, and the redefinition of mistakes as non-mistakes. The second strategy involved blame-shifting onto the hospital bureaucracy, subordinates and superiors, the patient, and the disease. The third, distancing strategy, of philosophising about the imperfections of

medicine, was used when all other strategies failed. Through this series of defences housestaff made themselves unaccountable to patients, the bureaucratic hierarchy of the hospital, the professional hierarchy of the Department of Internal Medicine, and faculty within the Department. Patients and managers were perceived as unable to understand medical issues, the professional hierarchy gave them little feedback, and faculty were out of touch. Housestaff only felt accountable to themselves and colleagues, although colleagues could not offer supervision and direction. Errors were brushed over lightly, and the potential for a bad reputation was perceived as sufficient to motivate better performance. The result was that doubt and guilt went unresolved, and housestaff vacillated between self and other blame and created a burden of self-criticism that was taken to justify the lack of evaluation. Mistakes were ruminated over rather than discussed and rigorously reflected upon. At the completion of training housestaff confidently interpreted themselves as moral. Protected by high status, they had joined an "insular and self-protective subculture" (Mizrahi 1984: 142), and were sanctioned for only the grossest mistakes.

Two aspects of Mizrahi's (1984) work are particularly useful. First, her emphasis on the connection between harm, performance pressure, and complexity suggests that medical mistakes can have significant causative depth. Second, Mizrahi (1984) found no moral order in medical training. Standards in the urban medical centre she studied were a world away from those in the elite institution where Bosk (2003) found rigorous attention to the best standards. The implication is that the medical culture of a hospital can be profoundly significant for safety.

Sorrow and horror

Marianne Paget (1988) also emphasised uncertainty and the burden of responsibility. However she argued that doctors were devoted to recognising, understanding, and avoiding errors through an "attitude of inquiry" that made learning an organising principle of medical work, driving morbidity and mortality conferences, autopsies, teaching rounds, and medical audits (Paget 1988: 98). The central issue from her perspective was the unavoidable reality that clinical work was necessarily error prone. The outcome was "the Being of Being mistaken", a state of sometimes diffuse, and sometimes pointed sorrow (Paget 1988: 148). The thoughts and the memories it stimulated made the experience of causing harm a "complex sorrow" (Paget 1988:

97). Paget was thus opposed to the “implicit structure of right and wrong” (Paget 1988: 81) and the “invective of blame” (Paget 1988: 157) that vilified those who err. Blaming doctors did not help. “Acting against the press of pain and illness, acting in the presence of death, requires support” (Paget 1988: 158).

The narrative analysis by Rick Iedema, Christine Jorm et al. (2009) of young anaesthetists experiences of harm expands upon the significance of the emotional burden that Paget (1988) emphasised as necessarily requiring understanding. While Iedema, Jorm et al. (2009) found that denial was significant, they linked it with complex feelings that were unresolved for institutional reasons. There were three narratives, each with different implications for learning, which doctors used to make sense of harm. The normalising narrative objectified error and its consequences, and made it easier for the doctor to set the event aside and continue working. Its basis was abstract descriptions that set reality at a distance, and allowed harm to be accepted as normal and inevitable. The functionalising narrative used elements of horror about error as a pedagogic strategy to reinforce learning. While doctors could not distance themselves from these events, the emotive impact of the narrative reinforced crucial lessons about the rules of practice.

The weakness of the normalising and the functionalising narratives for learning was that they were closed by a neat solution that left some learning unexplored. The third, problematising narrative, was unresolved. It contained significant elements of horror, uncertainty about the right course of preventive action, and possibly other complications such as issues concerning the hierarchical structures of medical work. Speakers expressing this normally private narrative were unable to bring it to a conclusion. Their inability to achieve closure was because of the institutionalised norm that errors are unfortunate and avoidable only in hindsight. Through this way of thinking doctors were unable to participate in open ended and unguarded discussions about harm, and they could not gain any insights into the complex social and organisational processes of medical work, and how these could be changed to improve safety. Consequently the socio-affective dimensions of clinical relations were under-developed, knowledge was not shared, and learning was compromised.

The institutional environment and risk

Freidson's (1970a) analysis of doctors' use of uncertainty as an excuse from responsibility, and his claim that denial is institutionalised, provides a foundational perspective on the failure of the medical profession to improve safety. Millman (1977), Mizrahi (1984), Paget (1988), and Iedema, Jorm et al. (2009) were also concerned with denial. However as this literature developed the theme of uncertainty became increasingly pervasive and difficult to overcome, while other problems, especially overwhelming pressure and guilt, further complexified the dynamics of repeated harm. Another less dominant theme in the literature is apparent in Bosk's analysis of how in some contexts doctors exercise normative control over behaviours leading to harm, and the work of Iedema, Jorm et al. (2009), who found that doctors were only partially effective in their efforts to learn from mistakes. These analyses suggest that while there are intentions within the profession to achieve safer care, the mechanisms to fully institutionalise it are lacking.

Overall, this literature suggests three lessons about safety. First, there is a need to institutionalise methods for doctors to explore errors so they can recover from the associated psychic damage. Second, doctors' investigations of errors must explore the relationship between harm and the social organisation of hospital work. Third, the causative impact of pressure in the emergence of harm cannot be discounted. Hospitals must be wary of the consequences of allowing pressure to proliferate.

The economic environment

The economic environment enables and constrains work inside hospitals. A large volume of the literature on in-hospital risks demonstrates, without necessarily focussing on this particular issue, how economic constraints can negatively affect the safety of healthcare. When there is a shortage of resources of staff time clinical work is necessarily conducted in an atmosphere of pressure. Pressure is a problem because, as identified in human factors research, it increases the frequency of unsafe actions. Physiological or psychological stresses caused by excessive

workload constitute one of many preconditions that can lead to unintended errors and mistakes, and the deliberate violation of protocols. In effect, risk increases when staff save time on tasks in order to perform more tasks, and when their attention is diverted by excessive arousal. Conversely, workplaces are safest when the workload is sufficient to maintain alertness, but the pressure to perform it is not overwhelming (Leape, Cullen et al. 1999).

Goal displacement and pressure

Elizabeth West (2000) has argued that pressure on the conduct of clinical work is an outcome of goal displacement, which arises when economic goals dominate the priorities of hospitals. The risk is that:

> If top managers set goals that cannot be met within current resources, they are setting up individual clinicians, teams, and organisations for failure of all different kinds, including causing harm to patients (West 2000: 125).

West (2000) has argued moreover that goal displacement not only constitutes a serious risk to safety, it is frequently evident in healthcare. While high reliability organisations with an exemplary record for safety enjoy an abundance of resources, hospitals operate in an economic environment where they are constantly under pressure from insufficient funding. In healthcare, resources of all kinds are stretched to do more with less. This pressure may lead to an excessive workload for staff, inadequate support for juniors, and shortages of facilities and equipment. Existing risks may be exacerbated and new ones introduced.

Research by Mary Dixon-Woods, Graham Martin et al. (2014) has shown that the poor reliability of clinical systems in the NHS was directly associated with constraints on resourcing. Systems were often designed to prioritise efficiency over safety, and staff lacked the skill and the time to investigate and fix problems because of a general squeeze on capacity. Moreover, poor process design and weak reliability were not only harmful to quality and safety, they reinforced inefficiencies, and created a vicious cycle of failure and pressure.

Excessive workload is the flipside is short staffing. A number of quantitative studies have shown a link between shortages of nurses and increased risks to patients. A study of over 500 US

hospitals found an inverse relationship between nursing numbers and some kinds of post-surgical infections and complications (Kovner and Gergen 1998). Another major US study linked high patient to nurse ratios with patient mortality and nurse burn-out and job dissatisfaction (Aiken, Clarke et al. 2002). A systematic review of the literature on nursing resources and patient outcomes in intensive care found that nursing numbers and adverse events were connected. A major factor in harm was insufficient time for nurses to perform preventive measures and patient surveillance (West, Mays et al. 2009).

More detailed evidence of the impacts of pressure on nurses is evident in a study by Mary Dixon-Woods, Anu Suokas et al. (2009) of how nurses on medical wards in four NHS hospitals responded to risk. Risk on these wards was constant, and much of it was traceable to the pressure of multiple competing tasks. Workflow was unpredictable and there were ongoing interruptions from a stream of crises both small and large. Nurses were frequently "rushed off their feet," and the expectation to "just get on with it" (Dixon-Woods, Suokas et al. 2009: 364, 368) was normalised as a part of the ward culture. There were shortages of time, highly trained senior staff, equipment, and isolation rooms for patients with dangerous infections. Staff practices, their forms of reasoning, and their accounts of risk, were all affected. Nurses routinely cut corners by defaulting from technically correct ways of working in order to save time. They did this even though they knew patient safety was at risk, but they rationalised their lapses through a variety of excuses about the minimal nature of the risk and the urgency of other priorities.

An evident pattern over recent decades in the conduct of medical work is its general intensification. Looking back in 2003 on his ethnographic study of surgery in a US hospital in 1979, Charles Bosk (2003: xiii) observed that "residents are taxed with sicker patients who have shorter lengths of stay; there is more work to do in less time." Similarly Allan Detsky and Don Berwick's (2013: 987) comparison of hospital care in the US during the 1970s with the current day suggested that, "in 2013, inpatient medical care in teaching hospitals is different: far more complex, more intense, and simply put, faster."

Unsafe pressure on performance in NHS hospitals has been evident over the last couple of decades. In the early 1990s Martin McKee and Nick Black (1992) noted that an overreliance on

junior doctors led them to work without adequate supervision and caused tiredness from excessive hours. The lack of supervision which resulted in juniors performing work without sufficient training and support was known to be associated with potentially serious mistakes. Tired doctors also communicated less well and displayed less compassion for patients. Anecdotally there was also the risk of many other mistakes, such as misreading prescriptions and administering wrong drug doses.

Goal displacement was pervasive in the NHS in the 1990s. Academic researchers, senior clinicians, and managerial staff all noted that clinical standards and culture were compromised by excessive attention to financial targets and other quantitatively defined performance measures (West 2000). While the policy of clinical governance sought to address this problem by increasing the emphasis on quality (Department of Health 1998), that goal was initially undermined by the inadequacy of NHS funding. Although there was a substantial increase in funding after 2000 (Bevan 2010c), which continued throughout most of the decade (Darzi 2009), many problems relating to pressure remained in evidence. In a review of studies from four NHS locations during that time Mary Dixon-Woods (2010) found that staff adapted to environmental strains that confronted them with multiple competing priorities by normalising an emphasis on getting things done, and rescuing situations from chaos. Rescue skills allowed conditions that undermined safety to be accepted as normal. Adaptations and tolerances hid problems that were only revealed when events “erupted into catastrophe” (Dixon-Woods 2010: 13).

One of the many implications of pressure on medical work is its effect upon communication. In a US study Kathleen Sutcliffe, Elizabeth Lewton et al. (2004) found that when medical staff were tired and fatigued their communication was less effective. This outcome was particularly problematic because communication was also identified as the most important factor contributing to errors. Pressure may distort communication in many ways. In Canada Sarah Whyte, Carrie Cartmill et al. (2009) found that team briefings intended as a safety measure prior to operations were avoided when teams were under pressure to shift patients through the theatre. David Hewett, Bernadette Watson et al. (2009) found that interspeciality communication between Australian doctors negotiating the care of patients were negatively affected by extreme workload and shortages of staff and beds. Professional groups that should

have cooperated in the interests of patients instead contested their responsibilities. When it was unclear which medical speciality was ultimately responsible there were 'intergroup' struggles as doctors who were called for assistance sought to avoid taking on the work. One registrar commented:

> It comes down to people being too busy and people trying to minimise their own workload. Because people are already busy you wouldn't believe the games people play with each other around here to try and not to see patients ... everybody's just trying to not take on too much work (quoted in Hewett, Watson et al. 2009: 1737).

Two reports from a study of operating theatres in a large NHS teaching hospital observed multiple impacts from pressure due to shortages of time, equipment, and staff. Justin Waring, Steve Harrison et al. (2007: 7) argued that the normalisation of risk was pervasive due to a mix of cultural factors, organisational complexity, and persistent managerial pressure "to get the word done, 'keep to the schedule', meet targets and use resources efficiently." Ruth McDonald, Justin Waring et al. (2006) found that these managerially imposed efficiency and throughput targets soured relations between clinicians and management. A factor that contributed to the pressure through resourcing was the instability of work teams and the use of agency staff. Instability meant that teams were less resilient under pressure (McDonald, Waring et al. 2006), they could not rely upon implicit understandings, they communicated poorly, they responded individually to errors, and the opportunity for reflexive team-based learning was reduced (Waring, Harrison et al. 2007). Resource shortages could also lead to the use of incorrect sized or sub-standard equipment that was sometimes adapted for purpose in the course of an operation. Pressure meant that operations could also be conducted in a rush or on the weekend, with staff working tired in order to keep up with the schedule. One anaesthetist, observing the complexity of the work, and the collective impact of numerous small risks, explained harm quite simply as the outcome of how "things build up" (McDonald, Waring et al. 2006: 186). A surgeon claimed that while senior hospital management would support them in the face of a patient complaint over surgical error, they would be in trouble with management if a patient complained about an operation being delayed. In effect, surgeons could not cancel operations because organisational factors were insufficiently geared to support safely (McDonald, Waring et al. 2006). The challenges of instability in medical teams has also been noted in the US by Allan Detsky and Don Berwick (2013: 988). Constant changes in teams "can

confound the best intentions of the workforce. Few other industries that depend on effective workforce cooperation would choose to be organized in this chaotic way."

A further toll of pressure on safety can be its effects on the psychological wellbeing of staff. The morale of nurses in NZ has recently declined for a number of reasons, including increasing workload and patient acuity (Walker 2015). The subsequent stress of these and other pressures has long been recognised as an important contributor to the persistent problem of high turnover in nursing (Currie and Carr Hill 2012). Post-traumatic stress syndrome and burnout syndrome are common amongst nurses (Mealer, Burnham et al. 2009). The stresses of medical work increases vulnerability to disorders such as depression, anxiety, and substance abuse, with negative implications for patient care. A review of international research found that burnout affect from 25% to 75% of physicians (Wallace, Lemaire et al. 2009). A recent study in a NZ hospital found that three-quarters of doctors had come to work sick in the last year, mainly to avoid burdening co-workers (Tan, Robinson et al. 2014).

The economic environment and risk

Goal displacement occurs when resources are diverted from patient care to economic objectives. The increasing complexity and pace of hospital care makes this issue especially significant. Human resource shortages creates pressure that can compromise safety in many ways. Pressure can affect communication, the performance of tasks, and the perception and control of risk. Over time the distorting effect of pressure on perception allows unsafe practices to become less visible so they are institutionalised into normal practice. The very evident lesson is that safety cannot be integrated into organisational systems when the pressure upon staff is excessive. The goal of throughput performance in healthcare needs to work alongside and not against the goal of safety. It is close to unimaginable that hospital staff could be expected to fulfil conditions of high reliability, such as being sensitive to weak signals of failure, reluctant to simplify, and sensitive to operations (Weick and Sutcliffe 2007), when they feel overwhelmed or near to it. The discussion here demonstrates why these safety enhancing actions are not practical in a pressured context.

Organisations and risk

The organisational level of analysis invokes structures, processes, and tasks. Organisational structure is an outcome of the division of labour and its associated hierarchy and sets of rules (Hall 1996). Within this structure important variables include the depth of the hierarchy, the extent to which tasks are broken down, the number of rules and how much they are observed, and the spread of decision making between the top and the bottom of the power hierarchy. Diane Vaughan (1999) has referred to this complex of roles, duty, and inequality as "power as structure." Reflecting the significance of power, W. Richard Scott (1992) described structure as a means through which management guide the thought and behaviour of employees.

Organisational processes are the social dynamics of the workplace. They both create and reflect the culture of the organisation. There are two distinct formulations of the process or relational perspective on organisations. One is that process and structure are closely connected, such that "organizational structure and processes are in constant and reciprocal interaction" (Hall 1996: 128). The other is that processes represent a different ontological view to a more structurally based perspective. While there may be a place for structure in the analysis, it is conceived of in processual terms, as something that is "continuously being created and recreated" (Scott 2001: 10913).

Organisational tasks are the technical work that occurs in what Scott (1992) calls the organisational core or functional centre of the organisation. Vaughan (1999) notes the paradox that while technologies are determinate and have real consequences, they are embedded in a social context and given meaning through processes of interpretation. Failure to correctly identify and manage the risks of technology creates the possibility of harm.

Organisational structure and processes

The very close interconnectedness of structure and process means that in the following the two are not given separate treatment. The discussion begins with an overview of the structural complexity of hospitals, and the implications of complexity for organisational processes in general, and safety in particular. This part of the discussion is largely theoretical in regards to safety, but some empirical detail is provided. The discussion then shifts to an empirical discussion that outlines a range of ways in which organisational complexity has been concretely identified as increasing risks to hospital patients. Topics covered include communication, the status hierarchy, organisational power, politics, and conflict; process failures; and the diffusion of responsibility. The discussion shows that the necessary complexity of hospitals as organisations creates social challenges that must be resolved if safety is to be improved.

Organisational complexity

Hospitals have been described as "the most complex human organisation ever devised" (Drucker 2002). This complexity is a source of risk that can only be overcome through effective processes of coordination, communication, and cooperation. However as complexity increases so too do the challenges of ensuring the effectiveness of these processes (West 2000).

The work of Shizuko Fagerhaugh, Anselm Strauss et al. (1987) explains the increasing complexity of hospitals care, and suggests some of the implications for organisational processes and safety. The organisational complexity of medical care is a product of Victor Fuchs's (1968) technological imperative, which sees doctors adopting new technologies according to the promise of improved healthcare. Fagerhaugh, Strauss et al. (1987) defined these new technologies as hardware composed of machines, drugs, devices, and procedures; and the software of knowledge, skills, and social organisation. The implementation of new technologies and practices affects organisational processes in two ways. First, logistical challenges due to demands for the space needed to accommodate new hardware and supplies can lead hospitals to run out of space, and cause their architecture to become rapidly antiquated. Departments

may then enter into conflict with one another as they contest ownership of the territory and the fiscal resources needed for their expanding technological apparatus.

The second implication for organisational processes is that the new technologies drive social change within hospitals by expanding the division of labour. Clinical groups become differentiated into specialist categories, and new workers such as technicians and engineers emerge. Collectively these groups may struggle over the ownership of tasks, further exacerbating inter- and intra-departmental conflict emergent from competition over space and other resources. Workers may also face difficulties due to the coordination that is necessary when many individuals have a stake in the care of the same patient. This leads to the creation of liaison nurses, expands middle management, and more time must be spent on task forces, committees, and meetings. For those in hospital administration the tasks of coordination, satisfying new equipment regulations, arbitrating between departments, and ensuring that supply inventories are maintained, become monumental. But while managers may seek answers in computerisation and administrative theories about how to overcome chaos, managerial reality is dominated by the need to put out fires.

Elizabeth West (2000) has summarised a further set of risks emergent from structural complexity as structural secrecy, a diffusion of responsibility, and limited communication due to the homophily principle. Structural secrecy, described by Diane Vaughan (1996), is a consequence of the way complex organisational structures can lead to the compartmentalisation of knowledge and information. When workers become more specialised their capacity for mutual understanding diminishes, making them less able to work effectively across organisational boundaries, and communicate important details about tasks.

The diffusion of responsibility is a consequence of a lack of clarity over obligations and the potential for individual contributions to go unrecognised because they are difficult to identify. Some aspects of individual clinical work in hospitals have very obvious implications for safety, but others, because of the “problem of many hands” do not. At the executive level, responsibility for safety is often undefined and accountability may be absent. More generally, across all levels of a complex system, situations may arise where workers do not concern themselves with some problems, or expect or imagine that someone else will fix them (West

2000: 124). Poor hand hygiene practices may be maintained in part because individual lapses have no obvious outcome (Dixon-Woods, Suokas et al. 2009).

The homophily principle describes a tendency for people to form relationships with those they are most similar to in salient dimensions. In organisations communication is most frequent and effective between individuals who are similarly positioned according to characteristics of status, professional allegiance, and gender. Members of groups that diverge from one another are more likely to restrict their communication to formal exchanges and avoid difficult topics and confrontations. In a healthcare setting, where occupational and professional barriers are often locked into the structure of the organisation, restrictions on communication are damaging to safety. The affects may be both direct, as in the situation where junior nurses feel unable to warn consultants about errors or transgressions of safety protocols, and indirect, by contributing to the build-up of risks through restrictions in the flow of information (West 2000).

Structure and communication

The challenges to effective communication which are created by the complex division of labour in hospitals are apparent in many studies of risk. Structural secrecy is evident when professional boundaries limit the transfer of knowledge. The existence of different professional groups in the operating theatre may restrict the flow of information because once risks are normalised within one group there can be little interest in communicating the information to others (Waring, Harrison et al. 2007). Surgeons may struggle during a briefing to describe the significant stages and challenges of a procedure they are about to perform, leaving others unprepared for contingencies they may need to respond to during risky stages of the operation (Whyte, Cartmill et al. 2009).

Status differences have been observed to be especially problematic for communication. They may reduce the effectiveness of teamwork because those who are less privileged in the hierarchy may be too deferential to draw attention to problems (Dixon-Woods 2010). In practice, operating theatres have been observed to be run by a set of unwritten rules, and a formal hierarchy which dictates that the surgeon is in charge. Nurses are unlikely to speak out if they see a patient subject to risk that could be prevented because they feared ridicule for

their “daft nursing ideas” (McDonald, Waring et al. 2005: 404). The hierarchy may also create a barrier to both the commencement and the effective performance of team briefings prior to surgery. Those attempting to initiative a briefing may fail to overcome this barrier (Whyte, Cartmill et al. 2009).

A particularly important study of clinical communication and its effect upon safety is Kathleen Sutcliffe, Elizabeth Lewton et al.’s (2004) analysis of errors committed by resident doctors in a large US teaching hospital. In this research, communication failures were identified as central to the vast majority of medical mishaps. The influence of poor communication was insidious, and it was often institutionalised into patterns of behaviour that determined the way entire groups and departments in the hospital communicated. Staff, residents especially, were “caught in a web of complex relationships” in which communication methods and “individual, relational and systemic factors” were all implicated (Sutcliffe, Lewton et al. 2004: 194).

The specific failures that Sutcliffe, Lewton et al. (2004) identified involved a lack of information, the method chosen, the influence of the social hierarchy, and the complexity of the organisation. The simplest failure was a basic neglect to let others know what was happening. This was especially problematic for resident doctors who could receive insufficient information from the attending. Information was also often not passed along when patients were transferred from community physicians, or when physicians from other departments were involved in their care. On other occasions the method of communication was problematic as happened when residents, attendings, and specialists wrote information about changes to patient treatment directly into medical records without saying anything. Staff needing to act on this information may have found it too late. Information transmitted through a number of individuals could become misinterpreted along the way.

Divisions of status created especially complicated problems for communication. Individual communicators faced difficulties with their level of upward influence, conflicting roles and role ambiguity, and interpersonal problems of power and conflict. These factors typically distorted communication, or caused it to be withheld as those with less social power were mindful of the need to appear competent, and to not upset, annoy, or interrupt those with more social power. Consequently residents could withhold information from attendings or specialists if it could

make them appear ignorant, and they avoided offering opinions about the best approach to care if their perspective differed from the attending. Nurses experienced similar difficulties with residents. The residents may have been unaware this was happening, and they could fail to understand how the nurse perceived them as threatening. Communication issues arising between residents and community physicians could also demonstrate the effect of structure through the problem of role ambiguity. When patients were transferred from a community physician into the hospital the boundaries between who had the authority to provide care, and who was responsible for it, was sometimes unclear, resulting in misunderstanding and conflict that placed patients at risk (Sutcliffe, Lewton et al. 2004).

Process failures

Organisational processes are critically important to safety, but as Mary Dixon-Woods, Graham Martin et al. (2014) have identified, healthcare organisations can be plagued by an endemic lack of process clarity and reliability. By carefully mapping eight clinical systems across several NHS hospitals they identified multiple hidden hazards "below the radar" of standard error reporting and risk management. Problems were so "big and hairy" and entrenched into organisations that they were often accepted as inevitable. Systems had never been purposefully designed, were undocumented, staff picked them up informally, and they were vulnerable to degradation. In one case renal patients on a surgical pathway faced 99 different hazards. The riskiest were a lack of medical review by senior doctors, and a lack of surgical plans. Communication and coordination were especially weak because of process failures that could often be traced to ineffective support structures. There were longstanding issues with IT, the layout and the design of facilities and equipment, and the coordination of key tests (Dixon-Woods, Martin et al. 2014).

Another more detailed analysis of process weakness and problems with design, enactment and control can be found in the work of Mary Dixon-Woods, Anu Suokas et al. (2009), which links process weaknesses with the social complexities and ambiguities of hospital structures. Problems arose:

> particularly if some kind of collaborative work was required, no one individual was overseeing the process from beginning to end, or coordination was required across professional, team, departmental and shift or time boundaries (Dixon-Woods, Suokas et al. 2009: 366).

Ambiguous responsibility and the need for cooperation catalysed the emergence of social tensions across boundaries. When patients were handed over there were difficulties with information not being passed on, patient notes becoming separated from patients, and important decisions not being communicated to all of the relevant parties. Pre-empting these challenges was "problematic for staff because it was often unclear who was able to, ought to, or was entitled to act to change the process" (Dixon-Woods, Suokas et al. 2009: 366). The continuity of process weakness was supported in some situations by their normalisation, and by a wider feeling of disempowerment amongst staff, who lacked the necessary mastery and means of asserting control. The fallout for staff was ongoing uncertainty and stress because they could not feel secure that events would unfold as expected. To try to manage these situations they may have indulged in additional acts of vigilance and diligence to check that things had not gone badly, and when these problems were identified they then needed to rescue the situation or deal with the consequences.

Organisational turbulence, described by Mary Dixon-Woods (2010), suggests the action of a similar dynamic to process weaknesses. Turbulence occurred when processes emerged from chaos rather than organisation. But while staff were often adept at rescuing situations, the act of rescue could normalise and reinforce turbulence. Surgeons who arrived late for operations on the assumption that operations always ran late contributed to operations being delayed. Adaptations could also make staff blind to risks as their risk accounting shifted from an emphasis on optimal performance to the management of chaos. Accumulations of small risks were tolerated, and only catastrophic failures created the impetus for change. Tolerance was further reinforced in some cases by the performance of professional identities, as was evident with surgeons who became skilled at operating under the pressure of trying conditions.

The diffusion of responsibility

The workings of a diffusion of responsibility, identified earlier as a problem of 'many hands' and insufficient recognition and accountability, can be seen affecting many processes inside hospitals. At worst it may be assisted by managerial efforts to mobilise fear as a way of preventing staff from 'blowing the whistle' about systemic failures. The anaesthetist Steve Bolsin, who spoke out about paediatric cardiac surgery at the Bristol Royal Infirmary which contributed to the death of possibly 30 babies, was forced to leave the NHS, and migrated to Australia (Neale, Vincent et al. 2007). In the contemporary NHS some doctors claim they have been informed that public criticism of safety issues would be detrimental to their employment (Jarman 2012).

In many situations where responsibility is lacking it is difficult to isolate the effects of individual action (West 2000). As a group, doctors prefer to see themselves as experts in specific medical tasks, rather than participants in a system where many different groups work cooperatively and responsibilities are shared (Berwick 1989). Suggesting some of the reasons doctors dislike organisational complexity, Christine Jorm, Jo Travaglia et al. (2007) found that when doctors denied their responsibilities for improving the system of care they identified it as monolithic, beyond their control, and divided by political struggles for power. Similar challenges were evident in Mary Dixon-Woods, Anu Suokas et al.'s (2009) analysis of process weaknesses, which indicated structural complexity, inter-departmental power struggles, and ambiguity as contributing to process breakdowns. Failures were perpetuated by the unwillingness of staff to accept responsibility for fixing a complex and difficult problem.

The breakdown of processes supported by the avoidance of responsibility generates varying risks to patients. Sometimes these may be serious and potentially fatal, as was evident in David Hewett, Bernadette Watson et al.'s (2009) analysis of challenges compromising the care of patients' suffering upper gastrointestinal bleeding (UGIB). This is a dangerous and life-threatening condition where delays in the coordination of multiple specialists from emergency medicine, internal medicine, gastroenterology, general surgery, and anaesthesia, can be critical.

The challenges that Hewett, Watson, et al. (2009) identified were of two kinds. The first was an underlying social divergence amongst specialists, who owed allegiance to their own particular group rather than the group of all specialists involved in the care of patients with UGIB. They referred to their colleagues from other departments by generic and impersonal descriptors (e.g. “gastro”) rather than name, and identified them as outsiders. This fostered internal solidarity and created the preconditions for conflict with other specialists. The second, structurally based problem was that there was considerable ambiguity in the rules which specified how patients with UGIB were to be managed between specialities. This made the diffusion of responsibility possible. There were no formal rules determining responsibility, and there was no formal provision for collective ownership. While admitting a patient onto the ward was one way in which ownership was determined, and some specialities were more likely to have to do this than others, ownership could evolve from this initial instance through negotiations between specialists as different aspects of a patient’s care was conducted. However ownership was not taken on easily because it required the specialist to coordinate with other departments for consultative assistance, and other specialists might feel that some aspects of the care they were asked to provide was not their responsibility. This problem became even worse when the consultant who “owned” the patient did not feel they were responsible for the patient because of the role played by other specialists. The lack of clarity over responsibility, and the fact that patients were perceived as owned rather than cared for, could lead to considerable debate between specialists about who was responsible for what. The consequences for patients were dangerous and potentially fatal delays in the delivery of care.

Organisational structure, processes, and risk

Research into the safety implications of hospital structures and processes further articulates the challenges of safety. It suggests the pervasive negative impact of pressure and how this environmental factor can be amplified by defective systems within organisations. Staff can struggle to respond to these failures in an organised way because they are already overwhelmed. When hospital care is dependent upon systems that are unfit for purpose multiple organisational processes are damaged. These process breakdowns involving the status hierarchy, a diffusion of responsibility, and poor communication are especially risky because of

the structural complexity of hospitals. They further escalate risks and catalyse them into patient harm. A system of this kind meets Charles Perrow's (1984) criteria of complex interactivity and tight coupling, making accidents normal. The most effective way to address these challenges would be to bring the greatest part of the focus to the most influential source of risk. In all likelihood this is the systems through which work is performed. While there are social problems that escalate the impact of poorly designed clinical systems, correcting the social issues would not repair the systems.

Organisational tasks

The final link in the causal chain that creates harm involves a task that may be performed poorly, inappropriately, is conducted too late, or omitted in error. As earlier discussion shows, task errors may be connected with institutional norms affecting the perception and control of risk, environmental pressure due to goal displacement, structural complexity, and dysfunctional processes. In the following there is a brief overview of the technical and cognitive challenges of hospital work, and then a discussion of a number of ways in which processes in specific contexts can lead to tasks and decisions being conducted in ways that are potentially harmful.

The problem of illness and technology

The meeting of the diseased human body, modern technology, and human cognition in the hospital is risky. Despite their essential commonalities, bodies and the course of illness are hugely variable (Rogers and Gaba 2011). The technological sophistication of treatment makes it "particularly prone to error" (West 2000: 120). Failure to correctly identify and manage technological risks adds to the possibility of harm (Vaughan 1999).

Technologies may be used incorrectly, they may be badly maintained, and they may harbour failures that increase the risk of operator error (Fagerhaugh, Strauss et al. 1987). The possibilities are seemingly endless. Some anaesthesia machines do not pump oxygen to

patients when the flow dial is set between numbers, risking brain damage or death. Syringes intended for one kind of use may be similar to those with a different purpose, and fatal if used in that way (Senders 1994). A lack of standardisation can mean that similar devices work differently. Between 2005 and 2010 the National Patient Safety Authority in the UK received over one thousand error reports about infusion pumps that performed unexpected actions when learning from one pump was transferred to another (Dixon-Woods 2013).

Technological risks can also arise indirectly. The electronic medical record has substantially expanded the volume of information, but it may obscure key facts and insights from busy doctors (Hirschtick 2012). Mobile communications technologies have "vastly increased" interruptions during important tasks (Detsky and Berwick 2013: 987).

The many technological sources of risk are a substantial focus of human factors research. Ergonomics, usability engineering, and user-centred design have all been advanced as ways of overcoming error at the human-machine interface (Gosbee and Lin 2001). However designing solutions and putting them into practice is challenging. There is a tendency in healthcare to rely upon less effective solutions such of education and training, rules and polices, and checklists and reminders. More effective solutions however such as forcing functions, automation and computerisation, and simplification and standardisation are not always appropriate. But while the best solution may be a combination of all, healthcare providers have a tendency to not create such strategies. Instead they continuously seek simplified "silver-bullet solutions" as responses to problems that have enormous underlying complexity (Joseph and Olivier 2012: 26-27).

The cognitive limits of being human

There is a multitude of simple and complex challenges in hospital care that require workers to always be attentive to tasks. However this may be challenging. As earlier discussion showed, pressure can be pervasive in hospitals and tasks may be performed badly as a consequence. However pressure is not the only factor in task failure. The risk of failure is always present with mental and physical tasks because of human fallibility.

James Reason (1990) had described many forms of fallibility with consequences for safety. Unsafe actions involve either violations or errors. Violations are deviations from safe and recommended practices due to poor motivation, or ineffective training, supervision and management. Errors are a result of aberrant mental processes during either automatic skill based functioning, or the conscious application of rules and knowledge. The former are unintended slips, which arise from interruptions, although the mental complexity of tasks can also be a factor. The latter are mistakes, caused by applying an incorrect rule, insufficient knowledge, or incorrectly interpreting a problem. Varieties of mistake include over generalisation from past experience; deciding on an initial piece of information; only considering evidence that favours a hypothesis; and favouring evidence that supports an initial course of action.

Pervasive failure

Many researchers have studied errors in the clinical environment. A study in an Intensive Care Unit in an Israeli hospital found that individual patients were subject to an average of 178 activities per day, of which 1.7 (0.95%) were erroneous. Twenty-nine percent of these errors were potentially capable of causing significant deterioration or death (Donchin, Gopher et al. 1995). Another study in an American Intensive Care Unit found that one fifth of medication doses involved a potentially harmful error. The major causes of error were a lack of drug knowledge (23%), slips and lapses (14%), drug misidentification (13%), and rule violations (11%) (Kopp, Erstad et al. 2006).

Mary Dixon-Woods' (2010) review of a number of ethnographic studies of patient safety in four NHS hospitals identified numerous risks emergent from violations, slips, and mistakes. Discipline was poor, work was frequently interrupted by distractions, and control in general over clinical tasks was often lacking. Distractions were routinely tolerated, with the charge nurse in one Accident and Emergency Department interrupted on 41% of occasions. There was a mean of 14 interference counts in the operating theatres. Disruptions were supported by theatre-in-use lights not being used, theatres being used as thoroughfares, case irrelevant conversations, newspapers, phone calls and pagers. These sometimes occurred during tasks that were vulnerable to interference. Many tasks were not performed correctly, including:

> equipment not being prepared, checked or in the right place; failing to undertake blood loss analysis; not managing perfusion correctly; not wearing masks or eye protection during operations; not maintaining proper standards of hygiene; omitting key surgical steps; starting procedures without everyone in the team being aware or ready, and without all the equipment and supplies being checked and in place; not reading back during instrumentation checking; not completing swab checks; and violating aseptic procedures (Dixon-Woods 2010: 13).

Sometimes these deviations from correct practice evolved as adaptations to organisational pressures or systemic failures. Adaptive behaviours meant that tasks were performed incorrectly, but staff may have been largely unaware of the risks to patients because the practice had been normalised. On other occasions staff conflicted over the rules, sometimes because of legitimate differences of professional opinion, and sometimes because of a refusal to follow a correct procedure such as wearing a surgical mask. Staff also sometimes adhered to rules that were pointless in the situation, but by making a display of compliance they were able to avoid censure, and were seen to be acting correctly.

Social norms and rituals

On many occasions task failures in hospitals are maintained by their normalisation (McDonald, Waring et al. 2005). Social norms may lead to risks being uncontrolled because they are balanced against other priorities and risks, accepted as the product of luck, and ignored as someone else's responsibility. Once risks are normalised social rituals can provide implicit support for the violation of correct practices.

An analysis of hygiene on medical wards by Mary Dixon-Woods, Anu Suokas, et al. (2009) identified normative work and cutting corners as two socially driven responses to risk. Normative work involved a kind of risk accounting by nurses in the context of competing priorities, where the "right thing to do" was "inherently contestable" (Dixon-Woods, Suokas et al. 2009: 365). Measures to control infections were weighed against the social and emotional needs of patients. While infectious patients should have been removed from the main ward and placed in isolation, this was frequently impossible because isolation rooms were already being used for patients without infections. These patients may have been given rooms because they were close to death, suffering terminal cancer, or about to receive bad news about their

deteriorating health. They could also have been disruptive on the ward, or in need of close attention that would have been too difficult to provide outside of the main work area. In these situations nurses made contestable decisions that prioritised the dignity and privacy of vulnerable patients, the pragmatics of ward management, and competing safety needs, ahead of technical risk management.

Social factors were also evident in "cutting corners" behaviour when staff violated correct practices without good reason, and knew they were doing something wrong (Dixon-Woods, Suokas et al. 2009: 365). Equipment was only rarely cleaned between patients, and hand washing was not consistently thorough amongst doctors, nurses, and everyone else who entered the ward. But while these behaviours violated professional identities staff excused themselves because they were busy and the risk was minimal. This avoidance of responsibility was supported by the loose coupling of corner cutting behaviours and harm. If an infection was passed on there was no way of knowing who had caused it and how. These practices were normalised. There were no formal sanctions against violations and those who asserted the correct way of doing things could be informally sanctioned for creating work. As one healthcare assistant commented, "If you say something here you're made to look like the big baddie" (quoted in Dixon-Woods, Suokas et al. 2009: 366).

Further insight into the role of social norms in risk control is evident in Ruth McDonald, Justine Waring et al.'s (2005) analysis of the medical and nursing politics of risk management. While doctors were highly aware of risk there were two ways in which they were unwilling to try to control it. The first involved procedures where there was a known level of risk, such as operations or the insertion of catheters, both of which involved the possibility of infection. Doctors accepted negative outcomes in these situations as predictable and acceptable on the basis of evidence about the rate of negative outcomes. They felt there was nothing they could do as infections were the result of bad luck. The second scenario arose when affective elements such as the doctor's mood on a given day and their emotional reactions to other staff and aspects of their personal lives intruded upon work, making them subject to normal human distractions. As with the previous risk scenario there was little evidence of planning or strategies being used as counter measures. Across both scenarios doctors justified any failures by invoking statistical studies on the probability of bad outcomes. In effect they used the

discourse of risk to identify adverse events as the product of chance, rather than their failure to adopt defensive measures. The scientific and ambiguous nature of this discourse allowed doctors the opportunity to excuse themselves from taking responsibility for mistakes.

The nursing attitude to risk was driven by the need to conform to standard rules, checklists, and protocols. The maintenance of a sterile environment for example was perceived as critical and achievable through the routine performance of actions specified in great detail. But while nurses spoke of these procedures as evidence based, they were unaware of evidence that either supported or refuted their protocols. Consequently they could follow outdated procedures that had not been corrected, fail to critically assess evidence and adjust practice accordingly, and not address safety issues that were unspecified in their manuals. The latter tendency was evident in nurses blaming, but not challenging, unsafe practices by doctors.

Another way of thinking about the influence of social norms on risk control is through the capacity of rituals to maintain unsafe practices. Justin Waring, Steve Harrison et al.'s (2007) analysis of tacit and customary processes relating to clinical risk in surgery and anaesthesia identified three ritualistic behaviours that supported the construction of a medical identify around ideals of individual competence and coping with the unexpected.

The mildest risks were passively tolerated as normal. They included staff being unfamiliar with theatre layout or equipment, equipment arriving late, electrical disruptions to equipment, incomplete equipment checks, patients incorrectly prepared for surgery, and inappropriately attired staff. There was little remedial action and a lack of communication about these risks across occupational boundaries.

More serious risks were accommodated by slight modifications to procedures. These were considered to be normal and safe, and suggestive of the need for consultants to exercise professional discretion in response to uncertainty. There could be changes to the schedule of operations, changes to anaesthetic preparations due to last minute cancellations or new information, reductions to the pace of operations to allow time for the arrival of equipment, and changes during operations because of variations in patient anatomy or disease. These

modifications were discussed only when they affected team work. They were usually unreported and learning was largely individual and emphasised the need for personal flexibility. The most serious risks resulted in innovative practices, especially amongst surgeons. The risk of harm was balanced against the potential for a positive outcome. Surgeons modified equipment intended for other uses, cut equipment to adjust for size, and large patients were propped unconventionally onto operating tables. While nurses may have anonymously completed reports after these events, surgeons perceived the risks as worthwhile and sometimes portrayed themselves as risk takers who broke the rules to gain a better outcome for the patient. Their individual solutions contributed to the maintenance of systemic problems, and the different ritualistic responses increased risk and normalised it. Tolerance, accommodation, and a lack of communication and reporting allowed risks to be overlooked and prevented systematic learning.

Diagnosis and decision making

Diagnostic and treatment decisions are foundational to medical practice. The potential for a wrong decision indicates the unavoidability of risk. According to Marianne Paget (1988), diagnosis is a process of discovery that unfolds over time through inferences, probabilistic thought, experimentation, and trial and error. These actions can become retrospectively mistaken as knowledge accumulates and changes. The actual frequency of diagnostic errors is not well known, but diagnoses may be wrong about 10-15% of the time (Graber 2013).

The extent of diagnostic risk is dependent upon the conduct of the decision process. For most of the twentieth century medicine was practiced according to the sway of localised traditions (Eddy 1990), and the 'non-sciences' of anecdotalism and classical inductivism (Fisher 1999). These paradigms ensured that the norms of treatment evolved according to a series of assumptions: that what most doctors did was correct; that experts could be relied upon; and that collective practice would converge upon the best treatment (Eddy 1990). Decisions were based more on clinical experience and less on scientific evidence. As Howard Becker, Blanche Greer et al. (1961: 234) observed in their study of medical training, students quickly learned when they progressed from the classroom to the hospital that "the magic phrase, 'In my experience ...' signals the settling of many disagreements."

Sociological observations of medical decisions suggest two perspectives on the process. On the one hand doctors are fully aware of uncertainty, and on the other they repress it. The riskiest perspective is the latter because of the possibility that information which is hard to reconcile is ignored. The alternative, a full awareness of uncertainty, is safer because it keeps the door to inquiry open. This does not mean that uncertainty can be overcome, only that information is more fully considered, and there is less risk of an incorrect decision.

The work of Renee Fox (1957, 2000) supports the view that doctors maintain a full awareness of uncertainty. Fox identified three irreducible uncertainties in medical practice. First, doctors were necessarily ignorant of some issues because of the impossibility of acquiring all of the lore of medicine. Second, some situations were objectively uncertain because of the limits of medical knowledge. Third, in times of uncertainty doctors could not know if the inadequacy was theirs, or if it reflected a gap in medical knowledge.

Fox (1957) argued that ambiguity affected all levels of medical practice. It caused doctors to be confused, to disagree with one another, and be proven wrong by the course of events. Medical students learned that medicine "is sometimes largely a matter of conjuring ... possibilities and probabilities." Their ultimate relationship to this uncertainty was accommodation. They accepted it, realised it could never be overcome, and made decisions according to "an experimental point of view" (Fox 1957: 212, 213). They also learned to appear confident and not convey the insecurity of uncertainty.

Some other analysts have taken a different perspective to Fox. Eliot Freidson (1970a) also emphasised uncertainty in medical practice, but argued that doctors usually tried to overcome it. Being unable to afford the thoughtful detachment of scientists, they showed five pragmatic tendencies in the face of uncertainty. First, doctors valued action and preferred to do something over nothing, even if the chances of success were slim. Second, they preferred to be confident and to believe in the value of their actions more than scientific proof allowed. Third, they relied upon results over theory and were prone to tinker when results were not forthcoming. Fourth, they worked subjectively through first-hand experience and gut instinct rather than book learning. Fifth, doctors emphasised indeterminacy and the uncertainty of events to support their pragmatism. Collectively, these actions repressed uncertainty.

Donald Light (1979) also argued that uncertainty was repressed in medical practice. In seeking professional status doctors needed to master knowledge that was complex and potentially overwhelming. By learning as much as possible, by specialising and limiting the field of what was to be known, and by adopting a school of thought, doctors could overcome their bewilderment and gain a sense of certainty. But the outcome of control was achieved by excessive confidence and insensitivity "to complexities in diagnosis, treatment, and client relations" (Light 1979: 320).

Paul Atkinson (1984: 953) similarly doubted the "radical doubt ... cultural crisis or *Angst*" that Fox identified as pervasive in medicine. For Atkinson, doctors were first and foremost pragmatic empiricists. They relied upon experience, and in their day to day practice they developed and routinised practical systems of rules, treatment philosophies, and approaches to clinical work. These patterns contradicted any possibly of their being "ideal-typical reflexive scientists" who strove to test and falsify every hypothesis (Atkinson 1984: 955).

The uncertainties of medical practice has been widely acknowledged. However as Freidson (1970a), Light (1979), and Atkinson (1984) demonstrated, the tendency for doctors to believe in the effectiveness of their work beyond what was scientifically indicated, and to subscribe to divergent schools of thought and philosophies of treatment, indicated a tendency towards dogmatism that is not in the interests of safety. A great challenge of medical work is to manage irrepressible uncertainty without relying upon simplified formulas. In the face of complexity, patient suffering, and pressure to get the work done, this is a lot to ask.

Organisational tasks and risk

The performance of clinical tasks invokes the complexity of bodies, illnesses, and technologies. The responses that are emergent to these challenges are often inadequate because tasks may be performed under pressure, human cognition has limited capacity, unsafe practices may become culturally normalised, and some uncertainties are difficult to overcome. When these challenges arise a kind of risk accounting is often generated in which risks are accepted as normal and not fully controllable. These responses may be maintained because there are standard rates of many kinds of adverse events, and catastrophic outcomes with easily

allocated blame are infrequent. However the tolerance of small risks increases the possibility of harm because as risks grow and spread the possibility emerges that they may combine in ways that cannot be predicted. For this pattern to change it is necessary for staff to believe that different forms of action are both possible and realistic. This outcome could be expected to be unlikely without collective and systemic change. If the system is perceived as monolithic and uncontrolled, then staff are unlikely to change practices that normalise harm.

Conclusion

This chapter has explored the in-hospital dynamics of risk and harm with the purpose of understanding how these events unfold, and where attention should be focussed to improve safety. The discussion covers theoretical and empirical perspectives on risk. In this conclusion I briefly review the theory, and draw upon the empirical material to make some suggestions about strategies that may be most effective for controlling and reducing risk.

Theories on risk demonstrate that risks are the outcome of the design and the working of complex organisational systems. Broadly, there are two perspectives on these systems. The first is that a lack of safety is caused by latent errors that are designed into the system, and remain hidden (Reason 2000); and by characteristics of complex interactivity and tight coupling (Perrow 1984). This perspective suggests that safety can be achieved by redesigning the system, and giving attention to small risks, so they do not combine in unexpected ways. The second perspective on safety is that organisations must learn to anticipate and contain failure. This means sensing the unexpected, avoiding simplification, being sensitive to operations, committing to resilience, and deferring to expertise. Together, these perspectives emphasise the importance of designing safety into the system, and encouraging the attitudes and behaviours of high reliability.

The more empirically focussed part of this chapter has shown that risks to patient safety emerge from the interconnections between institutional norms, the economic environment,

organisational structures and processes, and the performance of tasks. These in turn affect the cognition and action of staff. The many ways in which risks emerge from these components of social and organisational reality means that safety in hospitals can require multiple points of focus.

A very practical way of thinking about the dynamics of risk from a control perspective is to identify categories of risk that strategy can be constructed around. This categorisation can also suggest an approximate hierarchy of focus. This is not to say that some risks should receive less attention. It is a recognition that some risk have overwhelming power, and if they are not addressed effectively they have the potential to undo efforts in other areas.

It is possible to view the exploration of risk in this chapter as revolving around three primary factors. First, in many of the scenarios in which patients are exposed to risk, pressure is a common factor which sets other factors in motion and amplifies their effect. Second, communication has been identified as involved in the vast majority of medical mishaps (Sutcliffe, Lewton et al. 2004). It is frequently in evidence in the material presented. Third, many of the risks identified have a common basis in cultural factors that influence perception and support unsafe actions.

Goal displacement due to the prioritisation of economic objectives may be the most powerful risk factor in hospital care. The pressure created by insufficient human resources has been shown throughout this review to be connected to most of the other risk dynamics. By overloading staff with more work than they can perform safely in the time available pressure affects cognition and action in relation to the performance of individual tasks, it affects communication between staff, and it alters the ways in which staff perceive and act in relation to the risks that they encounter. Pressure is particularly problematic in hospitals because, as Charles Perrow's (1984) normal accident theory shows, complexly interactive and tightly coupled systems create the greatest risk, and pressure amplifies these characteristics. Pressure also meets the criteria in James Reason's (1990, 2000, 2001, 2004) model of organisational accidents as a latent failure and a root cause of error. As Reason argues, latent failures are designed into systems, and they will continue to create active errors at the sharp end of practice

until they are designed out. The sources of this pressure are the underfunding of healthcare (West 2000), and the poor design of clinical systems (Dixon-Woods, Martin et al. 2014).

The identification of pressure as a latent risk does not mean that 'solving' pressure would end the significance of the other risks that it amplifies. It means that these other risks would lose some of their salience, and developing solutions to them would become more realistic.

Poor communication has been identified as involved in the vast majority of medical mishaps (Sutcliffe, Lewton et al. 2004). However there were some risks in this review that it was not associated with, and in some cases poor communication was driven by pressure. This suggests that pressure could be the more dominant factor. Nonetheless, communication failures remains a powerful contributor to clinical risk. There can be no doubt that many of the harms associated with communication would continue to occur in the absence of pressure. In addition, resilient communication under pressure would benefit safety.

A major focus for improving communication needs to be the status hierarchy in hospitals, especially within the medical profession, and between the medical and nursing professions. As Sutcliffe, Lewton et al. (2004: 193) argue, communication failures arise "from vertical hierarchical differences, concerns with upward influence, role conflict and ambiguity, and struggles with interpersonal power and conflict." This is a particular aspect of failed communication that needs its own solution. However it is only one facet of the wider challenge of better communication.

It was evident throughout this chapter that hospital care is often affected by a cultural tendency to minimise and deny the significance of risk. While this factor was often related to pressure or made worse by it, this did not always follow. And, similar to poor communication, this risk would continue to cause harm even in the absence of pressure. As a form of practice it allowed numerous small risks to be normalised and tolerated as inevitable. Thought or effort was sometimes not expended on the possibility that these risks needed to be talked about across group boundaries, that planning was necessary, and that repair was possible through the redesign of systems. Instead these risks could be tolerated and ignored, and individual workarounds were initiated as adaptations. These practices were unsafe because when active

and latent errors accumulate within a system the possibility emerges that they can cause harm by combining in unexpected ways (Reason 1990). The appropriate response to these risks would be treat them as anticipations of failure that require containment in the short term (Weick and Sutcliffe 2007), and system redesign in the long term (Reason 2000).

In conclusion, risk control strategies need to prioritise ways of reducing the pressure on clinical work, ways of improving communication, and ways of changing the culture to one that actively controls and eliminates risk rather than tolerates it. These solutions reveal in turn an emphasis on economics and systems design; power and culture; and culture and system design. The inclusion of culture in the lower orders of this ranking in no way denigrates its importance. However, as Susan Silbey (2009) has argued, we need to be wary of the contemporary tendency to fall back upon culture as the first line of defence against harm in systems that are inherently unsafe.

Chapter 4

Implementing Safety Improvement

In the investigation of the risks of hospitalisation in the previous chapter I argued that the strategic priorities for risk control should be reducing the pressure on staff, levelling the status hierarchy, and cultural change to increase risk sensitivity and task safety. Pressure in the clinical environment driven by the prioritisation of economic objectives was identified as the most important strategic priority. Pressure was also sometimes the outcome of poorly designed clinical systems, which initiated a vicious cycle of failure that organisations could struggle to change.

This chapter is about breaking the cycle of failure and making safety improvement in hospitals achievable. Knowing how to do this work effectively is the most important priority of the patient safety movement. This is the work that promises to reduce harm. While additional resourcing may be necessary to reduce risk it is likely to be insufficient for improvement if practices do not change. Which practices can contribute to this outcome, and how those practices may be implemented to have their greatest effect, is the most valuable of all patient safety knowledge. It suggests where resources should be diverted to so change can have the greatest effect. In order to build an understanding in this chapter of how to do safety improvement I will review the major improvement methodologies and practices currently in use, and construct an outline of the most effective ways of improving safety.

This chapter is structured as a series of discussions about the improvement methodologies of quality assurance, medical audit, evidence-based medicine, human factors and ergonomics, and industrial quality improvement. For each there is a descriptive outline of the method and associated practices, some context about impact and outcomes, an analysis of the challenges of implementation and use, and an overview with suggestions about how each method may be most effectively implemented to improve safety. While these topics are treated separately, in reality improvement is often an eclectic process in which many practices are employed simultaneously. Sometimes these are relatively independent, and sometimes they are closely coordinated to work in combination with one another. This is particularly evident with quality improvement, which describes both a specific set of methods, and a generalised activity that may draw upon all of the practices described in this chapter. In the conclusion I argue that safety improvement needs to become a comprehensively supported whole-of-organisation activity, and I outline the requirements for this to occur.

Quality assurance

Methods

The regulation and inspection of hospitals began with the minimum standard in America in 1918. Over time the initial requirement for US hospitals to meet four basic standards for the provision of care has grown into a range of complex contemporary systems of inspection and measurement. As identified by Avedis Donabedian (2005) these measure the structural characteristics of hospitals and various processes and outcomes from which the acceptability of performance can be calculated. The intention is to identify where improvements may be necessary and prevent hospitals from falling below an acceptable standard. While regulation work is the province of governmental agencies, and (in America) private organisations with official recognition in the healthcare system, in recent decades private organisations in the US and in the UK have also provided information for ‘consumers’ on the quality of care in different

hospitals. A related development, beginning in the UK in 2001, involves the determination of a numeric performance rating for individual hospitals. This number is calculated from an algorithm using dozens of measures, including clinical ones such as wait times and quality (Smith and Busse 2010: 516-8). Performance scores are published in the UK alongside measures of critically important indicators, such as waiting times in emergency departments, where hospitals are expected to process most patients within a specified time frame (Bevan and Hood 2006a: 419-420). The intention is to focus efforts by offering hospitals financial incentives and greater autonomy as rewards for success, and reputational costs as punishment for failure (Bevan and Hood 2006b: 518-519). While hospitals in NZ are subject to a system of accreditation and there is measurement of various clinical indicators, there is no performance rating of hospitals, and no private agencies provide quality ratings. However in 2009 publicly reported targets were set, which included waiting times in emergency departments, and access to elective surgery and cancer treatment (Ministry of Health 2013).

Implementation and practice

While quality assurance does not provide a method of improvement, by signalling priorities and measuring performance it helps to shape clinical action and resource allocation. In these ways measurement and comparison has provided a focus for action, stimulated new infrastructure developments, improved the provision of evidence-based care, and assisted intelligence about the effectiveness of different approaches to safety (Meyer, Nelson et al. 2012: 964).

However the substantial benefits of quality assurance exist alongside a number of possible adverse consequences. In view of these negative outcomes some commentators have argued that the conduct and the purpose of measurement should be substantially reviewed. The discussion here identifies and explains the adverse effects of quality assurance, and briefly outlines alternatives that could contribute to improvement.

An early difficult with quality assurance in America, made worse by public reporting, was the tendency for measurement to justify punishment. Improvement was compromised because the

fear of reprisals drove defensiveness. Hospitals that were identified as less than average wasted resources in lengthy bureaucratic exercises to try to explain and excuse themselves. Individuals that could have some responsibility for safety incidents were reluctant to discuss and learn from their experiences because of the fear of being reported (Berwick 1989: 53-54). Very similar outcomes have been observed in the NHS, where public reporting motived by a belief in improvement through shame and reward "rarely" stimulated improvement (Mannion and Braithwaite 2012: 262). Even worse, efforts to manage hospitals strictly in accordance with officially sanctioned performance criteria was sometimes detrimental to safety. The failure of the hospital at Mid Staffordshire, judged by the Francis Inquiry to have provided "appalling" standards of care, was due in part to an excessive emphasis on meeting the performance criteria and targets necessary to achieve NHS Foundation Trust status (Francis 2013: 7, 13).

At least four explanations have been suggested for the connection between performance measurement and targets on the one hand, and failure to improve on the other. First, systems of compliance can make huge demands on resources. Between 2005 and 2011 the number of measures approved by the US National Quality Forum "skyrocketed," from less than 200 to more than 700. US hospitals currently spend about 90% of their measurement dollars on compliance needs for external stakeholders, with 10% left to support locally necessary improvements (Meyer, Nelson et al. 2012: 964-6). In the NHS the regulatory environment has created complex "priority thickets," that command substantial attention and distract senior managers from developing strategies to pursue locally necessary goals (Dixon-Woods, Baker et al. 2014: 109).

A second difficulty with measurement regimes is their tendency to antagonise clinicians and become disconnected from the reality of how outcomes are achieved in hospitals. The dominant emphasis on defects in the measurement of performance alienates clinicians, many important measures are of limited relevance to many clinical specialities and patients, and measures usually have a single event rather than a systemic focus (Mountford and Shojania 2012). A third and closely related problem is inaccurate measurement. A study of four major US rating systems found that only 10% of hospitals rated as high performers by any one system were given an equivalent rating by any other system (Austin, Jha et al. 2015). In the midst of its "appalling" safety crisis of 2005-2008 (Francis 2013: 7) Mid Staffordshire hospital was rated by

the Healthcare Commission as one of the four most improved in the NHS, and Dr Foster's Good Hospital Guide ranked it in the top ten for safety (Dixon-Woods 2013).

A fourth difficulty is the potential for performance measurement to generate a range of unintended consequences that distort the conduct of clinical work and generate varying degrees of dishonesty in measurement and reporting. These outcomes are reflected in an analysis of twenty different unintended consequences in the NHS that may have arisen because of performance targets (Mannion and Braithwaite 2012: 262). Most can be classified into the two major types of effort substitution, or focussing more on what is measured and less on what is not, and gaming, or the manipulation of data, so performance appears to be better than it is (Kelman and Friedman 2009). The view that targets may distort priorities and harm the quality of clinical work is consistent with the theory supporting modern quality practices. Hospitals are complex systems and targeting parts of the system is necessarily less effective as a means of improvement than focussing on the whole system (Gubb 2009).

The outcomes of some performance targets in the NHS and NZ, while seemingly effective, reveal more ambiguous outcomes on deeper analysis. Targets were apparently effective in the English NHS during 2001-2005 when wait times for admissions through emergency departments (EDs), ambulance calls involving a threat to life, and elective hospital admissions, were all reduced (Bevan and Hood 2006a: 419-420). There was no evidence of either effort substitution or gaming due to the ED target (Kelman and Friedman 2009). But meeting the ED targets shifted waiting to diagnostics, and increased bed occupancy, which worsened the risk of infections (Gubb 2009). Moreover, faster admissions during 2000-2007 produced no change in the time taken for patients to see a treating clinician (Jones and Schimanski 2010: 395).

ED targets in NZ hospitals appear to have compromised quality. Unlike in the NHS, where funding was specifically provided for targets, no allocated funding was provided to assist hospitals in NZ. Nonetheless, at least NZ$52 million was spent in EDs on targets over a period of 4½ years. Because the District Health Boards governing the hospitals were unaware if this expenditure came from efficiency gains, or resource transfers, the quality of care in other departments may have been compromised (Jones, Sopina et al. 2014).

A number of ideals have been outlined for the future of performance measurement and quality assurance. There have been calls for a more "judicious" and "balanced" approach to measurement (Mannion and Braithwaite 2012: 573). The costs of compliance should be reduced so space can be created for systems that better fit local improvement needs (Meyer, Nelson et al. 2012: 966). Clinicians should take greater responsibility for poorly organised systems of care, and work with colleagues, regulators, and patients to develop measurements that contribute to improvement (Mountford and Shojania 2012). Quality assurance could be more closely aligned with clinical treatment through a system that outlines treatment options according to patient need and preference (McGlynn, Schneider et al. 2014). Regulators could copy other safety critical industries and shift the focus from performance measurement to prescribing and checking the implementation of evidence-based systems that support safer clinical work (Dixon-Woods 2014b: 39'10").

Overview of quality assurance

Measurement plays an essential role in healthcare and improvement. It signals priority and creates mission (Dixon-Woods 2013). In the form of quality assurance and performance measurement it has assisted the implementation of improvements in safety (Meyer, Nelson et al. 2012: 964). But it also creates significant risks, which grow with the complexity of the system of measurement. There is "an awful lot of stupid measurement in healthcare" (Dixon-Woods 2013). The argument has been presented that healthcare is suffering from too much measurement of the wrong measures, that these measures are often inaccurate, that they shift priorities from the needs of improvement, and, that in the form of targets, they distort the quality of clinical practice by changing its focus. The theme of clinically useful measurement is returned to in the later discussion about quality improvement.

Medical audit

Methods

Audit is a formal learning system. Its basis emerged around 1900 when Ernest Codman began recording and analysing data about his patients and their diagnosis and treatment to determine the causes of surgical outcomes, and how improvements could be made (Reverby 1981). Contemporary audit is closely related to quality assurance and performance measurement, with the major difference being that the latter represents a bureaucratisation of audit, whereas clinical audit is controlled by doctors and directly aligned to practice through feedback and learning. Audit can also draw upon modern quality improvement methods.

There are many variations of audit practice. There may be qualitative investigation of a few cases in depth, or statistical analysis of a few characteristics of many cases. Both provide the opportunity for feedback, understanding, and change (Donabedian 2005). Practice may be prospectively investigated as it occurs, so change can be introduced in real time, or there may be a retrospective search backwards to identify patterns or investigate failures (Copeland 2005). Prospective audit as it is currently employed in the NHS measures the provision of care against explicit evidence-based standards of high quality, and seeks to bring practice into line with those standards. The process involves repeating a four step audit cycle of preparation and planning, performance measurement, change implementation, and sustaining change (Burgess 2011a, Burgess 2011b). In NZ prospective audit has become directly associated with the plan-do-study-act (PDSA) cycle of continuous quality improvement[6] (Ministry of Health 2002). Another widespread audit practice is the morbidity and mortality conference, which is a regular meeting of medical and surgical staff to discuss cases of death, harm, error, or unexpected outcomes (Orlander, Barber et al. 2002).

[6] See discussion page 155.

Implementation and practice

In the US and the UK medical audit has been made compulsory for doctors. In both instances the policy failed expectations. In America audit became a paper exercise practiced to meet legal obligations (Roberts, Coale et al. 1987). In the UK audit was expensive and ineffective (Neale, Vincent et al. 2007). The centrality of audit in policy declined in both systems, and other quality methods gained primacy.

Frequent poor implementation of audit belies the potential of this method. A Cochrane Review of randomised trials investigating the effect of audit and feedback on the work of mostly doctors, but also nurses and pharmacists, found generally small but potentially important improvements in practice (Ivers, Jamtvedt et al. 2012). Prospective audit can provide a rich understanding of the complex reasons for failures, and the opportunity to correct them (Burgess 2011b). One such small improvement was the use of prospective audit by doctors in an NHS hospital to achieve superior therapeutic doses of Gentamicin, with less trauma and blood sampling for delicate newborns (Bajaj and Palmer 2004). On a larger scale, the Confidential Inquiries into Peri-Operative Deaths were a retrospective audit initiated and controlled by NHS doctors that led to dramatic improvements in anaesthesia and surgical care during the 1980s (Neale, Vincent et al. 2007: 88).

Prospective and retrospective audit

The UK National Institute of Clinical Excellence (2002) has described the implementation of prospective audit as compromised by problems with poor design, data, management, commitment, follow-up, and support. Kieran Walshe (2002b) has argued that audit is an essentially simple method of improvement that normally failed because of a lack of leadership and problems with organisational culture. Robin Burgess (2011b) noted that audit was challenging because it was necessary to work with methodological rigour and complete and repeat the audit cycle. Sustained commitment over time and attention to detail were necessary. Often audits identified the same problems over and again, but managers and clinicians did not commit themselves to the actions necessary for change.

Nick Black and Elizabeth Thompson (1993) sought to understand the barriers to audit amongst doctors and identified them as generally supportive of the idea, but critical of implementation. Five factors explained why doctors criticised an idea they supported. First, because audit was shaped by the environment in which it was practiced, political tensions easily spilled over into the evaluation of practice. Second, doctors were complacent about clinical problems and preferred to emphasise managerial and administrative failures. Third, they were uncertain about the value of audit and questioned the opportunity cost of their time. Fourth, they neither understood it well nor practiced it correctly. Fifth, they felt that detailed knowledge of specific medical issues was necessary. But audits should primarily be a method of asking questions concerning the 'how' and the 'why' of medical practice.

Black and Thompson's (1993) analysis makes it clear that cultural change is necessary for audit to gain traction. Doctors would need to be free from stigmatisation for being less than perfect, and more willing to own errors and think of them as potentially preventable. Other necessary conditions include support from management, leadership from senior clinicians, completion and repetition of the audit cycle, and commitment to the use of learning to drive change (Burgess 2011b). Audit has been found to be most effective when performance was initially poor, and guidance about change was provided by a supervisor or a colleague. Feedback was most effective when provided both verbally and in writing on more than one occasion, and when clear targets and an action plan were included (Ivers, Jamtvedt et al. 2012).

The morbidity and mortality conference

The morbidity and mortality conference (MMC) has been subject to occasional in-depth investigation, and while some strengths of the process were evident, in all cases it required improvement in practice.

Marcia Millman (1977) found that the MMC was carefully orchestrated by doctors to ease feelings of guilt, restore a responsible self-image, and create the appearance that standards were being monitored and improved. Tactics employed for this purpose included excluding and ignoring cases of obvious error, focussing on helpless cases, creating confusion through excessive detail and the discussion of misleading symptoms, and blaming difficult patients.

Arnold Arluke (1977) similarly described the MMC (or death rounds) as a form of social control for maintaining the legitimacy of practitioners and profession. Cases were selected carefully and a well scripted ritual was repeated over and again until the smooth flow of complex academic information ended with the refrain of death, "even though we did everything we could for the patient" (Arluke 1977: 112). Few solid truths emerged from the process. Mistakes appeared excusable and understandable. Learning was individual and non-systematic:

> Lessons are not extracted from the discussion and communicated to those present. Individual cases at death rounds are not compared to previous cases, thus preventing the identification of patterns in patient care. In short, the process of instruction at death rounds seems to be a casual afterthought to the routine of the review. Somehow learning is presumed to take place in this setting without ever having to specify what it is that should be learned (Arluke 1977: 123).

Charles Bosk's (2003) analysis suggests a very different perspective. The evidence of honesty and systematic learning that he found suggests that localised cultures can have a powerful effect on the MMC.

Bosk (2003, originally 1979) described the MMCs he observed as involving open discussions about difficult cases and obvious errors, and the effective communication of learnings that could be applied in the future. This was particularly apparent in situations where the failure was unexpected. On those occasions a "hair shirt" ritual (Bosk 2003: 139) was performed, and complete responsibility for the failure was accepted. Witnesses avoided blame, emphasised the mysteries of the case, and sometimes admitted to similar mistakes themselves. Paradoxically, the ritual reinforced the power of the presenting surgeon through their public demonstration of the qualities of the healer: "humility, gentleness, wisdom" (Bosk 2003: 144). The show of humanity rounded their professional persona, and unconditional support and forgiveness was provided in return. But while the limits of action were accepted and mistakes were treated as inevitable, errors were simultaneously recognised and learned from according to the belief that their repetition could be prevented. The hair shirt ritual allowed for the forgiveness of unique mistakes, not the repetition of similar errors.

The strengths of the MMC as Bosk described it also suggests a notable weakness. The hair shirt ritual institutionalised individual responsibility. Bosk described no process for recognising the

systemic components of errors, which is a clear blind spot in the traditional medical understanding of error.

Overview of medical audit

Audit invokes technical, organisational, and cultural challenges. Audit design, and the collection and analysis of data, are technically difficult. Evaluation can be complicated because it may expose individual weaknesses, and because doctors may be uncomfortable with the idea that their performance needs to improve, and that errors are potentially avoidable. Adverse cultures may be critical of imperfection and medical culture in general can be fatalistic about mistakes. Completing and repeating audit cycles requires commitment to doing the work, acting on the results, and working cooperatively with managers to change systems. The MMC may fail through ritualistic excuses, obfuscated learning, and an individualistic rather than a systemic approach to error. The challenges of audit indicate the need for committed organisational action, supported by management and led by senior clinicians, so the audit cycle can be completed and repeated, and the findings acted on. The challenges of achieving these outcomes are returned to in the later discussion about quality improvement.

Evidence-based medicine

Methods

Evidence-Based Medicine (EBM) is a method of making medical practice more scientific. Its foundations were created by Alvan Feinstein, who drew upon clinical epidemiology to shift the focus of research supporting medical practice from laboratory science, to the conduct and the outcomes of clinical work. By classifying subgroups of patients and identifying the effects of treatment on each, Feinstein sought to reduce reliance on intuition in the diagnosis and

treatment of disease, and create a taxonomic, classificatory science of clinical care (Daly 2005: 29).

Clinical epidemiology emerged as a discipline in its own right at McMasters University in Canada in the 1960s, where David Sackett promoted it as a social movement and drove its development and translation into EBM (Daly 2005: 76). But while Sackett's work reflected Feinstein's emphasis on the need for a more scientific approach to medical practice, the focus also shifted to critical appraisal (Daly 2005: 88), and the classification of a hierarchy of evidence (Daly 2005: 77). These methods made randomised controlled trails (RCTs), and their synthesis through the technique of meta-analysis, central to the practice of EBM (Daly 2005).

RCTs constitute the "gold standard" of contemporary EBM (Timmermans and Berg 2003). They prioritise statistical analysis above laboratory learning, and alleviate the need for doctors to think through deterministic notions of cause and effect (Tanenbaum 1994). The pinnacle of evidence is the synthesis of multiple RCTs in the systematic review. If evidence from RCTs is unavailable then less scientific research such as small clinical trials, non-randomised research, and case-studies may be given evidentiary force (Timmermans and Kolker 2004).

Clinical epidemiology in the UK was significantly shaped by Archie Cochrane, who argued that medical care was often ineffective and dangerous, and that such practices should be identified and eradicated. Like Sackett, Cochrane viewed RCTs as the primary method for demonstrating what did and did not work in practice. For this purpose the Cochrane Centre and the Cochrane Collaboration was established in 1992 as a means of facilitating comprehensive overviews of the evidence in each specialised field of medical practice (Daly 2005: 137-139).

In practice, EBM relies upon either critical appraisal or the application of clinical practice guidelines. Critical appraisal requires doctors to widely investigate and interpret research so it can be applied to unique clinical situations (Harrison 2002). David Sackett and William Rosenberg (1995: 332) described this approach as achievable through active programs of professional development that make doctors into "life-long, self-directed learners of EBM." The guidelines approach is less demanding for busy doctors who may find the complexities of gathering and evaluating research evidence impractical. Knowledge is applied through

protocols that typically take the form of 'if ... then' algorithmic statements. While these may offer some room for professional discretion, they deprioritise clinical experience in favour of rules (Harrison 2002).

Implementation and practice

EBM has driven many improvements in quality and safety. Just a few examples include changes to patterns of asthma care in the UK, which reduced morbidity and mortality, and the use of guidelines for venous thromboembolism, which significantly reduced post-surgical thromboembolic complications (Greenhalgh, Howick et al. 2014: 1, 7). More generally however the adoption of EBM is often slow, and the publication of guidelines, evidence, and systematic reviews of clinical interventions have not had the intended outcome of radically improving clinical practice (Shojania and Grimshaw 2005). In the US patients receiving treatment for thirty different acute and chronic conditions were found to have been provided with only 54.9% of recommended basic care processes (McGlynn, Asch et al. 2003). Simultaneously, about 20-30% of healthcare spending in the US was wasted on overtreatment that increased patient risk (Wennberg, Fisher et al. 2008: 4). In response to overtreatment the *British Medical Journal* is currently conducting a *Too Much Medicine* campaign, and facilitating a series of *Preventing Overdiagnosis* conferences.

A critical consideration in evaluating the failure of the medical profession to advance evidence-based care is the problem of "too much evidence":

> The number of clinical guidelines is now both unmanageable and unfathomable. One 2005 audit of a 24 hour medical take in an acute hospital, for example, included 18 patients with 44 diagnoses and identified 3679 pages of national guidelines (an estimated 122 hours of reading) relevant to their immediate care (Greenhalgh, Howick et al. 2014: 2).

This problem is made worse by the ways in which evidence is communicated by the institutions that create it. Most evidence is methodologically robust, but unusable in practice (Greenhalgh,

Howick et al. 2014: 4). This creates some particularly challenging work for hospitals seeking to assist doctors in the implementation of EBM.

However too much unusable evidence is only one of many reasons for poor implementation. Some failures are clearly indicative of neglect at the sharp end. The evidence in support of hand washing is well known and definitive, but nonetheless poor hand hygiene standards are a contributing factor to infections affecting about one in eleven hospital patients. About 15%-30% of these infections may be preventable (Grol and Grimshaw 2003: 1226). The widespread availability of cleaning stations and signage to use them can help, but anecdotally this does not always work (Gordon 2012).

In many cases the barriers to EBM are deeply entangled with the complexity and the pressure of practice. A systematic review of why doctors did not follow guidelines and policies identified a myriad of challenges. There was a lack of awareness, familiarity, and agreement; doctors were uncertain if they would be able to put guidelines into practice, they questioned the likely outcome, and the inertia of previous practice needed to be overcome. Doctors also struggled to reconcile guidelines with patient preferences, they were confused by contradictions between guidelines, and there was a lack of time and resources to complete the necessary work (Cabana, Rand et al. 1999). Another systematic review found that failures appeared to be the result of working with very challenging clinical conditions, physician refusal of guidelines, poor dissemination of information, and a lack of feedback to physicians (Shortell, Bennett et al. 1998).

Systematic reviews have also examined the effectiveness of methods for implementing EBM. One such review identified seventeen distinct strategies. Most had some effect (about a 10% rate of improvement on average), but while many practitioners relied primarily upon educational material and continuing medical education to keep up to date with evidence, these were not very effective unless integrated with other interventions. The obstacles to change involved not only individual practitioners, but challenges with patients, the organisation of care, resources, leadership, and the political environment outside of hospitals. To achieve change, a range of strategies would be required addressing individual doctors, teams, and organisations. Some of the most effective methods were interactive small group meetings,

reminders, computerised decision support, computerisation, and mass media campaigns (Grol and Grimshaw 2003).

A report from a meeting of experts also argued for a multi-faceted strategy, with an emphasis on strong leadership, sufficient resources, multistage education, follow up, and feedback. It was also essential to consider unique factors involving the target group, practitioners perceptions, the setting, the desired change, and identified barriers to implementation. The strategy would need to involve all stakeholders, gain buy-in from local opinion leaders, and be widely communicated in detail. Computer-aided decision support systems could be helpful, nurses and pharmacists could be enlisted to provide support and reminders, and audit could provide a basis for feedback (Gross, Greenfield et al. 2001).

Stefan Timmermans and Alison Angell (2001) have shown the unique troubles that EBM presents for junior doctors. As residents in training the paediatric residents in their study were not autonomous and had to at least attempt EBM. Most adopted what was identified as a 'librarian' approach. They searched quickly for guidelines according to need, and judged them as authoritative if the source appeared to be credible. To save time, they often approached seniors for advice first. EBM was difficult because of the time it demanded, and the inadequacy of their skills for finding and evaluating information. Their poor information gathering skills led them to rely upon clinical experience or the opinions of seniors. Their poor evaluation skills led them to overestimate the certainties of research and apply guidelines dogmatically.

While the complexity of EBM is problematic for junior doctors, the positioning of seniors as autonomous professionals increases the possibility of resistance. In a review of commentary in medical journals about EBM, Helen Lambert (2006) identified six ways in which it was questioned, found wanting, and rejected. First, the translation of population evidence into individual treatment decisions was difficult. Second, while many hospital patients suffered multiple co-morbidities clinical trials typically only tested patients that needed single interventions, which meant that the complex interventions doctors were used to applying were untested. Third, it was feared that the exclusion of clinical skills from practice in favour of evidence would reduce clinicians to automatons without the craft skills needed for complex medical work. Fourth, the production of formulaic guidelines compromised clinical autonomy

and reduced the quality of care by preventing physician learning, and limiting patient choice. Fifth, the effectiveness and cost-efficiency emphasis of EBM discounted patients' views and their subjective experiences of healthcare. Sixth, in practice EBM was simply too difficult to introduce, disseminate, and implement.

A number of studies of clinical work show that the autonomy of senior doctors and the complexities of clinical practice may be fatal to the ideals of EBM. The implication is that the strict application of evidence and guidelines to some clinical tasks may be inappropriate. In a study of prescribing by general practitioners confronted with two forms of medication for depression, one of which was newer and recommended despite inconclusive scientific evidence of its superiority, David Armstrong (2002) found that decisions were governed by a logic of patient centeredness. Doctors referred primarily to their experiences of patients' responses to the different medications, specialists' decisions, discussions with patients about their needs and preferences, and the varying implications of distinct side effects for different patients.

While Armstrong's (2002) work concerned a recommendation with inconclusive scientific support, two other studies have shown how guidelines supported by evidence may also be sidelined. In an analysis of why guidelines were often ignored in urinary-incontinence surgery, Catherine Pope (2002) foregrounded the significance of variability. Patients varied in their suitability for surgery, several different procedures could be used, and the surgical act could be accomplished in a number of ways. At each stage unique factors relating to the patient, the surgeon, and external events affected decisions and reduced standardisation. Patient anatomy and clinical history varied. Surgeon's dexterity and strength differed, and they had particular skills, tacit abilities, and preferred ways of working. Equipment and staff provided by the hospital were inconsistent and changeable at short notice. The operation itself was unpredictable. In planning and completing operations safely, surgeons ignored guidelines and developed unique solutions based upon tacit knowledge.

The essential findings of Pope's (2002) work have been identified by Ruth McDonald, Justin Waring et al. (2006) as also relevant to anaesthesia and several other surgical disciplines. Standardisation was refused due to variables of patient, surgeon, and external events. For consultant doctors in all disciplines guidelines played an important but limited role. While

useful for teaching, guidelines were considered potentially dangerous for advanced work because they limited thinking. Consultants believed they had the experience, education, and intuitive capacity for non-standardised work, and they often discarded guidelines in order to make decisions in ways that could not be formulated into written rules.

Even guidelines intended to protect patients from dangerous infections may justifiably be ignored. In a study of the reuse of single use devices (SUDs) in anaesthesia, Graeme Currie, Michael Humpreys et al. (2009) found that clinicians were willing to go against guidelines and reuse devices despite the risk of bacterial and vCJD infections. Single use was an ideal of best practice, but reuse offered advantages for risk, quality, and economy. Risk judgments meant balancing what was theoretically possible, with clinical experience and the demands of quality and safety. Statistically minor risks were accepted as a part of providing the best care reasonably possible. Another consideration was that SUDs were manufactured to a lesser standard than reusable devices, which were safer due to superior quality. Sometimes SUDs were reused because they were immediately accessible, the situation was urgent, and delays were unsafe. Economic considerations counted because disposable anaesthetic equipment drained finances and compromised other aspects of care.

The finding that doctors might judge EBM as inapplicable to numerous clinical scenarios complicates this topic. There can be no simple assumption that obedience to evidence and guidelines is safe. Helen Lambert's (2006) perspective on changes in the communication of EBM suggests this outcome may be increasingly accepted as the reality of good practice. In the contemporary rhetoric of EBM according to Lambert, clinicians need to be in a dialogue with evidence, clinical expertise and judgment is necessary, and the use of evidence is an art. But not all have described EBM as so accepting of clinical skill. Trisha Greenhalgh, Jeremy Howick et al. (2014: 2) support the idea of a dialogue between evidence and tacit expertise, but argue that EMB has become compromised by an overemphasis on algorithmic rules that "can crowd out the local, individualised, and patient initiated elements of the clinical consultation." While guidelines and evidence matter, their implementation must be context sensitive.

Achieving an effective dialogue between EBM and tacit skill presents significant challenges for learning. Stefan Timmermans and Alison Angell (2001) have demonstrated why through an

analysis of the adoption of EBM by paediatrics residents. Some of these junior doctors advanced quality and safety in their practice by integrating EBM with clinical judgment. Broadly characterised as 'researchers', they were open to many sources of information. They experienced very high levels of uncertainty about how clinical conditions could be scientifically managed, and they didn't follow guidelines or evidence that seemed unsuited to patients or insufficiently robust. Researchers experienced this uncertainty as intrinsic to the growth of knowledge, and become highly tuned to patients' needs and their own "gut feeling." Some even adapted guidelines and sought to fill in gaps in the literature with estimates formulated on the basis of what was known. They needed to overcome challenges with time and the skill of finding and evaluating information. Their capacity for evidence-based clinical judgment suggested a complex but achievable way in which practice may continuously improve. However it also implied a role for hospitals, of improving access to information in support of judgment practices.

Overview of evidence-based medicine

Research about EBM suggests some inconsistencies. Evidence and guidelines are not having the expected impact on medical work. But the reasons are unclear. Systematic reviews point to an absence of sufficient quality information and resources for persuading, assisting, and enabling doctors. These challenges are particularly evident in the struggles of junior doctors to learn and apply EBM. However more experienced clinicians' perspectives suggests that EBM is not always tuned to the contingencies of clinical work. The extent to which contemporary EBM supports the exercise of clinical judgment by senior doctors is unclear. Some argue the institution increasingly accepts the value of expertise (Lambert 2006). Others find the opposite. (Greenhalgh, Howick et al. 2014).

Importantly, an emphasis on the value of clinical judgment, as the product of a dialogue between evidence and expertise, does not change one of the fundamental challenges of using evidence and guidelines. EBM is complex to apply in practice. This indicates that the institution

of EBM needs to change. It also suggests that hospitals have an essential role in providing the necessary infrastructure to support clinical decisions.

Human factors and ergonomics

Methods

Human factors and ergonomics is an eclectic discipline that emerged during the 1940s from efforts to improve the design of systems such as aircraft cockpits and factory workstations (Hendrick 2011). The International Ergonomics Association defines it as:

> The scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance (International Ergonomics Association 2014).

In *To Err is Human* the Institute of Medicine advocated for the application of human factors in healthcare "to reduce errors and improve reliability" (Kohn, Corrigan et al. 2000: 66). High Reliability Organisation Theory (HRO), developed from human factors research into organisations that have achieved high levels of safety in risky circumstances, offered a means for achieving this outcome. In HRO theory:

> Accidents can be prevented through good organizational design and management. Characteristics of high reliability industries include an organizational commitment to safety, high levels of redundancy in personnel and safety measures, and a strong organizational culture for continuous learning and willingness to change (Kohn, Corrigan et al. 2000: 57).

Healthcare presents complex challenges for high reliability. The pathways to events are too many for them all to be controlled. Hospitals cannot be shut down when risks proliferate. Some inputs, such as sick people, cannot be standardised, processes cannot be definitively specified,

and “actions, adjustments, and decisions must be undertaken in real time” (Schulman 2004: ii43).

Safety improvement through ergonomics involves applying three interconnected sets of practices. The first is patient safety risk management, which means collecting information about harm through incident reporting and audit; understanding causative factors through practices such as audit and root cause analysis; and controlling the risks of physical activity and cognitive processes. Requirements of the latter include assessing and redesigning biomedical devices, improving the organisation of work, using checklists and other tools to improve teamwork, implementing clinical actions that are scientifically proven to reduce harm, and changing organisational culture (Bellandi, Albolino et al. 2011).

The second set of practices is the ideal of system redesign. As collections of systems involving technology; people, including teams and departments; procedures and policies; and physical environments; organisations may need to be redesigned to become more consistent with human needs and abilities. Redesign emphasises physical activity, cognitive processes, and organisational or socio-technical systems design (Carayon 2011). The latter is the subject of macroergonomics, which focusses upon the strategic governance and organisation of the healthcare system as a whole, its supporting ICT infrastructure, and the structure of organisations (Bellandi, Albolino et al. 2011). Organisational design must prioritise both strategic control and the tactical autonomy of workers (Hendrick 2011). Tactical autonomy through the decentralisation of decision processes allows networks of clinicians to respond appropriately to unique scenarios (Bellandi, Albolino et al. 2011).

The emphasis on clinical autonomy is connected to a third set of safety practices based on the promotion of organisational culture as the “real enabler” of safety improvement (Bellandi, Albolino et al. 2011: 686). James Reason (1997: 195-6, 213) has described a safe culture as an informed, reporting, just, flexible, learning culture. This means that staff are informed about the factors that determine safety; errors and near misses are reported without blame; staff trust each other’s competence and integrity; control is exercised through expertise rather than hierarchy; and there is continuous learning and reform wherever necessary. Changing the culture of a hospital may involve surveys to identify problem areas (Itoh, Anderson et al. 2011),

training in safe attitudes and practices, communications campaigns to promote best practices (Bellandi, Albolino et al. 2011), and team training to improve communication, cooperation, and coordination (Baker, Salas et al. 2011).

Implementation and practice

Human factors involves many practices. Four of these that address the main social components of improvement practices in hospitals through human factors are discussed: team-training, communications protocols, critical incident reporting, and root cause analysis. The practice of large scale socio-technical systems design appears in the later discussion about industrial quality improvement.

Team training

It has been argued that teamwork competency is critical to reducing communications failures (Salas and Rosen 2013: 369). These may play a role in the "vast majority" of medical mishaps (Sutcliffe, Lewton et al. 2004: 194). But despite the benefits, the development of teamwork competency has not been systematically addressed by healthcare systems (Salas and Rosen 2013: 369).

A narrative synthesis of the literature on team-training identified moderate to high-quality evidence that it may positively impact team processes, clinical processes, and patient outcomes. The gains were potentially greatest when used as a foundation for other interventions (Weaver, Dy et al. 2014). At its best, team-training can have a transformative effect on safety culture and enable the emergence of attitudes and behaviours indicative of high reliability (Jones, Skinner et al. 2013: 391).

The cultural context of team training can have a powerful impact on outcomes. Hospitals with the worst culture benefit the least because they lack organisational support for all aspects of the process, including applying the skills taught (Jones, Skinner et al. 2013: 403). Resistance to

some aspects of training may be evident from medical staff, who can use their hierarchical power to inhibit open and free communication, and close down processes such as debriefings and graduated methods of challenge (McCulloch, Mishra et al. 2009). There is evidence that simulation based training may be the most effective way of overcoming hierarchical behaviours. But even with this method less influential staff may sometimes still be reluctant to express their concerns (Patterson, Geis et al. 2013: 389).

The implementation of team training is highly dependent on organisational factors including support from leaders, support for learning, and organisational commitment to measuring the outcomes (Salas, Almeida et al. 2009). There also needs to provide explicit support for the transfer of newly learned behaviours into the work environment (Jones, Skinner et al. 2013). Other critical factors can include the skill of trainers, rapid and systematic roll out, the engagement of doctors in leading the initiative at all stages, and full integration into policy and process (Thomas and Galla 2013: 432-433). Because of the potential for skills to decay over time, training needs to be a continuous activity with long term commitment (Weaver, Dy et al. 2014: 369). Gains can be sustained if efforts are continuous (Patterson, Geis et al. 2013: 390).

The substantial benefits of team training for safety improvement suggest that this relatively neglected practice needs to be more widely utilised. Its capacity to positively impact hospital culture makes it especially valuable because this benefits every other improvement activity.

Checklists

Checklists are increasingly used in hospitals to enhance team communication, ensure safety checks, structure information sharing, and standardise many other tasks. They have sometimes contributed to substantial safety improvement. In eight hospitals in different countries a nineteen item surgical safety checklist administered in three stages (prior to anaesthesia, prior to incision, prior to the patient leaving the theatre) was associated with a 36% decrease in the rate of surgical complications, and a similar reduction in the rate of death (Haynes, Weiser et al. 2009). In intensive care units in the state of Michigan a six item checklist was a focal tool in a programme that reduced the mean number of central line associated bloodstream infections, from 7.7 per 1000 catheter days, to 1.3 (Pronovost, Goeschel et al. 2010).

The dramatic safety improvements that have sometimes been associated with checklists obscure an ambiguous reality. Checklists sometimes fail, and they can undermine safety when there is no appreciation of how they work and what tasks they are most suited for (Bosk, Dixon-Woods et al. 2009). This risk is particularly apparent in highly bureaucratised hospitals where a form is "the solution to every safety problem" (Dixon-Woods 2013, Dixon-Woods, Baker et al. 2014: 109-110). Used thus, checklists demonstrate "magical thinking" about the simplicity of improvement (Dixon-Woods, Baker et al. 2014: 112). Both of the cases quoted earlier are relevant in this regard. In a clear illustration of the difficulty of transferring interventions from one context to another, a survey of Ontario hospitals that implemented the same surgical safety checklist found no significant reductions in operative mortality or complications (Urbach, Govindarajan et al. 2014). In an analysis of how bloodstream infections in the Michigan intensive care units were actually reduced extensive cultural and organisational change was identified as the real reason for the programme's success. While checklists have undoubted value, without comprehensive support from a suite of other changes they may achieve "not much at all" (Bosk, Dixon-Woods et al. 2009).

There are two primary challenges associated with the use of checklists. The first is their limited effectiveness with very complex tasks (Bosk, Dixon-Woods et al. 2009). Brian Hilligoss and Susan Moffatt-Bruce (2014) have shown their inadequacy for the patient handoff, where information about patients may be lost as staff changeover between shifts. Structured checklists, and communication protocols such as SBAR (situation, background, assessment, and recommendation) have addressed potential memory losses and ambiguities in this situation by organising information into paradigmatic (logical) categories. However some of the information that needs to be transferred during handoff is complex and involves multiple interdependent components. In these cases a narrative and a plot are necessary to link connected events into a meaningful whole. Narrative recognises the uniqueness of cases, and the need to co-construct understanding, accommodate ambiguity, and adapt stories for the audience. When situations necessitate the use of narrative understanding compliance with standardised checklists and protocols can increase risks to patients.

The second challenge with checklists is the difficulties of implementation. A cultural challenge for doctors with any checklist is the perceptions that they are infantilising, undermine

expertise, and impede swift decision making and action. Doctors may also find that checklists are imposed from above with no appreciation of their needs (Bosk, Dixon-Woods et al. 2009). Checklists in surgery, sometimes referred to as 'time-out' or 'surgical briefings', because they are used to initiate a pause in technical activity, followed by a structured discussion amongst multidisciplinary teams, are often incompletely used (Fourcade, Blache et al. 2011). In some hospitals full compliance with surgical checklists has been found to occur on just 10% of occasions. The process was performed to "keep it legal," but adapted to the social and organisational demands of surgical work. Workflow, busyness, and the socio-cultural dynamics of operating theatres create a mesh of challenges (Braaf, Manias et al. 2013: 651).

Workflow amongst staff in operating theatres is often asynchronous. There may not be a moment when all staff have free attention. With no point in time where a briefing seems to be appropriate, set-up tasks easily flow seamlessly into the act of surgery. When operations are conducted under the pressure of busyness pre-surgical briefings are less likely (Whyte, Cartmill et al. 2009). Overt and covert pressure may arise from surgeons demanding the swift movement of patients through the theatre, overbooked lists, audits of theatre efficiency, and the regular incorporation of unplanned cases (Braaf, Manias et al. 2013).

The socio-cultural dynamics of operating theatres can lead nurses to feel intimidated by the power of surgeons and anaesthetists. This dynamic and its tendency to close down communication may also exist between consultant surgeons and the senior registrars they are training in theatre (McCulloch, Mishra et al. 2009: 114). Resistance to briefings by senior medical personnel can take a number of forms. They may be silent and unwilling to communicate, non-responsive to requests, and speak quietly so others cannot be fully involved (Gardezi, Lingard et al. 2009). They may interrupt and halt the process (Whyte, Cartmill et al. 2009). Tribal affiliations can also interfere, with team members preferring to mostly share information within their own group, and exclude others (Gillespie, Chaboyer et al. 2010). Some staff may also lack the skills to involve others, and those needing to provide technical information may be unable to articulate it clearly (Whyte, Cartmill et al. 2009).

When workflow, busyness, and socio-cultural challenges interfere with briefings the process can often be abbreviated with the outcome that no one possesses all of the relevant

information. Nurses may be uncomfortable with being kept in the dark but feel unable to change the situation (Braaf, Manias et al. 2013). Medical staff may justify their non-participation on the basis that the action is pointless and merely replicates informal checks and other methods of sharing information (Whyte, Cartmill et al. 2009).

A number of approaches may improve compliance with checklists. Cultural change is needed to flatten hierarchies and make open questioning acceptable between groups in the operating theatre. Training in teamwork and communication may assist (Braaf, Manias et al. 2013). Doctors could be convinced of the value of briefings through opinion leaders, and senior doctors could explicitly support implementation instead of leaving it to nurses (Gillespie, Chaboyer et al. 2010). Providing research information about the safety benefits of briefings can also assist team receptivity. When teams are willing, the role of a 'champion', who breaks the ice, is critical. Nurses can perform this role. Champions are most effective when they demonstrate the team engagement motive. They need to be able to negotiate intergroup dynamics in the operating theatre through clear communication in form and content, not speaking across others, acknowledging them, and listening attentively (Whyte, Cartmill et al. 2009).

Checklists present appealingly simple solutions to complex improvement problems. They may fail because of the complexity of the challenges they address. Checklists are not suited to all safety problems. When they are, a high level of support for implementation is necessary. Cultural norms, tensions between staff, poor communication skills, unavailable tools, disorganisation, throughput pressure, and a lack of awareness of the benefits can all lead to displays of compliance, and incompletion of the process. Overcoming these challenges requires organisations to mobilise resources through management, build the support of senior doctors, and work to change the cultural norms that allow powerful groups to subvert processes.

Critical incident reporting

In high reliability organisations the reporting of accidents and near misses for the purpose of analysis and learning is an established cornerstone of safety improvement. In healthcare the process is fragmented and uncertain (Vincent 2003: 1051). While error reporting systems have

become a highly visible risk management tool their effectiveness has been compromised by substantial underreporting in the range of 50%-96% (Barach and Small 2000). Reporting is also dominated by mundane events rather than those that are most harmful (Shojania 2008).

The UK National Patient Safety Authority has identified multiple reasons for underreporting. Driven by a belief in perfection, staff may feel that errors are a sign of personal failure, they may worry about being blamed, fear that reports could be used against them by the public, media, and disciplinary bodies, and be apathetic about the likelihood of change. They may also be short of time, think that reporting is someone else's job, have difficulties using reporting systems, and feel overwhelmed by overlapping reporting requirements (Johnson 2011). Sociological accounts reflect the role of these factors while also implicating organisational politics, institutional norms, and the challenges of gaining accurate accounts of critical incidents. These problems suggest the deeper political and systemic complexities of reporting. A focus on no-blame as a cultural solution to underreporting may be only a part of the solution.

Siri Wiig's (Wiig and Aase 2007, Wiig and Lindøe 2009) work in Norwegian hospitals found that staff were reluctant to complete incident reports because the system appeared to support blame rather than learning and systemic change. The hospital's quality and safety committee were disengaged from the process and very little teaching was offered in response to reported information. Any teaching that was done tended to emphasise active (individual) rather than latent (systemic) failures, and there were concerns about legal sanctions, which mostly targeted individuals and not the hospital.

Justin Waring (2005b) has shown that non-reporting by doctors may be driven by an urge to preserve their professional autonomy from managers. Reporting into managerially controlled systems contradicted the NHS's culture of medical professionalism. It violated doctors professional hierarchy, their belief in not 'blowing the whistle' on one another, and their preference for professional control of error analysis. Doctors were only comfortable with reporting when it shifted blame onto organisational and managerial issues such as resources, equipment, and staffing. Their own errors were viewed as unavoidable, and they normalised common and routine mistakes. They also argued that managers could not meaningfully use

complex medical information, and would use reporting to reduce doctors' autonomy, bureaucratise clinical decisions, and measure performance.

Waring's (2004) analysis of medically controlled reporting shows that doctors will use systems that are integrated into their professional practices. In a study of five directorates, two specialist groups were positive about reporting. One used the hospital's system because it was linked into their professional education and departmental systems of audit, clinical governance, and quality improvement. The other group had also integrated reporting into their professional processes through an independent localised system. They were reluctant to share information from it with the hospital because of concerns about confidentiality and managerial interference. The other three specialist groups held similar concerns about allowing managers to be privy to information about errors. But while two had sought to resolve this tension by initiating localised professionally controlled systems, both had floundered because of a lack of time.

The process of information capture during reporting influences both the willingness of staff to report, and the quality of the information. Studies by Justin Warning (2009) and Cynthia Hunter, Kaye Spence et al. (2008) have shown the challenges of gathering accurate accounts of critical incidents. Justin Waring (2009) found these events could trigger strong feelings and confusion amongst staff seeking to understand them and allocate responsibility. But these complexities were sidelined during reporting, which required simple descriptions without recourse to feelings, complex causes, professional opinions, and the effects of professional boundaries and resource constraints. The brevity of the form drove inaccurate and superficial explanations that were paraphrased in the risk management department so incidents could be shaped into managerial categories. As a consequence affective and interpersonal staff knowledge was discounted; managers grew to perceive risk differently to clinicians; staff were potentially trained to think in predetermined categories; and groups and individuals continued to shift blame and evaluate themselves as safe, and others as unsafe.

The contingent relationship between reports and incidents has also been highlighted by Cynthia Hunter, Kaye Spence et al. (2008) in an analysis of reporting by nurses. The greatest part of the complexity of critical incidents was social. Many explanations were possible at this level

because incidents emerged from relational rather than causal factors. But efforts to “untangle” this “web” created even “more of a tangle” as additional opinions, experiences, and contextual events were included (Hunter, Spence et al. 2008: 100). There was also significant socio-affective work for staff seeking to manage the impact of errors upon patients, families, clinicians, and clinical relationships. The hospital did not acknowledge, record, or support this demanding work, despite its centrality to staff learning about safety. The bureaucratic-managerial learning system objectified events, reduced them to a linear causal trajectory, and sought solutions in standardised protocols that neglected the reflexivity of clinical work.

The abstraction of socio-affective learning that had been identified in many analyses of incident reporting is not all pervasive. Rick Iedema, Arthas Flabouris et al. (2006) have identified some doctors incident reports as self-reflective, focussed on organisational problems, and concerned with possible ways of reorganising work through locally produced knowledge. This outcome was assisted by the autonomy of the doctors, and the specific characteristics of the local system, which allowed doctors to reflect on events and record large amounts of free-flowing information.

On the whole, due to substantial underreporting and the poor quality of information, incident reporting systems in healthcare have not achieved their potential. They are compromised by their lack of contribution to systemic change, the fear amongst doctors that managerial control of reporting could lead to the bureaucratisation of medical work, and a limited capacity to reflect the complexities of clinical work. Each of these failings can be addressed.

Reporting systems need to be seen to be contributing to learning and systemic change. They also need to more accurately reflect the complexity of the problems they address. There is evidence that systems can be constructed to achieve this, that doctors can respond to them, and that they would be more consistent with how nurses experience critical incidents. Potentially however these systems could be politically challenging as more involved analysis is likely to uncover different perspectives on incidents. There may also be merit in encouraging doctors to take greater control of reporting, while still involving managers so systemic issues can be addressed. However cultural change amongst doctors may also be necessary to

encourage them to think more systemically, and to think of errors as potentially preventable rather than inevitable.

Root cause analysis

Root cause analysis (RCA) is a way of investigating and learning from serious incidents. In approximate consistency with NHS policy all adverse events and near misses in NZ hospitals are allocated a Severity Assessment Code rating of between 1 and 4. Code 1 and 2 incidents should be subject to an RCA (Health Quality and Safety Commission 2012b).

In an effort to identify the so called "root cause" of failure RCA asks three primary questions: what happened, how, and why? (Khorsandi, Skouras et al. 2012: 4). In practice, the implication of searching for a single or a small number of root causes is misleading as investigations should consider interconnected chains of events, and identify gaps in systems that should be defended from error (Vincent 2003: 1051).

The RCA process is usually conducted by a team (Khorsandi, Skouras et al. 2012: 5). It may involve about 20-90 person-hours of work (Wu, Lipshutz et al. 2008: 686), although in some extreme cases over 640 hours have been are required to complete the process (Card, Ward et al. 2012: 8). The stages of RCA include incident identification, organising a team, studying the work process, collecting facts about what went wrong, searching for causes, taking action, and evaluating the action. The methodology is variable and offers a toolbox of about 40 techniques including brainstorming, five whys, and narrative chronology (Nicolini, Waring et al. 2011a: 218).

The performance of RCA is demanding. Participants involved in the process may experience barriers including a lack of time, resources, and data and feedback; as well as difficulties with colleagues, teams, interprofessional differences, and unsupportive management (Braithwaite, Westbrook et al. 2006). Teams can find that it is much harder to identify solutions than problems. Outcomes are rarely followed up (Wu, Lipshutz et al. 2008).

Performance across organisations varies. A study of eight UK sites found that the process was exemplary in two, there was less depth in three, and in two it was virtually unrecognisable relative to the protocol. In part, difficulties may be due to insufficient training. Many organisations relied upon a cascade model of internal training but only about a fifth of those trained felt confident enough to train others (Wallace 2006).

Research from a Scottish hospital has offered some quantification of the performance of RCA. Because 53% of incident reports eligible for RCA were missing vital information or incoherent, an important aspect of the foundations of the process was often weak. Only 58% of relevant reports were subject to RCA, and just 14.8% of eligible incidents received recommendations that were implemented into clinical practice. Investigations tended to tackle only one aspect of an incident, and did not implement broad improvements. The existence of many reports about similar incidents suggested a general lack of problem resolution (Khorsandi, Skouras et al. 2012: 3).

The quality of RCA outcomes can be problematic. The two most common recommendations are re-education or writing a policy, but these are weak solutions with a low probability of reducing risk. The redesign of products or processes has a high probability of reducing harm, but these solutions are less commonly employed. Product redesign requires high level coordination with manufacturers (Wu, Lipshutz et al. 2008), and process redesign invokes complex organisational challenges (discussed later in the section about industrial quality improvement).

The multiple challenges of RCA, and a general lack of evidence of effectiveness, have fed concerns that its translation into the context of healthcare may be an expensive and ineffective waste of resources (Wu, Lipshutz et al. 2008: 685). This view is supported by a recent systematic review which found that a good understanding of risk through RCA did not necessarily lead to good risk control. There was generally limited evidence that RCA improves safety (Card, Ward et al. 2012: 8-9). The challenges of changing this outcome are detailed by a number of in-depth qualitative studies. But while it is difficult to utilise, the methodology does nonetheless offer considerable potential for safety improvement.

An initial challenge of RCA is building a good basis of information and expertise to work with. Documented information can be of variable quality. Staff may resist providing information and they may resist participating in teams because they are busy, disinterested, and suspicious about the agenda. They may seek to protect themselves and colleagues, and feel that RCA is not "real work." These barriers can mean that the analysis is compromised by incomplete knowledge and limited participation from key staff (Iedema, Jorm et al. 2008, Nicolini, Waring et al. 2011a: 219-221, Nicolini, Waring et al. 2011b: 36).

During analysis use of the narrative chronology method may exclude other techniques, possibly because it is more consistent with medical thinking. Many techniques offer a "helicopter view" which reflects an engineering perspective and suits different kinds of systems (Nicolini, Waring et al. 2011b: 37). The ordering and the amount of talk can reflect status hierarchies. Non-clinical facilitators may struggle to control domineering behaviour, and become lost in clinical details (Nicolini, Waring et al. 2011a: 221).

While policy literature describes RCA as purely rational (Nicolini, Waring et al. 2011b: 38), emotions are central to the process. Clinicians need to be highly reflexive about the processes being analysed, and the affective dimensions of the investigation itself. Analysis needs to be conducted at a systems level without blame, and emotional pressures and loyalties negotiated to maintain trust, even though anxiety, shame, and defiance can be aroused, and the findings are potentially momentous for those being investigated (Iedema, Jorm et al. 2006a). Participants may sometimes fail to manage these pressures. Unacknowledged emotions, especially blame, can harm cohesiveness and learning, and drive later lengthy corridor conversations about topics that were too difficult to formally address (Nicolini, Waring et al. 2011b: 38). When emotions are acknowledged, often through the support of seniors, self-reflection and improved learning can emerge (Nicolini, Waring et al. 2011a: 221).

Analysis during meetings can provide a valuable perspective for staff on work processes in other departments (Nicolini, Waring et al. 2011a: 221). Clinicians may be prompted to think reflexively, and discussion can enhance communication and learning across boundaries, and build networks with the potential to assist improvement well beyond the immediate RCA (Iedema, Jorm et al. 2006a). But risks also emerge. Analysis may become localised rather than

systemic (Nicolini, Waring et al. 2011b: 37). The search for root causes may be discarded as too complex, and difficult because of resourcing issues. Solutions may indicate a preference for simplicity, and emphasise discipline, training, and departmental action, rather than organisational changes with resourcing implications (Nicolini, Waring et al. 2011b: 38-39). An emphasis on clinical accountability, public confession, and the micro-analysis of error can disable intervention into organisational systems and policy (Iedema, Jorm et al. 2006a).

A perplexing analytic challenge for RCA is the contradiction between the specification that solutions must be tightly-coupled, and the contingencies of clinical work. To account for the complex and the non-routine nature of some processes teams may need to introduce solutions based around procedural slack or loose coupling, which would allow safety to be negotiated by flexible responses to situations as they unfold. But this possibility may be excluded by organisational rules (Iedema, Jorm et al. 2006b).

Analysis can also be affected by the need for closure and a final report demonstrating an effective process (Nicolini, Waring et al. 2011a: 222). Creating a document with correct style and language can take precedence over the need for change. Reports rarely capture different views about causes and responsibility. Linear narratives can obscure complex details about how factors relate and combine. The circulation of reports on multiple occasions to achieve consensus worsens this outcome (Nicolini, Waring et al. 2011b: 39).

When reports are delivered to risk managers they may be unprepared for the work of turning recommendations into sustainable changes (Nicolini, Waring et al. 2011b: 39). Changes involving work between departments are rarely enacted (Nicolini, Waring et al. 2011a: 222). Senior hospital management can perceive outputs as impractical, superficial, focussed on symptoms rather than root causes, and impossible to understand and implement. CEOs may be reluctant to sign them off. Managers may then enter into substantial work rejecting, revising, and renegotiating poor quality recommendations, and those that either exceed organisational capabilities, or are incompatible with existing initiatives (Iedema, Jorm et al. 2008).

The reality of RCA often does not match the intention of using rich insight into failure to drive safety improvement. The limited effectiveness of RCA is explained by challenges with participation, information, facilitation, hierarchy, emotions, and complexity. While the neat linear narratives of reports may appear to bring incidents to closure, this can obscure the contingencies of clinical work, and a lack of attention to systemic change.

Davide Nicolini, Justin Waring et al. (2011a) argue that the many difficulties of RCA can be explained by the way in which the process has been shaped by the twin political agendas of public legitimacy and bureaucratic governance. The ritual of RCA restores the legitimacy of healthcare systems in the wake of harm. The emphasis on actionable rather than necessary solutions reflects the pragmatics of managerialism. Both agendas build complacency and obscure the complexity of risk. To move beyond their limitations RCA needs to emphasise learning as an emergent, ongoing and contested process, rather than something that can be neatly summarised into a report. To support this orientation the process could encourage dissent about the complexity of organisational systems, develop tools that extend the narrative modes of thinking favoured by doctors, and emphasise the identification of common issues and recurrent factors across different investigations. Change could also be generated by better informing clinicians about the intentions of the process, improving facilitation, emphasising systemic change, and monitoring outcomes (Nicolini, Waring et al. 2011b: 40).

Overview of human factors and ergonomics

Human factors practices have been introduced into healthcare from industries associated primarily with engineering. Many of these imported techniques require translation to fit the distinctive needs and circumstances of healthcare. Team training, while underutilised, has potential to improve culture, to reduce harm by improving communication, and to create an environment that is more receptive to improvement in general. Checklists have been hailed for their capacity to improve safety by increasing the rigour of task performance and communication. But they offer a simplistic solution to complex problems. Without organisational commitment to substantially addressing contextual issues of resourcing and

receptiveness, checklists may prove to be virtually useless. With support, they can contribute to the improved performance of some tasks and processes. They are not suitable for complex tasks, despite being used for this purpose. Critical incident reporting and RCA have been problematic in healthcare. Most incidents are not reported and most RCA's fail to address systemic issues. While it may be possible to increase reporting by changing the methods and the control of reporting, the value of building a massive data base of incidents is marginal unless there is the will and the capability to do something about the problems identified. The application of RCA demonstrates the frequent incapacity of hospitals to use information about failure to change the structures and the processes which facilitate the provision of care. The challenges of achieving this outcome are discussed in the next section about industrial quality improvement.

Industrial quality improvement

Methods

Industrial quality improvement (hereafter quality improvement) became widely used in healthcare after quality assurance failed to lift performance and eliminate errors through inspection, punishment, and individual learning (Berwick 1989: 53, Coster and Buetow 2001: 28). Quality improvement seeks to design quality in (Coster and Buetow 2001: 28). It emphasises processes and systems rather than individuals, and preferred levels of care, rather than acceptable standards (Berwick 1989: 55).

The basis of quality improvement is Walter Shewart's work on industrial processes, and its refinement by W. Edwards Deming and Joseph Juran (Berwick 1989: 54, Colton 2000: 8,25, Varkey, Reller et al. 2007: 735). Fundamental goals include creating the quality that customers want, evaluating and improving processes in real time rather than after the event, and involving service delivery personnel in monitoring and improving standards. For a hospital department a

focus on the customer need means delivering quality to patients and other departments that support their care (Colton 2000: 10).

Quality improvement requires cultural change, managerial support, and the integration of improvement into everyday work so it does not become a project isolated from usual activities. Success may require "substantial" investment (DelliFraine, Langabeer et al. 2010). The necessary cultural changes include visionary leadership, greater respect for front line workers, and physician leadership in the improvement of processes. The latter suggests a new and challenging role for doctors, "as participants in processes, rather than as lone agents of success or failure" (Berwick 1989: 54-56).

The quality improvement methods include total quality management, often referred to as continuous quality improvement (CQI), lean, six sigma, and business process reengineering. They are often used in combination with one another (Varkey, Reller et al. 2007: 737, Powell, Rushmer et al. 2008: 3, 18, Taylor, McNicholas et al. 2013: 2). Many of their practices, such as statistical process control, flow charts, cause and effect diagrams, checksheets, Pareto diagrams, frequency distributions, run charts, regression analysis, and control charts require extensive mapping, measurement, and statistical analysis (Colton 2000: 13,14). The plan-do-study-act (PDSA) cycle of CQI involves planning a quality improvement intervention; carrying it out; measuring and studying the results to establish learning; and making changes. Cycles typically need many repetitions, and target incremental rather than dramatic change. In the rapid cycle change approach PDSA cycles provide a basis for change through sufficient rather than extensive data (Varkey, Reller et al. 2007: 736, Powell, Rushmer et al. 2008: 14-5).

Lean emphasises the elimination of waste in the form of corrections, waiting, transportation, overprocessing, inventory, motion, and overproduction. A central technique is value stream mapping, which outlines the structure of a process in order to identify necessary and unnecessary steps (Womack and Jones 1996, Powell, Rushmer et al. 2008: 17-8, DelliFraine, Langabeer et al. 2010: 213). Another is the use of *kaizens*, or rapid change events, to test and implement improvement ideas. The 5S method (sorting, shining, straitening, systematising, and sustaining) improves the speed of outputs by identifying the most efficient organisation of tools and processes (Varkey, Reller et al. 2007: 738).

Six sigma is a method of eliminating errors by controlling process variability. It places less emphasis on culture change than the other methods. Statistical process control is a key tool for identifying and separating common cause variations due to chance, from special or assignable variations caused by system defects. Improvement involves a five-step process of define, measure, analyse, improve, and control (DMAIC). Sometimes lean may be used to streamline a process before six sigma is applied to reduce variability (Varkey, Reller et al. 2007: 737, Powell, Rushmer et al. 2008: 19-20, DelliFraine, Langabeer et al. 2010: 213). Business process reengineering emphasises the complete redesign of processes from the ground up, rather than incremental change (Powell, Rushmer et al. 2008: iii).

Quality improvement has traditionally been implemented by teams that diagnose a problem, analyse its causes, and test interventions to drive improvement. A more recent development is the quality improvement collaborative, which involves multiprofessional teams from many hospitals working together under the guidance of experts (Øvretveit, Bate et al. 2002).

Implementation and practice

While the discussion here refers to the different quality improvement methodologies the issues identified have broader relevance. Quality improvement is often applied in conjunction with audit and human factors practices such as team training, safety culture training, and the use of checklists. It may also be used during the implementation of EBM. The issues discussed here therefore cover the implementation of quality improvement in its broadest sense.

The outcomes of improvement efforts reveal something of a paradox. While publication bias may have exaggerated the breadth of success, systematic reviews show that all of the methods are usually effective. This includes CQI (Shortell, Bennett et al. 1998), collaboratives for implementing CQI (Schouten, Hulscher et al. 2008), lean, six sigma and lean sigma in acute care (Glasgow, Scott-Caziewell et al. 2010), and CQI, lean, lean sigma, PDSA cycles, and statistical process control in surgical care (Nicolay, Purkayastha et al. 2012). Occasionally the outcomes have been spectacular. In 18 months, across 103 intensive care units, collaborative teams

participating in the Michigan Keystone Project reduced the rate of potentially fatal central line associated bloodstream infections, from a mean of 7.7 per 1000 catheter days, to 1.3. These improvements were sustained at 36 months post-implementation (Pronovost, Goeschel et al. 2010).

Safety improvement efforts however do not always match expectations. An epidemiological study of North Carolina hospitals that were highly engaged in safety improvement found that the rate of adverse events during 2002-2007 declined, but not significantly (Landrigan, Parry et al. 2010). The NHS's Safer Patients Initiative (SPI) was a comprehensive campaign in two phases implemented by collaborative teams during 2004-2008. Phase one hospitals received £750k in support, and phase two hospitals received £270k (annual budgets were £150-300M). An evaluation measured adverse events and mortality amongst high risk patients in medical wards, hospital wide mortality, perioperative care quality, intensive care outcomes, and infection rates. While significant improvements were achieved on some measures, they were matched by control sites (The Health Foundation 2011a, The Health Foundation 2011b). It is not known how the control hospitals achieved their outcomes (Dixon-Woods, Leslie et al. 2013: 2). Quite possibly policy pressures and emergent professional and scientific consensus drove them to implement similar practices (Bion, Richardson et al. 2013: 117).

Reflection on the outcomes of improvement programmes raises questions about the value of spend and the effectiveness of methods. Interestingly, the SPI was not necessarily a cost-failure. Because the value of a Quality Adjusted Life Year in England is about £30k, each Phase 1 hospital would have needed to save fewer than seven lives for five years to deliver a 'financial gain' on public money. Detecting an improvement of that magnitude was statistically impossible, and gains may manifest over longer time frames. It may also be that investment in the SPI, only 0.1% to 0.01% of hospital budgets, was insufficient (The Health Foundation 2011a: xiv-xv). These uncertainties highlight another important question, with implications for value. *What are the social and organisational challenges of improvement and how can they be overcome?*

Organisational support

Successful improvement requires many years of organisational support. Organisations need to provide a structure of planning and coordination, and build a culture that gives quality a collective significance. They also need to develop ways of negotiating political conflict, institutionalising learning, and inspiring commitment. They need to provide the appropriate infrastructure and technology. Leadership is a component of all of these challenges, and it is most effective when quiet and inclusive (Bate, Mendel et al. 2008: 169, 175-176). Leaders should avoid excessive talk of transformation, set goals that are realistic, and seek to bring everyone along with them (Dixon-Woods, McNicol et al. 2012: 4). However when momentum diminishes they may also need to spark enthusiasm (Ling, Soper et al. 2010: x). The work itself is often more demanding than initially imagined, and it may require staff to perform additional actions that are easily overlooked in the planning phase (Zuiderent-Jerak and Berg 2010).

Improvement requires managers and clinicians to work cooperatively. By being directly linked to projects managers can ensure resource availability (Dixon-Woods, Bosk et al. 2011). Support is strongest when improvements align with existing organisational goals (Ling, Soper et al. 2010: 60). When support from senior management is lacking, improvement may fail to transition from margin to mainstream, and staff may ignore projects until they go away (Dixon-Woods, McNicol et al. 2012: 5).

The necessity of organisational support is evident in the difficulties staff may have coping with the struggles of improvement. Achieving limited gains can lead to disillusionment and the feeling that 'nothing works' (Ling, Soper et al. 2010). Improvements may be pursued enthusiastically and then abandoned because of mistaken expectations that the process would be easy, inadequate expertise and investment, and a lack of reward for effort (Dixon-Woods, Baker et al. 2014: 112).

Accepting the need for improvement and setting priorities

Achieving safety requires hospitals to articulate a clear vision with explicit goals and a strategy for achieving them. Doing so signals organisational priorities, increases staff motivation, and

directs resource expenditure. However in the NHS hospital boards and frontline teams have been found to rarely set clear, challenging, and measurable improvement objectives. Instead they are often distracted by a proliferation of procedures and paperwork and the generalised dominance of compliance over improvement (Dixon-Woods, Baker et al. 2014: 109-110).

Recognising problems and gathering information about them is essential to improvement planning. Health professionals have traditionally resisted this activity because they believe local services are “satisfactory or even excellent” (Davies, Powell et al. 2007a: 129). This belief may be maintained despite multiple organisational difficulties that frustrate their efforts to provide quality care (Dixon-Woods, Baker et al. 2014: 109-111).

Highly bureaucratised cultures can subvert problem identifying capacities. The collection of large volumes of potentially valuable data can fail to affect change because it is not used to develop actionable knowledge and plans for change. Qualitative information about problems can be neglected because feedback about poor standards is dismissed as “whining or disruptive behaviour” (Dixon-Woods, Baker et al. 2014: 109-111). Even when executive managers use walk rounds specifically to gather information from front line staff they may remain oblivious to negative feedback and focus only on the positive (The Health Foundation 2011a).

In order to identify problems hospitals must pay closer attention to data analysis. They may also need to commission surveys of patients and staff, and use informal qualitative methods to deepen their understanding of experiences on the front line (Dixon-Woods, Baker et al. 2014: 110-111).

Gaining agreement about the reality of problems that staff are not concerned with requires the use of either comparative data that contextualises local outcomes, or patient stories that communicate the human cost of clinical failure (Dixon-Woods, McNicol et al. 2012: 4). If complacency can be disrupted, clinicians may begin to view safety problems as unacceptable (Dixon-Woods, Bosk et al. 2011).

Gaining agreement about methods

Improvement requires the investment of time in building networks amongst clinicians, convincing them of the value of methods, and showing them how they can be useful (Papadopoulos and Merali 2008). If this supporting work is not performed the process may be viewed with suspicion and have little legitimacy.

Doctors may have concerns about consequences for patients (Davies, Powell et al. 2007a), and they may fear that initiatives will be ineffective and waste limited resources (Davies, Powell et al. 2007b: 7). There can be disagreement about the meaning of quality, and how to achieve it (Dixon-Woods, McNicol et al. 2012). Apparently simple matters, such as the definition of a surgical infection, can be intensely debated (The Health Foundation 2011a: 31). Interventions may be inconsistent with preferred and seemingly effective methods of working (Dixon-Woods, McNicol et al. 2012). The improvement methodologies may be perceived as suitable to manufacturing only (Kaplan, Patterson et al. 2014) and lacking in scientific support (The Health Foundation 2011a). Where medical interventions require randomised controlled trails as proof of effectiveness, improvement can appear to be driven by the edict of gurus (Young and McClean 2009).

Interventions should only be pursued if evidence supports them. Clear facts and figures about outcomes need to be provided and forums created where they can be openly discussed and debated. Interventions should be tailored to suit circumstances (Dixon-Woods, McNicol et al. 2012). Further support can be gained through opinion leaders with relevant expertise who can convince others of the value of new ways of working (Dixon-Woods, Bosk et al. 2011).

The work of gaining legitimacy for solutions can be intellectually and emotionally demanding, and should not be underestimated. For staff willing to champion the process continuous effort may be required over an extended period. Proof of the value of a new course of action may require the rigorous analysis and adjustment of complex data on many different outcomes so doctors can be presented with accurate feedback about their work, and what is possible. This approach is powerful because doctors often have no objective idea about their outcomes relative to the severity of patients at first presentation (Bate, Mendel et al. 2008: 18).

Another way of advancing improvement is to build the capacity of staff to generate solutions. This work is easier when organisations enhance the trust between clinicians and managers by sharing control within relatively non-hierarchical structures (Bate, Mendel et al. 2008: 119-144). Open relationships, credible encouragement for collegiality and cooperation, and encouragement for local traditions of pride, excellence, and innovation can also make staff more receptive to change (Bate, Mendel et al. 2008: 35-55).

Specifying the programme theory

Agreement about how to proceed with change can be further enhanced by the articulation of programme theory about how and why a planned intervention will be effective (Dixon-Woods, McNicol et al. 2012: 5). Central to programme theory is the specification of a theory of change that links processes to outcomes through the work of specific mechanisms. Programme theory should identify the root causes of problems to be addressed, specify what is to be done to achieve what outcomes, describe the mechanisms of how and why change will occur, and outline a means of assessment. By comprehensively detailing theory organisations can clarify intentions, debate actions, maximise the use of expertise, uncover assumptions, plan for difficulties, and identify and correct failures. Theories of change can draw upon both academic literature (formal theory), and practitioner experience (informal theory) of what works. Academic literature can also provide mid-range theory that constructs a general framework for changes to be actioned through the programme theory. Mid-range theory might specify, for example, the need for active support from opinion leaders (Davidoff, Dixon-Woods et al. 2015).

Engaging staff

Engaging staff can be one of the biggest challenges of improvement (Dixon-Woods, McNicol et al. 2012: 6). The process is sensitive to communication, pressure, motivation, hierarchy, discipline, and technical assistance.

Communication

Communication is critical to staff engagement, but it is often of poor quality. Sometimes managerial communication is more rhetorical than sincere. It may side-line staff concerns about issues such as resource constraints, mergers, staff shortages, agency workers, and tensions between professional groups and departments in order to focus on problems with "workable solutions" (Waring and Bishop 2010a). Communication can also fail to reach the sharp end of practice, leaving staff unsure about how to action fundamental change processes such as PDSA cycles (The Health Foundation 2011a). Ignorance about methods may be quite wide-spread. One systematic review found that hospitals often did not follow key principles of PDSA cycles (Taylor, McNicholas et al. 2013), and another reported that lean interventions sometimes involved little more than individual feedback, with no effort to change processes (Glasgow, Scott-Caziewell et al. 2010).

Pressure

Pressure can drive a downward spiral of diminished morale (Dixon-Woods, Baker et al. 2014: 112). Alongside feelings of "initiativitis" it may contribute to an urge to control the turmoil of constant change (Fillingham 2007). It may also be an absolute limit on improvement capacity because existing work consumes all of the available resources of time and attention (Dixon-Woods, Suokas et al. 2009). In these situations staff may feel that structural changes designed to reduce pressure would be more valuable than process change (The Health Foundation 2011a). Pressure can similarly effect managers, who may feel too busy to be involved in improvement (Dixon-Woods, McNicol et al. 2012), and are more focussed on meeting targets and achieving financial balance (Fillingham 2007).

Overcoming pressure requires investment. "Organisational slack" can allow managers and doctors to work together to build an improvement infrastructure. "Slack" is not a luxury. It allows new forms of action, and it may be one the most crucial steps in supporting innovation (Bate, Mendel et al. 2008: 107). When staffing is adequate, systems are effective, and staff are in control of their work, improvement becomes a real possibility (Dixon-Woods, Baker et al. 2014: 111).

Motivation

Doctors have often been observed to be disengaged from improvement (Neale, Vincent et al. 2007). Nonetheless, they are central to the change agenda (Jorm, Travaglia et al. 2007). However the complex social structures and politics of healthcare present substantial barriers to their involvement (Arndt and Bigelow 1995). The culture of medicine is inwardly focussed and self-protective, and its speciality driven structure makes teamwork difficult (Jorm and Kam 2004). Quality and safety improvement has low status and is poorly rewarded (Ling, Soper et al. 2007: 9). Doctors may be unsure about how to apply some complex improvement methodologies, and they may be weary of change because cooperating with managers and reconfiguring established inter-professional relationships and rituals may threaten their professional status and autonomy (Davies, Powell et al. 2007a).

Managers can also be disengaged. To them, the change process can be more like a political campaign than an organisational reform. They may be unwilling to support it because the necessary changes to "organisational culture, strategy, and tactics ... are so profound and daunting that no sane executive would pursue continuous quality improvement if there was any conceivable alternative" (Blumenthal and Kilo 1998: 638).

Against these barriers, intrinsic motivation can be a powerful driver for setting improvement processes in motion. The intrinsic motive to care is almost universal amongst health professionals (Dixon-Woods, Baker et al. 2014: 109). Interventions that appeal to it can be highly motivational (Dixon-Woods, McNicol et al. 2012: 6). Hospitals may also need to be aware that the power of intrinsic motivation can be such that sometimes their most appropriate role is simply supporting the process. This was particularly evident in an AIDS treatment centre in the US where staff perceived their work as an issue of social justice and the expression of a shared calling of care and compassion. This value was applied to immediate care, and the adoption of improvement methodologies. Quality was further institutionalised through the cooperative and egalitarian values of the AIDs movement, which drove a flat organisational hierarchy and supported autonomous interdisciplinary teamwork (Bate, Mendel et al. 2008).

Motivational incentives offer another means of assisting improvement. There are at least five ways in which doctors may be encouraged and supported into improvement work. First, professional leadership often creates peer pressure, which encourages involvement. Second, many improvement activities enhance professional identify and status. These may include formal opportunities for discussing ideas, reflecting on service provision, and receiving critical appraisal, validation, and reassurance. Participating in team building and receiving training are also useful, as are being kept up to date with and being involved in the promulgation of guidelines. The use of participation to leverage support for business case arguments is a further benefit. Third, it is essential to build awareness about improvement needs, but, forth, action will only happen when there is a possible solution. Fifth, individual enthusiasts must be identified and supported (Ling, Soper et al. 2010).

The collaborative team approach can be especially effective for building participation because it mobilises normative pressure from colleagues rather than outsiders, making improvement a legitimate and necessary professional activity (Dixon-Woods, Bosk et al. 2011). However collaborate teams need support. Participants may be reliant upon seniors, but receive little help. They may have been volunteered, but doubt the importance of the project. They may lack resilience in the face of setbacks, feel unwilling, unconfident, unprepared for the workload, and unable to deal with internal differences and conflict (Øvretveit, Bate et al. 2002). Teams also need to be able to develop an identity outside of administrative and managerial bounds, even while they are retained within a top-down structure that manages competing interests. Although hospitals are powerless to 'make' teams bond, they can provide resources to support activities that advance the professional status of participants (Dixon-Woods, Bosk et al. 2011). Collaborative teams are often also more engaged when participants set personal goals and identify individual benefits (Øvretveit, Bate et al. 2002).

Hierarchy

Improvement can unsettle the established social order of the hospital and be culturally disruptive because it challenges hierarchical divisions between medical, nursing, administrative, and managerial staff. The work of overcoming hierarchical attitudes can require active work between senior managers and clinicians to support new ways of working (Kaplan,

Patterson et al. 2014). Team training offers a very effective method of reducing hierarchical behaviours at the micro level. When groups that are lower in the hierarchy, such as nurses, are required to check on work performed by those with greater power, such as doctors, it may be necessary to recruit senior members of the more powerful group to explicitly support the violation of outdated and unsafe forms of etiquette (Dixon-Woods, Bosk et al. 2011).

Discipline

While intrinsic motivation and normative pressure can make powerful contributions to staff engagement, disciplinary approaches may sometimes be needed to change behaviour. Peer review and audit data can offer explicit feedback and clarify staff accountability for some outcomes. The capacity for outcomes data to be explicitly compared to similar others is powerful, although it must be used carefully (Dixon-Woods, Bosk et al. 2011, Dixon-Woods, McNicol et al. 2012: 8). Data is not always accurate, and staff will resist measures that are perceived as unfair (Dixon-Woods, Leslie et al. 2012).

Technical assistance

Support can be particularly necessary for technical tasks involving data collection and auditing. The collection and analysis of quantitative data to track interventions can be one of the most difficult of all improvement tasks. Teams and organisations may fail to recognise the importance of setting systems up correctly, and selecting the right variables to measure (Øvretveit, Bate et al. 2002: 349). There may be concerns about the accuracy of the data (Davies, Powell et al. 2007a), and when there is compliance with initiatives such as PDSA cycles can be undermined (The Health Foundation 2011a). Constructing effective systems is time consuming and difficult. The risks of poor design include additional work, difficulties of use, and poor legitimacy (Dixon-Woods, McNicol et al. 2012). Managers need to ensure that systems of collection and analysis are functional and that staff are trained to use them and decide what measures are most important (Øvretveit, Bate et al. 2002: 349).

Prioritising clinical and patient focussed values

In the absence of initiatives from doctors senior managers may seek to control improvement processes. Sometimes this may occur through the co-optation of select groups of clinicians as leaders who direct change processes rather than work cooperatively with their peers (Waring and Bishop 2010a). The risk with managerial control is that clinical and patient focussed values are neglected. In the NHS clinical teams often feel that policies are too prescriptive and not clinically focussed (Dixon-Woods, Baker et al. 2014: 109-110). When change is directed from the top, staff may feel they have no control and no ownership of the process (The Health Foundation 2011a).

Prescriptive top-down improvement can result in two kinds of problems. The first is that designs are purely technical and fail to consider the social aspects of change. The reduction of variations in processes can increase the simplicity and the repetitiveness of work, and lead staff to resist standardisation because it threatens their autonomy, career progression, and skills (Joosten, Bongers et al. 2009). Standardisation can also reduce team flexibility, and it may force staff to work harder (Waring and Bishop 2010a).

The second problem with prescriptive change is the potential for value conflict and feelings of suspicion amongst staff that the true agenda is cost cutting (Young and McClean 2009). Improvement may then seem to be a way for managers to impose more work, monitor performance, and expose failure. These perceptions are not helped by poor communication from management and a lack of support for implementation (Papadopoulos and Merali 2008).

Improvement attempts have often been found to devalue patient focussed values, which are rarely prioritised relative to managerial ideals of efficiency, and the need to cut costs and reduce staffing (Radnor, Holweg et al. 2012). An analysis of board minutes from 71 NHS Trusts in 2010-2011 identified a total of 144 innovations, of which 73 prioritised productivity, while only 14 related to safety (Dixon-Woods, Baker et al. 2014: 112). When the balance is tipped in the direction of efficiency the value of throughput can conflict with the value of a complete medical response (Young and McClean 2008). Improvement then increases managerial power, and devalues quality, safety, and patient experience (Waring and Bishop 2010a).

The dynamics of prescriptive improvement can lead implementation teams to work in isolation from their colleagues, and redesign processes in ways that other staff struggle to apply. Techniques such as process streamlining may be used without sufficient consideration for how clinical work is done. Designs may appear unrealistic and inconsistent with contingencies that arise under pressure, and the reasons that practices have a specific form. Although efficiencies may be achieved, staff may feel that quality and safety is compromised, leading them to ultimately view improvement as a bureaucratic exercise requiring superficial displays of compliance (Waring and Bishop 2010a). Non-compliance can also extend to practices addressing problems that clinicians profess to be concerned about. Actions that are not monitored are not always performed. Staff may feel that there is so much reporting going on that there is little incentive to comply with anything outside of the requirements of the official monitoring regime (The Health Foundation 2011a).

Overcoming systemic complexity

The systemic complexity of hospitals makes implementation difficult, and vulnerable to derailment (Shortell, Bennett et al. 1998). When one part of a complex system is altered pressure may be displaced to somewhere else, and problems are not resolved, they change form. For this reason many improvements are short term and not sustained. The solution is to fix the system as a whole, not just its individual components (Ballé and Régnier 2007).

Complexity can drive conflict between risk management and the humanity of care. The prioritisation of some safety needs has been found to reduce the capacity of older patients in acute wards to control their belongings, physical being, personal space, privacy, and social interaction. The removal of these freedoms in the name of safety caused responses including boredom, grief, and humiliation (Hillman, Tadd et al. 2013).

Another consequences of complexity is that improvements may be limited to small technically focussed changes that cannot be extended across departments because of value differences. The change agenda is then compromised by the impossibility of realising significant gains such as system-wide pathways for patients (Radnor, Holweg et al. 2012).

The complexity of patient centred values means that there can be no simple solution to value based conflicts, and their capacity to limit improvement. In medicine there is “a bewildering array of value-concepts, reflected in a plethora of quality measures and frameworks” (Young and McClean 2008: 384). The Institute of Medicine (Committee on Quality of Health Care in America 2001), for example, has defined six clinical values and sought to link them with non-clinical healthcare priorities to create a framework of ten values for the delivery of care. But they have not specified how values should be prioritised under pressure. The many advanced views of value in healthcare are not systematically interconnected (Young and McClean 2008).

The problems of systemic complexity require a coordinated organisational solution. One approach, reflecting the human factors emphasis on socio-technical systems design, is to construct a system map that outlines patient movement through systems of care, and the technical, social, and organisational factors that influence outcomes. This understanding can identify points where coordination needs to be improved to reduce inter-departmental silos. While issues of communication and multidisciplinary teamwork across organisational boundaries also need to be addressed, the development of an overall plan is critical for problems at this level (Bate, Mendel et al. 2008: 101-118).

Sustaining improvement

Improvement projects run into the risk of being time-bound, such that gains are lost when the project ends and efforts move in other directions (Dixon-Woods, McNicol et al. 2012). The lack of a plan for sustaining improvement, and reliance upon individuals rather than institutionalising change into new systems and new ways of working, makes reversal likely on completion. Planning needs to ensure from the start that these needs are provided for (Øvretveit, Bate et al. 2002: 349). Organisations also need to be wary of limiting improvement skills to a select group of staff because rotation and attrition can cause a loss of knowledge, and damage the sustainability of change (The Health Foundation 2011a).

Overview of industrial quality improvement

Improvement efforts face many challenges. The basis of improvement is organisational commitment to a long-term process of building supportive structures, nurturing culture, negotiating conflict, institutionalising learning, inspiring commitment, and developing infrastructure (Bate, Mendel et al. 2008). These resources provide a basis of support for many challenges. There must be clear and measurable plans for improvement. Agreement must be built with staff about the necessary of change and the suitability of methods. Theories of change need to be articulated. Staff must be supported so they can fully engage in the process. Clinical and patient focussed values, must be prioritised. Complex systems of care must be subject to organisation-wide coordination, and improvements must be institutionalised into permanent new ways of working.

Mary Dixon-Woods (2012) argues that successful outcomes require multiple and often contradictory approaches. There must be strong leadership, and a participatory culture. Change needs to be subject to direction and control, while also being responsive to unique local needs. Critical feedback may be necessary, but blame must be avoided. There needs to be extensive planning and development, but without any loss of momentum. Multiple audiences must be appealed to, and none alienated. Winning the support of clinicians is especially significant so the process can be developed and driven cooperatively, rather than imposed from above.

Amongst the improvement challenges identified, three in particular are foundational. These are convincing staff of the suitability of methods, prioritising clinical and patient focussed values, and overcoming systemic complexity. If the groundwork of convincing staff about methods is done well momentum can be created that reduces the intensity of many other challenges. While it may be true that doctors need to take greater responsibility for improving systems of care (Jorm, Travaglia et al. 2007, Mountford and Shojania 2012), initiatives that are imposed without supporting evidence of effectiveness and a realistic implementation plan are likely to be resisted.

Prioritising clinical and patient focussed values is continuous with the need to convince staff about the suitability of methods. A clear weakness of improvement as it is often practiced is that these values receive insufficient priority. For intrinsic motivation to be inspired, so staff feel committed to changing systems and working differently, they need to be convinced that new ways of working will better help them to meet their goals for patients.

Many of the most significant improvement gains are due to coordinating the work across departmental boundaries. This challenge suggests the importance whole-of-system design in human factors theory. It also shows the limits of improvement projects which emphasise localised systems. While local improvement has undoubted value, many of the mechanisms of harm in hospitals involve difficulties of communication and coordination across departmental boundaries. Structural issues of this kind require organisational solutions (Dixon-Woods 2014b: 32’55”). But this necessity can be obscured by an overemphasis on small localised improvement projects (Dixon-Woods 2014a: 5’00”). The urgency for hospitals to explore large scale issues involving the whole system of care is discussed in the conclusion.

Conclusion

In this chapter I have described and analysed prominent methods of safety improvement. Their rich variety is matched by the elusiveness of the intended outcomes. While the suitability of methods is sometimes at issue, the challenges of improvement are mostly associated with implementation.

The discussion in this chapter has identified a number of organisational factors that are necessary for improvement, and a range of challenges to be overcome. The work of Paul Bate, Peter Mendel et al. (2008) provides a way of integrating this knowledge into a model of change that organisations can use to further enhance their improvement capacity. This model suggests that organisations need to transition improvement from a series of discreet projects to a generalised and self-sustaining organisational activity.

Bate, Mendel, et al. (2008: 167-170) argue that whole-of-organisation improvement is the product of multiple interconnected processes that emerge from staff responses to a set of generalised and universal improvement challenges. Processes depend on and construct organisational improvement, and must necessarily be directed at overcoming six universal challenges of structure, culture, politics, learning, motivation, and infrastructure. The ways in which organisations address these challenges through combinations of processes builds a unique improvement journey shaped by their distinctive history, culture, capabilities, and external contexts.

The process model of improvement is different from how this work is often conceptualised. Many improvement models describe an sequence of smoothly ordered steps that can be progressed by implementing the right factors composed of systems, structures, and methodologies (Meyer, Silow-Carroll et al. 2004). This perspective misses the reality of organisational change in two ways. First, those inside organisations experience change as "complex, messy and circular." The process may be planned, but it is not smoothly controlled and there is continuous struggle. Second, implementation involves staff in the work of creatively engaging with and articulating a range of organisational, social, and cultural resources. Improvement depends upon their capacity to access these resources and gather, generate, implement and adapt multiple theories of change to unique contexts. This process is contingent and it requires a diversity of theories (theoretical slack), and the avoidance of theoretical closure. The problem-solving capacities of staff need to be central to the improvement agenda (Bate, Mendel et al. 2008: 187-190).

Bate, Mendel et al. (2008: 205-208) suggest three general guidelines for applying the process model of whole organisational improvement. First, while there are universal challenges to be overcome (of structure, culture, politics, learning, motivation, and infrastructure), the work is done in unique ways. Its emergent and processual characteristics require a flexible and opportunistic mindset so actions can be adapted to context. Preparation, planning, and a clear sense of direction are important, but strategy cannot be too rigidly detailed. This may contradict a need organisations have to secure their internal and external legitimacy by presenting a rational and ordered image to themselves and the world. Second, while there can be no precise map of the journey, many forms of action are possible (56 unique solutions are

outlined as ways of meeting the six universal challenges). To gain an overview of their capabilities, how they are being used, their forms of articulation, and the challenges of putting them into practice, organisations can invest in the development of narratives that seek to understand "where they are or should be trying to get to" (207). The quality of this sensemaking process is a crucial determinant of an organisation's ability to meet challenges and guide the process of change. Third, organisations need to ensure a balance between technical and clinical improvement on the one hand, and its creative and social characteristics on the other. This means giving attention to often neglected issues of "identity, aesthetics, politics, leadership, value systems, organisational slack and learning" (Bate, Mendel et al. 2008: 208).

In this chapter I have described a range of safety improvement activities, highlighted the challenges of using them effectively, and identified knowledge about implementation that can be used to overcome those challenges. This work is ultimately most effective when it is fully supported by the organisation. Through long term programmes of change, resourcing, and expertise, safety outcomes in hospitals can be improved.

Chapter 5

Methodology

This thesis is ultimately concerned with patient safety in New Zealand public hospitals. So far it has focussed on context. The patient safety movement, the consequences of policy, and the dynamics of risk and improvement have all been reviewed. The next step is to provide a methodological outline of the original research that was conducted for this thesis. I begin this chapter with an explanation of how I choose my research topic, what my research objectives were, and the questions that I asked. I then discuss the qualitative interviewing methodology and its value for gathering data. I outline my intended and achieved participant sample, and consider the generalisability of the findings. Finally I describe the research processes of ethics approval, participant recruitment, interviewing, data analysis, and writing.

The research focus

Emergence of the topic

I first became interested in the topic of patient safety after conducting a very broad literature search to identify possible PhD topics about public hospitals in NZ.[7] I wanted something that

[7] These organisations were the specified focus of my Health Research Council scholarship.

was interesting, well covered in the literature, and provided an opportunity to contribute to the greater good. I had previously heard of the topic of patient safety, but failed to imagine why hospitals could be unsafe. When I found this literature and began to review it I was surprised because I had assumed that hospitals were mostly very safe, and this topic would only appeal to someone who worried a lot, was excessively cautious, and too cynical to trust the expertise of professionals. How could hospitals be risky when they had nurses and doctors and drugs? I was quite naïve. My views changed when I became aware that a substantial volume of human life and suffering was at stake, that adverse events were enormously expensive, and the topic was socially and organisationally interesting. Those were my motives.

When I initially searched the patient safety literature most of it referred to British and American hospitals. I found very little research about NZ. This suggested an opportunity, and I next sought to focus it. Research about patient safety usually emphasised either the dynamics of errors and harm, or the implementation of safer ways of working. In both cases the focus could be on specific or general risks. The latter suggested an opportunity for this research because it would allow me to gain a good understanding of the topic as a whole, rather than emphasising one aspect of it. Because I was very interested in connecting events inside hospitals with the general policy environment it seemed best to take a broad approach. I also wanted staff perspectives to guide this research. A broad approach would allow them to direct my attention to the challenges they were most concerned with. I also wanted the research to be primarily from a clinical perspective, so there would be a depth of understanding of the views of those most directly involved with the work. The best way to meet these priorities was to make this research about the challenges of patient safety from the perspectives of clinical staff. This appealed to me because while I was ultimately interested in policy, I believe that policy should be grounded in the practical realities of those who must put it into practice.

Research objectives

There were two specific objectives for this research about public hospitals in NZ. The first was to understand the challenges of reducing harm in the clinical environment. The second was to understand the challenges of implementing safety improvement.

Research questions

The questions that I used to answer the research objectives evolved over time as I become more familiar with the ways in which staff responded to my questions. Some initial questions were used less frequently, and others were added when topics emerged that contributed useful insights.

The main research questions were:

- What are some things you like/dislike about your work?
- How many hours do you work in a typical week?
- What are the main risks you are aware of trying to control and reduce in your work?
    - How do those risks emerge?
    - What are the challenges of trying to reduce risk?
    - How is risk affected by communication and co-ordination processes within and between departments and professional groups?
- What are the challenges that are associated with:
    - The implementation on new ways of working to improve quality and safety?
    - Systems and programs for improving quality and safety?
    - Clinical practice guidelines and protocols?
    - Hospital performance targets?
    - The hospital reporting system?
    - Medical systems of audit and error analysis?

Some questions were asked only occasionally, and became less important as the research progressed:

- Thinking about consultant doctors, junior doctors, and nurses; what are some things each of these groups do well to improve safety, and what are some things they need to improve?
- Is safety improving or reducing over time?

The emphasis given to different questions varied according to the interests and the role of those interviewed. A time limit during interviews (I asked participants for 30 minutes of their time) meant that not all of the questions were covered in depth in any one interview.

Methodological decisions

A qualitative methodology

The decision about the best research methodology depends on the kind of data that is most suitable for answering the research questions (Silverman 2006). I needed data that would help me to understand the challenges of safety from the perspectives of clinical staff. I wanted to know in-depth what those challenges were, how they happened, and why they were problematic.

My research questions were not suited to a quantitative approach. Quantitative research begins with the identification of a range of variables representing characteristics of the subject matter that can be counted, measured, and statistically analysed to identify patterns that are suggestive of correlations. This approach generates knowledge that is broad and robust, but it lacks a depth of understanding because the variables are heavily abstracted (Curtis and Curtis 2011).

My research was more exploratory and as such it was ideally suited to a qualitative approach. I needed to understand the richness of individual cases (Curtis and Curtis 2011), and the qualities of participant experience (Silverman 2004). I also needed to interpret the nature of social reality as participants comprehended it (Williams 1998). According to Catherine Hakim:

> Qualitative research is concerned with individuals' own accounts of their attitudes, motivations and behaviour. It offers richly descriptive reports of individuals' perceptions, attitudes, beliefs, views and feelings, the meanings and interpretation given to events and things, as well as their behaviour (Hakim 1987: 26).

In a similar theme Jennifer Mason (2002) has described qualitative research as emphasising an interpretive interest in the complexity of the social world, methods of data generation that are context sensitive rather than heavily standardised, and analysis and explanation that builds upon complex detail to produce rich contextual understanding. Insights of this kind were consistent with my research objectives.

An interview method

To answer my research questions I needed a dialogical method. I only seriously considered individual interviews, or a mix of observations and interviews. Group discussions were excluded because I anticipated it would be too difficult to recruit busy health professionals to meetings at a pre-determined time.

Interviews were favoured over observations because there was little possibility of a non-medical doctoral student being cleared to conduct observational research inside a hospital. The use of interviews raises some important questions about my research. Most sociological patient safety research uses ethnographic methods so researchers can observe staff while they are working. This allows researchers to witness and discuss real behaviour. In comparison interviews without observation may generate less contextual detail, and there is the possibility that staff might only focus on some challenges and avoid discussing others. These omissions could be deliberate, or they might be due to a failure of recall during an interview.

While the findings of an observational study would have been more detailed, there are three disadvantages to this approach. The first is that the observational method is very time consuming. This would have limited the number of staff who could be included in the research, and it would have been more difficult to generalise the findings with confidence. The focus may have been limited to one department in one hospital. Second, the detail provided by observational analysis might have exceeded my needs. While observations would have provided a useful context for the researcher who sought to understand how and why staff gave different kinds of attention to different risks and safety issues, their value would have been significantly less to the researcher who wanted to understand the challenges of risk and safety according to staff perception. Third, and related to the last point, interviews gave staff more control over the research findings. While a researcher observing staff might focus on risks they felt were important, an interviewer can only work with the material that staff provide. This meant that the research was driven more by the concerns of staff, and less by the researcher.

The central advantage of a qualitative interview methodology for this research was that it offered me the capacity to understand individual staff perspectives in depth, and to include a large number of different staff, with forty interviews planned across three departments in two hospitals. While interviewing is less commonly used in patient safety research, it was appropriate for the questions addressed in this research.

An interpretation of social reality

Sociological knowledge is broadly derived from either positivist or interpretivist methods. Positivism draws upon the model of the natural sciences, and theorises social reality as immediately perceptible and knowable (Guba and Lincoln 2005). This perspective emphasises the need for unbiased, objective, and precise methods, and highly structured and standardised interviews (Maseide 1990: 4). However an emphasis on “hard facts” is poorly suited to qualitative research, where information is conceptually formed into language, and knowledge does not exist independently of the ways it is known (Archer 1998: 69).

In interpretive sociology and qualitative methods the social world is conceived of as intersubjective, and "comprised of meanings, interpretations, feelings, talk, and interaction." These need to be scrutinised in their own terms (Gubrium and Holstein 1997: 13). Through interpretation the researcher subjectively investigates the subjectivity of others to make "clear the meaningful experience of agents and specifically why they believe the world is the way it is" (Williams 1998: 20). This process does not "provide the mirror reflection of the social world that positivists strive for." Instead, it offers "access to the meanings people attribute to their experiences and social worlds" (Miller and Glassner 2004: 126).

The subjectivity of interpretive sociology does not rule out the possibility of a kind of objectivity. In interactionism "objectified worlds" are recognised even though it is accepted that there is no "singular, objective or absolute world out-there" (Dawson and Prus 1995: 113). Clive Seale, Giampietro Gobo et al. (2007: 7) take this perspective further by arguing that interpretive research can and must relate to the problems of the day in ways that are convincing. The point of social research is to participate in "the great conversation that in practice is carried out in the world … where facts are 'out there' and can be collected … (as) … 'evidence.'"

Access to the intersubjective world through research requires an active and participatory style of interviewing. James Holstein and Jaber Gubrium (2004: 141) argue that interviewing should be a "collaborative accomplishment" between interviewer and interviewee. Similarly Tim Rapley (2007) has referred to the interview as a social and collaborative encounter in which objectivity is created by building on interactivity. This means that while an interviewer may shape the content of a discussion, they do not and cannot contaminate an interview, even when they ask participants leading questions, support them, and actively encourage their views.

Within the field of interpretivism there are many variations in approach and methodology. In their analysis of the idioms of qualitative research Jaber Gubrium and James Holstein (1997: 4,36) have identified the "method talk" of naturalism as a way of representing social reality though the metaphor of "being there." This allows a reality to be understood in its own terms, through rich descriptions of people, and their interactions in their native habitat.

The approach that I have taken to answering my research objectives is interpretive and naturalistic. I wanted to understand the challenges of risk control and safety improvement in quite literal ways, while also gaining insight into its complex social and organisational context.

Gaining answers to my research objectives though interpretive interviewing raised two intersubjective issues. First, I was an outsider. Participants may have felt that I did not really understand their experiences, and shaped their responses accordingly (Dwyer and Buckle 2009: 57). But while this issue had the potential to create inaccuracies, either in participants' accounts of safety challenges, or my understanding of their accounts, it is unlikely to have substantially impacted the research. There is no reason to think that participants would have been deliberately dishonest, and while I may have sometimes felt perplexed during an interview, I was normally able to clarify what needed to be understood at the time. Moreover, this challenge also afforded some advantages. As an outsider I was less at risk of falling for my own assumptions (Kanuha 2000: 444).

The second intersubjective issue was that there were differences between participants and myself in social status. I have previously experienced this issue while working as a qualitative researcher in the market research industry. Having conducted literally hundreds of in-depth interviews I have learned to manage it as best I can. Creating an impression of competence usually works when I feel that participants have more status, while being relaxed and friendly can be useful when I feel that my social status is about the same or higher. Some interviews may require a mixture of both. Conveying the correct persona and affect is sometimes challenging, and can only be managed as best as possible at the time of the discussion. But while qualitative interviews may ideally fit Erving Goffman's (1956) description of a "backstage" discussion, which is more honest and candid than exchanges in the "frontstage," where impression management is all important, there is value to be gained from relatively didactic discussions. What matters the most is that participants feel comfortable, so they can be honest, and their talk is focussed upon the primary interview questions.

The intersubjectivity of qualitative interviewing means that the data for this research was necessarily moderated by social dynamics. Participants offered accounts of experiences that were shaped through an interactional process with the interviewer. Feelings and perceptions

had an impact. This is the essence of qualitative research. I worked with these challenges as best I could by being sensitive to the social dynamics of interviews. The data collected was an account of real experiences that was shaped by an interactional process. The role of the latter does not override the foundational significance of the former.

One other important interpretive issue was the potential for participants to deny some safety challenges because of institutionalised norms, and assumptions about the safety of their practice and the organisation they worked for. This potential glossing of some safety issues was identifiable in two ways. First, some participants were useful because they provided information about widespread risks that others did not discuss. Second, the literature about in-hospital risk provided a useful means of identifying risks that received little discussion. While this may have meant that specific local details may have been missing, it was possible in some cases to suggest that these risks appeared to receive an insufficient focus of attention.

In summary, interpretive research can offer rich insights into the social world that the researcher investigates. This process is necessarily complex and intersubjective. The data that is gathered is an objectification of social reality. While there is the risk that information may be incomplete, the interviewer can only accept this challenge and work with it.

Sample

Sample considerations

In the interests of balancing thoroughness and workload doctoral students normally complete about forty qualitative interviews. This is a good general guide. As Margarete Sandelowski (1995) has observed, although small samples of around ten interviews may be sufficient for very homogeneous subjects, and some methods such as narrative analysis need fewer, for

other projects inadequate samples undermine credibility. Conversely very large samples present the risk of incomplete data analysis.

Given a target of forty interviews, the most important decision was the sample breakdown. In the following I describe the sample design that I sought to achieve, and why. The actual sample is then detailed.

Qualitative research samples may conform to a theoretical or purposive logic, they may attempt to be representative, and they may be illustrative (Mason 2002). Applied to my research these different strategies suggested the possibility of targeting many occupational groups, in many hospitals, departments, and wards. Some prioritisation was necessary, and it was guided by four considerations, with consequences as follows.

The first consideration was that I wanted to focus on the sharp end of hospital work. In this regard I wanted the sample to be as representative as possible, although I was prepared to accept that difficulties with recruitment could push it towards an illustrative type. I also only wanted to focus on those that performed the bulk of clinical work, i.e. nurses and doctors. Within each group I sought to include a range of perspectives according to seniority. I also wanted to include clinical managers from each group. In addition I wanted to involve service managers and quality managers. Both of these groups work closely with clinicians, and they potentially offered the chance to broaden my perspective on the challenges of clinical work.

The second consideration was that I wanted to be able to comparatively analyse the major departmental groups within hospitals. This meant comparing medicine and surgery, which is a fundamental division within the medical profession and an organising principle of hospital departments. To be able to make this comparison I would need strong representation at the level of specific departments to see if issues were the same or different in medicine and surgery. This comparison could be extended if I also included more than one hospital. Then I would also be able to compare different departments in the same hospital, and similar departments in different hospitals.

The third consideration was the number of interviews I would need to perform in a department to have a good understanding of that department. A common recommendation for qualitative samples is to continue interviewing until saturation is achieved. But this can be impractical when researchers need to plan in advance (Beitin 2012), as my ethics application required. It can also be difficult for researchers to be confident they have completed enough interviews to achieve saturation (Mason 2002). One of the few experiments designed to quantify saturation found that six interviews enabled the development "of meaningful themes and useful interpretations" (Guest, Bunce et al. 2006: 78). Another study found that four informants were sufficient if they were culturally competent in the context of the discussion (Romney, Weller et al. 1986). These findings suggested that individual units within my sample frame would need to contain no fewer than four participants.

The fourth consideration was my operational limits. My maximum capacity was forty interviews. Considering the criteria that I wanted to fulfil I was able to include three departments across two hospitals in this research. The construction of the sample in these ways suggested a hybrid theoretical-illustrative type. The sample would be theoretical because it was composed of units that could be compared. While there was some possibility that the sample would be representative because it included the two major occupational groups, it was likely to be illustrative because of the difficulty of balancing levels of seniority within departments. Moreover, a sample of two departments at the most could only be illustrative of conditions in the wider hospital. While this research is not 'just about one department' and it is not 'just about one hospital,' the representation of and within department means that it is still only illustrative of hospitals in NZ.

The final sample

I achieved a sample, detailed in *Table 1* (page 184), that largely reflected my intentions. Thirty-seven participants were recruited. They were interviewed between September 2012 and September 2013.

My actual sample demonstrated four divergences from the ideal. First, a clinical director declined. Second, more charge nurses were included than was intended because ward nurses were difficult to recruit. Third, there was a shortage of nurses from the one medical department. Fourth, the balance of junior and senior staff was uneven in most parts of the sample frame.

Table 1: Sample of interviews

	Hospital 1	Hospital 2		Totals
	Surgery	Medicine	Surgery	
Nurses	**4** *2 Junior* *2 Senior*	**2** *2 Junior*	**4** *3 Junior* *1 Senior*	**10**
Charge nurses	**2**	**2**	**1**	**5**
Doctors	**5** *3 Junior* *2 Senior*	**5** *1 Junior* *4 Senior*	**5** *3 Junior* *2 Senior*	**15**
Clinical directors	**1**	**1**	**-**	**2**
Service Managers	**1**	**1**	**1**	**3**
Quality Managers	**1**	**1**		**2**
Totals	**14**	**23**		**37**

Research processes

Ethics

Following the advice of an ethics advisor within the university this research was subject to ethical review by the Health and Disability Ethics Committee through the full review pathway. Ethics approval was granted in May 2012, on the condition that approval was also required at the local level, by the District Health Boards governing each hospital. This was subsequently granted (see *Appendix*, page 283).

All participants who expressed an interest in this research were provided with an information sheet about the purpose, method, and design of the research, and a confidentially agreement (see *Appendix*, page 283).

The confidentiality agreement outlined the research ethics. There were three main components. First, participants were advised that any information they provided would be used in the preparation of academic literature. Second, participants were advised that all efforts would be made to protect their confidentiality. In practice this meant that recordings, transcripts, and information with participant's names and contact details were securely stored, and anyone transcribing interviews signed a confidentiality agreement. In the reporting in *Chapter 6* and *Chapter 7* participants occupational role is identified according to the schema detailed in *Table 2* (page 186). Third, participants were given the right of withdrawal. This meant they could stop their interview at any time, and they could request a copy of their transcript, which they could edit or withdraw from the research within six weeks of their interview. While no participants withdrew, five requested copies of their transcript, and a few made very minor edits.

Table 2: Information about participants supplied in reporting

Occupational status	Title used in reporting*
Nurse level 1 – 2	**Junior Nurse**, ward nurse, nurse
Nurse level 3 - 5	**Senior Nurse**, ward nurse, nurse
Charge nurse	**Charge Nurse**, nurse
Houseofficer	**Houseofficer**, junior doctor, doctor
Registrar	**Registrar**, junior doctor, physician or surgeon, doctor
Consultant	**Consultant**, senior doctor, physician or surgeon, doctor
Clinical director	**Clinical Director**, senior doctor, physician or surgeon, doctor
Service manager	**Service Manager** or manager
Quality manager	**Quality Manager** or manager

***** *The title in bold is for indented quotes, which appear in Chapters 6 and 7 with a* ***fictional*** *name intended to protect participant confidentiality. When titles are referred to elsewhere in the narrative the more general terminology listed may be used.*

Participant recruitment

The recruitment process was different in each hospital. At *Hospital 1* initial enquiries to find participants were conducted by a service manager, who provided me with the contact details of interested staff.

At *Hospital 2* I contacted departmental administrators, clinical directors, and charge nurses, who forwarded email messages to eligible staff, and placed posters advertising the research. I also conducted a recruitment presentation for doctors in both departments. Interested participants then contacted me through email. When the numbers coming forward was less than anticipated some staff worked behind the scenes to find others who might be interested. Over time, these activities were successful in including the intended number of doctors in the research. Efforts to include nurses were less successful. On many occasions when I checked in with those assisting recruitment I was informed that staff were too exhausted at the end of

their shift to spend their spare time talking about work. In an attempt to better this situation I applied for and was granted ethical approval for nurses to be provided with a gift of $25 as a thank you for their time. This was not entirely successful and I was ultimately unable to meet the full intended quota for medical nurses.

Interviewing

Interviews were conducted at a time and place chosen by participants. This was usually a private office, but in two cases an open plan office was used, and one interview was in a participant's home. All interviews began with an introduction involving a review of the purpose and duration of the interview, and signing the written consent.

The interviews were highly variable according to differences between participants and my developing knowledge of the topic. The average interview was 47 minutes in length, and the range was 28 minutes to one hour and 30 minutes. I was aware throughout that participants were giving up their own time so I made every effort to keep to agreed times unless they clearly wanted to talk for longer.

While the interviews were in progress I sought to balance coverage of the questions I had planned with being mindful of the topics that seemed important to participants. Participants approached the interviews in many ways. Some adopted a professional persona and were very matter of fact. Some were very clear about the challenges they faced, others found them harder to articulate. Some were distressed by the topic or had very strong feelings about it. Several participants stated that they hoped the research would "make a difference."

I was aware throughout the process that participants were affected by the way I asked questions and responded to answers. This process was managed differently according to what seemed to make individual participants most comfortable. I was aware that the topic potentially implicated them as in some way responsible for harm. When I was aware that this

anxiety was present I attempted to relieve it in whatever way seemed most appropriate at the time. Mostly, this was not an issue.

Overall I was very pleased with the information collected. In hindsight, there were comments in some interviews that could have been followed up better, and some topics may have benefited from more direct questioning.

Data analysis and writing

I digitally recorded the interviews and had them transcribed. I thematically analysed the transcripts using *NVivo* software, and created eight nodes and fifty-nine sub-nodes. Some additional analysis was conducted informally by making connections across sub-nodes as I was writing my final report and by searching and re-reading relevant portions of transcripts.

At the conclusion of the research there was a good consistency in the main themes, and this gave me confidence in the integrity of the information. I unfortunately did not fulfil my ambition to comment on differences between departments and hospitals. While these were evident I decided to not focus on them because sample sizes within departments were too small. It was also evident that many issues were generalised across departments, and I elected to turn my attention there because of their importance and commonality.

Looking back on the interviews, I do not believe that they reveal a complete picture of the themes that I was interested in simply because this is such a complex and multi-layered topic. But I am confident that the information gathered reflects some of the most significant challenges that staff were working with.

Chapter 6

Risks to Patients in New Zealand Hospitals

Too many hospital patients are unintentionally harmed by failures in the processes through which medical care is delivered (Kohn, Corrigan et al. 2000). Although there is a large volume of research into the dynamics of in-hospital harm, to my knowledge there are no published qualitative studies of the challenges for frontline staff in NZ working to deliver safe care. However the rate of harm in NZ has been measured. In a review of medical records from 1998, 12.8% of patients admitted into hospitals suffered from an adverse event (Davis, Lay-Yee et al. 2001). The cost of treating these events has been estimated to be as much as 30% of public hospital expenditure, with errors accounting for 20% of all expenditure (Brown, McArthur et al. 2002).

In this chapter I develop an understanding of harm in public hospitals in NZ by reporting and analysing the views of hospital staff about the challenges of controlling risk and providing safe care. Analysis is guided by the review in *Chapter 3* of the risks of hospital care. That literature survey identified in-hospital risks as emergent from interconnections between the institutional environment, the economic environment, and hospital structure, processes, and tasks. I argued that the most powerful risks were those in relation to pressure, communication, and culture.

The analysis in this chapter both represents staff views, and thinks beyond what was said, to consider the unsaid. Representing staff perspectives is obviously important. Their immersion in the work of care delivery qualifies them to speak authoritatively about safety. However their very practical concerns, and the influence of institutional and organisational forces, also makes

their perceptions necessarily situational. There is the possibility that some risks might receive considerably less attention than others. Hence the dual purpose of this chapter, to grasp the urgency of risks that staff are highly sensitive to, and to identify others that are less prominent and could be discounted. Action to control risk must prioritise both kinds of threat.

The sample, questions, and the interview process through which the data for this chapter were collected is explained in the methodology in *Chapter 5*. In brief, participants were nurses, doctors, and service and quality managers from one medical and two surgical departments in two hospitals. Questioning sought to generate open discussion about their views on the major risks to patients, and the challenges of controlling those risks.

The analysis of risk here is in three stages. First, risks are described conceptually, as belonging to general categories that contribute to many different harms. Second, risks are described in detail, as the product of events with the potential for specific harmful outcomes. Third, some conclusions are drawn about risks in hospitals in NZ.

Generalised risk

The generalised risks to safety discussed here may contribute to the emergence of many different harms. Understanding risk at this level, prior to the later focus on the risks of specific harms, makes it possible to build a conceptual understanding of some broad underlying weaknesses in the defences against risk in the departments investigated. This generalised knowledge about the potential for failure suggests in outline the strategic priorities for safety improvement.

Participants in this research explained the challenges of safety primarily by referring to the impacts of short-staffing and pressure. Short-staffing was the main but not the only source of pressure. Short-staffing and pressure also contributed to the emergence of two other generalised risks, involving breakdowns in communication and teamwork. While

communication difficulties had deeper roots than pressure alone, failures of teamwork were attributed entirely to pressure.

The challenges of the four generalised safety risks identified by staff are described here. Most of the narrative is derived from the views of clinical staff, with occasional reference to service and quality managers. This overview of risk provides the foundation for a detailed analysis of the dynamics of specific patient harms in the section after.

Short staffing

Many staff talked about an excess of work and a lack of capacity to perform it. Nurses were more likely than doctors to link under-capacity to short-staffing. However on the occasions when doctors did discuss short-staffing it was very strongly associated with poor safety:

> I think the biggest challenge is staffing, that's where the holes are *(Christine, Clinical Director).*[8]

> Lack of staff is the biggest threat to patient safety. Up until this point there has been not enough attention paid to the risks that patients are placed under when there aren't enough staff. While I acknowledge that there's a financial restraint I think that frequently we are under-staffed as a hospital. That includes the medical services at night in particular so after ten o'clock until eight in the morning there aren't enough doctors, junior doctors on site *(Frank, Consultant).*

> Our medical department saw a tremendous increase in the number of patients during the winter time and it's ridiculous. We have one houseofficer covering fifteen wards. That's unheard of. Fifteen wards, a whole medical, at night, which is worse. And often a first year houseofficer. That is unheard of, and it's not changed *(Adil, Houseofficer).*

Because of insufficient staffing at nights in one of the surgical departments there was no 24 hour availability of a senior consultant, which compromised the safety of acutely injured patients, who were unstable and needed urgent treatment. Similarly in the medical department senior staff were not available outside of the hours of about 8am to 5pm. While the director

[8] As outlined in the *Methodology* all names reported with these indented quotes have been fictionalised to protect participant confidentiality.

would have liked to change this situation, it was impossible for cost reasons, and even existing rosters could not be filled.

Houseofficers in one hospital blamed the shortage of medical staff on insufficient recruitment, and the assumption that exhausted doctors would fill gaps in the roster at short notice. Houseofficers sometimes could not claim leave because there was no way of covering their absence. They felt that their dedication was being exploited.

Nurses were more willing than doctors to identify short-staffing as a safety problem.

> I think the biggest challenge that I really encounter. I'm talking about our work, for my safety and everybody's safety, it's the staffing level that we have. I don't think we have enough staff to cover all the patients, especially in the night. So it's really hard *(Rachael, Senior Nurse).*

A surgical nurse described safety as steadily declining because of short-staffing to the point where it was currently "bad." She felt executive managers were unaware of the pressure on clinical staff, and did not sufficiently support nurses. Another felt that managerial ambitions to deliver more care and increasing quality were impossible because staffing was too low. A number of both surgical and medical nurses commented that they were frequently required to care for additional patients because nursing numbers were insufficient due to a freeze on the hiring of new staff. A charge nurse felt this freeze was denying them the "appropriate number of staff," with nurses often "frantic" and having to "put out fires". A medical nurse blamed the cuts for a breakdown of team work amongst nurses.

There was considerable discussion about nurse to patient ratios. One medical nurse claimed that ratios had changed from one to four, to one nurse for every "five or six patients, even seven or eight patients." On three occasions in the last six months this nurse had cared for seven patients, which was "really unsafe." The ratio on the ward was usually about one to five-and-a-half. In surgery a couple of nurses claimed they often cared for six patients. Relief through a reduction in numbers was sometimes possible if one patient was very high acuity. But relief was uncommon. Sometimes short staffing was worsened by absenteeism due to illness, which one nurse blamed on the stress of the work and the hazards of working with the

unwell. Another nurse had being informed by a duty manager that on one occasion 26 nurses had called in sick, but because of shortages only seven could be replaced. This outcome was blamed on the hospital that had run down the pool of available replacements. In one ward a nurse claimed that taking time off for illness or injuries, such as strains due to lifting patients unassisted, could provoke a telling-off from the charge nurse, despite that manager being generally sympathetic to nurses and the pressures they were under.

The nursing shortage was also observed by a doctor:

> From a nursing perspective as well I know that some of the wards struggle with the amount of nurses that they have relative to the number of patients and you know my perception is that sort of patient to nursing ratios here are worse than they are, certainly where I trained in the US so I think the whole issue around staffing is one that the hospital needs to address more productively. And it's all well and good if it's a quiet night but if it's a busy night then patients are at risk *(Frank, Consultant).*

Staffing issues were also evident with occupational therapists, physiotherapists, and social workers. These staff were less available than in the past, and pressure was forcing them to prioritise and leave some tasks "off the end of the list."

Pressure

While pressure may be unavoidable in an acute care hospital, there was evidence in this research that it had become excessive and unsafe. This was the dominant challenge that staff identified for safety. Pressure was a problem because of how it changed the conduct of work, and because of its impact upon many aspects of hospital culture.

The ways in which nurses and doctors talked about pressure was different. While doctors acknowledged the impact of pressure, they also tended to normalise and enjoy the challenge of working under pressure:

> I've always enjoyed a pressured environment *(Adil, Houseofficer).*

> Working hard is what we do, we, you know I think we welcome that as doctors *(Carlos, Registrar).*
>
> It's what we signed up for *(Michael, Registrar).*
>
> And so a lot of the surgical registrars actually enjoy coming here, even though it's probably one of the busiest hospitals, they actually get a lot of work and see a lot of pathology and they enjoy it. So it's really, really busy, but I think that's what makes it really good *(Andrew, Consultant).*

One of the ways in which doctors managed pressure was to continuously work very long hours. Participating doctors' claims about the amount of time they spent at work amounted to 57 hours a week on average. They did this willingly because of their personal ambitions and the needs of patients. At the same time, long hours were also expected, especially for those at the junior end of the scale:

> I work 75 to 80 hours, sometimes a bit more. It is my own ambition, but also you can't just leave if someone is sick. Conscience takes over, ethics as well, you can't just leave them *(Adil, Houseofficer).*
>
> Some of our junior doctors and sadly some of our senior doctors' clock watch a bit. 'I'm off, I'm out of here, it's four o'clock or whatever. Somebody else can patch up whatever mess I've left behind.' That sort of thing really upsets me, but most doctors work incredibly hard and are dedicated. There's only a few *(John, Consultant).*
>
> It's also about you gaining the skills and experience you need in order to be an effective consultant. While you might not have to be here 65 hours a week, you need to be here a certain amount of time to get a certain amount of operating to be able to develop those skills. You're not going to get those skills if you're not here doing any work *(Paul, Registrar).*
>
> The way this whole system works is that we are pressured to work long hours to make a good impression to the senior doctors and that's the way we get good references to get into the training system *(Karen, Houseofficer).*
>
> I have my official hours but I try to help out wherever I can with committees and things. There's a project that I've been doing that I've probably put several thousand hours of my own time into *(Bjorn, Consultant).*
>
> I think the amount of work that we do is probably appropriate I think working the 100 hours that historically they used to do was crazy, that was dangerous, but I think we've got the balance about right. I think if you start doing less than that like in the UK it's counter-productive. It's really safe it's fantastically safe, but unfortunately at the end of peoples training they can't do a lot of things, and their on the ground working

> knowledge isn't that great 'cos they haven't had the exposure that we used to get. You learn an awful amount just by being here and doing it *(Richard, Consultant).*

While the volume of work and the expectations on doctors to perform frequently placed them under considerable pressure, they generally claimed to be resilient to this challenge. But despite their reported ability to cope, there were difficulties associated with achieving this goal:

> It's bad but you just sometimes can't be bothered. Often towards the end of the day you might not document things as well as you should because you'd rather go home or you don't document at all because you're tired or you forget. Often things slip your mind because you've got so many things in your mind that you forget that you were supposed to be organising a scan or something. Those things catch up on you. But it is concerning. I've only ever had two needle stick injuries and both have been at the end of a night shift. I don't know whether that was because I was tired or I was rushed because you're always a bit busier on nights *(Karen, Houseofficer).*

> Pressure will wreak havoc with staff member's health, fatigue levels, exhaustion and they get stressed and they might have little blips, but overall staff will just simply work harder and help each other *(Cathy, Consultant).*

Learning to manage pressure was something that senior doctors sometimes described as a necessary skill, which developed with experience:

> I can be awake for so long but I can soon tell when I hit the wall. You know time to go home *(Michael, Registrar).*

However, as will be evident later in the analysis of the risks of specific kinds of harm, pressure had clear consequences for safety. While doctors generally claimed that they could cope with pressure, they also very readily identified it as a factor that contributed to risks building up in a number of the processes and tasks they were involved in.

For nurses, busyness appeared to be just as pervasive as it was for doctors. Most of them referred to it as a continuous feature of the work:

> Every minute is precious and so we fill up every minute of every day with just ticking things off that need to be done *(Sophia, Senior Nurse).*

> It's pretty much really busy. I get one or two days a year that runs like I planned, and not a single day the same, you know, just something pops up *(Jung-soon, Junior Nurse).*

> We've got only one body, we wish we can be multiples sometimes *(Daiyu, Junior Nurse).*

Unlike doctors, nurses never referred to busyness or pressure as enjoyable. The reasons why were apparent in the ways in which busyness affected themselves, their relations at work, and the quality and the safety of their work with patients:

> With the changes, trying to cut costs and less nurses, and patients' getting more sick, and especially over winter, lots of patients coming with pneumonia and cardiac conditions and lots of MIs and us as nurses, and especially the doctors as well, you really feel the strain *(Jessica, Junior Nurse).*

> The mornings are the worst because you start at seven and the first hour or two you want to try and have all the observations done for all five patients, and all medications done for all five patients, and then in between that the doctors are coming stealing charts to review the patients and then changing plans and changing things, and then you've got to try to get people washed and showered, and then those things done as well *(Emma, Junior Nurse).*

For the charge nurses busyness could be managed to some extent by doing overtime. But this was less of an option for ward nurses, whose choices boiled down to maybe an extra hour of administrative work, not taking allocated breaks, and prioritising tasks. Administrative work after hours was typically not enjoyed. Missing allocated breaks appeared to be common:

> Sometimes some nurses don't go for breaks. It can pose a risk, you are tired, you are hungry *(Lisa, Junior Nurse).*

> Our level of acuity is bumped up a little so we get really tired really easily and a lot of the time we don't go for our breaks or we don't go for our breaks on time, so you do get down in the dumps really quickly. Just need to eat something, just got to find the time to eat. During the shift I sort of don't have enough time to think about how tired I am. It's when you leave that you are just like 'holy moly that was crap', or I am tired, like most of the time I just want to go straight to bed *(Linda, Junior Nurse).*

Some nurses were directly questioned about the safety implications of not having breaks:

> Interviewer: So you don't get to take breaks sometimes?
> Nurse: Oh most days, especially on a 12 hour shift, you often don't get a break after your lunch break, so you'll work to 7.30-8.00 o'clock at night without another break.
> Interviewer: Is that risky?
> Nurse: Yep *(Sophia, Senior Nurse).*

> Nurse: I think generally we manage but you feel like you know sometimes you're managing, but staff are not getting breaks or going off an hour late to, to get things done you know so I think staff are very dedicated in this area and do put their all into it. They're on their feet all day sometimes, it's a lot of pressure.
> Interviewer: Can mistakes or accidents happen under those situations?
> Nurse: Well I think they're more likely *(Danielle, Senior Nurse).*

Prioritisation appeared to be an essential skill that nurses grew better at with experience:

> So this ward is definitely very busy and I guess you just really have to learn quite quickly how to prioritise, like what things need to be done first, like what is my most urgent thing that I need to do, what things can I leave until later and what time, if there is a specific time for things, how can I fit all these things in to get mostly these medicines on time. So there is an art to it *(Judy, Junior Nurse).*

> It's near panic sometimes. You do need to make a choice about what you need to do but I know from experience that that won't last it'll be a finite situation and you know you just have to get through that day and leave what you can't do and you'll do the rest the next day and we do tell the girls you know it's a 24 hour job and if you can't complete everything in your shift hand it on you won't be thought of as a bad nurse there's only so much you can do *(Sharon, Charge Nurse).*

Through prioritisation attention could be given to the tasks that really needed it:

> I don't make mistakes with the important stuff *(Sophia, Senior Nurse).*

But prioritisation was not a saviour from the risks of pressure, especially for the more junior nurses. For them, pressure had a far more overwhelming character to it. And even for the experienced nurses prioritisation was risky. When the pressure came on, because it was normal to stretch the time frame that some tasks should have been completed within, the magnitude of some risks increased.

The one quality manager spoken to was very clear about the reality of excessive pressure on nurses, and the risks this presented to safety:

> We kind of resort to education. But education is the fall back and it doesn't work. You can educate them until the cows come home, but they are busy. Part of the problem actually I think with nurses is they've got a huge number of things to attend to. They've got people being admitted and discharged from the ward all the time. So it's full on with these complex patients. So I think stuff drops off their radar, and that's a human factors problem. I think that we haven't recognised that as much as we should

> in terms of just how much complexity can one person manage, there's a lot of that kind of stuff that impacts hugely on nursing staff that we haven't recognised *(Rochelle, Quality Manager).*

The service managers were also aware of the intense pressure upon nurses, but they did not tend to see pressure as compromising safety. Their thinking was supported by three kinds of observation. First, patient complains about nurses were less serious than those involving doctors. Nurses did not tend to be accused of significant harms, they were instead implicated for being rushed, communicating poorly, and not protecting privacy. Second, there were emergency support mechanisms for nurses, such as a specialist backup team that were available when necessary. Third, at least one of the managers spent time on the ward to stay in touch with nurses, and found them very supportive of one another when the pressure was on. However despite these reasons for thinking that pressure was not causing nursing work to be unsafe, there was nonetheless some equivocation in how the service managers spoke about the safety of nursing under pressure. While nurses might sometimes not practice at their "best level", safety would not be compromised "very much", and nurses wouldn't feel unsafe "on the whole".

Communication

As the transfer of information communication involves interpersonal processes that may or may not be technologically mediated. When technologically supported communication was discussed the systems in use were often described as problematic. Booking between departments relied upon inefficient paper based systems. Doctors scheduling outpatient appointments would not know if they were kept, and there were "continuing examples" of patients "turning up six months later with an inoperable tumour or some sort". Communications systems intended to link nurses and doctors were sometimes inadequate to the task. Their failings however were equally technological and social. The way in which they were used betrayed inter-group tensions.

The medical and surgical handover process was risky because of the potential for information to go missing. While there had been efforts in some departments to introduce a more structured process, nights could still be fragmented and uncontrolled:

> The junior doctors just switch phones or pagers at a certain time and off you go. There's no formal discussion with the seniors *(Edward, Consultant).*

In addition processes that normally worked well could still fail when doctors were under pressure and forgot to pass along information. Some of this risk arose because of the "quite vestigial" IT systems that had no capacity to share information in real time, and a lack of space which precluded staff from recording detailed information when it was needed. Efforts by departments to improve these systems had come unstuck or were delayed because of the inability of IT to support better systems, and the complications of improvement. As a result handovers were sometimes managed through a handwritten jobs list.

Doctors generally did not disclose any difficulties in their personal communications with one another. There were many brief comments which suggest that communications within departments were very good. One department was described as quite non-hierarchical, which was particularly beneficial for communication. However the Clinical Director was very clear that there was plenty of room for progress:

> Communication is always an issue. A lot of the communication breakdowns occur because people are just too busy to communicate properly *(Charles, Clinical Director).*

Occasionally there were other hints from different departments about problematic relations between doctors. A consultant surgeon observed that there could be difficulties with juniors who were disobedient, forgetful, or might "not communicate with you when they should." Consultants had insufficient control of the hierarchy because they were responsible for an unmanageable number of junior doctors, and it was impossible for them to build rapport, and to be available as often as they were needed.

Although a number of doctors described positive collegial relations with those in other departments, communication between doctors appeared to sometimes be at its worst across

departmental boundaries. Those in need of assistance were a source of pressure upon the ones called to provide it. Blocking or stalling requests was a way to avoid being overloaded.

Nurses did not confess to any difficulties in their communications with doctors. However some nurse's observations of other nurses indicated that communication was problematic. There were junior nurses who were fearful of talking with doctors, especially consultants, in case they should appear ignorant, wrong, or failed to understand what was said. This fear of doctors was reflected in the observations of a charge nurse, who noted that efforts to encourage nurses to accompany doctors on their morning rounds had been unsuccessful. The blame was partly attributed to some doctors, who saw rounds as an exclusively medical activity, and excluded nurses from the discussion. However other doctors were more inclusive. Tensions in the way of better communication may have included nurses not wanting to prioritise working with doctors, lacking confidence, having previous bad experiences, and feeling unable to reorganise other tasks in order to free up the necessary time. The charge nurse felt that while nurses emphasised busyness, the real reason was being "nervous or scared" of doctors. The same problem was evident in nurses being unwilling to phone consultants directly, despite a departmental initiative to make this a routine event.

Some comments from doctors were indicative of the tensions that may have affected the way they communicated with nurses. A houseofficer suggested that some nurses communicated "a lot of crap" by failing to correctly brief them with basic details about patients' conditions. Nurses could leave phone messages with no name for who to contact, and they sometimes avoided direct communication by resorting to message based systems that were typically delayed, but allowed the nurse to enter 'doctor contacted' into their records. Under pressure, doctors could be hugely frustrated by the lack of timeliness and useful information.

When doctors discussed communication with nurses there was very little suggestion that they felt their power and status could make it difficult for some nurses to talk about their concerns or raise questions and challenges. Although several doctors commented positively about nursing, only one, a female, specifically addressed the importance of maintaining good communication with nurses. Generally however, aside from there being occasional evidence of frustration or avoidance, the narrative from nurses, especially charge nurses, and from doctors,

was that communication was good and improving. While there must have been some truth to this claim – some of the sentiment appeared real, departments had made structural changes to bring the groups closer, and there had been training in improving communication – the tensions and observations that were occasionally expressed in interviews suggested nonetheless that communication was sometimes difficult.

Teamwork

When nurses described communications difficulties with other nurses they virtually always linked their concerns to the breakdown of teamwork. The nursing handover was only ever mentioned on a few occasions. It was reported to be either generally good, aside from occasional lapses when things were forgotten, or, by a charge nurse, as "an ongoing challenge", despite a range of systems designed to improve it.

Teamwork was described by nurses as critically important to the correct performance of their role. However it was problematic and declining in a number of wards in this research. When nurses discussed teamwork as failing it was directly associated with the pressures created by short staffing:

> You say you work in a team, then a lot of people work individually and they don't help each other. So it's a real shame it's gone like that. But all the medical wards are the same at the moment *(Jessica, Junior Nurse).*

> When I started teamwork was great, but it just sort of decreased and it's gone to pieces a little bit, people aren't helping other people. It's sort of just like 'these are my patients, that's all I do' *(Linda, Junior Nurse).*

> Everyone's trying to get their workload done and get their tasks done. And if they stop and help you with this now that's going to put them further behind. They're already probably behind and then you want me to do this as well. I'm going to be further behind and at the end of the night I'll be the one staying and still doing my work, because you will have gone *(Emma, Junior Nurse).*

Poor teamwork had implications for a number of different kinds of risks because nurses could not complete tasks correctly or at all without the assistance of others. This meant that some

risks had to be tolerated. A very visible aspect of this tolerance was not answering the bells that patients rang when they needed assistance:

> People are sitting there writing their notes and all these bells are going off, and to me that bell could be someone who is about to faint or have a heart attack or something, and no one is really answering *(Linda, Junior Nurse).*

Bells were not answered in part because patients continuously sought attention for reasons that appeared trivial to nurses who were overloaded with tasks. Nurses could also be anxious to complete paperwork so they could go home on time. Comments from a charge nurse implied that this could cause significant tension:

> That's something that staff get annoyed with each other about if they don't teamwork, and if someone hears a bell and doesn't help them. Answering bells is a big deal *(Samantha, Charge Nurse).*

The failure of nursing teamwork did not come to the attention of all of the service managers. In one case a manager had developed the view that nurses coped with short-staffing by dividing the additional work amongst themselves. The reality however was that nurses disagreed with this practice and viewed it as compromising safety. What was perceived by this manager as "nurses supporting each other" was actually nurses agreeing under pressure to accept more work.

Overview of the generalised safety risks

While most doctors did not discuss staffing levels, it was clear from a few comments by seniors that there was sometimes unsafe pressure during nights because of too few houseofficers, and the non-availability of senior staff. The houseofficers who worked overnight were very clear that safety was sometimes deeply compromised during nights. While nurses could also face particularly intense pressure on night shifts, they appeared to find daytimes difficult as well because of how short-staffing frequently increased the number of patients they were required to care for. Nurses clearly felt that this pressure was unsafe. As the intensity of work increased teamwork amongst nurses declined, creating further risk. While nurses did not describe their

work as catastrophically unsafe, they admitted that some important tasks were not performed, and the likelihood of mistakes increased. It appeared that in this context the concept of safety became flexible and it was necessarily shaped to the demands of the situation. Nursing managers and service managers were more or less aware of these risks. But they did not always make the connection between growing risk and declining safety.

Intra-group communication was generally not discussed. Inter-group communication, between nurses and doctors, and between doctors in different departments, received a minor share of the focus of participant talk. Quite often that talk, when it did occur, was about the technology of exchange, not social communication. When communication was talked about as a social event involving different groups with different needs and different levels of social power, it was often described rather blandly, as “good” and “improving”, relative to a past where things were not good. However there was clear evidence that across-department communication between doctors was compromised by tensions over access to resources in short supply. There was also some evidence of tensions between nurses and doctors, although this topic appeared to be largely avoided.

The generalised risks of short-staffing, pressure, communication, and teamwork are analysed in greater depth in the conclusion of this chapter, where they can be considered alongside evidence about the risks of specific harms.

The dynamics of risk and harm

The generalised risks to safety contributed to the emergence of the risks of specific harms. These risk processes are described here. Understanding them in depth provides insight into the real consequences of the proliferation of generalised risk inside hospitals. Once generalised risks become established they are difficult to control and they can lead to patients being harmed in a multitude of ways. While there are opportunities for risk control in addressing

different aspects of the sequences of events described here, interventions must not only target the mechanisms of specific risks, they must address the generalised ones as well.

The risks that staff mentioned are shown in *Table 3* (below), and discussed immediately after. The numbers on the table represent a count of how many staff mentioned each risk. The numbers do not suggest anything about the depth or the extent of the discussion. When a participant mentioned the same risk more than once, the risk was still rated as receiving one mention.

Table 3: Risks to patients mentioned by staff

Risk	**Doctors #** n=17 surgical: 11 medical: 6	**Nurses** n=15 surgical: 11 medical: 4	**Managers** n=5 service: 3 quality: 2	**Total staff mentioning this risk** n=37
Medication	8	13	2	23
Diagnosis and decision making	16	-	2	18
Falls	1	8	2	11
Physiological deterioration	6	3	1	10
Dehumanisation	2	8	-	10
Pressure ulcers, Immobilisation	1	7	1	9
Infection*	4	3	-	7
Surgical complications	6	-	-	6
Preventive failures	1	2	-	3

 # The surgical and medical division amongst doctors is by department worked in. Of the eleven 'surgical' doctors two were houseofficers, and nine were either trainee or qualified surgeons.

** Infection risks are treated as a surgical complication when they were described as the result of surgery.*

The risks of medications

The risks of medications were mentioned far more than any other risk, and they generated considerable discussion.

Doctors' described multiple potential problems with drugs, including drug interactions, prescribing the wrong drug, and mistakes in the dose, timing, route, and wrong patient. Many of these problems stemmed from nurses, who could make errors when they were rushed. Some of the risks of medication were due to relatively trivial causes, such as writing the wrong name in error, writing illegibly, and confusion between the 'everyday' and 'every now and then' categories on the charts.

Surprisingly, very few doctors' discussed some of the more serious kinds of drug errors that had nothing to do with nurses. Weaknesses in their in-depth knowledge of prescribing could lead doctors to prescribe the wrong drug, dangerous combinations of drugs, and too many drugs. One consultant particularly emphasised the importance of checking and rechecking the chart, and along with another doctor they noted the value of having experienced nurses review the chart as well, so errors did not creep in at any stage of the process. However this work was often not completed:

> In my duties on the pain service we go round and visit every ward in the hospital and we review the charts on a regular basis and you usually see errors of some sort. Sometimes they're subtle, sometimes they're obvious and big, and people get harmed *(Bjorn, Consultant).*

One reason for these failures was suggested by a quality manager who pointed out that many nurses lacked the experience and the knowledge necessary to spot errors on the chart. Comments from a nurse who was able to perform this task indicated its necessity because of the errors committed by fatigued doctors:

> It's obviously not safe having a really tired individual to look after patients. They chart medications wrong, they chart medication that is written down in the hyposensitivity, so nurses correct them, like doses are wrong. They have a huge impact from being lethargic *(Jung-soon, Junior Nurse).*

Very few doctors discussed how they or any doctor could make mistakes like this when they were tired.

Errors could also occur because chart review was neglected. While charts were supposed to be reviewed during transcription, this work could be performed in a rush at 2am by a houseofficer who did not know the patient. Houseofficers sometimes avoided chart reviews during transcription because the work was "annoying" and doctors were "already busy enough". While some doctors felt the review process was "probably" having an effect, a consultant claimed it was too often neglected, and blamed busyness, disengagement, and the hospital for giving insufficient attention to the training of houseofficers:

> You have senior people who may be disengaged but they may just be bloody busy doing other things and they don't appreciate that it's important to sit down at every ward round and read through the drug charts and make sure that everything makes sense *(Bjorn, Consultant).*

The risk of over-medication was described in depth once in this entire project:

> If you go and take the average old patient of eighty on the wards you'll probably find they're on five, ten or sometimes even fifteen, or god help them twenty different medicines, most of which are probably not indicated and certainly I find it difficult in my head and heart to justify administering more than about five or six medicines to most people because most of them don't need them and in most cases you are ramping up your risk of adverse drug interactions *(Bjorn, Consultant).*

It should be a concern that this major risk was discussed so little, and described as pervasive when it was.

For nurses the risks of medications were very immediate and pressing. Nurses described many ways in which things could go wrong, and a few commented that through drug errors they could kill someone at any time. A charge nurse described drug errors as due to "individual practice." But many nurses found individual practice difficult to perfect because of situational pressures.

Nurses sought to observe a medication protocol of the correct patient, drug, dose, route, and time. But they could break it intentionally or unintentionally. Intentional violations involved the

deliberate use of shortcuts, which nurses often justified because they were busy and short of time:

> When you've got antibiotics they're supposed to be pushed through over three to four minutes, but you could be tempted, and I've seen other nurses push them through quite quickly, because if you can push it through in two minutes you've saved two minutes rather than waiting the whole four *(Emma, Junior Nurse).*
>
> And a lot of the time, you are meant to check the medication label and the chart with the patients' wrist band and ask for their name, but when you're in a rush sometimes that does not happen to be honest, and that's how medications are given by mistake as well *(Jessica, Junior Nurse).*

Protocols for restricted medications were often not observed. Two nurses were required to obtain and provide these together so one could observe and check the other. But nurses would collect the medication together, as the machine would only dispense when both were present, and then separate so that delivery was performed individually. A charge nurse, aware of this practice, said it was "hard to regulate" and explained it as a "time thing" because nurses were unable or unwilling to put other duties on hold. A junior nurse, who had spotted and helped adjust incorrect doses, said "it cannot always happen, again because of the short staffing." A description offered by another junior nurse suggested that the practice was normalised:

> Nurse: And the biggest thing that I found hard to get my head around is the administration of controlled drugs. We are so busy or we don't have time for two nurses to go to the bedside and double check everything. We just can't. No matter how hard, well, no matter how hard you try it just can't be done.
> Interviewer: Is that all of the time or just some of the time?
> Nurse: All the time.
> Interviewer: So continuously?
> Nurse: Yeah, I've never, maybe as a new grad, but since, I've never had someone come with me to administer a controlled drug *(Linda, Junior Nurse).*

Even the first part of the task, gaining agreement to go to the dispensing machine with someone, was difficult because "everyone is doing stuff."

Unintentional medication protocols were due to variable causes including distractions, stress, poor concentration, insufficient attention, multitasking, and general busyness. These challenges were particularly intense for new nurses, who could provide pain relief in a panic

without consideration for the necessary protocols. A junior nurse confirmed that the normal pressures of looking after the acutely unwell could easily affect decision making:

> I made an error giving the wrong type of insulin when I was a new grad because I was under a lot of pressure, like that day was really, really busy. It's quite possible if you are very, very tired, and overworked, and work in an environment where there is a lot of pressure at the back of your shoulder *(Jung-soon, Junior Nurse).*

But it was quite possible that juniors were safer because fear made then cautious. According to senior and charge nurses a later drift into complacency was the bigger challenge because nurses could become easily distracted and ignore routine safety checks. Referring to the five rights, a charge nurse emphasised that discipline was essential:

> It's drummed in so much. I think there was one point there were people were gosh, the five rights, it's drummed in so much, they know all about it. So they know. They don't necessarily do. But then it's been brought around into our yearly training, just how important this is, that this has become, we know it's repetitive, we know the system with it, but this is what has happened. And I guess it just changes people's way of thinking. Yeah it might be annoying, but it's safe *(Amanda, Charge Nurse).*

The discipline to "do" correctly could however easily come unstuck because of risks that nurses did not adequately consider. A patient might be medicated in the Emergency Department (ED), and this would be charted on their ED record, but if this information was not handed over verbally a nurse in the receiving department might repeat the dose because they did not check the ED chart. A reverse problem could occur if medication was charted in the ED, but not given because the patient was transferred before administration.

It was very easy for nurses to accidentally ignore the five rights. However the charge nurse who attributed this failure to not checking also invoked boredom with the routine of nursing:

> It's something they do every day, they think they can't do wrong, complacent. Just yeah, they know the patient so well. And they might not realise that actually they have developed an allergy to something and they just assume, 'oh I know who you are, your allergies, I know that, you are the right person', and just give it. They've done it for so long, especially our long term patients are the ones they get so familiar with that they think it's okay to just give the medication, they will be fine, 'I know this person, I know your meds inside out, don't need to double check' *(Amanda, Charge Nurse).*

As a quality manager observed, checking wrist bands before medicating could seem "kind of dopey". Boredom and routine could also lead to conversation in the medication room, which was supposed to be avoided:

> "We're human, we are all working together, how can we not talk?" *(Daiyu, Junior Nurse).*

A further cause of error according to a charge nurses was "rushing and speeding". Haste was invoked by many nurses seeking to explain drug risks. One senior nurse described her ward as so chronically busy that only important medications could be provided on time, others were delayed. A junior nurse commented that distractions due to "so many things happening" could lead a nurse to forget to provide medication. Distractions included other nurses requesting checks on antibiotics or controlled drugs, trainee nurses asking lots of questions, patients ringing the bell, family members, and so on. Distraction was a normal risk of the work:

> It's so easy to make a mistake, it's so easy to, and you've just got to really focus on what you are doing. But then you can't walk from the nurses' station to a room without getting distracted. It being a phone call or a doctor calling your name or a family member or a patient has had a fall, there's a code, there's always something going on. So usually when you go to do something you need to be prepared that you are going to get distracted doing that *(Jessica, Junior Nurse).*

There were many ways in which distraction could lead to accidental harm:

> The doctor might chart a medication and you could be talking about a patient but you are doing the medication for someone else. So because you are talking about that patient with another nurse, you could be discussing a different medication, you could go to that patient by mistake. And that has happened before with patients as well. You've got that person in mind, you've just been talking about them, you can just walk to them and really the other nurse doesn't really know what is going on, so you just keep walking and you can kind of give it and that's a big mistake too *(Jessica, Junior Nurse).*

Unintentional violations could also be because of uncertainty or not knowing what medication to provide. Sometimes inexperienced houseofficers were unsure of doses, in which case the nurse might advise the doctor. More commonly a nurse might be unable to read what the doctor had written, or the dose was unclear, or seemed wrong. Nurses would then try to translate the medication name or contact the doctor. The latter was the safest, but also the

least desirable option, as doctors could be difficult to contact. Nurses were especially reluctant to contact the consultant if other doctors were unavailable. A number of nurses reported being confident in translating poor handwriting and incorrect doses.

Another challenge for nurses was missing medication charts and medication changes. Charts could be removed from folders and not returned, and patients could not be dosed correctly until the chart was found. Searching for the chart was frustrating and annoying. Folders could also contain the wrong chart. If the patient's identification was not checked and matched with the chart, the patient could receive someone else's medication. This happened "a lot", especially with acute patients needing many transfusions.

A further cause of unintended protocol violations was a lack of teamwork or tensions between nurses and doctors that drove poor communication. When doctors prescribed a stat (immediate) dose during their morning round by writing this into the chart they might not inform the nurse:

> Sometimes they'll even chart a stat drug for the nurse on the drug chart but not tell the nurse, and it's only when the nurse eventually gets back to the clinical notes and pulls up the drug chart for her next load of drugs that she sees it and goes 'oh actually they've got a stat drug charted two hours ago, that hasn't been given because no-one told me about it' *(Graeme, Charge Nurse).*

The risks of medications were considerably more present in the mind of nurses than they were for doctors. For a few doctors this issue appeared to be something of a crusade, but changing behaviour was difficult, and it did not appear to be well supported by the hospitals. Nurses were confronted with multiple challenges in providing medication safely, but because of situational pressures and inattention on their part, protocol violations and medication errors were an ongoing problem.

The risks of diagnosis and decision making

Issues with diagnosis and decision making were referred to almost exclusively by doctors. One doctor described this risk as probably the biggest risk that they faced on behalf of their patients. The major difficulties associated with this process were making the right decision, and the social and technological challenges of gathering the necessary information.

Diagnoses were of variable complexity. Performing complex diagnoses under time pressure was risky because decisions could become less rigorous. According to a surgical consultant there was generally less time available for gathering and consider evidence:

> Surgeon: The concern is that we might miss particular results and findings. I think one of the real important things that we do is try to spend time with patients and at least make them feel that they've been listened to.
> Interviewer: Yeah and that's less, you're less able to do that now?
> Surgeon: There's less time for that, absolutely less time for that. It's much more 'What are you here for? Okay we'll do this test, we'll do that test, we'll cut that off'.
> Interviewer: Could that be an issue in terms of not always picking up the extra bits of information that they might reveal?
> Surgeon: Absolutely and there was a woman that I saw this morning that we'd seen three or four times and each time we got a little bit more information and actually it all in the end made sense. If we hadn't had the opportunity to see her so frequently well we might have missed some of the stuff that pointed towards the diagnosis *(Richard, Consultant).*

In addition to time-pressure, being tired and busy could also made diagnosis challenging:

> When you are busier and you are tired, you don't have as much time to spend with the patient that you would like to spend. I think sometimes there are always temptations to take short cuts and I think a lot of that is borne out by the fact that if you are busy on-call and you are the only one with the phone there's two options there, you take the short cut or you stay at work longer. I think most of us would choose to stay at work longer, but that can be quite tiring and that can affect safety in other less tangible or hard to measure ways in terms of fatigue and missing things. And that's not in terms of taking short cuts, but that's just not thinking of things because you are tired and missing other possibilities of the diagnosis *(Paul, Registrar).*

With experience it become possible to untangle the cognitive distortions created by pressure, some of the time at least:

> This probably inevitably happens, but I've become quite good, I think, at recognising when I am feeling uncomfortable about something and you know there will be an option to take a shortcut and I think I've become quite good at recognising when that is inappropriate. That's sort of really just a gut feeling *(Paul, Registrar).*

Nonetheless, pressure was risky for decision making:

> Diagnoses can be missed because people didn't have the time to properly assess the patient, either by taking appropriate history or by doing a thorough enough physical exam when there are lots of patients. Whenever someone is stretched to capacity everything begins to break down cognitively. When you get busy you tend to take shortcuts and you tend to shift from deductive reasoning to sort of inductive logic and you use all the other bits of information to come up with a diagnosis rather than starting off broadly and narrowing things down *(Frank, Consultant).*

While planning, slowing things down, and dissociating from pressure could help, control sometimes remained elusive, and decision-making suffered:

> I think things tend to go badly when planning isn't there, when things are rushed, when you don't have time to review all the information that's needed for a particular patient's management. And that can sometimes happen when you're busy on call, when you've got a number of sick patients, when you're hard pressed to do a number of different things. For example you're pressed to attend a meeting, to see patients on the ward, you have a clinic in the midst of that, you're trying very quickly to manage patients, and you might not manage to get all the information. So some of those decisions might not be the best because of the fact that you're struggling for time *(Carlos, Registrar).*

It seemed clear that doctors wanted to implicate pressure as one of the important reasons why their plans were sometimes mistaken. But none seemed comfortable with settling for pressure as an excuse or a reason. There could be equivocation between implicating pressure and trying to retain responsibility:

> I did make a mistake just before I went away on leave, but I had a hell of a lot of patients, and diagnostically I got it wrong, partly because it was a very bizarre diagnosis. But also because of distractions in the situations in which we were working, with lots of patients, lab results were down, and all that sort of stuff. So it's very easy for doctors there to say 'Well it wasn't me that made the error, my cognitive error was the direct result of everything else that was going on', and of course that's true. It's very easy for me to blame those other circumstances *(John, Consultant).*

On other occasions however doctors seemed to suggest that pressure sometimes passed a threshold which became almost overwhelming, and they were no longer safe:

> The busyness is ridiculous, it's unmanageable, it's so easy to see how mistakes could happen *(Adil, Houseofficer).*

> Sometimes I feel I don't trust myself as much as I should because you think 'Oh am I missing something, am I tired?' I can work a 15 hour day or a 70 hour week and at the end of the week I'm still thinking and processing and making good decisions but I truly don't know whether I am as good. I do think that the hours that we do are probably sometimes unsafe and if you talk to patients they'll often say 'But you were here this morning', and you say 'Yeah I worked all day', and they often kind of look at you as if 'Do I really want this doctor looking after me?' *(Karen, Houseofficer).*

> One day you'll be absolutely fine, other days you are simply so busy that you are really, really stretched and you really, really hope that each patient does get a fair deal *(Cathy, Consultant).*

A matter that was infrequently discussed was the wisdom of diagnostic investigations. According to a clinical director that there was a general tendency to over-investigate:

> There's a whole lot of investigations of patients which are done on the basis of 'God they just might have something'. There's loads and loads and loads of tests that are done and I think 'How the hell does this person who is at the very end of their life, you know, does it really actually matter whether they've got a dissecting thoracic, does it really matter if they've got a brain tumour, does it really matter if they've had a heart attack?' And actually you know if your ninety three and you're in a rest home when you've only got six months more to live why are we doing all these tests? So we do a whole lot of unthinking things in the in the name of safety which we need to pull back from *(Christine, Clinical Director).*

Investigations also sometimes gave the wrong result. While doctors might intuit this because of other conflicting signals, calling colleagues to consult could lead to tensions if other doctors refused to give up their time. Differing opinions about the need for review "could cause a lot of conflict between different specialities." Tension was heightened when there were implications for patient management, but sometimes they were not resolved and matters had to be settled by the natural course of an illness.

Delays in diagnostic testing in other departments was a source of considerable frustration. Methods for booking investigations in one hospital, such as radiological exams and

colonoscopies, were less than ideal. The paper based process was “quite cumbersome”, and doctors often had insufficient time for a telephone discussion. This made it hard to provide information about the urgency of the test, to know of the procedure was booked, what its time-frame was, and if it had been rescheduled. The department planned an electronic system but this presented technical issues for implementation.

In some cases tests required negotiation with and advice from doctors in other departments. Tensions could develop in these situations when the doctor ordering the test or requesting the consultation felt the matter was routine, but the receiver held a different opinion. Three doctors explicitly stated that communication of this kind between departments was “always” a problem or an issue, and other doctors similarly described situations in which difficulties were evident. Underfunding, overloading, and busyness were invariably blamed for delays which effected many departments and could be anything from occasional to frequent:

> Well I think sometimes some specialities can be a bit resistant to coming and seeing patients, maybe because they are short staffed or maybe, for whatever reasons, it may not be as open as it is *(Adil, Houseofficer).*

> Interdepartmental discussion and communication is a real problem. Part of that comes from say the cardiology department, because they get so many referrals I’m sure, and every single person who has a raised troponin will talk to cardiology about it and so the fact that they are often very short on the phone and they don’t want to come and see your patients and they often provide not terribly helpful advice is probably a reflection on their workload as well. It’s certainly a hard part of our job *(Karen, Houseofficer).*

Services could be denied to doctors at many different levels of seniority. Requests could be denied to junior doctors, even when they acted on the instructions of a senior. The result could be the frustrating waste of half an hour of the houseofficer’s time, and a delay for the patient whose booking might be shifted to the next day. Senior doctors could also find that bookings for tests and scans were frequently difficult. In non-urgent cases delays sometimes lasted for more than a week. While visiting the service might help, it consumed time, and the problem was not always fixable. But unless the matter was discussed with a consultant or someone known personally, departments “almost put walls up” to deny the service:

> You sort of feel like sometimes you're banging your head against a brick wall just trying to get things done that should really just be a tick box, 'Can we get this done? Next box, done' *(Michael, Registrar).*

All doctors sometimes obstructed others in order to make their work more manageable:

> Because all the specialities are all so busy we try and you know reduce I guess, make sure the workload we have remains something we can all sort of handle *(Nathan, Registrar).*

But delays had clear implications for safety:

> There can be very significant delays. If we have delays in getting services from gastroenterology then the diagnosis of a cancer may be delayed and we certainly have examples of that *(Charles, Clinical Director).*

The ultimate success of a booking is dependent upon the coordination processes through which it is fulfilled. But sometimes there were failures due to the neglect of small details and confusion over time, day, location, and reschedules. Effort spent preparing and sending patients was then wasted, and further delays arose. These issues were sometimes made worse by busyness, with "nurses running here and there for their patients", and departments "prioritising their own immediate needs" ahead of requests for outside assistance.

The risks of diagnosis and decision making by doctors involved two kinds of challenges. First, decisions made under the stress of tiredness and pressure could be wrong. Doctors acknowledged that while they could try to control these factors, they were not always successful. Second, there could be delays in accessing diagnostic information from other departments. These delays appeared to be quite entrenched and sometimes they were harmful.

The risks of patient falls

Most of the discussion about the risks of patient falls was generated by nurses. This risk was also briefly referred to by a doctor, a quality manager, and a service manager. The quality

manager noted that falls were still occurring despite a huge prevention programme, and it was difficult to know what was, and what was not working. A challenge was that nurses did not always put learning about screening and prevention into practice. Contradicting this, the service manager claimed the hospital no longer "tolerated" falls, and that was "an amazing step forward for the organisation".

The one consultant who did speak about falls was critical of preventive possibilities, and the attention that falls received. Falls could happen to any patient, including those at low risk, and it was not possible to monitor all patients. Falls possibly gained attention because they were easy to measure, but they caused less harm to patients than some other risks.

Commentary from nurses clearly indicated the difficulties of prevention. Many, including a charge nurse, either claimed that falls were not always preventable, or described situations in which they felt unable to control the risk. While a couple of nurses did maintain that falls were preventable, one qualified this with the conditional "when we continuously monitor the patient", and both nurses later discussed situations in which they felt that falls could not be prevented. One of these occasions was at night time, when nurses looked after ten patients. Although only one patient might be high risk, nurses could not monitor that many patients all of the time. Another nurse found the same problem in afternoon shifts, when they were often understaffed, with three nurses on the ward when there should have been five. On those occasions multiple factors could contribute to a fall. One case involved a demented patient who was placed in a room that was not easily visible from the nurses' station. The ward was short-staffed, nurses were "running frantically," there was pressure from the Emergency Department to accept a patient, and the room was the only one available. The patient later tried to walk to the toilet when no nurses were around, and fell and broke a hip.

The other instance in which a nurse went back on their earlier claim that falls were preventable involved another case in which a patient also fell and broke a hip, and later died from surgery to repair the hip. Although the patient was capable of independent mobilisation, when they went to the toilet one day they were nonetheless instructed to ring a bell for assistance so they could be helped to stand up from the toilet. The patient was not high risk, and the nurse was being cautious in offering assistance. The patient declined the offer, and fell. The feelings of

helplessness this incident created amongst some nurses was reflected in a couple of other falls scenarios that also seemed difficult to control. Some patients needed two or even three nurses to assist them to the bathroom. Because their toilet visits were necessarily delayed until the required number of nurses was available, they were at risk of attempting the action alone. Other patients needed frequent help to the toilet:

> A lot of the time they come with diarrhoea or a urinary tract infection, so they are constantly going back and forth to the toilet, and us as nurses, we can't be there all of the time. We like to be there, but on the afternoon shifts, sometimes we only have three of our ward nurses on when we should have five. So that is another reason how patients can fall over *(Jessica, Junior Nurse).*

Patients could be given a bed-pan, but most preferred to use the toilet "no matter what."

Some of the above examples demonstrate that patient compliance with behaviours for saving them from falls was problematic. More generally, some patients simply refused to cooperate with their care plans. Confused patients were at risk, because they were not in control of their actions, and cognitively functioning ones were as well because they could choose to ignore instructions. Patients had also been known to fall with a 24-hour caregiver, and patients not considered to be at risk had similarly injured themselves. One patient even became dizzy and fell while awaiting discharge, and was readmitted.

The use of technical interventions to reduce falls was generally perceived as positive by nurses, but with caveats. Even experienced nurses could find it difficult to make the right judgment call about the best preventive measure. There was disagreement about side rails. Some nurses described these as unsafe because of the risk of patients becoming stuck, and sustaining skin tears. Some nurses' favoured low beds for at risk patients but others found that these made it easier for patients to get out of bed and walk. The value of non-slip socks was not questioned, but this measure was largely inadequate in isolation.

Patient falls were deceptively difficult to reduce. They had gained significant attention and resourcing, but under pressure nurses struggled to make answers work in practice.

The risks of physiological deterioration

The risks of physiological deterioration were mostly discussed by doctors. The issues discussed included identifying deterioration, communicating about it, and the capacity for an appropriate response.

Doctors depended upon nurses for information about deterioration. Nurses' abilities were particularly critical during nights when houseofficers had many patients to look after. With exceptions, doctors mostly felt that nurses did this well, although a quality manager noted that they sometime erred on the side of not contacting doctors in case they were badly received. The Physiologically Unstable Patient scoring system provided an effective resource to assist identification, although discretionary judgment was variable, and challenging for junior nurses.

A major concern for nurses was that busyness could distract them from noticing deterioration. Busyness was especially problematic when nursing very sick patients that were not judged by the care coordinator to be sufficiently unwell for one-on-one nursing. While missing deterioration through busyness with another patient was "not a very good excuse", it could be a significant difficulty:

> So we have six patients and then three discharges, three admissions, beds with two post-ops, and lots of things going on. And in that case you know that this patient is sick but then you have a million other things to do, so then you start to catch up on doing things, I mean you've done everything for the sick patient and you think 'Okay he'll be all right for half an hour.' And then you turn your back and start to do other things and then of course as time goes you can lots of distractions, and then you might go back more than half an hour later *(Daiyu, Junior Nurse).*

A related challenge for nurses was when patients were temporarily placed in unsuitable rooms:

> Sometimes our wards are so busy, we are fully flexed out with patients, we have patients sometimes having to go in our TV room, and that's not really safe because we don't have any oxygen or anything there. All we've got is a call bell, so if that patient had a cardiac arrest, we are not really near anything. And when it's not close to us we probably wouldn't see it, if it happened. So we don't really like putting patients in there but sometimes we have no choice, because the whole hospital is full and we keep getting patients sent up to us *(Jessica, Junior Nurse).*

Once deterioration was identified however there were four ways in which communication about it could become muddled. First, the iBleep system provided nurses with an "appalling" means of communicating with doctors. There was no provision for return communication, messages provided little information and no indication of urgency, nurses did not know if the doctor had received the message, and messages were difficult to view and rank. Second, the daytime paging system was information deficient. Nurses sent their number to the pager but doctors knew nothing about urgency, and sometimes found that no one knew anything when they called. Doctors could later find 'doctor contacted' in the patients notes. Third, nurses sometimes phoned doctors directly, but they neglected the SBAR (situation, background, assessment, recommendation) communication protocol, and were unable to provide necessary information such as basic facts about the patient's diagnosis. Fourth, nurses could neglect to direct phone mobiles, even in situations of some urgency, because an alternative computerised task system was available. To add to the challenges of this system, nurses could use it to create tasks that doctors saw as unnecessary.

While contact with doctors was a significant intervention for deteriorating patients, subsequent decisions was sometimes of poor quality. In one of the hospitals, especially at nights, where there was "a very high threshold to call the on-call consultant", many emergency decisions were handled by junior doctors.

A further difficulty was that chronically unstable patients could not always be provided with the care that they needed. Some required a higher level of nursing care than could be provided on the ward, but they could not be shifted to the Intensive Care Unit or the Surgical High Dependency Unit, because of policies specifying that patients could only be moved to these locations for particular interventions. In effect, while identification often worked well, it did not necessarily result in a higher level of care:

> They overestimate the possibilities of what nurses on the ward can do – their knowledge and their ability to care and provide what those patients might need *(Edward, Consultant).*

The retention of these patients on the ward created a conflict between their needs and others, forcing nurses to decide who was to miss out on the "care that they need."

The deterioration process was challenging on multiple levels. Busy nurses sometimes missed it, although seemingly not frequently. Systems for communicating were sometimes inadequate or poorly used, with inter-group tensions leading to the avoidance of direct talk. Some patients' needs were difficult to provide for, which stretched the capacity of nurses, and compromised the safety of others.

The risks of dehumanisation

The risk of dehumanisation covered a range of experiences affecting patients and staff. Dehumanisation was often a consequence of patient neglect, and it sometimes reduced safety. It was mostly the concern of nurses. Dehumanisation contradicted an emphasis in nursing on the emotional, mental, and spiritual components of health.

Dehumanisation was the outcome of nurses having to prioritise technical tasks over care for the patient. Interpersonal care, grounded in listening and conversation, was problematic when necessity pushed technical needs to the forefront:

> Basically it becomes task orientated, so you are just going in there, doing observations and medications and having to leave, so you've really got to cut time. You can't really talk to the patient and really care for them *(Jessica, Junior Nurse).*
>
> If you've got people of high acuity that you are looking after you might just focus on tasks rather than sitting down with people, asking them the questions that you need to know to look after them better *(Judy, Junior Nurse).*
>
> We're short so we don't have enough time to really spend with them it's just like more task, task, task *(Lisa, Junior Nurse).*
>
> It's just very task, do the antibiotics, do the observations, whatever, haven't got time to really talk to you, look after you, it's just get these tasks done ... I don't feel like I'm doing a good job, I mean a robot could run in and do observations *(Emma, Junior Nurse).*

Care was especially necessary when patients were afraid of hospital, lonely, did not have visitors, were unwell in the midst of other significant life crises, and were faced with immanent death. While one charge nurse described a decent death as involving appropriate pain relief,

they were also highly aware of patients' needs for conversation and to have their most basic physical requirements provided for. The failure of nurses to provide for these needs sometimes drove complaints:

> And then the family come in and the family get upset thinking, 'you are not caring for my mum or dad', and especially if we've got a patient who is passing away. Then we have to try and explain because it's so hard to understand the hospital dynamics and what is going on here. And family, all they want to see is, 'are you looking after my mum or dad, are they comfortable, are they eating or drinking?' But all the time they come in at the moment where they need to go to the bathroom or they are in pain and it looks like we're not doing our job. So it's really hard on us nurses as well when that happens *(Jessica, Junior Nurse).*

> If the meal comes at quarter past 12 sometimes patients still aren't fed by one o'clock if there is something happened. And it's always the time when the family will come in and they will go 'oh you know why hasn't my dad been fed or why hasn't my sister or brother been fed', and that can be hard as well. It's really hard for us to explain to them why we haven't done that *(Jessica, Junior Nurse).*

When patients wet or soiled themselves it was dehumanising. A surgeon mentioned that patients sometimes might not be cleaned up "for a period of fifteen minutes." A nurse claimed she "might have to leave a patient in a wet nappy for a couple of hours because I haven't got the time to change them." These stresses could lead nurses into conflict with patients and families, and create upset for nurses when managers fed complaints back to them.

Some nurses felt that doctors managed patients' anxieties inappropriately though medication.

> It can be frustrating for them with the waiting, most of the time they're very anxious because of the surgery, so they always ring the bell and then you just say 'what do you want?' And they just say 'pain relief', but you don't know the underlying cause of it *(Lisa, Junior Nurse).*

Getting pain relief on time could be difficult. Patients might arrive from the Emergency Department with incomplete paperwork, nurses could be busy with sick patients, nights were busy, and time was consumed by safety protocols and precautions against theft:

> I would say night shift, like for example controlled drugs, you've only got three nurses on in the night shift, sometimes two because one has gone on break and four people are asking for pain relief and one is incontinent and you've got to try and sort

> everyone out. But sometimes you are going to have to get people to wait for their pain relief for, to me, an unacceptable amount of time *(Linda, Junior Nurse).*
>
> In the name of safety you have to have two nurses to check the opiates and things like that and sign them out of the machine, but in reality what that means is a patient's lying there in pain, they ask for pain relief, nurse disappears and doesn't come back for half an hour or three quarters of an hour because she has to go and find somebody else to sign off the machine with her, check the medication, and check that they're not up to any funny business *(Juliet, Registrar).*

Another issue of dehumanisation was the conflict between medical priorities, patient need, and time pressure. Having patients nil by mouth for an extended period was not judged to be medically significant, but it subjectively mattered to patients. If a procedure was cancelled patients would want to eat, but nurses could struggle to gain permission because the doctor was difficult to contact, and rated the issue as a low priority. Patients might then constantly ring the bell, and the nurse would have to decide whether to answer each call, or ignore it and risk something more serious being at issue.

Consent matters in healthcare, but some patients might not understand their care plan. Doctors sometimes had loud and clear conversations at patients who had little or no comprehension. The question 'is that all right?' was met with a nod from the patient. Consent gained by doctors, according to a charge nurse, was "pretty good now" but there was a "reasonable amount" of patients "not really understanding" their care plan.

Dehumanisation did not usually risk safety. But it did violate the values of patients and nurses, and it could trigger adverse emotional responses in both groups.

The risks of pressure injury and insufficient mobilisation

If patients are not turned frequently they were exposed to the risk of pressure injuries in the form of decubitus ulcers, which potentially required surgical treatment. If they were not mobilised, recovery could be delayed, and blood clots could form. These risks were discussed mostly by nurses, but also by a doctor and a service manager, with most of the focus on

pressure injuries. The discussion was usually very brief. In one case a charge nurse acknowledge that patients could not be turned as often as they should, but said that care was “pretty good” nonetheless, and it was negative to talk about the bad things. Another charge nurse maintained that all pressure sores were preventable because resources, teaching, education, and care plans were all available. While other nurses did not dispute that claim, they indicated that this risk was a low priority on a busy ward. When they were busy nurses would stretch the time frame within which patients were shifted or mobilised to an upper acceptable limit. Turing patients was in itself risky, with skin tears possible on very old patients. Nurses also risked injuring themselves when moving heavy patients without the support of other nurses. But gaining assistance was challenging when the other nurses who were all busy, and asking was difficult if teamwork was failing.

The risks of infections

The risks of infections (surgical infections are discussed as ‘surgical complications’) were mentioned by a small group of doctors and nurses. Usually the discussion was brief. One consultant, described by others as a “handwashing Nazi,” was constantly trying to get doctors who “simply don’t clean their hands”, to improve their standards. Another rated handwashing by doctors during rounds as “average”, and another commented that consultants were “not very good at hand hygiene.” Nonetheless there had been some improvements due to awareness campaigns and other initiatives supported by the hospital. Handwashing stations and gel containers on the ward had helped, and a programme in one hospital was improving standards. Busyness and distractions were presented as one reason for non-compliance when facilities were available. Audits of compliance could show improvement, but standards declined when monitoring finished.

A number of nurses emphasised the importance of a variety of hygiene protocols. However a junior nurse observed that nurses often avoided handwashing and equipment cleaning when they were busy. Vital sign monitors were not appropriately cleaned between patients in the

morning, and luers were not always swabbed correctly. Another nurse commented that compliance with handwashing was "not good," and nurses were being "reminded all the time."

While nurses occasionally blamed themselves for poor infection control they more readily implicated doctors. Doctors might not wash their hands between patients on rounds, junior doctors didn't always swab IV lines before use, and some doctors needed instruction about hygiene when visiting patients that they knew were in isolation. But while some nurses were comfortable challenging doctors it was only senior nurses who said this, and they claimed that junior nurses were afraid of pointing out the importance of good hygiene to doctors. At the same time there were also doctors whose practices were very good, and in response to a norovirus outbreak explicit calls from consultants to improve standards had made a difference.

While there were claims that standards overall were getting better, it was evident that infection control remained less than ideal.

The risks of surgical complications

The risks of surgical procedures were described by only about half of the surgeons interviewed. These risks were partly beyond their control:

> There's a saying that the surgeon with no complications doesn't operate *(Carlos, Registrar).*
>
> If you operate enough unfortunately it's a statistics game, I always tell patients *(Andrew, Consultant).*

Some complications arose for no apparent reason. Surgical infections were expected to occur within a window of acceptable rates, but there was no talk about ways of improving upon standard rates. Relative to these standards one department was reportedly "pretty good." In another department there was not "lots of safety issues" and risks were "more to do with kind of dotting the i's and crossing the t's." Some surgical harms could be traced to patient

physiology, which might only become evident during surgery, especially if it was acute. They were “frustrating and scary at the same time, and you deal with it.”

The risk of errors by surgeons was usually but not always acknowledged. In one case it was claimed that technical errors with disastrous consequences for patients could happen entirely by chance, and there was no reason why. One surgeon did reflect upon the causes of error, and identified pressure as a factor that could lead a surgeon to accidentally skip certain stages of a procedure. They could also fail to plan for contingencies, which meant that something needed unexpectedly during the operation was unavailable. It was claimed by another surgeon that the surgical safety checklist had reduced this problem, but there was no discussion about the challenges of implementing this practice except that older surgeons didn’t like to use it. Another planning risk involved information about the details of patients’ interventions, which could go missing during handovers. Errors could also be because of inexperienced surgeons working under inadequate supervision and not following correct practice.

There was some brief discussion about standardisation in surgery, in which a tendency was observed towards greater standardisation, while surgeons also sought to retain elements of their individual skill and preference.

Overall, it was quite remarkable that surgical risks received such a minor share of the discussion. When this topic was approached complications were often described as the product of fortune. While these surgeons were in all probability highly skilled and competent, the lack of reflection upon how and why they might occasionally be lead into error was not suggestive of a completely safe orientation to practice.

The risks of preventive failures

Failures of prevention involved the neglect of actions that could safeguard patients from a variety of harms either inside or outside hospital. They involved inadequate assessments of in-

hospital risks, and failures to communicate effectively with patients about how to manage their conditions.

Nurses' risk assessments of patients sometimes required them to ask questions that may have been uncomfortable. When nurses avoided questions that were too hard risks could not be identified and harm was more likely.

Pressure on both doctors and nurses sometimes meant that patients did not receive information about prevention:

> My main concern as a nurse is that we only give bare minimum care. So patients get their drugs. Things that give better outcomes long term like education, proper management of their heart failure, I don't see that happening *(Graeme, Charge Nurse).*
>
> Often the patients lose out because you do the paperwork rather than sitting down and explaining to them what's happening and what your plan is for them. When you have ten discharge summaries hanging over your head it's very difficult to spend that time, and the discharge summary is a very tangible thing, it sits on your shelf and it waits for you to do it. That tends to get done because the patient interaction, it's not measurable in any way, and no-one knows if you've done it or not, so often that gets pushed down the list of importance *(Karen, Houseofficer).*

Subsequently patients "often bounced back" to hospital because they did not understand their diagnosis and treatment, may have discontinued their medication, and did not keep follow up appointments.

Failures of prevention represented lost opportunities because staff were either overloaded or hid some skill shortages.

Overview of the risks of harm

Two kinds of risks were the dominant focus of participants' attention when they discussed the challenges of working safety. The largest part of their discussion was devoted to medication harms. Under pressure, nurses found it extremely difficult to deliver medications correctly all

of the time. They could not consistently overcome the distractions of a multitude of pressures. While various forms of discipline were the expected solution, distraction was a powerful nemesis. Medication harms were not nearly as much of a concern for doctors. While some actions were being taken, these risks appeared to be a serious and ongoing problem that was receiving insufficient attention. Diagnostic and decision risks gained the greatest focus of doctors' attentions. They were keenly aware of how their decisions could be compromised by pressure. While doctors had developed skills for managing pressure, they sometimes acknowledged that they could not always avoid failure because of how pressure affected their cognitive processes.

Six risks received a moderate share of the discussion. Nurses were educated that all falls were preventable, but in reality multi-tasking made this impossible. The physiological deterioration of patients was challenging because of the additional demands that these patients made upon nurses' workloads and attention. Dehumanisation did not usually compromise safety but it caused emotional distress for patients and nurses. Potentially it also compromised nurses' motivation. The risks of pressure injuries and insufficient mobilisation were identified as acceptable because other priorities were more important. Infection control was also problematic, and risk taking here was often acceptable too. In this case however pressure was not the prime reason for risk tolerance as cultural factors were also influential. Surgical complications received very little discussion and while in all probability the surgeons were highly competent, they appeared to have few explicit strategies for controlling the causes of errors. Preventive risks were occasionally mentioned. Because of other priorities there was little possibility of giving attention to prevention.

The challenges of the risks of harm show that safety is deeply problematic for staff in the departments which participated in this research. These findings are further elaborated and explained in the conclusion.

Conclusion

This chapter has identified safety risks in the departments studied as driven primarily by short-staffing and pressure, with communication also playing a role, and a breakdown of teamwork amongst nurses sometimes significant. It has found a tendency for doctors to neglect some risks. Many other risks appeared to not be the subject of effective control. These findings need to be explained and considered in the light of the current literature on this topic. The explanation here first considers the narratives though which staff presented their views about the challenges of safety. These narratives are briefly evaluated, and the overall conclusions about risk are contextualised. Research is then considered about communication, non-systematically controlled risks, and the link that has been established between pressure and risk in other research. These issues are the suggested focus of action to improve safety.

Human experience exists primarily in the form of narratives or stories (Bruner 1991). During their interviews staff drew from 'safe' and 'unsafe' narratives to explain the challenges of safety. There was also an in-between narrative where safety was difficult to articulate. Participants could draw upon all of these narratives, although overall preference was given to the unsafe narrative.

According to the 'safe' narrative hospitals were progressively improving safety, while also responding to growing demands for their services, and greater expectations from government. Performance was increasing in all areas. There could be some cultural resistance to change, but education, reorganisation, new ways of working, and increasing expectations all brought progress. While there were clinical risks, staff were getting better at controlling them. From this perspective things were 'pretty good' or even excellent, problems were matters of detail, staff did not come to work to cause harm, there were few tensions between staff, and things were generally getting better all of the time.

The 'unsafe' narrative identified risks as either not improving or increasing. Short-staffing and pressure were the main reasons for the lack of safety, although occasionally cultural resistance was implicated. Executive management in hospitals could be non-supportive and unaware of

safety problems because they were focussed on finances and throughput. The growth of paperwork was getting in the way of real work. In this context risks were an ongoing and inevitable aspect of the work, there was not enough time to control all of them, and harm was inevitable. Staff expressing this narrative were variably angry, upset, cynical, and resigned to doing the best they could in difficult circumstances. Their interviews could be brief and cathartic, pointed and precise, or rambling as one worry fed into another. Their major priority was systemic change.

The findings of this research suggest that the safe narrative was not credible. It was a story of minimisation and denial. This judgment is based mostly upon the consistency and the strength of the points made by staff expressing the unsafe narrative, and information about risks that slipped out while staff tried to communicate the safe narrative. This is not a surprising finding. Achieving safety in hospital care is an international problem, and as the analysis of the policy environment in NZ in *Chapter 2* has shown, there is every reason to think that NZ hospitals would experience similar problems to those that have been found in the USA and in England. A surprising finding would be the claim that safety was well controlled in the departments investigated. Of course this does not make the current situation any more acceptable, but given that this is the case it is important to be clear about some general characteristics of the challenges for safety. In particular, while short-staffing and pressure were problematic, there were risks involving communication, and clinical risks emergent from errors in prescribing, medication charts, and surgery, were given very little attention.

Communication was discussed in interviews. But there was very little emphasis on communication between doctors within departments, between nurses and doctors, and between nurses. These findings suggest a notable blind spot in the discussion of risk. Research by Kathleen Sutcliffe, Elizabeth Lewton et al. (2004: 193-194) found that communication failures were “associated” with the “vast majority” of medical errors. Communications between doctors, and between doctors and nurses broke down because of “hierarchical differences, concerns with upward influence, conflicting roles and role ambiguity, and interpersonal power and conflict” (Sutcliffe, Lewton et al. 2004: 186). Doctors also failed to understand how nurses could perceive them as threatening. While better information transfer is often promoted as a solution, the social complexities of effective communication make this

goal far “more difficult than it looks”, and remedies need to target groups, subunits, and organisations (Sutcliffe, Lewton et al. 2004: 193-194).

The lack of emphasis on the risks of medication harms involving doctors, and surgical complications, suggests a further blindness to some risks. This gap is especially significant in the light of research in NZ which identified the three main causes of adverse events as operations (24.3%), systems (24%), and drugs (12.3%) (Davis, Lay-Yee et al. 2001: 36).

The exercise of insufficient control by doctors over some risks has been identified previously. In an analysis of tacit and customary processes in surgery and anaesthesia, Justin Waring, Steve Harrison et al. (2007) identified risk control as grounded in rituals of tolerance, accommodation, and innovation. These solutions meant that action was localised and reactive, systemic problems affecting safety were not addressed, and there was no systematic learning about how teams could work together to improve safety. Similarly Ruth McDonald, Justine Waring et al. (2005) found that while doctors were highly aware of risk, they typically did not develop plans or strategies to control some of the ways in which things could go wrong. This applied to affective distractions that could lead to error, and the risk of adverse events in general, which were excused on the basis of statistics about rates of harm. Importantly however, this discourse about statistics was vague and non-scientific.

The studies above did not specifically address prescribing risks, but their general principles are relevant. Harm may be accepted as an occasional part of the normal pattern of events, and risks are responded to as they materialise into harm, with insufficient planning for prevention.

These conclusions that risks involving communication, prescribing, and surgery are under recognised suggest important priorities for safety improvement. But it is necessary to remain mindful of the context in which these challenges arise. Pressure due to short-staffing has been identified in this research as the dominant safety challenge. This is a well-recognised problem in healthcare. As Elizabeth West has argued:

> If top managers set goals that cannot be met within current resources, they are setting up individual clinicians, teams, and organisations for failure of all different kinds, including causing harm to patients (West 2000: 125).

Other research on clinical risk supports this conclusion. In a review of the NHS Patient Safety Research Programme, Mary Dixon-Woods observed that:

> Organizations that were unable to provide orderly, supportive environments, and that made staff at the sharp end balance too many competing priorities, shifted the emphasis to 'getting on with things'. Sloppy practices tended to occur when practitioners were under pressure … They controlled what they could control, got used to compensating, making do and taking short-cuts (Dixon-Woods 2010: 15).

Safety in the departments participating in this research was being undermined by the normalisation of pressure, which effected the perception of risk and the performance of tasks.

Chapter 7

Safety Improvement in New Zealand Hospitals

The NZ Health Strategy is committed in principle to improving the quality of health services (Minister of Health 2000: iii,9). The vision of high quality includes safety as one of the key dimensions of quality (Minister of Health 2003: vii,viii). In practice however this vision has been challenging because of disengagement between clinicians and managers and the neglect of quality and safety improvement in hospitals (Ministerial Task Group on Clinical Leadership 2009). Challenges of sustainability have also emerged due to the increasing proportion of GDP that is being consumed by healthcare (Ministerial Review Group 2009: 3). Accordingly, in the interests of both safety and saving the unnecessary costs of preventable harm, a Health Quality and Safety Commission was established in 2010. The Commission is charged with developing a comprehensive range of programmes to support health professionals to improve quality and safety (Ministerial Review Group 2009: 22,26).

The establishment of a dedicated organisation in support of quality and safety improvement in NZ provides a foundation for change. However turning new knowledge into routine practice invokes complex problems of implementation (Grol and Wensing 2013). Improvement challenges the capacity and the commitment of professionals and organisations (Bate, Mendel et al. 2008). Recent analysis of how these challenges are working out in NZ has found that while hospitals were increasingly focussed on quality and safety improvement, staff did not feel supported to do this work (Gauld and Horsburgh 2012a). Staff also perceived a lack of

cooperation between occupational groups, and felt that hospital management were not truly committed to improvement (Gauld and Horsburgh 2015).

This chapter is devoted to understanding the challenges of safety improvement from the perspective of healthcare professionals in NZ. The sample, questions, and the qualitative interview process through which data were collected is explained in the methodology in *Chapter 5*. In brief, participants were nurses, doctors, and service and quality managers from one medical and two surgical departments in two hospitals. Questioning sought to generate open discussion about their views on the challenges of performance targets, error reporting, evidence-based medicine, and quality improvement.

The analysis of improvement here is in four stages. First, participant's views of performance targets are discussed. Second, the incident reporting and learning system is discussed. Third, quality and safety improvement is discussed through an analysis of safety programs conducted by nurses, clinical practice guidelines in medical work, and improvement projects conducted by doctors. Fourth, some conclusions are drawn about safety improvement in the departments and hospitals participating in this research.

Performance targets

Performance targets have been introduced into NZ hospitals to improve patient outcomes and satisfaction, and to motivate hospitals to meet unmet demands for elective surgery and cancer treatment (Ministry of Health 2014). When the issue of targets was raised in interviews most attention was focussed on the Emergency Department (ED) six hour rule, which specified that 95% of patients received into the ED should be admitted onto a ward within six hours, or discharged, or transferred to another hospital. Waiting times for surgery were also occasionally discussed.

Nurses' perceptions of targets

There were some differences in nurses' views about the six hour ED rule. The charge nurses were divided between advocacy and criticism, the ward nurses were either critical, or appeared to be resigned to a situation they did not like.

Four of the charge nurses discussed the ED rule, and two were supportive. Four reasons were offered in support of the rule. First, it valued patient experience. Patients did not like to sit and watch a clock, and data from the Ministry of Health was very clear that "consumers" were dissatisfied with excessive wait times in the ED. Second, research identified better outcomes for patients who spent less time in the ED. Third, targets had a motivating effect upon nurses. They gave nurses "something to aspire to", reduced excessive "leeway", and prevented staff from becoming "too lax." Fourth, the rule was not applied dogmatically. Patients were not moved if it was unsafe to shift them. Against these benefits, only one perverse outcome was identified. Sometimes wards were held responsible for breaches (breaking the rule) which, if the charge nurse investigated, might not be their fault.

Charge nurses who were critical of the ED target did not deny that they had the capacity to lift performance when used appropriately. As was suggested, "each metric has a good thought behind it." However these nurses also felt that targets were not appropriately supported by the hospital, and generated four perverse or unfair consequences. The first was that bad feelings were created though an emphasis on "blame and shame." In one of the hospital's ward performance was reported in a newsletter circulated throughout the hospital, and charge nurses' names were highlighted in red when the ward failed. This shaming was perceived to reflect a wider "underlying suspicion that staff sometimes play games" in order to avoid taking patients. Because of this suspicion charge nurses needed to investigate failures and make judgments about outcomes, even when they may have felt that nurses were being "run ragged" because of short-staffing. Hospital managers however were not always sympathetic about staff shortages. They might point to the presence of students and healthcare assistants, although wards could be short of these as well. These tensions appeared to have contributed to

interdepartmental resentment. A "silo mentality" was said to have developed in the ED, with "some strong figure heads saying we must play the game."

The second perverse outcome was the potential for "dumb decisions" affecting individual patients to be made because of the metric, and a general tendency to play to the numbers, rather than the needs of different patients. This meant that patients could be rushed up to a ward without being adequately assessed, their treatment plan could be incomplete, and medications might not be charted. Patients could also be moved before a room was available, and be temporarily placed in a lounge, which was unsafe as nurses were less able to monitor them, and if there was an emergency some equipment was unavailable. Patients had also been moved when some staff felt that moving them was either unsafe, or humiliating for the patient.

The third perverse outcome was the potential for the needs of all patients to be compromised is some way by the pressure of meeting the target. Targets could distort clinical priorities when resourcing was insufficient:

> There is a disconnect obviously with management because they are not on the floor. And I think if management get behind something it's great. But there's a lot of focus on targets and obviously meeting the target, and that's where a lot of energy goes, if there is a target most of the energy will go into meeting the target. But the rest of the stuff that has to still be done every day or is really important just sort of falls away. So I think that can distract, you know, a target here distracts from some of the other important stuff as well *(Samantha, Charge Nurse).*[9]

This pressure was sometimes quite intense. In one of the hospitals the ED was reportedly sometimes overflowing and unsafe because it was at 130% of capacity, and across the hospital in general "everyone (was) putting their hands up saying we are at maximum capacity." In these circumstances targets could be met by discharging patients from the ED on computer, while keeping them still waiting. At the same time nurses in already busy departments were pressed to accept more patients:

> We also have patients here in the ward and it's just more work for us, we don't even have enough time for those patients, and it's just another thing that you need to do *(Lisa, Junior Nurse).*

[9] As outlined in the *Methodology* all names reported with these indented quotes have been fictionalised to protect participant confidentiality.

> The ED are always calling up saying 'I need to hand over a patient we're going to breach' and it's like 'we haven't got a bed or the patient's still in the room and we've got no space to put them', so yeah that can be a challenge. It's just busy because you've literally got one case going out and the next one coming in, but it's kind of just how it is *(Emma, Junior Nurse).*

Overall, charge nurses' views diverged about the ED target. Some felt that compliance was possible without consequences, and the target motivated nursing performance. Other charge nurses and ward nurses felt that the safety of all patients was being compromised, because without sufficient resourcing the target necessarily distorted clinical priorities. The target could also drive tensions between staff and departments over issues of responsibility and blame. This outcome was driven in part in one of the hospitals by the use of shame as a means of trying to ensure compliance. In this environment, when the pressure came on and reputations were at stake, it appeared that judgments about capacity, which effected patient safety, were necessarily flexible.

Doctors' perceptions of targets

Only six of the doctors interviewed mentioned targets. Their responses ranged from supportive, to ambivalent, to strongly opposed.

Only one doctor was strongly opposed to targets, which they described as improvement by forcing doctors to "scurry around" faster, with the risk that focussing on only parts of a complex system would create "revenge effects" that could be harmful to patients. Their preference was for a re-engineering approach driven by data analysis, but while this was happening "here and there", most efforts lacked sophistication and demonstrated a poor understanding of quality improvement methods:

> There's enormous potential for us to actually improve things and do better but then you have to buy into adequate measurement, you have to buy into changing the processes rather than just shouting at people and waving the big stick and telling them to meet the targets. You actually have to invest some effort and time and money into educating people so they know what they're doing, and you have to carry on

> continually measuring important things so that you can actually get it right *(Bjorn, Consultant).*

This doctor was one of the few spoken to who volunteered any depth of knowledge about improvement methodologies.

Targets were an immediate and pressing concern for a number of the surgeons, who were under pressure to meet targets because of their concerns about patients' needs, the promotion of efficiency within their departments, and the organisational necessity of meeting targets. One of the big challenges they faced was the organisational processes that supported targets. In one department there were tensions between surgeons and nurses who organised the theatre, with the surgeon indicating that nursing inefficiencies slowed the schedule, and another frustrated about having to provide information on multiple occasions. Inefficiencies were also due to the constantly changing makeup of surgical teams. Changing the schedule was difficult because it risked the "cardinal sin" of an empty operating theatre.

The surgical department in one hospital was reported to be very successful at meeting targets. The service manager was "fantastic" at motivating the surgeons, senior clinical management were very effective and highly respected, and the collegial and "patient first" attitude of surgeons in the department reduced the number of squabbles over who should perform specific operations. There was also an absence of distraction from private practices. However while the necessity of meeting targets was accepted, the risk of burnout increased, and there appeared to be some ambivalence about the pressure that targets created:

> Well from my limited experience in the public for the last four years, the harder you work and the more you achieve the more is expected of you, and you know, targets are set, and it's alright for the Ministry to say these are the targets, like waiting lists, waiting time targets and so forth, and it's easy for them to say here's your budget still but you have to improve and you have to get it down to, your waiting list down to five months and then four months. So what are you going to do? *(Andrew, Consultant).*

Surgical targets were also identified as problematic because resources were not increasing to support the target, and sometimes they were being withdrawn:

> Our waiting lists at the moment they're going from six months to five months to four months, which kind of we're doing with creative ways (including using operating

> rooms in another building), but then all of a sudden one of the creative ways will get kai-bosched, so you can't do it that way anymore, but you still have to stick to your four month target and that's la-la land you know, that's ridiculous *(Natasha, Consultant).*

The ED rule was briefly discussed by several doctors. Those who were supportive emphasised the context of systemic improvements, which allowed patients to be moved more quickly. The rule did not create additional work, it only meant that decision makers had to present themselves to patients sooner. In one hospital there was additional resourcing of diagnostic and testing systems that had previously caused delays. At the other breaches had stimulated the analysis of causative factors, which drove changes in the staffing schedule to improve the availability of doctors. The ED had also improved their patient flow monitoring systems, and there was better communication and monitoring of patients' needs.

Doctors who were ambivalent or critical of the ED rule raised a number of concerns. A couple of them questioned the research in support of targets, and argued that it was flawed, and that there were studies showing negative clinical impacts. Diagnostic procedures or information gathering in support of diagnosis could demand more than the six hours allocated. Patients could then be transferred without being "properly reviewed", which was "potentially unsafe." Patients could also be admitted needlessly and discharged the next day having created additional administrative work:

> A substantial proportion of the patients that I see on the wards have been pushed up inappropriately. They could actually have been sent out from the admission planning unit, but because there was no particular bed they had to get shoved out because of the six hour rule. They get shoved into the ward, and I just discharge them from there the next day. It's little things like that which concatenate and place stress on the system *(Bjorn, Consultant).*

Registrars could be conflicted over the need to prevent patients from breaching the time limit, and having to hold them in the ED while awaiting diagnostic results. If tests indicated the need for further testing, or an urgent transfer to the operating theatre, outcomes in both cases could be achieved quicker if the patient was still in the ED. It was claimed in one hospital that diagnostic systems which supported faster movement from the ED had not received sufficient

additional resourcing to support quicker decisions. It was also argued that the rule had resulted in gaming of the system through data being manipulated.

Doctors' views of targets largely depended on their perception of whether or not sufficient additional resourcing was provided to support the target. Resourcing appeared to be variable between hospitals, and between different elements of the systems that supported targets. In some cases resourcing was provided, in others it was not. There was some evidence of tensions between occupational groups that restricted performance, and there were signs that the ED target sometimes created inefficiencies because of how it shaped clinical decisions. A small number of doctors were able to quote research studies that questioned the clinical merit of targets. But only one doctor claimed the expertise to suggest a better approach through system re-engineering. Generally the doctors were not as vocal about targets as nurses were.

Service managers' perceptions of targets

The service managers' expressed a spectrum of views about targets. Some were generally very positive and highly committed to this focus:

> We sold it more round better for staff, better for patients; this would give us better care delivery to our patient group. And the by-product of that would be that we would meet the target. And so that's what my messaging to all my teams is around, this is about what we need to do, what is best for patients, and the by-product of that is we will meet the targets *(Sarah, Service Manager).*

> We've got to do much more with much less and it's huge, so it's exciting though, very exciting. You've got to maximise every minute of your list but you can't overrun because that costs money and you can't under book because you're wasting time so it's like this constant tension all the time, but it's good because it's a challenge and it keeps you on your toes *(Anne, Service Manager).*

Motivational work with staff was critically important if targets were to be achieved. This was easier in departments where collegiality was strong and clinical leaders were highly respected. It was also possible to draw upon surgeons' competitiveness to increase their motivation.

Those who strongly supported targets viewed them as very beneficial for patients:

> It's all good pressure because it means that we're doing a better thing for the patient we're getting them up there earlier. Often we admit patients for observation to see whether they're going to need surgery. The Clinical Director always says admit if you have any doubt, admit the patient, doesn't matter about the demands put on you by the management, don't second guess yourself. So it hasn't compromised that for us at all, so it's brilliant for the patient *(Anne, Service Manager).*

All of the service managers identified gains for patients from targets of faster service in the ED and more elective surgery. However while targets were not identified as leading to specific negative outcomes for patients, one of the managers felt that clinical staff saw little connection between the realities of patients' needs, and the clinical journey that was necessary to secure the best outcome for them:

> Quite often you have to come to hospital while we figure out what we're going to do to you that's why you've come because you're not well and we don't always know just looking at you within six hours at the front door *(Helen, Service Manager).*

Service managers' could also view targets as difficult to meet because of resourcing issues, which had become problematic due to reductions in funding, and caution driven by concerns over safety. The resourcing problem was particularly frustrating because some patients were admitted to meet the target, not treated, and discharged the next day.

Targets also generated quite substantial challenges affecting staff motivation and morale. Surgeons were said to "whine and carry on" about the expectations they were presented with. Their belief in the quality of the care provided and the hard work they were putting in could be undermined when the numbers suggested otherwise. The result was demoralisation when the department failed "because of the bit that you are measuring." Staff could also become "numb" to the measures, and records were creatively adjusted to demonstrate compliance. A reassertion of the blame culture and finger-pointing of the "bad old days" was also evident, which was "not a good outcome from a team perspective."

The perspectives of service managers' on targets reflected the both views of some of the doctors, and their own emphasis on the urgency of throughput. When the views of surgical

clinicians were represented this group were sometimes described as resistant because of conflicts with clinical priorities. Targets also appeared to be exerting a cost on team morale and cohesiveness. Reflecting this outcome, some service managers were not sympathetic to the difficulties that targets presented for clinical staff.

Overview of performance targets

Across all of the occupational groups there were differing views about the value of targets. There was however a tendency for clinicians to be more likely to identify negative consequences, and for service and clinical management to be more supportive. The biggest challenge that targets presented was resourcing. While staff sometimes felt that additional capacity was available to meet targets, often it seemed that this was either not the case or additional resourcing was insufficient. As some of the advocates of targets emphasised, they were about doing more with less. In this sense the role of targets was motivational. They were a way for staff to work harder and smarter. However motivational negatives were also associated with targets, including demoralisation, blame, and reduced cooperation. There were also possible adverse consequences that affected both efficiency and safety. The increased tendency to admit to meet the ED target was possibly causing unnecessary admissions. Staff, particularly nurses, were diverted from clinical processes to admission and discharge processes. A surgeon raised the potential for burnout. While some service managers promoted targets strongly, their enthusiasm was not moderated by the need to also meet measurable quality and safety targets. In a few cases doctors questioned the merit of the research in support of targets, and one also argued that targets were a poor substitute for in-depth analysis of the system to identify where improvements were most necessary.

Incident reporting and learning

The NZ National Reportable Events Policy 2012 specifies that healthcare providers must have localised processes for reporting safety incidents to support learning and systemic improvement (Health Quality and Safety Commission 2012a). Patients who are dissatisfied with the care they receive are able to make a complaint to the Health and Disability Commissioner.

Nurses and incident reporting

Nurses appeared to be quite exasperated about the value of the reporting process. It appeared to promise them something but it did not deliver. While some nurses described themselves as willing to complete reports, they often saw their colleagues as less likely to report. Other nurses felt that non-reporting was common, both by themselves and others:

> Not all the nurses are filing those reports because you just can't be stuffed *(Jung-soon, Junior Nurse).*

> It's sort of like 'I should be reporting every time I feel unsafe or like I am doing something that shouldn't be done this way', but I just don't report it and I know that there's a lot of people that don't report it, if it is reported at all on our ward *(Linda, Junior Nurse).*

The benefits the nurses hoped to gain from reporting was the opportunity to provide feedback which might change the organisation and the resourcing of their ward. But while they were generally positive about the idea, there were three aspects of the practice that led them to question its value. The first barrier was the opportunity cost of the time needed to complete a report, which was anywhere from ten minutes to half an hour. Because this work was often done at the end of the day tiredness and other commitments outside of work could get in the way:

> I guess once again for us it's hard to find time to do an incident report. So most times we will either do them on our breaks or we do them after we've finished a shift. A lot of the time things aren't being put on the incident report, like short staffing. They say

> to us that it is something to put as an incident report, but we just don't have time to do it *(Linda, Junior Nurse).*

The second barrier to reporting was that nurses could be uncertain if reporting achieved anything. Some ward nurses mentioned that their charge nurse reviewed reports, but they were uncertain what happened to the information afterwards. There was speculation that reports were read and ignored. The lack of feedback combined with an apparent absence of action to fix identified problems caused a loss of faith in reporting. One nurse complained that the only feedback she received was when a report was completed incorrectly, and another said that management invariably downgraded the seriousness of the incidents she reported.

A number of nurses felt that the lack of both feedback and change contributed to less reporting:

> So we feel like, what's the point of doing a half hour risk pro when we could be doing six a day, and we are not getting any results back. We don't know. What are they doing to improve the hospital? What are they doing to improve patient care? We don't know what's going on *(Jessica, Junior Nurse).*

Charge nurses varied in their attitudes to reporting. One was of the belief that a reduction in the number of reports about medication harms indicated that these events had been on the decline. Another felt that there was considerable under reporting. Another made an effort to use reports as learning opportunities, although doing so was demanding:

> I'm not perfect. Sometimes I don't, because it's just a time thing and I haven't got the opportunity to sit down, but I do make every effort that if somebody does do a Risk Pro I go back to them or I take it back to the team and we discuss it so that we can take the learning from it *(Marie, Charge Nurse).*

The third barrier to reporting by nurses was possible social complications. One nurse did not want to be seen as the one who was always reporting the same thing, such as short staffing. Another felt that incident reporting needed to be approached carefully as it could have a negative impact on relationships between nurses. Being reported on was potentially upsetting, it could cause tension between nurses, and nurses could be "told off" by the charge nurse. Nurses could also lose confidence and "torture" themselves for making an error. However not all nurses expressed these kinds of concerns, and in some cases incidents were reported regardless of the potential for others to be upset.

Nurses described two patterns in their reporting behaviour due to barriers of time, the apparent lack of change, and the social consequences of reporting. One was to report as many incidents of a particular kind as possible so management could be altered to the growth of specific risks, such as short staffing. After nothing happened nurses gave up and reported less. The other pattern of behaviour was to simply allow some risks to become normalised. One nurse described incidents witnessed by herself and other nurses that were obviously very unsafe, but were ignored because no harm eventuated and it would take "ten minutes to fill out a form." In other cases some unsafe actions by nurses was routinely ignored "because it's become such a norm that it's just not reported."

Many nurses had become highly disillusioned about reporting, mostly because they saw insufficient action in response to their major safety concerns. They could also tend to ignore risks which had become normalised. While some charge nurses made dedicated efforts to use reporting to assist local learning, systemic priorities and the localised meanings tended to marginalise the significance that nurses attached to reporting.

Doctors and incident reporting

Doctors made very little if any use of the reporting system. A clinical director complained that when reports were completed they were dominated by a few kinds of events such as falls and skin tears. Adverse drug reactions, which constituted a significant risk, were largely absent, as were reports of near misses.

The reasons why doctors did not report were largely either procedural, or related to feelings of mistrust in the system and a preference for traditional medical systems of error analysis. While some doctors were advocates for more reporting, they were often at the same time very critical of how the hospital responded to the information gathered.

A number of procedural factors partly explained the lack of reporting. Doctors may have never been shown how to use the system, some found it complicated and unclear, data was difficult to enter, and other tasks were more urgent. Fault was found with both the hospital and doctors:

> I don't think there's a lot of transparency behind the process, not intentionally, I just think it's a complex system and most people don't have the time or the inclination to learn about what happens with these things that get put into the hospital reporting system *(Frank, Consultant).*

Non-reporting was also because of the medical ethos of perfectionism, which made it difficult for doctors to admit to doing something wrong. Similarly near misses were not perceived to be important.

Doctors were also disinterested in reporting because they preferred medically controlled systems such as the morbidity and mortality conference. This meeting was perceived as particularly appropriate for addressing issues of error and harm because it offered greater trust in the audience who received the information, there were superior and more immediate opportunities for learning, and collegial relationships were not jeopardised by the act of "dobbing others" in through an incident report.

The lack of trust in reporting was quite a significant barrier to some doctors. There were concerns that information would be gathered and used punitively. There had been instances where houseofficers were telephoned and received a "telling off" because of their involvement in events that had been channelled into the serious review process. A serious review "means you are angry with someone and you are blaming someone."

A number of doctors were advocates for incident reporting and they wanted the system to be used more often. Greater use of the system offered the opportunity for better analysis and the possibility of systemic change through the more rigorous use of data. However some of these doctors were at the same time critical of how information from reporting was currently being used by the hospital. Information appeared to be not well used and often it seemed to be completely unused. A consultant who had been involved in reviewing incident reports felt that

there was “seldom” any change in how problems were handled, and there was “never” any feedback:

> My impression was that a lot of stuff was pushed under the carpet a bit. People thought ‘oh it’s another risk pro problem so we’ll just talk to the junior staff and educate them.’ You’d pay lip service to stuff and it wouldn’t necessarily be followed through *(Richard, Consultant).*

Another consultant reflected similar concerns about inaction which were related to managerial efforts to cover up mistakes:

> The information seems to disappear into a hole. Other people review what you have written and reassess and almost always downgrade the significance of what you are doing because there is presumably an organisational push to reduce the number of serious events because they don’t like reporting them. I’ve been part of reviews of significant events, and the way that the organisation responds to Risk Pro incidents is just inadequate. There is usually a tendency to minimise the importance and to minimise any changes and to minimise the publication of these. So the Health and Disability Commissioner publishes, usually anonymously his investigations and recommendations. Now do we see in this hospital any sort of publication about what are the major sources of risk and what are we doing about them? If there is such a document I don’t know where it is. Almost certainly it will be unintelligible to somebody like me who isn’t in on the act *(John, Consultant).*

There were multiple barriers to doctors using the incident reporting system, including the inertia of not using it. Doctors were reluctant to provide information for systems they did not control. While some doctors wanted to see more reporting because of the promise that it might support systemic change, some of the advocates were at the same time concerned that existing reports were not used effectively and were often trivialised.

Overview of incident reporting

While some charge nurses worked quite hard to maximise the educational benefits of incident reporting, many nurses felt that higher management disregarded incident reports. This destroyed their faith in the system, and made them cynical about the role of management in safety. They responded by reporting less. Many nurses did not bother to report risks that were

either normalised, or did not result in immediate harm. Doctors largely did not use reporting because they preferred to rely upon medically controlled systems of error analysis. There was some discontent amongst doctors who had taken an interest in the analysis and use of error reports because of what they saw as a tendency towards inaction and minimisation of the seriousness of reported incidents. These concerns closely paralleled those raised by nurses, who felt that incident reporting was not driving systemic change towards greater safety.

Quality improvement

Nurses and quality improvement

Nurses were involved in many processes to improve quality, safety, and efficiency. Some of this work has already been referred to in *Chapter 6*, where processes for maintaining safety were discussed. The focus here is changes to systems of working.

One of the foundations of improvement was gaining “buy in” so nurses would “own” the process and changes could be durable over time. In one case the process was assisted by consulting nurses about the design of a new filing system for clinical records. The system was later adopted in other wards, which made it easier for nurses to be transferred back and forth to cover staffing issues. Successful change could also require the right “spin”. Linking compliance to skills accreditation could work, but when change was difficult the charge nurse might also need to provide reminders, hold nurses accountable, and generally be “on the case all of the time”.

Improvement was often supported by audits of processes and outcomes. Audit results were displayed around wards, charge nurses and service managers kept files of charts in their offices, and results were published in the hospital newsletter.

The improvement process was ongoing and comprehensive. The focus was largely on the organisation of clinical systems and the standardisation of processes for controlling clinical risks. Activities included training sessions, admission and discharge planning, the development of care plans with risk assessments, the reorganisation and tidying of wards, checking equipment, and implementing new methods of risk control into routine practice. Although these processes generated a lot of paperwork, there were also efforts to simplify written tasks. The impact of paperwork received minimal discussion. It was mentioned that there was in general an increasing emphasis on the need for accurate records of plans and care provided. While this increased thoroughness had made the process of admitting patients onto a ward more demanding and time consuming, nurses also gained a greater awareness of patients' specific needs, and how to keep them safe. Comments by a charge nurse, "if it's not documented it didn't happen," emphasised the significance of processes for recording plans and actions.

There was occasional mention of checklists. One nurse liked checklists because they provided an easy reminder. A more senior nurse felt they were more relevant to those with less experience. Another nurse felt that some checklists were too long and there wasn't time to read all of the items. A doctor worried that nurses did not engage with the list, and simply checked all the boxes. Another doctor felt that there had been a decline in the capacity of junior nurses to make judgments of their own because they relied too much on checklists. Similarly a quality manager was concerned that nurses read lists, but didn't engage with the instructions as they hurriedly ticked all of the boxes.

Nurses did not dispute the overall value of improvement activities. Some identified programs that they liked and which improved the quality of their work. However they also sometimes questioned some aspects of improvement, and they did not always feel that their efforts were fully supported by the hospital. While this ambiguity was especially evident amongst the ward nurses, it could also be found coming from charge nurses as well. Although the charge nurses were generally more supportive of improvement, even those who were enthusiastic echoed some of the challenges that the ward nurses were keenly aware of.

When charge nurses were positive about improvement the reasons were simple. They could see the results in audits and in their observations of what was happening. The signs included care plans for all patients, easier access to information, fewer infections from central lines, wounds healing faster, and more frequent checks of safety equipment and patient identification. Similarly ward nurses mentioned many programmes they found beneficial. The well organised ward initiative made aspects of their work easier and faster and reduced the risk of medication errors. Protected meal times were making patients less likely to reject food after being interrupted while eating. While some risk assessments were difficult to judge, nurses improved with experience and were more alert to at risk patients. Training sessions were improving medication practices and increasing awareness of correct hygiene.

But despite these gains for quality, virtually all of the nurses identified significant challenges with making improvement programs work. Many of these were directly associated with resourcing, but is some cases resourcing was not the only issue, and culture and motivation were important as well. In combination these factors created at least five identifiable barriers to improvement.

The first barrier to improvement was that when resources were limited projects could only be partly implemented. There were several modules to the releasing time to care program, but some wards had not implemented all of them. The well organised ward (WOW) programme proceeded in stages, and in some wards only some rooms had been tidied.

A second barrier was that it could be difficult to make any aspect of a project work with insufficient or even no dedicated resources. This was widely experienced. One solution that prevented its occurrence was the provision of an improvement specialist and coach, but this was uncommon. According to one of the charge nurses hospital management had supported quality improvement, but only “to a degree.” While projects given supernumerary time had made “huge progress”, implementation was impossible when nurses were on a full patient load. Another charge nurse felt there was an expectation from management that projects such as releasing time to care, which required nurses to audit how other nurses used their time, could be completed without additional resourcing:

> It was expected to be resourced completely internally so you know get your nurses to do it, we won't give you any dedicated time. Initially there was, but then money became tight and then the resources sort of dried up. It just became an expectation that you would do it *(Graeme, Charge Nurse).*

In effect, the program conflicted with clinical demands. When this happened improvement was doubly difficult because it lost the support of staff:

> They had to pull the staff away, one staff is just working doing the patient load and the other staff is just following this nurse where this nurse could've been taking six patient loads, so I didn't like it *(Daiyu, Junior Nurse).*

Once staff felt too busy and not sufficiently resourced to do improvement many aspects of the process could become unwelcome. Sometimes this applied to tasks that were not directly related to patient care, such as auditing:

> Some of the stuff that comes out is a little bit like that. It's too much about documenting and auditing and keeping a paper trail and proving that you've done it, rather than actually allowing and freeing up time to do stuff. That I think can be a frustration. I think if people want auditing and monitoring and it's going to be useful then great. But if it's just to say 'yeah, that was great, we've done a good job', pat ourselves on the back, you know, it's not a good use. Our resources are too precious to waste that way *(Samantha, Charge Nurse).*

Sometimes staff also took a dislike to tasks that were directly intended to provide better care, and sometimes these tasks suffered. The practice of hourly rounding, which required nurses to check on their patients every hour, was described by a very experienced nurse as unrealistic because even one demanding patient could make the practice impossible. These doubts were reflected by the failure of implementation in another ward, where nurses prioritised their own assessment of the urgency of tasks:

> It hasn't taken off, it's a good idea, but the practical aspects of hourly rounding when you've got a really high acuity ward with staff who are really busy. The theory absolutely, you should see your patients every hour, and you should go through some of that stuff, but it's just, the practical stuff around that was really difficult and we were auditing whether it happens every hour, and it just doesn't. I don't think we can be that prescriptive about the care we provide. I think there has to be some flexibility *(Samantha, Charge Nurse).*

A third barrier to improvement was that programmes could slip backwards and become neglected. Sometimes this could happen when specialist resources that supported the process at the start were later withdrawn. On other occasions initiatives such as the Well Organised Ward (WOW) programme were vulnerable because staff became too busy or lacked the discipline to maintain the process:

> It's good in principle, when the store room got all done it was lovely but then keeping it like that is another issue. You find people put things in there that aren't supposed to be there, you get things left on the floor when you're not supposed to have anything stored on the floor, it's all supposed to go on the shelves. It could be a time factor, maybe some places are not as busy, and they've got a bit more time to keep on top of things. Also I think sometimes maybe you lose momentum a little bit, everybody's really engaged to begin with but as time's gone by people just maybe forget about it a little bit. I mean our ward can be so busy so full on, you get people missing breaks and everything cos they're just so busy, so I guess that kind of thing just gets forgotten about a little bit *(Danielle, Senior Nurse).*

Another reason the WOW programme could slide, according to a service manager, was that while nurses wanted to care for and be with people, quality programmes often demanded attention to paperwork and the organisation of rooms and equipment. Nurses did not always easily give their attention to this kind of work.

A fourth barrier mentioned by a charge nurse was that only economically measurable improvements tended to gain resources. While projects could be measured to show fiscal savings achieved through reducing the time nurses spent on some tasks, not all improvements were easily measurable. Good communication was critically important, but hard to measure and difficult to finance.

A fifth barrier to improvement was the pressure upon charge nurses and the tendency for their skills to be diverted from daily clinical needs. Virtually all of them described this as problematic. Improvement work could compromise their capacity to remain in touch with and monitor the nurses on their ward. The need to exercise specialised leadership duties could prevent them from providing the practical assistance that ward nurses frequently needed to "put out fires." One way of working around these demands was to spend additional time at work. But this could

meant that improvement was premised, at least in part, upon voluntary overtime by the charge nurse:

> The expectation is very clear that it is done within the time that I am allocated to do my job, which is the 40 hours a week. If I look at the breakdown of what I am expected to achieve within a 40 hour week as a charge nurse, and I plan it, and I have done this. I plan out my month in advance, week in advance with meetings and things like that in the time that I need to do performance coaching, I am in deficit for about 100 hours each month. But it's because I am so conscientious and passionate about improving opportunities for patients and staff, I'll put in the extra, because I'm a workaholic *(Marie, Charge Nurse).*

These pressures however exacted wider costs. The risk of "overloading with additional quality projects" included a loss of morale, and the potential for reduced quality because staff expertise was less available for clinical work, and more tuned into bureaucratic needs:

> I would say it's a lot of clerical stuff and management. A lot of demand is to present stats and audits and so forth, which is taking you off the floor, a lot of paperwork I feel. It has grown over the last year. More sort of turning clerical. All the demand is taking you away from the floor *(Amanda, Charge Nurse).*

The unfortunate consequence of these challenges was that while charge nurses' believed in improvement, they could feel quite torn about the particularities of methods:

> And then it's like 'oh shit it doesn't work like that', and you are immediately having a battle, which the intended outcome is good, but how you are trying to get there, you end up arguing, you know, I've had arguments about stuff that I believe in, but I am arguing against because of the way it's being implemented *(Samantha, Charge Nurse).*

The improvement processes led by nurses were claimed to be achieving better outcomes in a number of aspects of performance in the departments involved in this research. However at the same time the process was enormously challenging, and it sometimes seemed to suffer delays and slide backwards. Because of issues with resourcing, and also culture and motivation, things often did not go as well as was intended. Nurses were sometimes unconvinced of the value of some activities because in they experienced these as detracting from other aspects of the care they needed to provide. While nurses clearly wanted to provide the best care possible, they struggled with multiple demands. In effect, they sometimes resisted improvement work because it did not equip then with ways of working that they felt capable of making effective.

Doctors and quality improvement

Doctors were involved in quality improvement in two ways. First, they sought to improve clinical quality and safety through processes of audit, training and education, and through the application of clinical practice guidelines and policies. Secondly doctors also worked collectively and with management to design and implement changes to the systems that supported medical work.

Clinical quality improvement

The use of audit to improve specific clinical activities was mentioned infrequently. The practice was said to be applied reasonably often, and was sometimes effective. However it was claimed that information was not widely communicated afterwards, and unless published, results were usually lost in the system.

The morbidity and mortality (M&M) conference was discussed occasionally. For one of the medical consultants this process was failing, but not only because of the very real difficulties of judging medical outcomes:

> Oh well it's been discussed in the M&M meeting, full stop and very little changes. They have become an end in themselves, rather than there being any actual hard changes to practice or even formal recommendations. So I think people have a misplaced sense of security that they are doing something when actually very little happens *(John, Consultant).*

From the perspective the director, it was very easy for this process to focus on mistakes. These however we of no interest because mistakes in medicine are normal, and focussing on them served no purpose aside from destroying individual self-confidence. The greater challenge therefore was to identify the changes that could be made to systems to improve safety.

A different but related set of issues were apparent with audit and the M&M meeting in one of the surgical departments. All of the surgeons identified problems with the meeting. It was suggested that when the results of audits were presented there was a lack of self-criticism, and

insufficient emphasis on analysing how systems could be changed to improve outcomes. The process was further compromised by insufficient rigour in the recording of complications, an emphasis on "ticking-the-boxes", and information was often collected at month-end when memories had begun to fade. Recall was not assisted by a tendency to not want to report events if doing so would reveal a higher than normal rate of complications. This urge may have been partly because mistakes were not easily accepted in the M&M meeting is some departments:

> You kind of feel naked in the room I guess so you don't want to be doing that, but I think that it's absolutely important *(Michael, Registrar).*

For other surgeons however the meeting was "about as good as it can get", and provided learning for individuals and the department as a whole. While the system missed "a lot of the subtleties", it did "capture the major complications" and issues that required systemic change, such as returns to theatre and deaths. But while the department had become "very good at identifying issues", and dedicated committees had worked on these over a number of years with assistance from the quality and safety committee, "we didn't have the resources to make a difference and stop them (returns to theatre and deaths) from happening."

Houseofficers in the other surgical department described the M&M meeting as "fantastic" and "excellent" because of its transparency, lack of blame, and the emphasis on learning. Both the director and a consultant surgeon similarly described the meeting in terms of individual learning, identifying systemic issues, and avoiding blame:

> Again the fact that it is collegial and it's not about one upmanship here. It's not that I am too scared to tell someone I made a mistake, because otherwise they'll use it against me down the line. I don't have to worry about that. We all know that we make mistakes here. They're not going to hold it against me if I make a mistake, and if someone else makes a mistake I'm not going to go 'oh God they're hopeless' *(Andrew, Consultant).*

Processes in support of education were mentioned rarely. Two out of the three doctors who did refer to clinical education felt it was given insufficient emphasis. However in one case a medical consultant was leading the formal training of houseofficers in a deductive method of diagnosis to improve decision making:

> When you get busy those things tend to break down and if you haven't practiced those skills oftentimes errors can come in and patients can be put at risk because I'm so busy you've got chest pain but you look pretty good, it can't possibly be a heart attack and that's how I sort of approach you from that point on *(Frank, Consultant).*

The same consultant was also working to improve consultants' teamwork skills by developing a mechanism for them to be provided with feedback from junior doctors and charge nurses about what they were like to work with.

The form of clinical improvement that was discussed most often was the application of protocols and clinical practice guidelines. For the less experienced doctors guidelines appeared to be relatively non-problematic. For a houseofficer they provided a foundation of clarity and security for junior doctors who lacked the experience to make their own judgments. The number of guidelines was not numerically overwhelming, and most decisions were based on training and experience. There was an expectation that the significance of guidelines would diminish over time. A registrar similarly described guidelines as relatively straightforward in surgery, as opposed to medicine, because most treatment was relatively standard. However another surgeon saw guidelines as more complicated because there were promoted by a number of organisations. Nonetheless the use of guidelines was more manageable than immersion in the original research. A medical consultant took this perspective further, and categorically stated that doctors did not have the time to indulge in critical appraisal.

But while guidelines offered some advantages for practice, adherence was complicated for two reasons. First, there was a need to interpret value and applicability. Second, it could be difficult to know what guideline to use. Comments from a director of surgery expressed the difficulty of judgments about value. Guidelines were important, but they were also only a part of the decision process:

> There is a fine line between having a policy which controls what you do and allowing clinical skill and training and acumen to actually mollify practice to suit an individual patient because all patients are different. So there's a fine line between standardising care, minimising unwarranted clinical variation in clinical practice, which we try and do, and allowing clinicians the freedom to actually manage a patient the best way they see how *(Charles, Clinical Director).*

Other doctors found similar reasons for caution. A medical consultant noted that guidelines often could not be applied to geriatric patients because of their extreme vulnerability and multiple co-morbidities. The director of the department felt that guidelines were "generally not tempered by common sense". They were sometimes used uncritically and the hospital overinvested in testing and treating patients for any and all deviations from expected norms. Discretion was required to balance the risks and the benefits of investigations, and to judge the wisdom of treating conditions that might be better left alone. Fortunately, with experience, doctors become better at interpreting guidelines. A medical consultant echoed this view, arguing that excessive pre-cautionary testing kept patients in hospital for longer, risked infections, drove up costs, and led to the possibility of others missing out on more urgently required treatment.

The second problem, of knowing what guideline to use, appeared to be a more serious issue, and it was entrenched at a systems level. This was partly due to the profusion of guidelines and difficulties with selecting the right one. Guidelines from hospitals and professional associations on the same topic could conflict. There were other information sources as well:

> It's tough I mean you get information from your colleagues from journals and from going to conferences and things, and you know it's constantly changing. If there's some sort of landmark paper that comes out generally it sort of filters out pretty quickly, especially in New Zealand which is quite savvy when it comes to keeping up with literature and that sort of thing. But certainly it can be a bit challenging at times with the sheer amount of information that's being generated *(Michael, Registrar).*

Many doctors commented on this issue. One outcome was confusion and a tendency for doctors to "choose guidelines according to their own prejudices." A further tendency was for non-evidence-based expert opinions to be mistaken for scientific guidelines. But while both hospitals sought to address this problem through systems, policies, and the specification of rules for practice, these systems were themselves complex and difficult to use. Clinicians often complained that they could not find guidelines when they needed them:

> There is an increasing emphasis on the need to have protocols and checklists and procedure lists for everything we do. That sounds good on paper. In terms of implementing it it's very difficult to do that. We have a couple of hundred policies, procedures and guidelines in this hospital. They're all available on the computer but they generally are lost in the bulk and the number of them and so a lot of the policies

> and procedures that we have probably go into our filing system and hardly ever get seen again. There's just too many of them and I think people get a degree of comfort having written a policy, whether it actually changes practice varies a lot *(Charles, Clinical Director).*

A very similar difficulty was identified by a medical consultant:

> In an organisation like this we produce policies for Africa. You have no idea how many clinical policies there are. Does anybody look at them? No, because it's much easier to write a policy than to market a policy. Nobody goes to the trouble of saying, here is our new policy on the treatment of asthma. But it's in there somewhere, I bet there's a policy, but nobody looks at it. They are hardly communicated at all. I certainly don't know what most of them are. It's a case of a waste of time and effort frankly. At the very senior level in the quality industry, this view that people have to have policies for everything and I don't know what evidence there is for having policies for everything. But it's pretty clear in this hospital that all these policies are only roughly followed and nobody knows they're there until something goes wrong and somebody says 'what's your policy?' The Health and Disability Commissioner actually is very bad at saying, 'you need a policy on such and such', and so everybody makes a policy on such and such and nothing happens, nothing changes *(John, Consultant).*

According to this consultant the underlying problem was a lack of emphasis on the clinical education of doctors. There was also a tendency for polices to be used during investigations to apportion blame. These perspectives on insufficient education to improve practice, and blame from investigations by the Commissioner, were also voiced by other consultants in the department.

Three ways of improving the clarity of information about guidelines had been implemented or were in progress. First, a medical consultant had edited a handbook that was frequently used in the hospital and provided advice for doctors and nurses about how to manage specific patient issues. Second, one of the surgical departments had a policy of reviewing policies, which had reduced overall numbers, but not eliminated the problem. One of the hospitals was developing, with difficulty because of technical issues, a new system to make it easier for staff to access policies by computer.

All doctors were involved in processes of clinical quality improvement. Auditing was occasionally applied, but results could be lost in the system. There were different perspectives about the morbidity and mortality meeting. Meetings risked blame, a lack of rigour, and they

could provide a forum which showcased concern, but achieved little. While all department sought to make these meetings free of blame, not all of them had achieved this outcome. All departments also sought to use the meeting to identify systemic issues. Sometimes however these could be identified, but not fixed. There was rather more agreement amongst doctors about the challenges of using guidelines and polices. These presented particularly complex issues of selection that were not assisted by the poor quality of hospital information systems, and lack of effective communication of policies. There were calls for better information, communication, and also for more education. Doctors strongly needed greater systemic support, rather than too many policies that potentially lay dormant in the system, only to emerge later in support of blame because of an adverse event.

Quality improvement projects

Doctors had some involvement in quality improvement projects addressing anything from discrete clinical processes to systemic change within and across departments.

In one of the surgical departments a consultant had been involved over several years in a number of operationally focussed projects for improving aspects of quality and efficiency. One project was guided by an external expert who used process engineering to improve the patient journey and staff workload. The outcome was a reduction in waiting and time spent in pre-admission clinics.

Other projects within the department however were not successful because of issues with resourcing and political struggles across departments. One such project that sought to improve patient experience during the pre-admission phase had foundered on several occasions and was ultimately discontinued despite a need for better quality in this area. Another, which drew upon sentinel event and audit data to try to reduce returns to theatre and patient mortality, had been difficult to bring to resolution. Although the project had identified causative factors, senior management decisions and inter-departmental politics had prevented change, despite the support of the quality department. Barriers included the availability of resources and problems with culture, especially in relation to gatekeepers who controlled access to outside services. There were delays in getting patients into the operating theatre, difficulties in gaining

access to the Intensive Care Unit (ICU) for patients who needed a higher level of care but didn't fit the ICU admission criteria, and the hospital would not support the availability of senior staff overnight. The consultant describing these issues was pessimistic about prospects for other projects because while pressure was growing to increase volumes and meet even steeper performance targets, additional resource was often not being provided to support quality improvement:

> We're expected to do a lot of stuff without extra resource. If we are going to look at patients journeys and improving their experiences and decreasing errors and complications then I think senior management need to actually resource us better to do that, and we need to get more nurse specialists who are able to do research for us and map problems. We're busy clinicians and we're expected to do all the productivity as well as trying to improve the quality *(Richard, Consultant).*

There was "half a dozen projects" that could be attempted in the department if resourcing was available.

Operationally focussed change was also occurring in the medical department, and senior management had been supportive. Roster changes had improved the availability of consultants, including those from other departments. There had also been an increase in the number of registrars working overnight, which had improved the safety of the admissions process. There were further plans to create a High Dependency Unit for patients needing a higher level of care than could be provided on the wards, but who could not be sent to the Intensive Care Unit. Another plan involved merging the system of separate medication charts between emergency department and ward to reduce medication errors. However this programme of change was compromised by fiscal shortages, which prevented the availability of senior staff overnight, and a lack of capacity within the department to improve many aspects of clinical systems:

> I suspect that if we were a commercial enterprise designing cars for example we would have more people on the design floor making the modifications. I think we could do with more stepping back from the clinical coal face, analysing the data, seeing where the holes are, making the changes *(Christine, Clinical Director).*

There were many possibilities for change. One included a way of improving the system for utilising X-Ray charts, which sometimes "fell of the back of a desk," resulting in failures of

diagnosis because the system would not flag that an x-ray had been ordered but the results had not been processed. Another involved fax referrals which could fail during transmission, with the outcome that patients were not booked for follow up visits and sometimes came to attention later when they had deteriorated and become untreatable.

Four reasons were expressed to explain the lack of small improvement projects. First, the quality department were not particularly visible. Second, there was burnout in the quality department, as there was generally with doctors who took on quality improvement. Third, short term economics dominated safety:

> It feels as though all of the additional resource that's been put in is to achieve fiscal efficiency as opposed to safety. That's the challenge because it's very hard to justify in dollar terms investments into safety, I mean you can usually cook something up but it's not so easy to identify that an investment to make things safer is going to be worth it *(Christine, Clinical Director).*

Fourth, there was lack of expertise about how improvement worked. One medical consultant described doctors' ideas about systemic improvement as impractical and showing "pretty isolated thinking." Another consultant, while not denying that doctors were "bloody busy", emphasised a lack of understanding of quality improvement methods, and an unwillingness to be involved in processes of change:

> It's a very difficult thing to engineer safety and most people haven't bought the message because it's actually about re-engineering practices. You also need to actually redesign the processes. There are lots of little things that could be done better but people see them as boring or not their work *(Bjorn, Consultant).*

The four barriers to improvement meant that many doctors expressed very little engagement with quality projects. All of these barriers were related to or made worse by excessive busyness, which drove doctors to focus almost exclusively upon clinical work. A consequence of this focus, particularly evident in comments by a surgeon, who was unable to attend the committees and the meetings where decisions about improvement were made, was that improvement work was often done for doctors. While one director described a number of formal and informal processes for doctors to provide feedback on changes within the department, requests to consultants for feedback sometimes gained a response rate of only 10%.

The general disengagement of doctors from many aspects of improvement could mean that when they were presented with new ways of working they didn't like what was required, and they felt subject to processes that made no sense:

> I think part of what gets me is that sometimes things that are in place, a check and a balance are well meaning but just in the context of our, our day to day life, are not high on the priority list, and the people who sometimes put them in place and suggest that we do them I feel that they need a reality check of what we actually do. And often it'll be just something to do with some piece of paperwork that documents or checks something. But that's all fine and well in principle, but in the reality of what our life is actually like it's so low on the priority list that you know you sort of almost get offended by having to be asked to do it kind of thing, because that person or the manager or whoever's come up with that process just clearly has no idea of what your life is like *(Natasha, Consultant).*

> We have charts for wound care, we have charts for nutrition, we have balance charts to see how well the patients totter to the toilet. We have all these charts. Rarely are they ever filled in completely, rarely properly, and rarely appropriate to the patient even. It would be much better I think if we just scrapped a lot of the extra safety charts, and went back to basics, had notes and prescription, and that's probably it *(Juliet, Registrar).*

The busyness of many doctors meant in effect that they were often working within the context of systems that others had developed, they felt little ownership of the process, and preferred traditional ways of working.

Overall, with exceptions, achieving systemic improvement and involving doctors in quality improvement could be exceptionally difficult. There were shortages of resources, a tendency to focus on efficiency over safety, inter-departmental cooperation was sometimes challenging, doctors were extremely busy and more focussed on immediate clinical matters, the appropriate expertise was in short supply, and doctors sometimes experienced little ownership of change and rejected it. Doctors who perceived the importance of this work could feel anything from a sense of powerlessness, to strong feelings of frustration about the lack of support and capacity provided by the hospital to make it possible. There was energy and enthusiasm for change that appeared to be being wasted.

Quality managers' perceptions of quality improvement

The quality managers in both hospitals identified the busyness of doctors as a significant barrier to quality improvement. Time pressure could severely impact any possibility of cooperative relationship building between clinicians and the quality department:

> Manager: Well, it's difficult from the point of view in that they haven't got time to get to meetings. Their workloads are such that they, you know, and I am thinking about the global trigger tool project I do, we haven't had any clinicians come to meetings. One of them is a surgeon and she's not there some days and she's got surgery booked and she just won't, hasn't got time, end of story. So we never see her. You just can't engage them.
> Interviewer: It must be hard to make the project work in that case?
> Manager: Hopeless sometimes. And that varies across services I think. But they are really, really busy people and so time is a huge factor for them. They are not released from their duties to do anything. Well they do get a certain amount of time, but the workload they have and the things that they want to do just take up most of their time. Time is a huge restraint *(Rochelle, Quality Manager).*

Cultural issues were also evident, creating scepticism and dismissiveness about the need and the possibility of improvement. Doctors mostly thought of quality as the product of individual expertise rather than teamwork and systemic change. Quality was also perceived as an add-on and not a core component of work. Consequently improvement ideas needed a very high level of proof for doctors to put them into practice:

> They need evidence and proof and they will question everything to the 'nth degree. So you have really got to know your stuff and they have really got to see that it makes sense. And they come at it from a very critical and analytical kind of approach. So you've really got to convince them that this is the right thing to do *(Rochelle, Quality Manager).*

> You've got to be able to demonstrate a relationship between a process change and an improved outcome and if you can make that connection then yes, doctors will buy it. Having good ideas isn't adequate in the medical setting, you've got to demonstrate the veracity of the concept, it's got to be examined, studied properly and say yes if we change from X to Y approach then it will produce a lower rate of a complication and so on *(Steve, Quality Manager).*

Doctors also preferred to leave some changes to others:

> Quality stuff is quite operational. Their focus is their patient and their clinical work. They just want other people to make sure that the systems are in place *(Rochelle, Quality Manager).*

Quality managers' perspectives confirmed doctors' identification of pressure as a substantial barrier in the way of change. They also identified the need to work very hard with doctors to show that changes could make a difference. However because of limitations of time it was difficult to build these relationship.

Overview of quality improvement

There were some similarities in the challenges of quality improvement for both nurses and doctors. Both groups were remarkably busy, improvements were often sought in the face of resource shortages, and culturally based resistance to change could emerge as a consequence. These dynamics affected the work of the two groups in different ways.

Nurses wanted to get on with the process of caring for patients. While quality improvement sometimes made this possible, there were also occasions when it seemed to create additional work and get in the way of better care. Usually this was because of improvements being pushed through without sufficient support for implementation. Nurses responded to these situations either by thinking that improvement represented an ideal that was unrealistic because of the constraints they needed to work within, or they viewed the intended improvement as pointless and irrelevant.

Doctors appeared to have more freedom in how they responded to the quality agenda. They were more able to continue practising in accordance with traditional norms, albeit with some increasing complexity because of the growing emphasis on clinical protocols. They were also faced with more paperwork for checking and recording different aspects of their work. In some case these systems could be relatively simple to work around.

Many doctors did not appear to be heavily involved in projects to improve localised aspects of quality, although this work was important to some of the senior consultants. These doctors found that quality improvement work could be rewarding, because significant change was achievable, frustrating, because efforts sometimes failed, and irrelevant, because there simply was not the capacity to attempt it in the first place. Improvement work was also associated with the risk of burnout. Overall, the capacity to improve safety was lacking because busy doctors did not have to time, they were clinically focused, and they did not have the expertise to change systems.

Conclusion

This analysis of participants' views on the challenges of performance targets, incident reporting, and quality and safety improvement has shown that improvement processes as a whole encountered substantial difficulties that often could not be overcome. These failings are theorised in the following through the work of Paul Bate, Peter Mendel et al. (2008), who conceptualised improvement as a process of overcoming universal challenges of structure, culture, politics, learning, motivation, and infrastructure. By considering the solutions that Bate, Mendel et al. (2008) have outlined in relation to each of these challenges it becomes possible to identify where improvement was compromised. Consequences can be further elaborated through reference to the wider literature on improvement.

This conclusion is an overview only of the challenges of the safety journey in the hospitals and departments in this research. Because of the detail in the model that Bate, Mendel et al. (2008) provide, and the limited focus of the interview discussions, the analysis is exploratory. An important context for this discussion is *Chapter 6*, which identified risk as substantially driven by short-staffing and pressure. These factors impacted improvement as well.

Bate, Mendel et al. (2008: 205) found that structural and cultural challenges were central to improvement. This research suggests that short-staffing and pressure caused a structural

weakness in the improvement apparatus. It appeared that this structural issue was reinforced by two cultural weaknesses, of insufficient measurement, and some complacency about risk.

The structural weakness, connected to pressure, that was particularly evident was the absence of "organisational slack for quality." Slack is vitally important to improvement because it "enables staff periodically to stand back from everyday operations and think and work on service development issues" (Bate, Mendel et al. 2008: 179). "Slack is not a 'surplus' or a 'luxury' but something that needs to be built into an organisation for it to continually support innovation and improvement" (Bate, Mendel et al. 2008: 107). When the author of the classic 1960s text on the diffusion of innovations, Everett Rogers, was once asked to say one thing he would do 'to get innovation going', his reply was 'simply create slack' (quoted in Bate, Mendel et al. 2008: 107). In a study of culture in the NHS Mary Dixon-Woods, Richard Baker et al. (2014) found that:

> When staff had access to appropriate resources, perceived that staffing levels were adequate with the right skill mix, and had systems that functioned effectively, they felt that they could complete their work successfully, could explore new ways of improving quality and could develop reflective practices. This reinforced their levels of motivation and morale in a virtuous circle (Dixon-Woods, Baker et al. 2014: 111).

However Dixon-Woods, Baker et al. (2014: 111-112) also found that many NHS staff felt powerless to bring about change because they were overwhelmed by systems problems. Similarly in this research there was a lack of time for staff to participate in and initiate quality improvement. Doctors were "burnt out," the quality and safety department in one hospital at least was "not particularly visible," improvement work was sometimes expected "without extra resource," "half a dozen projects" were possible in one department if resource was available, and there were just as many unexplored options in another.

A cultural failing that was signalled in this research was the absence of a scientific culture that "values data, measurement and evidence in both medical and managerial practice, while being strongly task- and results-driven" (Bate, Mendel et al. 2008: 181). There was not an absence of measurement, in fact there were very many measures of productivity, and also of some clinical processes and outcomes in nursing, medical, and surgical work. But while inaccuracies sometimes crept into audit analysis the larger difficulty, as one consultant observed, was a

general lack of expertise amongst both clinicians and managers in systems measurement, statistical analysis, and the interpretation of measurement in the service of safety. Because of this there was sometimes limited progress at the level of system design, and it was very easy for performance targets to dominate. As Tuen Zuiderent-Jerak and Marc Berg (2010) have argued, when simplistic and monolithic notions of effectiveness are employed, the normative purpose of improvement is undermined.

Gathering data and using it effectively to achieve change is a well know improvement challenge, and one of the most difficult that improvement teams must confront (Øvretveit, Bate et al. 2002: 349). In the NHS insufficient attention to measuring quality and safety contributed to organisational failures because money and activity were more easily measured, and became the true priorities. Creating a clinical culture that valued data would substantially benefit improvement, but is not easily done (Donaldson and Darzi 2012: 969-970).

A further culturally based weakness was the absence of a culture of mindfulness, "of being awake to quality and safety concerns." An aspect of this practice that was missing was "problem sensing" or "actively seeking out weaknesses in organisational systems" (Bate, Mendel et al. 2008: 181). Not doing this may be evident in a lack of concern with soft data about staff experience, comfort seeking behaviours that create the impression all is well, and the dismissal of criticism "as whining or disruptive behaviour" (Dixon-Woods, Baker et al. 2014: 111). The potential for outcomes of this sort were evident in the way in which some nurses felt that incident reports were not responded to, some doctors felt that the seriousness of incidents were usually downgraded, and there was no widely available information about systemic risks in the hospital. It was also evident that doctors who reported a personal and professional interest in safety felt the need to state that they were not "whingers," and saw their concerns as controversial and sometimes unwelcome. Surgeons who questioned targets were referred to "whining and carrying on."

While structure and culture are often central to improvement work, issues of politics, learning, motivation, and infrastructure are also critically important. But in most of these areas as well, weaknesses were evident. Politically, with exceptions, many staff did not appear to be actively engaged in improvement and nor did they express a sense of real ownership over improvement

processes. This included nurses, charge nurses, registrars, and consultant doctors, who described some improvement activities as impractical because of the urgency of other tasks. This challenge has been identified in many contexts. A lack of ownership is one of the biggest challenges of improvement. Its causative factors can include pressure, disagreement about methods, and suspicion about the motives of change agents (Dixon-Woods, McNicol et al. 2012: 881). Changing this outcome can require working closely with groups resisting change, providing evidence about problems and solutions, involving them in the design of solutions, and mobilising their professional networks in support of change (Dixon-Woods, McNicol et al. 2012: 879-881). But these actions require dedicated resource.

It appeared that the emotional challenge of motivating and engaging staff in improvement (Bate, Mendel et al. 2008: 184) was not being met. Staff were hardworking, and they were clearly conscientiousness and committed to individual excellence. But while there was some emotional investment in safety it did not appear to translate into a powerful collective momentum for change. Partly this may have been because of the exhaustion that was evident amongst some nurses and doctors. Safety improvement sometimes became a distraction from the urgency of getting work done. Research in other settings has found that doctors often perceive quality and safety as a low status activity that is poorly rewarded (Ling, Soper et al. 2007: 9). In the NHS the Safer Patients Initiative struggled for many reasons including the fact that staff were already busy, they were tired of multiple initiatives, and some safety processes seemed only to increase the volume of paperwork (The Health Foundation 2011a: 28,34).

One of the infrastructural requirements of improvement is supportive information technology (Bate, Mendel et al. 2008: 185). The IT systems in these hospitals hindered the flow of information between doctors during the patient handover, and made it difficult to find information about policies and guidelines. In effect, information that supported safety through the better use of clinical guidelines become lost in the system. This is concerning because responses to serious incidents and complaints often generated new policies.

This chapter has reported on the challenges for staff working to improve the safety of clinical care in three departments in two NZ hospitals. The analysis of performance targets, incident reporting, and quality improvement suggests that while there has been progress in some

aspects of safety, gains were compromised by the direct and indirect effects of insufficient resourcing. This limited the implementation of existing programmes to improve nursing care, and prevented doctors from engaging more widely in systemic improvements. The lack of economic commitment to safety allowed measures of throughput to dominate care processes. There was a failure to provide slack so staff could dedicate time to safety improvement, and the IT infrastructure was inadequate for some tasks. It appeared that the culture of measurement, and of mindfulness to safety was weak. It also appeared that staff were not actively engaged in improvement, did not feel ownership of it, and emotional momentum had not been generated.

These findings are disheartening, but not unusual in the patient safety literature. The commitment to safety improvement in the NZ Health Strategy needs greater attention. From the limited sample and the focus of questioning in this research it appears that the substantial fiscal savings that could be generated by a significant reduction in the number and severity of adverse events are unlikely to be realised.

Chapter 8

Patient Safety in New Zealand in Context

In this thesis I have explored patient safety with a particular emphasis on the challenges for clinical staff in public hospitals in NZ. I have shown that the delivery of safe healthcare is dependent upon human cognition and action in complex organisational systems that are embedded in political, economic, and institutional environments. To reflect these challenges I have investigated safety from a number of perspectives. First, I have outlined the problems, challenges, and strategies of the patient safety movement. This allowed the analysis to be grounded in an understanding of the extent of medical harm, and the strategies for progressing safety. Second, I have reviewed literature about the consequences of policy for American, English, and NZ hospitals. This review has identified a shift in the institutional power base of contemporary healthcare, and the consequences of different approaches to policy. Third, I have reviewed literature about risk control and safety improvement, and build an understanding of risk and safety. Fourth, I have interviewed staff in NZ so they can express their views, which I have reported and interpreted through the literatures about risk and safety.

In this conclusion I review the evidence about the challenges for patient safety for NZ. While these challenges are not particularly unique, it is possible to identify their distinct manifestations in the departments and hospitals that were investigated for this thesis. After outlining these challenges I comment on the strengths and weakness of my research, its contribution to the literature, the implications for policy, and the potential for further research about this topic in NZ.

I began this thesis in *Chapter 1* with an outline of the emergence of the patient safety movement, and a review of the available evidence to determine if efforts over the last one and a half decades have made a difference. A consideration of the rate of all harms in a variety of healthcare systems suggests that there is insufficient evidence to know if contemporary efforts are improving overall safety. Two strands of evidence give some perspective on this issue. First, the few comparative studies available suggest that rates of harm, in some contexts at least, may have declined, but not significantly (Landrigan, Parry et al. 2010, Baines, Langelaan et al. 2015). Second, while not comparable because of their focus on differing populations, some studies of medical records in America from about the last decade have shown higher rates of harm (Landrigan, Parry et al. 2010, Office of the Inspector General 2010, Classen, Resar et al. 2011) than was evident in a variety of international studies covering 1984 to 2004 (de Vries, Ramrattan et al. 2008). This outcome could however be a product of improved documentation and methodological differences, including a contemporary tendency to count the prevalence of less serious harms that do not extend hospitalisation. Because of a lack of directly comparable information it is difficult to know what overall changes are occurring. What is clear nonetheless, is that contemporary hospitals remain measurably unsafe. This is a reality, despite the many initiatives and programmes that have been implemented globally in the decade and half since *To Err is Human* first widely exposed the risks of hospital treatment (Kohn, Corrigan et al. 2000). The rate of harm in healthcare constitutes a significant threat to public health, and a fiscal burden on healthcare budgets. In NZ adverse events have been found to be associated with 12.9% of hospital admissions (Davis, Lay-Yee et al. 2001). The cost of these events may be as much as 30% of the total hospital budget, with preventable harm due to error accounting for 20% of the total budget (Brown, McArthur et al. 2002).

Despite ongoing harm, safer healthcare is a real contemporary possibility. In *Chapter 1* it was noted that the Agency for Healthcare Research and Quality in America has recently published evidence of multiple practices that are scientifically proven to improve safety. There are ten strongly encouraged strategies and another twelve are encouraged. “Although substantial gaps in the evidence base remain, more than enough evidence exists to prompt decisive action” (Wachter, Pronovost et al. 2013: 350). But while this knowledge is promising, practices must be implemented to have an effect. This necessity indicates the significance of the policy

environment. Policy determines what changes are pursued, and reactions to policy, which are emergent from the approach to implementation, effect the outcomes of intended changes.

In *Chapter 2* I developed a comparative analysis of healthcare policies and consequences in America, England, and NZ, with the intention of identifying policy challenges in general, and specific challenges with relevance to NZ. Following Donald Light (1995, 2010) I argued that the quality and safety agenda has contributed to a shift in the balance of institutional power in healthcare, with medical dominance giving way to managerial dominance. The outcome is an increasing emphasis on standardisation and a more bureaucratic-scientific approach to medicine. While this is potentially beneficial to patients because less medical autonomy means greater compliance with safer practices and fewer unnecessary procedures, the risks of managerial dominance include the subversion of necessary medical discretion, and an overemphasis on economic measures, which can distort clinical priorities and reduce quality and safety.

The example of the English NHS shows that centrally controlled healthcare is vulnerable to the excesses of managerialism. While policy in the NHS articulated a commitment to a long term programme of improvement beginning around 1998, this ideal was compromised by organisational turbulence due to constant and expensive processes of restructuring. The dominance of managerial values meant that clinical and patient focussed values were sidelined, and the system became driven by economic targets, performance criteria, and an emphasis on top-down change that disempowered clinicians. Subsequently an atmosphere of fear, shame, and blame was created, and clinical groups were frequently disengaged from the improvement process. While gains were achieved nonetheless, there was often resistance, and outcomes were uneven and sometimes poor or even disastrous. The NHS is currently plagued by financial difficulties driven by austerity.

At the other extreme, medical dominance can be equally destructive for quality and safety. Before 1970, the historical dominance of the medical profession in America kept safety off the policy agenda. After 1970, to around 2005, there was considerable conflict between medical and managerial agendas. The profession sought to retain its traditional autonomy, while managers, supported by policy, proclaimed the importance of quality, but were primarily intent

upon cost control. Neither group was the true champion of safety. Progress has only been made in America in recent years though a range of factors including a normative shift in values, promotion of the business case for quality, a rigorous system of process based regulation, and a series of national improvement campaigns (Wachter 2010a). The recent Partnership for Patients, supported by an investment of US$1 billion, improved safety, and returned cost savings greater than three times the initial investment (Clarkwest, Chen et al. 2014). In comparison, relatively smaller investments in the NHS, such as the Safer Patients Initiative, struggled to have an effect beyond routine improvements that were already emergent from new practices (The Health Foundation 2011b). The lesson is that while better safety protects health, saves lives, and delivers substantial economic gains, many kinds of action and an appropriate and quite substantial investment can be necessary to support change.

The challenges for NZ at the level of policy over the last decade and a half can be thought about in two interconnected stages. In the first stage, after a period of experimentation with market reforms during the 1990s, a system of District Health Boards (DHBs) was created to implement a Health Strategy emphasising clinical governance and the continuous improvement of quality and safety (Minister of Health 2000, 2003). The period that followed was notably unsuccessful. The DHBs tended to work in isolation and did not share information and expertise, they suffered limited resourcing, there was a lack of expertise and evaluation, and there were signs of medical priorities dominating nursing (Wright, Malcolm et al. 2001, Malcolm, Wright et al. 2002). In addition there was no national infrastructure to support improvement, no requirement to implement best practice, and while benchmarking information was gathered, it was only marginally relevant to quality and safety. A Quality Improvement Committee was not formed until 2007 (Gauld 2009a).

The second and current stage in NZ began with the *Time for Quality Agreement* (2008) between senior doctors and the DHBs. This agreement expressed a formal commitment to teamwork between doctors and managers, with managers agreeing to support professionals, who agreed to work at service improvement. Around this time two reports diagnosed the quality agenda as failing and sought to get it back on track. *In Good Hands* (Ministerial Task Group on Clinical Leadership 2009) recognised a sense of general disengagement between doctors and managers, and called for greater clinical leadership. A Ministerial Review Group (2009)

identified spending as unsustainable, recommended a number of efficiencies that would also improve quality and safety, and called for a dedicated organisation to support safety improvement. Subsequently the Health Quality and Safety Commission emerged in 2010. But while these recent reforms have been progressive for safety, healthcare in NZ remains financially constrained to some extent by internal inefficiencies. Transaction costs are unnecessarily high because of duplication between some central agencies, there is poor centralised control over the relatively autonomous DHBs, and by international standards NZ has a large number of DHBs relative to the size of its population (Gauld 2012).

The contemporary landscape of quality and safety in NZ hospitals is characterised by the intentions to promote clinical leadership, and implement programmes of improvement. At the whole-of-system level these fundamentals of safety have only begun to receive serious attention in about the last five years. They face the substantial hurdle of a chronic shortage in the medical workforce. In 2007 there were 0.8 specialists per 1,000 head of population in NZ, the lowest in the OECD, and about half that of the United Kingdom (1.8) and the United States (1.5) (Powell 2010). Over time this shortage has not changed, and an undersupply of specialists has become "the 'norm' for many public hospital departments" (ASMS 2014: 6).

In recent years a number of studies, mostly surveys, offer some insight into current improvement challenges in NZ. There are mixed signals, with evidence of progress alongside signs that the change process may have stalled in some important ways. Staff have felt that quality and safety has become a goal of every clinical and resourcing initiative, that clinical leadership has been enabled, and that there are partnerships between clinicians and management (Gauld and Horsburgh 2012a). However there have also been substantial difficulties with staff not having the time and not feeling supported to do improvement work. There are also indications of weak partnerships between clinicians and managers, strained relationships, and managerial commitment in "lip service only" to supporting clinical governance practices (Gauld and Horsburgh 2012a, Gauld and Horsburgh 2015). Alongside the lack of commitment to distributive clinical leadership there have also been signs of a "resurgent managerialism" in some DHBs (Powell 2013a).

The analysis of the policy environment in NZ in *Chapter 2* makes it clear that resourcing and collaborative effort are vital to patient safety, but these priorities have both struggled relative to a managerially driven cost agenda. That chapter also provides some hints about the complexity of the work of safety. The review of the literature about in-hospital risk in *Chapter 3* further elaborates upon this complexity through an analysis of the dynamics of risk and harm. These dynamics are explained with reference to the ways in which organisational environments (institutional and economic) and organisations (structure, processes, and tasks) affect the cognition and action of staff inside hospitals. I argued in the conclusion of that review that a risk control strategy needs to prioritise the most influential causes of harm, which were identified as pressure, communication, and risk perception. Pressure is a dominant safety risk because of its capacity to affect all of the other risks. It constitutes what James Reason (1990) has described as a latent risk which is designed into the system and combines periodically with other gaps in the defences to cause harm. The sources of pressure in hospitals are resource shortages (West 2000), and inefficient clinical systems (Dixon-Woods, Martin et al. 2014). Both increase staff workload and the probability of error. The remedy for insufficient staff time is to increase economic investment in hospitals, and redesign clinical systems to improve their efficiency. Communication risks can emerge from many sources, but a particularly significant driver can be the status hierarchy and the complexity of relationships, which can result in communications being distorted or withheld due to tensions driven by hierarchical differences (Sutcliffe, Lewton et al. 2004). While reducing hierarchical gaps cannot be a singular solution to this problem, it is a necessary place to begin. Risk perception is a product of organisational and institutional forces. Its characteristic subtlety and pervasiveness makes it a particularly difficult problem to address. Nonetheless improvements to this and other aspects of safety are possible.

In *Chapter 4* I reviewed the safety improvement methodologies of quality assurance, medical audit, evidence-based medicine, human factors and ergonomics, and industrial quality improvement. The analysis emphasised what these methods may achieve, and the challenges of implementation. There is a risk that they may be used inappropriately, they may lead to the bureaucratisation of safety, there are challenges of organisational politics and resourcing, and poor implementation can trigger superficial displays of compliance, and even outright resistance. Nonetheless, there is good evidence that all of the methods are potentially beneficial for safety. The conditions for effective implementation include organisational

support; agreement about necessity, priority, and methods; specification of the programme theory; staff engagement; the prioritisation of clinical and patient focussed values; overcoming complexity; and sustaining change. Paul Bate, Peter Mendel et al. (2008) have described this process through the metaphor of an organisational safety journey in which there is a long term commitment to overcoming universal challenges of structure, culture, politics, learning, motivation, and infrastructure. While organisations solve these challenges in unique ways, it is vitally important to create "organisational slack for quality", so staff can step back from everyday operations, think about quality, and work upon improving it (Bate, Mendel et al. 2008: 179). Similarly Mary-Dixon Woods, Richard Baker et al. (2014: 111) have observed that staff are able to work at improvement when resourcing, staffing, and the mix of available skills are appropriate to already existing work.

It is evident from the preceding analysis of both risk and improvement that pressure is a key challenge for patient safety. This reflects the tensions that were evident in the earlier discussion about policy in NZ, in which a contradiction was observed between the ambitions of clinical governance and quality improvement, and the availability of resources. This is a particularly serious problem given the reality that healthcare in NZ consumes a growing share of GDP and is approaching unsustainability (Ministerial Review Group 2009). It invokes what Elizabeth West (2000) has described as the threat of goal displacement, where healthcare priorities are compromised by economic objectives, and clinical teams are set up to fail (West 2000). A critically important question must therefore be answered. Should more resources be invested to improve safety? I think about this question here in two stages. First, I review my analysis of the discussions I was involved in with hospital staff in NZ, which are reported in *Chapter 6* and *Chapter 7*. These perspectives were derived from n=37 qualitative interviews with nurses, doctors, and service and quality managers, in three departments in two hospitals. Second, I identify some opportunities for healthcare in NZ to free up financial resources, and for hospitals in all contexts to achieve safety improvement.

According to the staff perspectives reported in *Chapter 6* pressure was a pervasive factor in the emergence of risk. The underlying problem was short-staffing, which affected both nurses and doctors, and was particularly but not only evident in the hospitals during nights. Short-staffing drove pressure, which in turn contributed to both poor communication amongst all staff, and

a breakdown of teamwork amongst nurses. These factors dominated the explanations that staff offered about a range of clinical risks that their patients were exposed to. Pressure was the most pervasive risk factor of all. It was a part of the causal chain of many kinds of harm, and staff spoke about their capacity to control it in probabilistic terms. Pressure drove medication errors by both nurses and doctors, it contributed to flawed medical decisions, and it meant that nurses could not always control the risks of falls and pressure injuries. Nurses could also feel that the humanity of care was sometimes compromised. When nursing teamwork broke down these risks were even more difficult to control. Under pressure, nurses violated protocols, and these violations were then normalised.

The observation that pressure was a dominant generalised risk factor does not negate the relevance of other risks. Institutional and organisational factors were also sometimes important. Poor communication was only discussed occasionally, and in all likelihood it was a far greater risk than many staff were willing to acknowledge. Research in other hospitals has shown that communication is a factor in most adverse events (Sutcliffe, Lewton et al. 2004). In addition there was a tendency to not acknowledge some clinical risks that are well known in the literature. Doctors discussed medication harms infrequently, although on the occasions when these were mentioned they were described as poorly controlled because of the effects of pressure and insufficient emphasis on thoroughly checking and reviewing medication charts. Many surgeons gave little attention to discussing the challenges of surgical risks. Infection risks were infrequently discussed by staff of all kinds. When they were mentioned, compliance with protocols was described as variable. The non-discussion of these clinical risks, and the generalised risks of poor communication, indicates that denial was a risk that was enhanced by, and worked in combination with pressure, to reduce safety.

The discussions with staff about improvement reported in *Chapter 7* covered performance targets, the incident reporting system, and a variety of methods of safety improvement, including audit, evidence-based medicine, and improvement projects. There were mixed views of performance targets. While some service and clinical managers perceived these as necessary and motivational, many staff contended that a shaming approach to failure was hurtful, there was an underlying assumption that staff were lazy, the pressure of targets damaged teamwork, resourcing was insufficient, and the quality of some clinical decisions had declined, which

created additional work. Targets were also perceived as a way of producing numbers that looked good, rather than improving the system overall.

The reporting system was viewed with little enthusiasm, and some cynicism. Nurses lost faith in the system when repeated reports about the same risks produced no action. Doctors were largely disengaged, either because of mistrust, or a lack of interest and know-how. There was some dismay that the system could not provide useful information about major risks. It was also claimed that the seriousness of incidents was frequently downgraded. Despite these multiple failings however, and because of the promise of what might be achieved, some staff were interested in improving and making greater use of the system of reporting.

Responses to improvement projects frequently revealed the impact of pressure. Nurses were positive about the idea of improvement, and some improvement practices, but their perceptions were heavily moderated by whether or not they felt they had the time to participant in these activities. In one case a charge nurse argued against practices that she agreed with, but disliked because resourcing challenges made them impractical. A number of doctors described some practices as irrational and pointless. Compliance in some cases was marginal. These latter forms of resistance may have been driven in part by the perception that managers were trying to bureaucratise safety into existence, and by processes simply being handed to doctors who were too busy to become involved in the redesign stage. As Mary Dixon-Woods, Richard Baker et al. (2014: 879) argue, it is essential to "match goals and ambitions to what is realistically achievable and focus on bringing everyone along with you." Staff sometimes appeared to be working with processes they had no part in designing, disagreed with, and could not or would not fit into their essential daily routines.

While some doctors had completed medically and surgically orientated improvements in their departments, shortages of time and resources meant that the volume of this work was less than ideal. Some improvements were not even thought about, let alone attempted, and others could not be bought to completion because of a lack of wider support from the hospital. This outcome was particularly frustrating for those doctors who were willing to do this work. Others could see the necessity for similar projects, but were resigned to the lack of resources and capacity, or were wary about the burnout that could affect project champions.

It appeared that short-term economic criteria were often behind the inability to advance improvement. The limits of these criteria were evident in a ward where the charge nurse had identified communications training as a potentially useful way of improving the delivery of care. But this training could not be financed because it was too hard to demonstrate a cost benefit. Accounting criteria ruled that the nurse's observation of an obvious need, and the findings of research, which has shown that communication failures are involved in the vast majority of adverse events (Sutcliffe, Lewton et al. 2004), and that team-training can transform safety culture (Jones, Skinner et al. 2013), were not countable as numeric inputs into the analysis of benefits. As a clinical director observed, justifications for safety had to be "cooked up", it was far harder to show a measurable benefit for the bottom line.

The dominance of input costs in accounting calculations was probably premised in part upon a shortage of data about the frequency and the costs of preventable harm. It was probably also due to the substantial difficulties of accurately gathering a sufficient volume of this information and being able to isolate the impact of any one intervention. These and other factors often made safety improvement unrealistic, and contributed to an overall sense of inertia. The work was insufficiently supported by the hospitals and staff were insufficiently engaged because their attention was dominated by immediate clinical duties. As a consequence there were failings across nearly all of the general categories of this work that Paul Bate, Peter Mendel et al. (2008) have identified. Structurally, there was insufficient time for quality. Culturally, there was a lack of focus on measurement, and a culture of mindfulness, of being awake to quality and safety problems, was missing. Politically, staff did not appear to have a sense of ownership over improvement, and because of that they seemed to not have any real passion for it. When that passion was in evidence it could take the form of a resigned or frustrated enthusiasm because of what could *not* be done. Emotionally, motivation was lacking because improvement could be a distraction from more urgent clinical duties. For doctors, doing improvement without support meant risking burnout. Some infrastructural systems, such as information technology for assisting handovers and the application of policies and guidelines, were "vestigial" and insufficient.

In this exploration of the challenges of patient safety in NZ public hospitals I have emphasised pressure in the clinical environment due to resource shortages as one of the major challenges

to be overcome. This should make it clear that the answer to my earlier question, if more resources should be invested to improve safety, must be 'yes'. But where should these resources come from in a fiscally constrained environment? There are two answers to this question. First, as argued by Robin Gauld (2009b, 2012), there is the potential in NZ for savings to be realised through structural changes that have the capacity to reduce transaction costs. This could be achieved in a number of ways. Central organisations with overlapping responsibilities, such as the National Health Board and the Health Quality and Safety Commission, could be amalgamated into a single agency. That agency could have greater authority over the DHBs. The number of DHBs, which is excessive relative to the very small population of NZ, could be reduced. If successful these changes would free up resources for many purposes, not simply for safety.

A second source of additional resourcing is the economic payback of better safety. These potential gains are well known, but to be realised some initial investment is required. When the NZ Health Strategy was refined half a decade ago a Ministerial Review Group (2009) identified improved safety as a substantial cost savings opportunity, albeit with the price of centralised expertise to support improvement. The challenge now is to consider if this support is sufficient? The evidence from this research shows that more needs to be done within hospitals, and that actions need greater support to be effective. Currently, action is too often marginalised. Hospitals are not as comprehensively involved in improvement as they could be.

How hospitals could prioritise safety more in a fiscally constrained environment is the critical question. It is necessarily important for investments to support actions with strong evidence of effectiveness. Fortunately, plenty of options are available and the evidence-base is fast maturing (Marshall, Pronovost et al. 2013). In recent years the Association of Healthcare Research and Quality in America identified ten "strongly encouraged" safety strategies and "encouraged" another twelve (Shekelle, Pronovost et al. 2013: 365-6). However because improvement is necessarily both a technical and a social process these actions need to be adapted to context through a full understanding of how and why they may be most effective (Bosk, Dixon-Woods et al. 2009). When improvement is approached superficially, without knowledge of how it may be shaped to unique local contexts, it runs the risk of producing ritualistic displays of compliance, and even outright resistance (Waring and Bishop 2010a). In

these circumstances organisations can sometimes be unaware that processes are failing, and they can fall into the complacency of assuming that their safety issues have been resolved (Bosk, Dixon-Woods et al. 2009). The challenge therefore is to judiciously utilise the growing base of knowledge about the implementation of improvement, which is outlined in *Chapter 4*. To support these kinds of changes organisations can become involved in processes of reflection on the social components of implementation. The construction of organisational narratives through research can assist sensemaking (Bate, Mendel et al. 2008). "Ultimately, the only way to know exactly what a complex system will do is to observe it" (Plsek and Greenhalgh 2001: 627). This knowledge can be fed back into practice through a collaborative process in which the practical expertise of clinicians and the theoretical rigour of social research are central to the process of change (Marshall, Pronovost et al. 2013).

As I bring this thesis to a close it becomes important to consider the limits of this analysis, the opportunities for further research, and the contribution these findings make to the literature. There are some limitations to this research. First, the qualitative sample that supports my analysis is illustrative only and not representative of all departments and all hospitals in NZ. It may be that the essential challenges could be framed differently in those other contexts. That said, the findings from the interviews reported here are broadly consistent with the finding of patient safety research in many other contexts, and with other research of staff across hospitals in NZ. The second limitation concerns the interview process. Interviews were relatively brief (47 minutes on average), and because they were exploratory many topics were covered. The breath of the focus meant that coverage of individual aspects of the two central topics was often necessarily quite brief. There is the potential for the exploratory findings that have been developed here to be considerably refined in detail. I would be interested to know more about such topics as the control of prescribing harm and surgical harm. I would be interested to know more about the "safety journey" (Bate, Mendel et al. 2008) in NZ hospitals: How is this process developing and changing over time? The analysis here of risk and safety in three departments in two hospitals has been very exploratory, and is short of detail in many areas.

This thesis contributes to the literature about patient safety by adding to the relatively small volume of socially and organisationally focussed research about safety in NZ hospitals. More research about this topic in NZ could greatly assist future efforts and the focus of resources.

There are substantial fiscal benefits on offer. There is also a moral obligation to protect the vulnerable. In times of ill health or injury leading to hospitalisation – which sooner or later will impact the lives of most of us – our safety, and that of those we care for and love, is dependent upon complex systems that can too easily deliver unintended adverse outcomes. This research has shown that safer care is possible, but if hospitals in NZ are to achieve it, they must have greater support.

Appendix

Ethical approval

Health and Disability Ethics Committees

Northern X Regional Ethics Committee
Private Bag 92522
Wellesley Street
Auckland 1141
Phone: (09) 580 9105
Fax (09) 580 9001
Email: northernx_ethicscommittee@moh.govt.nz

24 May 2012

Mr Peter James Beaver
102a Huia Road
Pt Chevalier
Auckland 1022

Dear Peter

Re:	Ethics ref:	**NTX/12/EXP/107** (please quote in all correspondence)
	Study title:	The effects of organisation and governance on patient safety in NZ public hospitals. PIS/Cons V#2, 24/05/12
	Investigators:	Mr Peter James Beaver (Principal), Dr Steve Mattewman (Supervisor)

Thank you for your application received 15 May 2012 and amended documents on 24 May.

The above study has been given ethical approval by the Chairperson of the **Northern X Regional** Ethics Committee under delegated authority.

Approved Documents

- Information sheet/Consent form version [2 dated 24/05/2012]
- Interview Guide [version 1 dated 07/05/2012]
- Confidentiality agreement for transcribers [version 1 dated 07/05/2011] – please amend year to 2012

This approval is valid until 31 July 2013, provided that Annual Progress Reports are submitted (see below).

Amendments and Protocol Deviations

All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:

- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study
- the method of recruitment

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports

The first Annual Progress Report for this study is due to the Committee by **24 May 2013**. Please note that progress reports are the responsibility of the researcher and forms can be found on the website, www.ethicscommitttees.health.govt.nz. (Website will change after July 2012 to

Participant information sheet

PhD Thesis Research, Department of Sociology, The University of Auckland.

'The effects of organisation and governance on patient safety in New Zealand public hospitals'

Thank you for expressing an interest in my confidential sociological study seeking to understand the views of hospital managers, doctors and nurses on patient safety in NZ public hospitals.

I will be interviewing a total of forty doctors, nurses, and managers from different departments and wards in two to four different public hospitals in NZ.

The interviews will be conducted by myself, a PhD Candidate, will take up to 30 minutes, and will be digitally recorded. They may be conducted in any quiet location you wish.

Participation is voluntary. You may end the interview, or ask for the recorder to be stopped during the interview without explanation. You may withdraw your entire interview from the research, without explanation, up to six weeks after the interview.

Your interview will be transcribed, and you may ask for a copy of this to edit up to six weeks after the interview. The transcript will not include mention of your name or the hospital or ward in which you work. A paper copy will be stored in a locked filing cabinet, and the electronic transcript and original recording will be kept on a password protected computer.

The interview material will be drawn upon to prepare a PhD thesis, and possibly other oral presentations and written publications. This will involve interview transcripts being thematically analysed, with extracts from the interviews used as illustrations of themes or of outlying points of view. These quotes will be identified only by the occupational identity of the person making them (nurse, doctor, manager) and the department they work in. The hospital will be referred to only by a number (Hospital 1, 2, etc.).

Every attempt will be made to keep your identity confidential. This includes in written material arising from the research. But despite all possible precautions neither confidentiality nor anonymity can be guaranteed in small scale qualitative studies of this kind.

Just before the interview, I will ask you to sign a consent form, which will be stored separately from any other information in a locked cabinet at the University of Auckland.

If you have questions about the research please let me know. You are also free to contact my supervisor (Dr Steve Matthewman in the Department of Sociology at the University of Auckland, phone 3737 599 extn. 88616), and the Head of Department where I am studying (Professor Alan France, phone 3737 599 extn. 84507).

This study has received ethical approval from the Northern X Regional Ethics Committee for the period 1 July 2012 – 31 July 2013 (approval NTX/12/EXP/107). It has also been locally approved by the DHB that you work for.

Sincerely,

Peter Beaver
PhD Candidate
Department of Sociology
The University of Auckland

Participant consent

PhD Thesis Research, Department of Sociology, The University of Auckland.

'The effects of organisation and governance on patient safety in New Zealand public hospitals'

I have read the Participant Information Sheet and understand the nature of the research. I have had the opportunity to ask questions and had them answered to my satisfaction.

I agree to take part in the research project, given the following:

- I understand the interview will take up to 30 minutes of my time.
- I may stop the interview at any time without explanation.
- The interview will be digitally recorded by the researcher, and I may choose to have the recorder turned off at any time during the interview without explanation.
- The interview may be transcribed by a third party who will have signed a confidentiality agreement.
- Transcriptions of the interview will not contain any identifying information about me. This includes my name, job title, where I work in the hospital, and the name of the hospital. On the transcript I will be identified only by a unique number, and my occupational status (defined only as Doctor / Nurse / Manager)
- My participation is entirely voluntary and if I take part I am free to withdraw my interview material anytime within six weeks of participating in the interview.
- I am free to ask for a copy of the transcript of my interview if I wish, and I can ask that changes are made to the transcript up to six weeks after completion of the interview.
- Every attempt will be made to keep my identity confidential. This includes in written material arising from the research. I understand that despite these precautions neither confidentiality nor anonymity can be guaranteed in small scale qualitative studies of this kind.
- A paper transcript of my interview will be stored securely and then shredded once the PhD thesis has been completed and any academic papers related to the thesis have been published.
- An electronic copy of my transcript will be securely stored on a pass word protected computer at the University of Auckland for six years after the thesis has been completed, and then deleted.
- While the PhD thesis is being prepared data will be stored in a locked filing cabinet or a password protected computer, but it may from time to time be in the principle researcher's workspace.
- This consent form will be stored separately from the research data, in a locked filing cabinet on the University of Auckland campus for six years. It will then be shredded.
- I have been given the opportunity if I wish to contact the project supervisor (Doctor Steve Matthewman in the Department of Sociology at the University of Auckland, phone 3737 599 extn. 88616), and the Head of Department (Professor Alan France, phone 3737 599 extn. 84507).
- I understand this study has received ethical approval from the Northern X Regional Ethics Committee for the period 1 July 2012 – 31 July 2013 (NTX/12/EXP/107), and locally by the DHB that I work for.

Date:
Participant Name:
Participant Signature:
Contact street address, email address and telephone number:

Bibliography

Aiken, L. H., S. P. Clarke, D. M. Sloane, J. Sochalski and J. H. Silber (2002). "Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction." The Journal of the American Medical Association **288**(16): 1987-1993.

Appleby, J., A. Galea and R. Murray (2014). The NHS productivity challenge - Experience from the front line. London, The Kings Fund.

Archer, M. (1998). Social theory and the analysis of society. Knowing the Social World. T. May and M. Williams. Buckingham & Philadeplhia, Open University Press.

Arluke, A. (1977). Social control rituals in medicine: the case of death rounds. Health Care and Health Knowledge. R. Dingwall, C. Heath, M. Reid and M. Stacey. London, Croom Helm.

Armstrong, D. (2002). "Clinical autonomy, individual and collective: the problem of changing doctors' behaviour." Social Science & Medicine **55**(10): 1771-1777.

Arndt, M. and B. Bigelow (1995). "The implementation of total quality mangement in hospitals: how good is the fit?" Health Care Management Review **20**(4): 7-14.

ASMS (2013). The Public Hospital Specialist Workforce - Entrenched shortages or workforce investment?, Association of Salaried Medical Specialists.

ASMS (2014). Taking the temperature of the public hospital specialist workforce, Association of Salaried Medical Specialists.

Atkinson, P. (1984). "Training for certainty." Social Science & Medicine **19**(9): 949-956.

Austin, J. M., A. K. Jha, P. S. Romano, S. J. Singer, T. J. Vogus, R. M. Wachter and P. J. Pronovost (2015). "National Hospital Ratings Systems Share Few Common Scores And May Generate Confusion Instead Of Clarity." Health Affairs **34**(3): 423-430.

Baines, R., M. Langelaan, M. de Bruijne, P. Spreeuwenberg and C. Wagner (2015). "How effective are patient safety initiatives? A retrospective patient record review study of changes to patient safety over time." BMJ Quality & Safety **24**(9): 561-571.

Baines, R. J., M. Langelaan, M. C. de Bruijne, H. Asscheman, P. Spreeuwenberg, L. van de Steeg, K. M. Siemerink, F. van Rosse, M. Broekens and C. Wagner (2013). "Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study." BMJ Quality & Safety **22**(4): 290-298.

Bajaj, M. and K. Palmer (2004). "Gentamicin usage in newborns — a simple and practical regime." Pharmacy World and Science **26**(4): 242-244.

Baker, D., P., E. Salas, J. B. Battles and H. B. King (2011). The Relation between Teamwork and Patient Safety. Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, Second Edition, CRC Press**:** 185-198.

Ballé, M. and A. Régnier (2007). "Lean as a learning system in a hospital ward." Leadership in Health Services **20**(1): 33-41.

Ballin, J. C. (1975). "Editorial: the ADR numbers game revisited." The Journal of the American Medical Association **234**(12): 1257.

Barach, P. and S. D. Small (2000). "Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems." BMJ **320**(7237): 759-763.

Barr, D. P. (1955). "Hazards of modern diagnosis and therapy - the price we pay." The Journal of the American Medical Association **159**(15): 1452-1456.

Bate, P., P. Mendel and G. Robert (2008). Organizing for Quality: The Improvement Journeys of Leading Hospitals in Europe and the United States. Oxford & New York, Radcliffe Publishing.

Bates, D. W., D. J. Cullen, N. Laird, L. A. Petersen, S. D. Small, D. Servi, G. Laffel, B. J. Sweitzer, B. F. Shea, R. Hallisey, M. Vander Vliet, R. Nemeskal, L. L. Leape, A. P. S. Group, D. Bates, P. Hojnowski-Diaz, S. Petrycki, M. Cotugno, H. Patterson, M. Hickey, S. Kleefield, J. Cooper, E. Kinneally, H. J. Demonaco, M. D. Clapp, T. Gallivan, J. Ives, K. Porter, B. T. Thompson, J. R. Hackman and A. Edmondson (1995). "Incidence of Adverse Drug Events and Potential Adverse Drug Events." The Journal of the American Medical Association **274**(1): 29-34.

Bates, D. W., L. L. Leape and S. Petrycki (1993). "Incidence and preventability of adverse drug events in hospitalized adults." Journal of General Internal Medicine **8**(6): 289-294.

Battles, J. B. (2005). "Commentary." Quality and Safety in Health Care **14**: 225-226.

Becker, H. S., B. Geer, E. C. Hughes and A. L. Strauss (1961). Boys in White. Student Culture in Medical School. Chicago, The University of Chicago Press.

Beecher, H. K. and D. P. Todd (1954). "A study of the deaths associated with anesthesia and surgery." Annals of Surgery **140**(1): 2-34.

Beitin, B. (2012). Interview and sampling: How many and whom. The Sage Handbook of Interview Research: The Complexity of the Craft. J. F. Gubrium, J. A. Holstein, A. B. Marvasti and K. D. McKinney. Thousand Oaks, Sage Publications.

Bellandi, T., S. Albolino, R. Tartaglia and S. Bagnara (2011). Human Factors and Ergonomics in Patient Safety Management. Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, Second Edition, CRC Press**:** 671-690.

Berwick, D. (2008). "A transatlantic review of the NHS at 60." BMJ **337**: 212-214.

Berwick, D. M. (1989). "Continuous Improvement as an Ideal in Health Care." New England Journal of Medicine **320**(1): 53-56.

Berwick, D. M., A. D. Hackbarth and C. J. McCannon (2006). "IHI replies to "The 100,000 lives campaign: a scientific and policy review"." Joint Commission Journal on Quality and Patient Safety **32**(11): 628-630.

Best, M. and D. Neuhauser (2004). "Ignaz Semmelweis and the birth of infection control." Quality and Safety in Health Care **13**(3): 233-234.

Bevan, G. (2008). "Changing paradigms of governance and regulation of quality of healthcare in England." Health, Risk & Society **10**(1): 85-101.

Bevan, G. (2010a). "Performance Measurement of “Knights” and “Knaves”: Differences in Approaches and Impacts in British Countries after Devolution." Journal of Comparative Policy Analysis: Research and Practice **12**(1-2): 33-56.

Bevan, G. (2010c). "If neither altruism nor markets have improved NHS performance what might?" Eurohealth **16**(3): 20-23.

Bevan, G. and C. Hood (2006a). "Have targets improved performance in the English NHS?" BMJ **332**(7538): 419-422.

Bevan, G. and C. Hood (2006b). "What's measured is what matters: Targets and gaming in the English public health care system." Public Administration **84**(3): 517-538.

Bhatia, A., S. Blackstock, R. Nelson and T. S. Ng (2000). "Evolution of quality review programs for medicare: Quality assurance to quality improvement." Health Care Financing Review **22**(1): 69-74.

Bindman, A. B., P. R. Lee and J. M. Luce (1994). A brief history of health care quality assessment and improvement in the United States. The Western Journal of Medicine. **160:** 263+.

Bion, J., A. Richardson, P. Hibbert, J. Beer, T. Abrusci, M. McCutcheon, J. Cassidy, J. Eddleston, K. Gunning, G. Bellingan, M. Patten and D. Harrison (2013). "'Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England." BMJ Quality & Safety **22**(2): 110-123.

Black, N. and E. Thompson (1993). "Obstacles to medical audit: British doctors speak out." Social Science & Medicine **36**(7): 849-856.

Blumenthal, D. and C. M. Kilo (1998). "A Report Card on Continuous Quality Improvement." Milbank Quarterly **76**(4): 625-648.

Bosk, C. L. (2003). Forgive and Remember: Managing Medical Failure. Chicago, University of Chicago Press.

Bosk, C. L., M. Dixon-Woods, C. A. Goeschel and P. J. Pronovost (2009). "Reality check for checklists." The Lancet **374**(August 8): 444-445.

Braaf, S., E. Manias and R. Riley (2013). "The 'time-out' procedure: an institutional ethnography of how it is conducted in actual clinical practice." BMJ Quality & Safety **22**(8): 647-655.

Braithwaite, J., W. B. Runciman and A. F. Merry (2009). "Towards safer, better healthcare: harnessing the natural properties of complex sociotechnical systems." Quality and Safety in Health Care **18**(1): 37-41.

Braithwaite, J., M. T. Westbrook, N. A. Mallock, J. F. Travaglia and R. A. Iedema (2006). "Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme." Quality and Safety in Health Care **15**(6): 393-399.

Brennan, T. A. and D. M. Berwick (1996). New Rules: Regulation, Markets, and the Quality of American Health Care. San Francisco, Jossey-Bass.

Brennan, T. A., L. L. Leape, N. M. Laird, L. Hebert, A. R. Localio, A. G. Lawthers, J. P. Newhouse, P. C. Weiler and H. H. Hiatt (1991). "Incidence of Adverse Events and Negligence in Hospitalized Patients." New England Journal of Medicine **324**(6): 370-376.

Brereton, L. and V. Vasoodaven (2010). The impact of the NHS market. London, CIVITAS: Institute for the Study of Civil Society.

Brook, R. H. and K. N. Lohr (1981). "Quality of care assessment: its role in the 1980s." American Journal of Public Health **71**(7): 681-682.

Brown, C., T. Hofer, A. Johal, R. Thomson, J. Nicholl, B. D. Franklin and R. J. Lilford (2008). "An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement." Quality and Safety in Health Care **17**(3): 170-177.

Brown, P., C. McArthur, L. Newby, R. Lay-Yee, P. Davis and R. Briant (2002). "Cost of medical injury in New Zealand: a retrospective cohort study." Journal of Health Services Research and Policy **7**(suppl_1): 29-34.

Bruner, J. (1991). "The narrative construction of reality." Critical Inquiry **18**: 1-21.

Burgess, R. (2011a). How to use this book. New Principles of Best Practice in Clinical Audit (second edition). R. Burgess. Oxford, Radcliffe Publishing.

Burgess, R. (2011b). Introduction - Foundations, tradition and new directions - the future of clinical audit in a new decade. New Principles of Best Practice in Clinical Audit (second edition). R. Burgess. Oxford, Radcliffe Publishing.

Butterworth, T., K. Jones and S. Jordan (2011). "Building capacity and capability in patient safety, innovation and service improvement: an English case study." Journal of Research in Nursing **16**(3): 243-251.

Cabana, M. D., C. S. Rand, N. R. Powe, A. W. Wu, M. H. Wilson, P.-A. C. Abboud and H. R. Rubin (1999). "Why don't physicians follow clinical practice guidelines? A framework for improvement." The Journal of the American Medical Association **282**(15): 1458-1467.

California Medical Association (1977). The report on the Medical Insurance Feasibility Study. San Francisco, California Medical Association.

Carayon, P. (2011). Human Factors and Ergonomics in Health Care and Patient Safety. Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, Second Edition. Boca Raton, CRC Press**:** 3-16.

Card, A. J., J. Ward and P. J. Clarkson (2012). "Successful risk assessment may not always lead to successful risk control: A systematic literature review of risk control after root cause analysis." Journal of Healthcare Risk Management **31**(3): 6-12.

Care Quality Commission (2014). The State of Health Care and Adult Social Care in England 2013/14. HMSO, London.

Cavendish, C. (2013). "An Independent Review into Healthcare Assistants and Support Workers in the NHS and social care settings."

Chassin, M. R. and J. M. Loeb (2011). "The Ongoing Quality Improvement Journey: Next Stop, High Reliability." Health Affairs **30**(4): 559-568.

Chassin, M. R., J. M. Loeb, S. P. Schmaltz and R. M. Wachter (2010). "Accountability Measures — Using Measurement to Promote Quality Improvement." New England Journal of Medicine **363**(7): 683-688.

Clarkwest, A., A. Chen, M. Higgins, V. Cheh, J. Zurovac, K. K. Kranker, G. M. Tignini, R. Fornango, J. Lewis, S. Bateman, S. Felt-Lisk and R. Fair (2014). Project Evaluation Activity in Support of Partnership for Patients: Task 2 Evaluation Progress Report, Center for Medicare and Medicaid Innovation.

Classen, D. C., R. Resar, F. Griffin, F. Federico, T. Frankel, N. Kimmel, J. C. Whittington, A. Frankel, A. Seger and B. C. James (2011). "'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured." Health Affairs **30**(4): 581-589.

Clwyd, A. and T. Hart (2013). A Review of the NHS Hospitals Complaints System - Putting Patients Back in the Picture, Williams Lea.

Cohen, I. B. (1984). "Florence Nightingale." Scientific American **250**(3): 128.

Colton, D. (2000). "Quality Improvement in Health Care." Evaluation & the Health Professions **23**(1): 7-42.

Committee on Quality of Health Care in America (2001). Crossing the Quality Chasm : A New Health System for the 21st Century. Washington, DC, National Academy Press.

Cooper, J. B., R. S. Newbower, C. D. Long and B. McPeek (1978). "Preventable anaesthesia mishaps: A study of human factors." Anesthesiology **49**: 399-406.

Cooper, M. R. (2004). Quality Assurance and Improvement. Health Care Administration: Planning, Implementing, and Managing Organized Delivery Systems. L. F. Wolper. New York, Jones and Bartlett.

Copeland, G. (2005). A Practical Handbook for Clinical Audit, Clinical Governance Support Team.

Copeland, J. (1825). "The Hippocratic Oath." The London Medical Repository, Monthly Journal, and Review **3**(January to June).

Coster, G. and S. Buetow (2001). Quality in the New Zealand health system: background paper to the National Health Committee. Wellington, Ministry of Health.

Cure the NHS. (2015). "About Cure the NHS." accessed 10 June 2015, from http://www.curethenhs.co.uk/about-cure-the-nhs/.

Currie, E. J. and R. A. Carr Hill (2012). "What are the reasons for high turnover in nursing? A discussion of presumed causal factors and remedies." International Journal of Nursing Studies **49**(9): 1180-1189.

Currie, G., M. Humpreys, J. Waring and E. Rowley (2009). "Narratives of professional regulation and patient safety: The case of medical devices in anaesthetics." Health, Risk & Society **11**(2): 117 - 135.

Curtis, B. and C. Curtis (2011). Social Research: A Practical Introduction. London, Sage Publications.

Daly, J. (2005). Evidence-Based Medicine and the Search for a Science of Clinical Care. Berkeley, University of California Press.

Darzi, A. (2009). "A Time for Revolutions — The Role of Clinicians in Health Care Reform." New England Journal of Medicine **361**(6): e8(1)-e8(2).

Davidoff, F., M. Dixon-Woods, L. Leviton and S. Michie (2015). "Demystifying theory and its use in improvement." BMJ Quality & Safety **24**(3): 228-238.

Davies, H., A. Powell and R. Rushmer (2007a). "Why don't clinicians engage with quality improvement?" Journal of Health Services Research & Policy **12**(3): 129-130.

Davies, H., A. Powell and R. Rushmer (2007b). Healthcare professionals' views on clinician engagement in quality improvement. A literature review. London, The Health Foundation.

Davis, P., R. Lay-Yee, R. Briant, S. Schug, A. Scott, S. Johnson and W. Bingley (2001). Adverse events in public hospitals: principle findings from a national survey. Wellington, Ministry of Health.

Davis, P., R. Lay-Yee, A. Scott and R. Gauld (2007). "Do Hospital Bed Reduction and Multiple System Reform Affect Patient Mortality?: A Trend and Multilevel Analysis in New Zealand Over the Period 1988-2001." Medical Care **45**(12): 1186-1194.

Dawson, L. L. and R. C. Prus (1995). "Postmodernism and linguistic reality versus symbolic interactionism and obdurate reality." Studies in Symbolic Interaction(17): 105-124.

Day, P. and R. Klein (2004). The NHS Improvers - A study of the Commission for Health Improvement. London, The King's Fund.

de Vries, E. N., M. A. Ramrattan, S. M. Smorenburg, D. J. Gouma and M. A. Boermeester (2008). "The incidence and nature of in-hospital adverse events: a systematic review." Quality and Safety in Health Care **17**(3): 216-223.

Degeling, P., S. Maxwell, J. Kennedy and B. Coyle (2003). "Medicine, management, and modernisation: a "danse macarbe"?" BMJ **326**: 649-652.

Degeling, P. J., S. Maxwell, R. Iedema and D. J. Hunter (2004). "Making clinical governance work." BMJ **329**(7467): 679-681.

Dekker, S. W. A. and T. B. Hugh (2014). "A just culture after Mid Staffordshire." BMJ Quality & Safety **23**: 356-358.

DelliFraine, J. L., J. R. I. Langabeer and I. M. Nembhard (2010). "Assessing the Evidence of Six Sigma and Lean in the Health Care Industry." Quality Management in Healthcare **19**(3): 211-225 210.1097/QMH.1090b1013e3181eb1140e.

Dent, M. (1993). "Professionalism, educated labour and the state: hospital medicine and the new managerialism." The Sociological Review **41**(2): 244-273.

Dent, M. (1995). Doctors, peer review and quality assurance. Health Professionals and the State in Europe. T. Johnson, G. Larkin and M. Saks. London & New York, Routledge.

Department of Health (1989). Working for Patients. London, HMSO.

Department of Health (1998). A First Class Service: Quality in the new NHS. London, HMSO.

Department of Health (2000). An Organisation with a Memory. London, The Stationary Office.

Department of Health (2001). Building a Safer NHS for Patients: Implementing an Organisation with a Memory. London.

Department of Health (2006). Safety First - A Report for Patients, Clinicians and Healthcare Managers. London, COI.

Department of Health (2008). High quality care for all: NHS next stage review final report, Department of Health.

Department of Health (2010). Equity and excellence: Liberating the NHS, The Stationery Office.

Dershewitz, R. A. and R. J. Gross (1980). "Why medical audits are in disfavor." Archives of Internal Medicine **140**(2): 168-169.

Detsky, A. S. and D. M. Berwick (2013). "Teaching physicians to care amid chaos." The Journal of the American Medical Association **309**(10): 987-988.

Dixon-Woods, M. (2010). "Why is patient safety so hard? A selective review of ethnographic studies." Journal of Health Services Research & Policy **15**(Suppl 1): 11-16.

Dixon-Woods, M. (2013). What we know about how to improve quality and safety in hospitals, The Health Foundation, Website presentation accessed 13/6/2014.

Dixon-Woods, M. (2014a). Understanding the challenges of improving safety in clinical systems. Presentation at 'Ideas for change' conference, The Health Foundation.

Dixon-Woods, M. (2014b). Measuring what matters - how can we know we are delivering prudent healthcare? 100s Lives Improvement O Fywydau, NHS Wales.

Dixon-Woods, M., R. Baker, K. Charles, J. Dawson, G. Jerzembek, G. Martin, I. McCarthy, L. McKee, J. Minion, P. Ozieranski, J. Willars, P. Wilkie and M. West (2014). "Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study." BMJ Quality & Safety **23**(2): 106-115.

Dixon-Woods, M., C. L. Bosk, E. L. Aveling, C. A. Goeschel and P. J. Pronovost (2011). "Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program." Milbank Quarterly **89**(2): 167-205.

Dixon-Woods, M., M. Leslie, J. Bion and C. Tarrant (2012). "What Counts? An Ethnographic Study of Infection Data Reported to a Patient Safety Program." Milbank Quarterly **90**(3): 548-591.

Dixon-Woods, M., M. Leslie, C. Tarrant and J. Bion (2013). "Explaining Matching Michigan: an ethnographic study of a patient safety program." Implementation Science **8**(70): 1-13.

Dixon-Woods, M., G. Martin, C. Tarrant, J. Bion, C. Goeschel, P. Pronovost, L. Brewster, L. Shaw, L. Sutton, J. Willars, D. Ketley and T. Woodcock (2014). Safer Clinical Systems: evaluation findings - Learning from the independent evaluation of the second phase of the Safer Clinical Systems programme, The Health Foundation.

Dixon-Woods, M., S. McNicol and G. Martin (2012). "Ten challenges in improving quality in healthcare: lessons from the Health Foundation's programme evaluations and relevant literature." BMJ Quality & Safety **21**(10): 876-884.

Dixon-Woods, M., A. Suokas, E. Pitchforth and C. Tarrant (2009). "An ethnographic study of classifying and accounting for risk at the sharp end of medical wards." Social Science & Medicine **69**(3): 362-369.

Dixon, A. and C. Ham (2010). Liberating the NHS - The right prescription in a cold climate? London, The Kings Fund.

Donabedian, A. (1978). "The Quality of Medical Care." Science **200**(4344): 856-864.

Donabedian, A. (1989). "The End Results of Health Care: Ernest Codman's Contribution to Quality Assessment and Beyond." Milbank Quarterly **67**(2): 233-256.

Donabedian, A. (2005). "Evaluating the Quality of Medical Care." Milbank Quarterly **83**(4): 691-729.

Donaldson, L. J. and A. Darzi (2012). "Quality measures: bridging the cultural divide." BMJ Quality & Safety **21**(11): 969-972.

Donchin, Y., D. Gopher, M. Olin, Y. Badihi, M. R. Biesky, C. L. Sprung, R. Pizov and S. Cotev (1995). "A look into the nature and causes of human errors in the intensive care unit." Critical Care Medicine **23**(2): 294-300.

Dopson, S. (2009). Changing forms of managerialism in the NHS: heirarchies, markets, and networks. The New Sociology of the Health Service. J. Gabe and M. Calnan. London & New York, Routledge.

Driver, T. H. and R. M. Wachter (2012). "Can healthcare go from good to great?" Journal of Hospital Medicine **7**(1): 60-65.

Drucker, P. (2002). Managing in the Next Society. New York, St. Martin's Griffin.

Dwyer, S. C. and J. L. Buckle (2009). "The Space Between: On Being an Insider-Outsider in Qualitative Research." International Journal of Qualitative Methods **8**(1): 54-63.

Eddy, D. M. (1990). "Practice policies: Where do they come from?" The Journal of the American Medical Association **263**(9): 1265-1275.

Edwards, N., M. J. Kornacki and J. Silversin (2002). "Unhappy doctors: what are the causes and what can be done?" BMJ **324**(7341): 835-838.

Edwards, N. and M. Marshall (2003). "Doctors and managers: a constructive dialogue has to replace mutual suspicion." BMJ **326**(7381): 116-117.

Ellwood, P. M. (1988). "Outcomes management: A technology of patient experience." New England Journal of Medicine **318**(23): 1549-1556.

Exworthy, M. and S. Halford (1999). Professionals and managers in a changing public sector: conflict, compromise and collaboration? Professionals and the New Managerialism in the Public Sector. M. Exworthy and S. Halford. Buckingham & Philadelphia, Open University Press.

Fagerhaugh, S. Y., A. Strauss, B. Suczek and C. L. Wiener (1987). Hazards in hospital care: ensuring patient safety. San Francisco, Jossey-Bass.

Fillingham, D. (2007). "Can lean save lives?" Leadership in Health Services? **20**(4): 231-241.

Fisher, B. (1999). "From Halsted to prevention and beyond: Advances in the management of breast cancer during the twentieth century." European Journal of Cancer **35**(14): 1963-1973.

Flanagan, J. (1954). "The Critical Incident Technique." Psychological Bulletin **51**(4): 327-358.

Flynn, R. (1999). Managerialism, professionalism, and quasi-markets. Professionals and the New Managerialism in the Public Sector. M. Exworthy and S. Halford. Buckingham & Philadelphia, Open University Press.

Flynn, R. (2002). "Clinical governance and governmentality." Health, Risk & Society **4**(2): 155-173.

Folli, H. L., R. L. Poole, W. E. Benitz and J. C. Russo (1987). "Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals." Pediatrics **79**(5): 718-722.

Fougere, G. (1993). Struggling for control: The state and the medical profession in New Zealand. The Changing Medical Profession: An International Perspective. F. W. Hafferty and J. B. McKinlay. New York & Oxford, Oxford University Press.

Fougere, G. (2001). "Transforming health sectors: new logics of organizing in the New Zealand health system." Social Science & Medicine **52**(8): 1233-1242.

Fourcade, A., J.-L. Blache, C. Grenier, J.-L. Bourgain and E. Minvielle (2011). "Barriers to staff adoption of a surgical safety checklist." BMJ Quality & Safety **21**(3): 191-197.

Fox, R. C. (1957). Training for Uncertainty. The Student Physician: Introductory Studies in the Sociology of Medical Education. R. K. Merton, G. G. Reader and P. L. Kendall. Cambridge, Massachusetts, Harvard University Press.

Fox, R. C. (2000). Medical uncertainty revisited. Handbook of Social Studies in Health and Medicine. G. L. Albrecth, R. Fitzpatrick and S. C. Scrimshaw. London, Sage.

Francis, R. (2010). Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 – March 2009 Volume I London.

Francis, R. (2013). Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London, The Stationary Office.

Freidson, E. (1970a). Profession of medicine: a study of the sociology of applied knowledge. New York, Dodd, Mead & Company.

Fuchs, V. R. (1968). "The Growing Demand for Medical Care." New England Journal of Medicine **279**(4): 190-195.

Gaba, D. M. (2000). "Structural and organizational issues in patient safety: A comparison of health care to other high-hazard industries." California Management Review **43**(1): 83-102.

Gabe, J., D. Kelleher and G. Williams (2006). Understanding medical dominance in the modern world. Challenging Medicine (Second Edition). D. Kelleher, J. Gabe and G. Williams. London & New YorK, Routledge.

Gardezi, F., L. Lingard, S. Espin, S. Whyte, B. Orser and G. R. Baker (2009). "Silence, power and communication in the operating room." Journal of Advanced Nursing **65**(7): 1390-1399.

Gauld, R. (2009a). Revolving Doors: New Zealand's Health Reforms - The Continuing Saga (Second Edition). Wellington, Health Services Research Centre and Institute of Policy Studies.

Gauld, R. (2009b). "Improving New Zealand's health system performance: Challenges for the way forward." Eurohealth **15**(3): 32-35.

Gauld, R. (2012). "New Zealand's post-2008 health system reforms: Toward re-centralization of organizational arrangements." Health Policy **106**(2): 110-113.

Gauld, R., S. Al-wahaibi, J. Chisholm, R. Crabbe, B. Kwon, T. Oh, R. Palepu, N. Rawcliffe and S. Sohn (2011). "Scorecards for health system performance assessment: The New Zealand example." Health Policy **103**(2–3): 200-208.

Gauld, R. and S. Horsburgh (2012a). Clinical Governance Assessment Project: Final Report on a National Health Professional Survey and Site Visits to 19 New Zealand DHBs. Dunedin, Centre for Health Systems, University of Otago.

Gauld, R. and S. Horsburgh (2012b). Clinical Governance Assessment Project: Analysis of Three Quality and Safety Questions in a National Survey of New Zealand Health Professionals. Dunedin, Centre for Health Systems, University of Otago.

Gauld, R. and S. Horsburgh (2015). "Healthcare professionals' perceptions of clinical governance implementation: a qualitative New Zealand study of 3205 open-ended survey comments." BMJ Open **5**(1): 1-7.

Gauld, R., S. Horsburgh and J. Brown (2011). "The clinical governance development index: results from a New Zealand study." BMJ Quality & Safety **20**(11): 947-952.

Gilbert, B. J., E. Clarke and L. Leaver (2014). "Morality and markets in the NHS." International Journal of Health Policy and Management **3**(3): 371-376.

Gillespie, B. M., W. Chaboyer, M. Wallis and C. Fenwick (2010). "Why isn't 'time out' being implemented? An exploratory study." Quality and Safety in Health Care **19**(2): 103-106.

Glasgow, J. M., J. R. Scott-Caziewell and P. J. Kaboli (2010). "Guiding Inpatient Quality Improvement: A Systematic Review of Lean and Six Sigma." Joint Commission Journal on Quality and Safety **36**(12): 533-540.

Goffman, E. (1956). The Presentation of Self in Everyday Life Edinburgh, University of Edinburgh.

Goran, M. J. (1979). "The Evolution of the PSRO Hospital Review System." Medical Care **17**(5): i-47.

Goran, M. J., J. S. Roberts, M. A. Kellogg, J. Fielding and W. Jessee (1975). "The PSRO Hospital Review System." Medical Care **13**(4): 1-33.

Gordon, S. C. (2012). "Ask me if I cleaned my hands." The Journal of the American Medical Association **307**(15): 1591-1592.

Gosbee, J. and L. Lin (2001). The role of human factors engineering in medical device and medical system errors. Clinical Risk Management: Enhancing Patient Safety. C. Vincent. London, BMJ Publishing Group.

Graber, M. L. (2013). "The incidence of diagnostic error in medicine." BMJ Quality & Safety **22**(Suppl 2): ii21-ii27.

Greenhalgh, T., J. Howick and N. Maskrey (2014). "Evidence based medicine: a movement in crisis." BMJ **348**(3725): 1-7.

Greenhalgh, T., G. Robert, F. Macfarlane, P. Bate and O. Kyriakidou (2004). "Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations." Milbank Quarterly **82**(4): 581-629.

Greenwood, R. (2007). Organization theory. Blackwell encyclopedia of sociology. G. Ritzer. Malden, Massacheusetts, Blackwell Publishing.

Grol, R. and J. Grimshaw (2003). "From best evidence to best practice: effective implementation of change in patients' care." The Lancet **362**(9391): 1225-1230.

Grol, R. and M. Wensing (2013). Implementation of change in healthcare: a complex problem. Improving Patient Care. R. Grol, M. Wensing, M. Eccles and D. Davis. Chichester, West Sussex, Wiley-Blackwell/BMJ Books.

Gross, P. A., S. Greenfield, S. Cretin, J. Ferguson, J. Grimshaw, R. Grol, N. Klazinga, W. Lorenz, G. S. Meyer, C. Riccobono, S. C. Schoenbaum, P. Schyve and C. Shaw (2001). "Optimal Methods for Guideline Implementation: Conclusions From Leeds Castle Meeting." Medical Care **39**(8): II-85-II-92.

Guba, E. G. and Y. S. Lincoln (2005). Paradigmatic controversies, contradictions, and emerging confluences. The Sage Handbook of Qualitative Research. N. K. Denzin and Y. S. Lincoln. Thousand Oaks, Sage Publications.

Gubb, J. (2009). "Have Targets Done More Harm than Good in the English NHS? Yes." BMJ **338**(7692): 442-443.

Gubrium, J. F. and J. A. Holstein (1997). The New Language of Qualitative Method. New York, Oxord University Press.

Guest, G., A. Bunce and L. Johnson (2006). "How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability." Field Methods **18**(1): 59-82.

Hackbarth, A. D., C. J. McCannon, L. Martin, R. Lloyd and D. R. Calkins (2006). "The hard count: Calculating lives saved in the 100,000 Lives Campaign." ACP Guide for Hospitalists **April**: 1 - 5.

Hakim, C. (1987). Research Design: Strategies and Choices in the Design of Social Research. London, Allen & Unwin.

Hall, R. H. (1996). Organizations: Structures, Processes, and Outcomes (sixth edition). Englewood Cliffs, New Jersey, Prentice Hall.

Ham, C. (2010a). "Improving performance in the English National Health Service." Eurohealth **16**(3): 23-25.

Ham, C. (2010b). "Improving the performance of the English NHS." BMJ **340**.

Harmfreecare. (2015). "NHS Safety Thermometer." Retrieved 22 April 2015, from http://harmfreecare.org/measurement/.

Harrison, S. (2002). "New Labour, Modernisation and the Medical Labour Process." Journal of Social Policy **31**(03): 465-485.

Harrison, S. (2004). Medicine and management: Autonomy and authority in the National Health Service. Governing Medicine: Theory and Practice. A. Gray and S. Harrison. Berkshire, Open University Press.

Harrison, S. and W. I. U. Ahmad (2000). "Medical Autonomy and the UK State 1975 to 2025." Sociology **34**(1): 129-146.

Harrison, S. and K. Checkland (2009). Evidence-based practice in UK health policy. The New Sociology of the Health Service. J. Gabe and M. Calnan. London and New York, Routledge.

Harrison, S., M. Moran and B. Wood (2002). "Policy emergence and policy convergence: the case of 'scientific-bureaucratic medicine' in the United States and United Kingdom." The British Journal of Politics & International Relations **4**(1): 1-24.

Haxby, E., D. J. Hunter and S. Jaggar (2010). An Introduction to Clinical Governance and Patient Safety. Oxford, Oxford University Press.

Haynes, A. B., T. G. Weiser, W. R. Berry, S. R. Lipsitz, A.-H. S. Breizat, E. P. Dellinger, T. Herbosa, S. Joseph, P. L. Kibatala, M. C. M. Lapitan, A. F. Merry, K. Moorthy, R. K. Reznick, B. Taylor and A. A. Gawande (2009). "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population." New England Journal of Medicine **360**(5): 491-499.

Hayward, R. A. and T. P. Hofer (2001). "Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer." The Journal of the American Medical Association **286**(4): 415-420.

Health Quality and Safety Commission (2012a). New Zealand Health and Disability Services – National Reportable Events Policy 2012. Wellington, Health Quality and Safety Commission.

Health Quality and Safety Commission (2012b). Severity assessment criteria tables. Health Quality and Safety Commission. Wellington.

Health Quality and Safety Commission (2014). Making health and disability services safer: Serious adverse events reported to the Health Quality & Safety Commission 1 July 2013 to 30 June 2014. Wellington, Health Quality and Safety Commission.

Health Quality and Safety Commission. (2015). "Our Programmes." Retrieved 23 April 2015, from http://www.hqsc.govt.nz/our-programmes/.

Healthcare Commission (2009). Investigation into Mid Staffordshire NHS Foundation Trust, Commission for Healthcare Audit and Inspection.

Hendrick, H. W. (2011). Historical Perspective and Overview of Macroergonomics. Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, Second Edition, CRC Press**:** 45-64.

Hewett, D. G., B. M. Watson, C. Gallois, M. Ward and B. A. Leggett (2009). "Intergroup communication between hospital doctors: Implications for quality of patient care." Social Science & Medicine **69**(12): 1732-1740.

Hilligoss, B. and S. D. Moffatt-Bruce (2014). "The limits of checklists: handoff and narrative thinking." BMJ Quality & Safety **23**(7): 528-533.

Hillman, A., W. Tadd, S. Calnan, M. Calnan, A. Bayer and S. Read (2013). "Risk, governance and the experience of care." Sociology of Health and Illness **35**(6): 939-955.

Hirschtick, R. E. (2012). "John Lennon's elbow." The Journal of the American Medical Association **308**(5): 463-464.

Hoddinott, B. C., C. W. Gowdey, W. K. Coulter and J. M. Parker (1967). "Drug reactions and errors in administration on a medical ward." Canadian Medical Association Journal **97**(17): 1001-1006.

Hogan, H., F. Healey, G. Neale, R. Thomson, C. Vincent and N. Black (2012). "Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study." BMJ Quality & Safety **21**(9): 737-745.

Holstein, J. A. and J. F. Gubrium (2004). The active interview. Qualitative Research: Theory, Method and Practice. D. Silverman. London, Sage Publications.

Hunter, C., K. Spence and A. Scheinberg (2008). "'Untangling the web of critical incidents': Ethnography in a paediatric setting." Anthropology & Medicine **15**: 91-103.

Hunter, D. J. (2006). From tribalism to corporatism: The continuing managerial challenge to medical dominance. Challenging Medicine (Second Edition). D. Kelleher, J. Gabe and G. Williams. London & New York, Routledge.

Iedema, R., A. Flabouris, S. Grant and C. Jorm (2006). "Narrativizing errors of care: Critical incident reporting in clinical practice." Social Science & Medicine **62**(1): 134-144.

Iedema, R., C. Jorm and J. Braithwaite (2008). "Managing the scope and impact of root cause analysis recommendations." Journal of Health Organization and Management **22**(6): 569-585.

Iedema, R., C. Jorm and M. Lum (2009). "Affect is central to patient safety: The horror stories of young anaesthetists." Social Science & Medicine **69**(12): 1750-1756.

Iedema, R. A. M., C. Jorm, J. Braithwaite, J. Travaglia and M. Lum (2006b). "A root cause analysis of clinical error: Confronting the disjunction between formal rules and situated clinical activity." Social Science & Medicine **63**: 1201-1212.

Iedema, R. A. M., C. Jorm, D. Long, J. Braithwaite, J. Travaglia and M. Westbrook (2006a). "Turning the medical gaze in upon itself: Root cause analysis and the investigation of clinical error." Social Science & Medicine **62**(7): 1605-1615.

IHI (2013). Evaluation of five million lives campaign. Email sent to Peter Beaver 15 March.

IHI. (2015). "5 Million Lives Campaign." Retrieved 20 March 2015, from http://www.ihi.org/offerings/Initiatives/PastStrategicInitiatives/5MillionLivesCampaign/Pages/default.aspx.

Illingworth, J. (2015). Is the NHS getting safer? London, The Health Foundation.

International Ergonomics Association. (2014). "What is ergonomics." Retrieved 3 July, 2014, from http://www.iea.cc/whats/index.html.

Itoh, K., H. B. Anderson and M. D. Madsen (2011). Safety Culture in Health care. Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, Second Edition, CRC Press**:** 133-162.

Ivers, N., G. Jamtvedt, S. Flottorp, J. M. Young, J. Odgaard-Jensen, S. D. French, M. A. O'Brien, M. Johansen, J. Grimshaw and A. D. Oxman (2012). Audit and feedback: effects on professional practice and healthcare outcomes (Review), The Cochrane Collaboration.

James, J. T. (2013). "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care." Journal of Patient Safety **9**(3): 122-128.

Jarman, B. (2010). Common themes from three US reports on standards and quality of care in the NHS submitted to the Department of Health in England www.ajustnhs.com.

Jarman, B. (2012). "When managers rule." BMJ **345**: 1-2.

Jencks, S. F. and G. R. Wilensky (1992). "The health care quality improvement initiative: A new approach to quality assurance in medicare." The Journal of the American Medical Association **268**(7): 900-903.

Jensen, C. B. (2008). "Sociology, systems and (patient) safety: knowledge translations in healthcare policy." Sociology of Health & Illness **30**(2): 309-324.

Jha, A. and D. C. Classen (2011). "Getting Moving on Patient Safety — Harnessing Electronic Data for Safer Care." New England Journal of Medicine **365**(19): 1756-1758.

Jick, H. (1984). "Adverse drug reactions: The magnitude of the problem." Journal of Allergy and Clinical Immunology **74**(4, Part 2): 555-557.

Jick, H., O. Miettinen, S. Shapiro, G. Lewis, V. Siskind and D. Slone (1970). "Comprehensive Drug Surveillance." The Journal of the American Medical Association **213**(9): 1455-1460.

Johnson, C. W. (2011). Human Factors Engineering of Health Care Reporting Systems. Handbook of Human Factors and Ergonomics in Health Care and Patient Safety, Second Edition, CRC Press**:** 423-448.

Jones, K. J., A. M. Skinner, R. High and R. Reiter-Palmon (2013). "A theory-driven, longitudinal evaluation of the impact of team training on safety culture in 24 hospitals." BMJ Quality & Safety **22**: 394-404.

Jones, P. and K. Schimanski (2010). "The four hour target to reduce emergency department 'waiting time': A systematic review of clinical outcomes." Emergency Medicine Australasia **22**(5): 391-398.

Jones, P., E. Sopina and T. Ashton (2014). "Resource implications of a national health target: The New Zealand experience of a Shorter Stays in Emergency Departments target." Emergency Medicine Australasia **26**(6): 579-584.

Joosten, T., I. Bongers and R. Janssen (2009). "Application of lean thinking to health care: issues and observations." International Journal for Quality in Health Care **21**(5): 341-347.

Jorm, C. and P. Kam (2004). "Does medical culture limit doctors' adoption of quality improvement? Lessons from Camelot." Journal of Health Services Research & Policy **9**(4): 248-251.

Jorm, C., J. Travaglia and R. Iedema (2007). "Why Do Doctors Not Engage with the System?". The Discourse of Hospital Communication: Tracing Complexities in Contemporary Health Care Organizations. R. Iedema. New York, Palgrave MacMillan.

Joseph, A. C. and S.-C. Olivier (2012). "From Discovery to Design: The Evolution of Human Factors in Healthcare." Healthcare Quarterly **15**(Special Issue): 24-29.

Kanuha, V. K. (2000). ""'Being" native versus "going native": Conducting social work research as an insider." Social Work **45**(5): 439-447.

Kaplan, G. S., S. H. Patterson, J. M. Ching and C. C. Blackmore (2014). "Why Lean doesn't work for everyone." BMJ Quality & Safety **23**(12): 970-973.

Karch, F. E. and L. Lasagna (1975). "Adverse drug reactions - a critical review." Journal of the American Medical Association **234**(12): 1236-1241.

Keats, A. S. (1979). "What do we know about anesthetic mortality?" Anesthesiology **50**(5): 387-392.

Kelman, S. and J. N. Friedman (2009). "Performance Improvement and Performance Dysfunction: An Empirical Examination of Distortionary Impacts of the Emergency Room Wait-Time Target in the English National Health Service." Journal of Public Administration Research and Theory **19**(4): 917-946.

Kenny, C. (2008). The Best Practice: How the New Quality Movement is Transforming Medicine. New York, Public Affairs.

Keogh, B. (2013). "Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report."

Khorsandi, M., C. Skouras, K. Beatson and A. Alijani (2012). "Quality review of an adverse incident reporting system and root cause analysis of serious adverse surgical incidents in a teaching hospital of Scotland." Patient Safety in Surgery **6**(21): 1-6.

Klein, R. (2013). "The Twenty-Year War over England's National Health Service: A Report from the Battlefield." Journal of Health Politics, Policy and Law **38**(4): 849-869.

Kohn, L. T., J. M. Corrigan and M. S. Donaldson, Eds. (2000). To Err is Human: Building a Safer Healthcare System. Washington D. C., National Academy Press.

Kopp, B. J., B. L. Erstad, M. E. Allen, A. A. Theodorou and G. Priestley (2006). "Medication errors and adverse drug events in an intensive care unit: Direct observation approach for detection." Critical Care Medicine **34**(2): 415-425.

Kovner, C. and P. J. Gergen (1998). "Nurse Staffing Levels and Adverse Events Following Surgery in U.S. Hospitals." Journal of Nursing Scholarship **30**(4): 315-321.

Kritchevsky, S. B. and B. P. Simmons (1991). "Continuous quality improvement: concepts and applications for physician care." The Journal of the American Medical Association **266**(13): 1817-1823.

Lambert, H. (2006). "Accounting for EBM: Notions of evidence in medicine." Social Science & Medicine **62**(11): 2633-2645.

Landrigan, C. P., G. J. Parry, C. B. Bones, A. D. Hackbarth, D. A. Goldmann and P. J. Sharek (2010). "Temporal Trends in Rates of Patient Harm Resulting from Medical Care." New England Journal of Medicine **363**(22): 2124-2134.

Leape, L., D. Berwick, C. Clancy, J. Conway, P. Gluck, J. Guest, D. Lawrence, J. Morath, D. O'Leary, P. O'Neill, D. Pinakiewicz and T. Isaac (2009). "Transforming healthcare: a safety imperative." Quality and Safety in Health Care **18**(6): 424-428.

Leape, L. L. (1994). "Error in Medicine." The Journal of the American Medical Association **272**(23): 1851-1857.

Leape, L. L. (2000). "Institute of Medicine Medical Error Figures Are Not Exaggerated." The Journal of the American Medical Association **284**(1): 95-97.

Leape, L. L., D. W. Bates, D. J. Cullen, J. Cooper, H. J. Demonaco, T. Gallivan, R. Hallisey, J. Ives, N. Laird, G. Laffel, R. Nemeskal, L. A. Petersen, K. Porter, D. Servi, B. F. Shea, S. D. Small, B. J. Sweitzer, B. T. Thompson, M. Vander Vliet, A. P. S. Group, D. Bates, P. Hojnowski-Diaz, S. Petrycki, M. Cotugno, H. Patterson, M. Hickey, S. Kleefield, E. Kinneally, M. D. Clapp, J. R. Hackman and A. Edmondson (1995). "Systems Analysis of Adverse Drug Events." The Journal of the American Medical Association **274**(1): 35-43.

Leape, L. L. and D. M. Berwick (2005). "Five Years After To Err Is Human: What Have We Learned?" The Journal of the American Medical Association **293**(19): 2384-2390.

Leape, L. L., D. M. Berwick and D. W. Bates (2002). "What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety." The Journal of the American Medical Association **288**(4): 501-507.

Leape, L. L., D. J. Cullen, M. D. Clapp, E. Burdick, H. J. Demonaco, J. I. Erickson and D. W. Bates (1999). "Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit." The Journal of the American Medical Association **282**(3): 267-270.

Leatherman, S. and K. Sutherland (2008). The Quest for Quality: Refining the NHS Reforms - A Policy Analysis and Chartbook. London, The Nuffield Trust.

Lembcke, P. A. (1967). "Evolution of the medical audit." The Journal of the American Medical Association **199**(8): 111-118.

Light, D. (1979). "Uncertainty and Control in Professional Training." Journal of Health and Social Behavior **20**(4): 310-322.

Light, D. (1995). Countervailing powers: a framework for professionals in transition. Health Professionals and the State in Europe. T. Johnson, G. Larkin and M. Saks. London & New York, Routledge.

Light, D. (2008). "Will the NHS strategic plan benefit patients?" BMJ **337**: 210-212.

Light, D. (2010). Health-care professions, markets, and countervailing powers. Handbook of Medical Sociology, Sixth Edition. C. E. Bird, P. Conrad, A. M. Fremont and S. Timmermans. Nashville, TN, Vanderbilt University Press.

Ling, T., B. Soper, M. Buxton, S. Hanney, W. Oortwijn, A. Scoggins and N. Steel (2007). An Evaluation of The Health Foundation's Engaging with Quality Initiative. London, The Health Foundation.

Ling, T., B. Soper, M. Buxton, S. Hanney, W. Oortwijn, A. Scoggins and N. Steel (2010). How do you get clinicians involved in quality improvement: An evaluation of the Health Foundation's Engaging with Quality Initiative - a programme of work to support clinicians to drive quality forward. London, The Health Foundation.

Loeb, J. M. (2004). "The current state of performance measurement in health care." International Journal for Quality in Health Care **16**(suppl 1): i5-i9.

Lohr, K. N. and R. H. Brook (1984a). "Quality assurance in medicine." American Behavioral Scientist **27**(5): 583-607.

Lohr, K. N. and R. H. Brook (1984b). Quality assurance in medicine: Experience in the public sector. Santa Monica, The Rand Corporation.

Lohr, K. N. and S. A. Schroeder (1990). "A Strategy for Quality Assurance in Medicare." New England Journal of Medicine **322**(10): 707-712.

MA. (2009). "NHS Modernisation Agency and Affiliated Programmes." Retrieved 16 April 2015, from http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4991386.

Macintosh, R. R. (1948). "Deaths under Anaesthetics." British Journal of Anaesthesia **21**: 107-136.

Macrae, C. (2014). "Early warnings, weak signals and learning from healthcare disasters." BMJ Quality & Safety **23**: 440-445.

Malcolm, L., L. Wright, P. Barnett and C. Hendry (2002). Clinical leadership and quality in District Health Boards in New Zealand. Wellington, Ministry of Health.

Mannion, R. and J. Braithwaite (2012). "Unintended consequences of performance measurement in healthcare: 20 salutary lessons from the English National Health Service." Internal Medicine Journal **42**(5): 569-574.

Marnoch, G. (1996). Doctors and Management in the National Health Service. Buckingham, Open University Press.

Marshall, M., P. Pronovost and M. Dixon-Woods (2013). "Promotion of improvement as a science." The Lancet **381**(9864): 419-421.

Maseide, P. (1990). "The Social Construction of Research Information." Acta Sociologica **33**(1): 3-13.

Mason, J. (2002). Qualitative Researching. London, Sage Publications.

McCannon, C. J., A. D. Hackbarth and F. A. Griffin (2007). "Miles to Go: An Introduction to the 5 Million Lives Campaign." Joint Commission Journal on Quality and Patient Safety **33**(8): 477-484.

McCannon, J. and D. M. Berwick (2011). "A new frontier in patient safety." The Journal of the American Medical Association **305**(21): 2221-2222.

McCulloch, P., A. Mishra, A. Handa, T. Dale, G. Hirst and K. Catchpole (2009). "The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre." Quality and Safety in Health Care **18**(2): 109-115.

McDonald, R., J. Waring and S. Harrison (2005). "'Balancing risk, that is my life': The politics of risk in a hospital operating theatre department." Health, Risk & Society **7**(4): 397-411.

McDonald, R., J. Waring and S. Harrison (2006). "Rules, safety and the narrativisation of identity: a hospital operating theatre case study." Sociology of Health & Illness **28**(2): 178-202.

McGlynn, E. A., S. M. Asch, J. Adams, J. Keesey, J. Hicks, A. DeCristofaro and E. A. Kerr (2003). "The Quality of Health Care Delivered to Adults in the United States." New England Journal of Medicine **348**(26): 2635-2645.

McGlynn, E. A. and R. H. Brook (2001). "Keeping Quality On The Policy Agenda." Health Affairs **20**(3): 82-90.

McGlynn, E. A., E. C. Schneider and E. A. Kerr (2014). "Reimagining Quality Measurement." New England Journal of Medicine **371**(23): 2150-2153.

McKee, M. (2013). "Improving the safety of patients in England." BMJ **347**: 1-2.

McKee, M. and N. Black (1992). "Does the current use of junior doctors in the United Kingdom affect the quality of medical care?" Social Science & Medicine **34**(5): 549-558.

McLellan, A., J. Middleton and F. Godlee (2012). "Lansley's NHS "reforms"." BMJ **344**.

Mealer, M., E. L. Burnham, C. J. Goode, B. Rothbaum and M. Moss (2009). "The prevalence and impact of post traumatic stress disorder and burnout syndrome in nurses." Depression and Anxiety **26**(12): 1118-1126.

Meyer, G. S., E. C. Nelson, D. B. Pryor, B. James, S. J. Swensen, G. S. Kaplan, J. I. Weissberg, M. Bisognano, G. R. Yates and G. C. Hunt (2012). "More quality measures versus measuring what matters: a call for balance and parsimony." BMJ Quality & Safety **21**(11): 964-968.

Meyer, J. A., S. Silow-Carroll, T. Kutyla, L. S. Stepnick and L. S. Rybowski (2004). Hospital Quality: Ingredients for Success - Overview and Lessons Learned. New York, The Commonwealth Fund.

Miller, J. and B. Glassner (2004). The "inside" and the "outside": Finding realities in interviews. Qualitative Research: Theory, Method and Practice. D. Silverman. London, Sage Publications.

Millman, M. (1977). The Unkindest Cut. New York, Morrow.

Mills, D. H. (1978). "Medical insurance feasibility study-A technical summary." Western Journal of Medicine **128**: 360-365.

Minister of Health (2000). The New Zealand Health Strategy. Wellington, Ministry of Health.

Minister of Health (2003). Improving quality (IQ): a systems approach for the New Zealand health and disability sector. Wellington, Ministry of Health.

Minister of Health (2003). IQ Action Plan: Supporting the Improving Quality Approach. Wellington, Ministry of Health.

Ministerial Review Group (2009). Meeting the Challenge: Enhancing Sustainability and the Patient and Consumer Experience within the Current Legislative Framework for Health and Disability Services in New Zealand.

Ministerial Task Group on Clinical Leadership (2009). In Good Hands - Transforming Clinical Governance in New Zealand.

Ministry of Health (2001). Toward clinical excellence: Learning from experience. Wellington, Ministry of Health.

Ministry of Health (2002). Toward clinical excellence: An introduction to clinical audit, peer review and other clinical practice improvement activities. Wellington, Ministry of Health.

Ministry of Health (2008). Briefing for the Incoming Minister of Health. Wellington, Ministry of Health.

Ministry of Health. (2010). "Quality Improvement Agency: Health Quality and Safety Commission: Functions, Powers and Funding." Retrieved 28 March 2013, from http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/quality-improvement-agency-health-quality-and-safety-commission-functions-powers-and-funding.

Ministry of Health (2013). Targeting Waiting Times. Wellington, Ministry of Health.

Ministry of Health. (2014). "About the health targets." accessed 14 June 2015, from http://www.health.govt.nz/new-zealand-health-system/health-targets/about-health-targets.

Minuck, M. (1967). "Death in the operating room." Canadian Journal of Anesthesia / Journal canadien d'anesthésie **14**(3): 197-204.

Mizrahi, T. (1984). "Managing medical mistakes: Ideology, insularity and accountability among internists-in-training." Social Science & Medicine **19**(2): 135-146.

Moser, R. H. (1956). "Diseases of medical progress." New England Journal of Medicine **255**(13): 606-614.

Mountford, J. and K. G. Shojania (2012). "Refocusing quality measurement to best support quality improvement: local ownership of quality measurement by clinicians." BMJ Quality & Safety **21**(6): 519-523.

Mundinger, M. O. (1999). Foreword. Florence Nightingale: Measuring Hospital Care Outcomes. Illinois, Joint Commission on Accreditation of Healthcare Organizations.

Nabhan, M., T. Elraiyah, D. R. Brown, J. Dilling, A. LeBlanc, V. M. Montori, T. Morgenthaler, J. Naessens, L. Prokop, V. Roger, S. Swensen, R. L. Thompson and M. H. Murad (2012). "What is preventable harm in healthcare? A systematic review of definitions." BMC Health Services Research **12**(128).

National Advisory Group (2013). A Promise to Learn – A Commitment to Act, National Advisory Group on the Safety of Patients in England.

National Institute for Clinical Excellence (2002). Principles for Best Practice in Clinical Audit. Abingdon, Radcliffe Medical Press.

Natof, H. E. and M. S. Sadove (1958). Cardiovascular Collapse in the Operating Room. Philadelphia, J. B. Lippincott.

Navarro, V. (1989). "Why some countries have national health insurance, others have national health services, and the United States has neither." International Journal of Health Services **19**(3): 383-404.

Neale, G., C. Vincent and A. Darzi (2007). "The problem of engaging hospital doctors in promoting safety and quality in clinical care." The Journal of the Royal Society for the Promotion of Health **127**(2): 87-94.

Neuhauser, D. (1999). Preface. Florence Nightingale: Measuring Hospital Care Outcomes. Illinois, Joint Commission on Accreditation of Healthcare Organizations.

NHS England. (2015a). "About Sign up to Safety." Retrieved 2 April 2015, from http://www.england.nhs.uk/signuptosafety/about/.

NHS England. (2015b). "5,000 Safety Fellows." 22 April 2014, from http://www.england.nhs.uk/ourwork/patientsafety/fellows/.

NHS III. (2013a). "Helen Bevan on Setting Improvement Goals." Retrieved 16 April 2015, from http://www.institute.nhs.uk/index.php?option=com_content&task=view&id=61&Itemid=24.

NHS Improving Quality. (2014). "Announcement of the Patient Safety Collaborative Programme." Retrieved 2 April 2015, from http://www.nhsiq.nhs.uk/news-events/news/announcement-of-the-patient-safety-collaborative-programme.aspx.

NHS Modernisation Board (2002). The NHS Plan - A Progress Report. The NHS Modernisation Board's Annual Report 2000-2001. Department of Health, London.

Nicolay, C. R., S. Purkayastha, A. Greenhalgh, J. Benn, S. Chaturvedi, N. Phillips and A. Darzi (2012). "Systematic review of the application of quality improvement methodologies from the manufacturing industry to surgical healthcare." British Journal of Surgery **99**(3): 324-335.

Nicolini, D., J. Waring and J. Mengis (2011a). "Policy and practice in the use of root cause analysis to investigate clinical adverse events: Mind the gap." Social Science & Medicine **73**(2): 217-225.

Nicolini, D., J. Waring and J. Mengis (2011b). "The challenges of undertaking root cause analysis in health care: a qualitative study." Journal of Health Services Research & Policy **16**(suppl 1): 34-41.

Nightingale, F. (1863). Notes on Hospitals (third edition). London, Longman, Green, Longman, Roberts, and Green.

NPSA (2004a). Seven Steps to Patient Safety: The Full Reference Guide, National Patient Safety Institute.

NPSA (2004b). Ready, steady, go! - The full guide to implementing the cleanyourhands campaign in your trust, National Patient Safety Agency.

NPSA. (2011a). "About the cleanyourhands campaign." Retrieved 27 March 2015, from http://www.npsa.nhs.uk/cleanyourhands/about-us/.

NPSA (2011b). Patient Safety First: 2008 to 2010 the Campaign Review. http://www.patientsafetyfirst.nhs.uk/Content.aspx?path=/Campaign-news/current/campaign-review/, National Patient Safety Agency.

Nuffield Trust (2010). The Coalition Government's NHS reforms: an assessment of the White Paper. London, The Nuffield Trust.

O'Leary, D. S. (1988). "Quality assessment moving from theory to practice." The Journal of the American Medical Association **260**(12): 1760-1760.

Office of the Inspector General (2010). Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Rockville, M. D., Department of Health and Human Services.

Orlander, J. D., T. W. Barber and B. G. Fincke (2002). "The Morbidity and Mortality Conference: The Delicate Nature of Learning from Error." Academic Medicine **77**(10): 1001-1006.

Øvretveit, J., P. Bate, P. Cleary, S. Cretin, D. Gustafson, K. McInnes, H. McLeod, T. Molfenter, P. Plsek, G. Robert, S. Shortell and T. Wilson (2002). "Quality collaboratives: lessons from research." Quality and Safety in Health Care **11**(4): 345-351.

Paget, M. A. (1988). The Unity of Mistakes: A Phenomenological Interpretation of Medical Work. Philadelphia, Temple University Press.

Papadopoulos, T. and Y. Merali (2008). "Stakeholder Network Dynamics and Emergent Trajectories of Lean Implementation Projects: A Study in the UK National Health Service." Public Money & Management **28**(1): 41-48.

Patterson, M. D., G. L. Geis, T. LeMaster and R. L. Wears (2013). "Impact of multidisciplinary simulation-based training on patient safety in a paediatric emergency department." BMJ Quality & Safety **22**: 383-393.

Percival, T. (1803). Medical Ethics; or A Code of Institutes and Precepts, adapted to the Professional Conduct of Physicians and Surgeons. Manchester, S. Russell.

Perrow, C. (1984). Normal Accidents: Living with High-Risk Technologies. New York, Basic Books.

Pierce, E. C. (1996). "40 years behind the mask: Safety revisited." Anesthesiology **84**: 965-975.

Plsek, P. E. and T. Greenhalgh (2001). "The challenge of complexity in health care." BMJ **323**(7313): 625-628.

Pope, C. (2002). "Contingency in everyday surgical work." Sociology of Health & Illness **24**(4): 369-384.

Powell, A. E., R. K. Rushmer and H. T. O. Davies (2008). A Systematic Narrative Review of Quality Improvement Models in Healthcare. Edinburgh, NHS Quality Improvement Scotland.

Powell, I. (2010). New Zealand Medical Specialist workforce hits international rock bottom. The Specialist, Association of Salaried Medical Specialists**:** 1-2.

Powell, I. (2011). Is our health leadership in a state of kef? The Specialist, Association of Salaried Medical Specialists**:** 1-3.

Powell, I. (2013a). Was Winston Churchill wrong? The Specialist, Association of Salaried Medical Specialists**:** 5-6.

Powell, I. (2013b). E-grade for DHBs over support for distributive clinical leadership. The Specialist, Association of Salaried Medical Specialists**:** 1-2.

Powell, I. (2014). DHBs FAILING over distributive clinical leadership. The Specialist, Association of Salaried Medical Specialists**:** 1-3.

Pronovost, P. J. and G. W. Bo-Linn (2012). "Preventing patient harms through systems of care." The Journal of the American Medical Association **308**(8): 769-770.

Pronovost, P. J., C. A. Goeschel, E. Colantuoni, S. Watson, L. H. Lubomski, S. M. Berenholtz, D. A. Thompson, D. J. Sinopoli, S. Cosgrove, J. B. Sexton, J. A. Marsteller, R. C. Hyzy, R. Welsh, P. Posa, K. Schumacher and D. Needham (2010). "Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study." BMJ **340**: c309.

Pronovost, P. J. and R. Lilford (2011). "A Road Map For Improving The Performance Of Performance Measures." Health Affairs **30**(4): 569-573.

Pronovost, P. J. and R. M. Wachter (2013). "Progress in Patient Safety: A Glass Fuller Than It Seems." American Journal of Medical Quality.

Quam, L. (1989). "Improving clinical effectiveness in the NHS: an alternative to the white paper." BMJ **299**(6696): 448-450.

Radnor, Z. J., M. Holweg and J. Waring (2012). "Lean in healthcare: The unfilled promise?" Social Science & Medicine **74**(3): 364-371.

Rapley, T. (2007). Interviews. Qualitative Reserach Practice. C. Seale, G. Gobo, J. Gubrium and D. Silverman. London, Sage Publications.

Reason, J. (1990). Human Error. Cambridge and Massachusetts, Cambridge University Press.

Reason, J. (1997). Managing the Risks of Organizational Accidents. Farnham and Burlington, Ashgate.

Reason, J. (2000). "Human error: models and management." BMJ **320**(7237): 768-770.

Reason, J. (2001). Understanding Adverse Events: Human Factors. Clinical Risk Management: Enhancing Patient Safety. C. A. Vincent. London, BMJ Publishing Group.

Reason, J. (2004). "Beyond the organisational accident: the need for “error wisdom” on the frontline." Quality and Safety in Health Care **13**(suppl 2): ii28-ii33.

Relman, A. S. (1988). "Assessment and Accountability." New England Journal of Medicine **319**(18): 1220-1222.

Reverby, S. (1981). "Stealing the golden eggs: Ernest Amory Codman and the science and management of medicine." Bulletin of the History of Medicine **55**(2): 156-171.

Robb, G. and M. Seddon (2010). "Measuring the safety culture in a hospital setting: a concept whose time has come?" Journal of the New Zealand Medical Association **123**(1314): 66-76.

Roberts, J. S., J. G. Coale and R. R. Redman (1987). "A history of the joint commission on accreditation of hospitals." The Journal of the American Medical Association **258**(7): 936-940.

Rogers, J. and D. Gaba (2011). "Have we gone too far in translating ideas from aviation to patient safety?" BMJ **342**: 198-199.

Roland, M. and R. Rosen (2011). "English NHS Embarks on Controversial and Risky Market-Style Reforms in Health Care." New England Journal of Medicine **364**(14): 1360-1366.

Romney, A. K., S. C. Weller and W. H. Batchelder (1986). "Culture as Consensus: A Theory of Culture and Informant Accuracy." American Anthropologist **88**(2): 313-338.

Rubin, H. R., W. H. Rogers, K. L. Kahn, L. V. Rubenstein and R. H. Brook (1992). "Watching the doctor-watchers: How well do peer review organization methods detect hospital care quality problems?" The Journal of the American Medical Association **267**(17): 2349-2354.

Sackett, D. L. and W. M. C. Rosenberg (1995). "On the need for evidence-based medicine." Journal of Public Health Medicine **17**(3): 330-334.

Salas, E., S. A. Almeida, M. Salisbury, H. King, E. H. Lazzara, R. Lyons, K. A. Wilson, P. A. Almeida and R. McQuillan (2009). "What Are the Critical Success Factors for Team Training in Health Care?" The Joint Commission Journal on Quality and Patient Safety **35**(8): 398-405.

Salas, E. and M. A. Rosen (2013). "Building high reliability teams: progress and some reflections on teamwork training." BMJ Quality & Safety **22**: 369-373.

Salter, B. (2007). "Governing UK medical performance: A struggle for policy dominance." Health Policy **82**(3): 263-275.

Sanazaro, P. J. and D. H. Mills (1991). "A critique of the use of generic screening in quality assessment." The Journal of the American Medical Association **265**(15): 1977-1981.

Sandelowski, M. (1995). "Sample size in qualitative research." Research in Nursing & Health **18**(2): 179-183.

Savage, G. T. and E. S. Williams (2007). Performance Improvement in Health Care: The Quest to Achieve Quality. Introduction to Health Care Management. S. B. Buchbinder and N. H. Shanks. Sudbury, Jones and Bartlett.

Scally, G. and L. J. Donaldson (1998). "Clinical governance and the drive for quality improvement in the new NHS in England." BMJ **317**: 61-65.

Schimmel, E. M. (1964). "The Hazards of Hospitalization." Annals of Internal Medicine **60**(1): 100-110.

Schouten, L., M. Hulscher, J. Everdingen, R. Huijsman and R. Grol (2008). "Evidence for the impact of quality improvement collaboratives: systematic review." BMJ **336**(7659): 1491-1494.

Schulman, P. R. (2004). "General attributes of safe organisations." Quality and Safety in Health Care **13**(Supplement II): ii39-ii44.

Scott, W. R. (1992). Organizations: Rational, Natural and Open Systems (Third Edition). New Jersey, Prentice Hall.

Scott, W. R. (2001). Organization: Overview. International Encyclopedia of the Social & Behavioral Sciences. J. S. Neil and B. B. Paul. Oxford, Pergamon**:** 10910-10917.

Scott, W. R. (2004). "Reflections on a Half-Century of Organizational Sociology." Annual Review of Sociology **30**(1): 1-21.

Seale, C., G. Gobo, J. Gubrium and D. Silverman (2007). Introduction: Inside qualitative research practice. Qualitative Research Practice. C. Seale, G. Gobo, J. Gubrium and D. Silverman. London, Sage Publications.

Seddon, M. (2007). Safety of patients in New Zealand hospitals: A progress report. Wellington, Health & Disability Commissioner.

Senders, J. W. (1994). Medical devices, medical errors, and medical accidents. Human Error in Medicine. M. S. Bogner. New Jersey, Lawrence Erlbaum Associates.

Sharpe, V. A. (2000). "Behind Closed Doors: Accountability and Responsibility in Patient Care." Journal of Medicine and Philosophy **25**(1): 28-47.

Sharpe, V. A. and A. I. Faden (1998). Medical Harm: Historical, Conceptual, and Ethical Dimensions of Iatrogenic Illness. Cambridge, Cambridge University Press.

Shekelle, P. G., P. J. Pronovost, R. M. Wachter, K. M. McDonald, K. Schoelles, S. M. Dy, K. Shojania, J. T. Reston, A. S. Adams, P. B. Angood, D. W. Bates, L. Bickman, P. Carayon, L. Donaldson, N. Duan, D. O. Farley, T. Greenhalgh, J. L. Haughom, E. Lake, R. Lilford, K. N. Lohr, G. S. Meyer, M. R. Miller, D. V. Neuhauser, G. Ryan, S. Saint, S. M. Shortell, D. P. Stevens and K. Walshe (2013). "The Top Patient Safety Strategies That Can Be Encouraged for Adoption Now." Annals of Internal Medicine **158**(5_Part_2): 365-368.

Shekelle, P. G., P. J. Pronovost, R. M. Wachter, S. L. Taylor, S. M. Dy, R. Foy, S. Hempel, K. M. McDonald, J. Øvretveit, L. V. Rubenstein, A. S. Adams, P. B. Angood, D. W. Bates, L. Bickman, P. Carayon, S. L. Donaldson, N. Duan, D. O. Farley, T. Greenhalgh, J. Haughom, E. T. Lake, R. Lilford, K. N. Lohr, G. S. Meyer, M. R. Miller, D. V. Neuhauser, G. Ryan, S. Saint, K. G. Shojania, S. Shortell, D. P. Stevens and K. Walshe (2011). "Advancing the Science of Patient Safety." Annals of Internal Medicine **154**(10): 693-696.

Shekelle, P. G., R. M. Wachter, P. J. Pronovost, K. Schoelles, K. M. McDonald, S. M. Dy, K. Shojania, J. Reston, Z. Berger, B. Johnsen, J. W. Larkin, S. Lucas, K. Martinez, A. Motala, S. J. Newberry, M. Noble, E. Pfoh, S. R. Ranji, S. Rennke, E. Schmidt, R. Shanman, N. Sullivan, F. Sun, K. Tipton, J. R. Treadwell, A. Tsou, M. E. Vaiana, S. J. Weaver, R. Wilson and B. D. Winters (2013). Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Rockville, MD, Agency for Healthcare Research and Quality.

Shojania, K. (2012). "Deaths due to medical error: jumbo jets or just small propeller planes?" BMJ Quality & Safety **21**(9): 709-712.

Shojania, K. G. (2008). "The frustrating case of incident-reporting systems." Quality and Safety in Health Care **17**(6): 400-402.

Shojania, K. G., B. W. Duncan, K. M. McDolnald and R. M. Wachter (2001). Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD, Agency for Healthcare Research and Quality.

Shojania, K. G. and J. M. Grimshaw (2005). "Evidence-Based Quality Improvement: The State Of The Science." Health Affairs **24**(1): 138-150.

Shojania, K. G. and E. J. Thomas (2013). "Trends in adverse events over time: why are we not improving?" BMJ Quality & Safety **22**(4): 273-277.

Shortell, S. M., C. L. Bennett and G. R. Byck (1998). "Assessing the Impact of Continuous Quality Improvement on Clinical Practice: What It Will Take to Accelerate Progress." Milbank Quarterly **76**(4): 593-624.

Silbey, S. S. (2009). "Taming Prometheus: Talk About Safety and Culture." Annual Review of Sociology **35**(1): 341-369.

Silverman, D. (2004). Who cares about experience? Missing issues in qualitative research. Qualitative Research: Theory, Method, and Practice. D. Silverman. London, Sage Publications.

Silverman, D. (2006). Interpreting Qualitative Research. London, Sage Publications.

Sinkowitz-Cochran, R., A. Garcia-Williams, A. Hackbarth, B. Zell, G. R. Baker, C. J. McCannon, E. Beltrami, J. Jernigan, L. C. McDonald and D. Goldmann (2012). "Evaluation of Organizational Culture among Different Levels of Healthcare Staff Participating in the Institute for Healthcare Improvement's 100,000 Lives Campaign." Infection Control and Hospital Epidemiology **33**(2): 135-143.

Smith, P. C. and R. Busse (2010). Targets and Performance Measurement. Performance Measurement for Health System Improvement : Experiences, Challenges and Prospects. P. C. Smith. Cambridge, Cambridge University Press.

Smith, R. (2001). "Why are doctors so unhappy? There are probably many causes, some of them deep." BMJ **322**(7294): 1073-1074.

Som, C. (2009). "Sense making of clinical governance at different levels in NHS hospital trusts." Clinical Governance: An International Journal **14**(2): 98-112.

Spiegelhalter, D. (2013). "Have there been 13 000 needless deaths at 14 NHS trusts?" BMJ **347**: 1-2.

Stone, S. P., C. Fuller, J. Savage, B. Cookson, A. Hayward, B. Cooper, G. Duckworth, S. Michie, M. Murray, A. Jeanes, J. Roberts, L. Teare and A. Charlett (2012). "Evaluation of the national Cleanyourhands campaign to reduce Staphylococcus aureus bacteraemia and Clostridium difficile infection in hospitals in England and Wales by improved hand hygiene: four year, prospective, ecological, interrupted time series study." BMJ **344**.

Sutcliffe, K. M., E. Lewton and M. M. Rosenthal (2004). "Communication Failures: An Insidious Contributor to Medical Mishaps." Academic Medicine **79**(2): 186-194.

Swage, T. (2000). Clinical Governance in Health Care Practice. Oxford, Butterworth-Heinemann.

Swage, T. (2004). Clinical Governance in Health Care Practice (2nd edition). Oxford, Butterworth-Heinemann.

Tan, P. C., G. Robinson, S. Jayathissa and M. Weatherall (2014). "Coming to work sick: a survey of hospital doctors in New Zealand." The New Zealand Medical Journal **127**(1399): 23-35.

Tanenbaum, S. J. (1993). "What Physicians Know." New England Journal of Medicine **329**(17): 1268-1271.

Tanenbaum, S. J. (1994). "Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research." Journal of Health Politics Policy and Law **19**(1): 27-44.

Taylor, M. J., C. McNicholas, C. Nicolay, A. Darzi, D. Bell and J. E. Reed (2013). "Systematic review of the application of the plan–do–study–act method to improve quality in healthcare." BMJ Quality & Safety **23**(4): 290-298.

The Commonwealth Fund Commission on a High Performance Health System (2011). Why not the best? Results from the national scorecard on U. S. health system performance, The Commonwealth Fund.

The Health Foundation (2011a). Safer Patients Initiative: Phase One. London, The Health Foundation.

The Health Foundation (2011b). Safer Patients Initiative: Phase Two. London, The Health Foundation.

The Health Foundation. (2015). "Safer Patients Network." Retrieved 17 April 2015, from http://www.health.org.uk/areas-of-work/programmes/safer-patients-network/.

The Joint Commission (2014). America's Hospitals: Improving Quality and Safety - The Joint Commission's Annual Report 2014, The Joint Commission.

The King's Fund (2015). Quarterly Monitoring Report 14, The King's Fund.

The NHS Confederation (2013). Challenging Bureaucracy. London, The NHS Confederation.

Thomas, E. J., D. M. Studdert, H. R. Burstin, E. J. Orav, T. Zeena, E. J. Williams, K. M. Howard, P. C. Weiler and T. A. Brennan (2000). "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado." Medical Care **38**(3): 261-271.

Thomas, L. and C. Galla (2013). "Building a culture of safety through team training and engagement." BMJ Quality & Safety **22**: 425-434.

Thorlby, R. and J. Maybin (2010). A high performing NHS? A review of progress 1997 - 2010. London, The King's Fund.

Time for Quality (2008). Agreement between Association of Salaried Medical Specialists and 21 District Health Boards, Association of Salaried Medical Specialists.

Timmermans, S. and A. Angell (2001). "Evidence-Based Medicine, Clinical Uncertainty, and Learning to Doctor." Journal of Health and Social Behavior **42**(4): 342-359.

Timmermans, S. and M. Berg (2003). The Gold Standard: The Challenges of Evidence-Based Medicine and Standardization in Health Care. Philadelphia, Temple University Press.

Timmermans, S. and E. S. Kolker (2004). "Evidence-based medicine and the reconfiguration of medical knowledge." Journal of Health and Social Behavior **45**: 177-193.

Treasury (2005). Value for money in health – the DHB sector. Wellington, The Treasury.

Urbach, D. R., A. Govindarajan, R. Saskin, A. S. Wilton and N. N. Baxter (2014). "Introduction of Surgical Safety Checklists in Ontario, Canada." New England Journal of Medicine **370**(11): 1029-1038.

Varkey, P., K. M. Reller and R. K. Resar (2007). "Basics of quality improvement in health care." Mayo Clinic Proceedings **82**(6): 735+.

Vaughan, D. (1996). The Challenger Launch Decision: Risky Technology, Culture and Deviance at NASA. Chicago, University of Chicago Press.

Vaughan, D. (1999). "The dark side of organizations: Mistake, misconduct, and disaster." Annual Review of Sociology **25**: 271-305.

Vincent, C. (2003). "Understanding and responding to adverse events." New England Journal of Medicine **348**(11): 1051-1056.

Vincent, C., P. Aylin, B. D. Franklin, A. Holmes, S. Iskander, A. Jacklin and K. Moorthy (2008). "Is health care getting safer?" BMJ **337**.

Vincent, C., S. Burnett and J. Carthey (2013). The measurement and monitoring of safety. London, The Health Foundation.

Vincent, C. and J. Reason (1999). Human Factors Approachs in Medicine. Medical Mishaps: Pieces of the Puzzle. M. M. Rosenthal, L. Mulcahy and S. Lloyd-Bostock. Buckingham and Philadelphia, Open University Press.

Wachter, R. M. (2010a). "Patient Safety At Ten: Unmistakable Progress, Troubling Gaps." Health Affairs **29**(1): 165-173.

Wachter, R. M. (2010b). "Patient safety at 10 years: How far have we come? What's next?" OR Manager **26**(3): 1-4.

Wachter, R. M., P. Pronovost and P. Shekelle (2013). "Strategies to Improve Patient Safety: The Evidence Base Matures." Annals of Internal Medicine **158**(5_Part_1): 350-352.

Wachter, R. M. and P. J. Pronovost (2006a). "The 100,000 live campaign: a scientific and policy review." Joint Commission Journal on Quality and Patient Safety **32**(11): 621-627.

Wachter, R. M. and P. J. Pronovost (2006b). "The authors reply." Joint Commission Journal on Quality and Patient Safety **32**(11): 631-632.

Walker, L. (2015). NZNO Employment Survey 2015. Welington, New Zealand Nurses Organisation.

Wallace, J. E., J. B. Lemaire and W. A. Ghali (2009). "Physician wellness: a missing quality indicator." The Lancet **374**(9702): 1714-1721.

Wallace, L. M. (2006). "From root causes to safer systems: international comparisons of nationally sponsored healthcare staff training programmes." Quality and Safety in Health Care **15**(6): 388-389.

Walshe, K. (1999). "Improvement through inspection? The development of the new Commission for Health Improvement in England and Wales." Quality in Health Care **8**: 191-196.

Walshe, K. (2002a). "The Rise Of Regulation In The NHS." BMJ **324**(7343): 967-970.

Walshe, K. (2002b). "Principles for Best Practice in Clinical Audit (Book Review)." Quality and Safety in Health Care **11**(4): 392.

Walshe, K. (2010). "Reorganisation of the NHS in England." BMJ **341**(3843).

Walshe, K. and T. G. Rundall (2001). "Evidence-Based Management: From Theory to Practice in Health Care." Milbank Quarterly **79**(3): 429-457.

Waring, J. (2007). "Adaptive regulation or governmentality: patient safety and the changing regulation of medicine." Sociology of Health & Illness **29**(2): 163-179.

Waring, J., S. Harrison and R. McDonald (2007). "A culture of safety or coping? Ritualistic behaviours in the operating theatre." Journal of Health Servives Research & Policy **12**(suppl_2): 3-9.

Waring, J. J. (2004). "A qualitative study of the intra-hospital variations in incident reporting." International Journal for Quality in Health Care **16**(5): 347-352.

Waring, J. J. (2005b). "Beyond blame: cultural barriers to medical incident reporting." Social Science & Medicine **60**(9): 1927-1935.

Waring, J. J. (2009). "Constructing and re-constructing narratives of patient safety." Social Science & Medicine **69**(12): 1722-1731.

Waring, J. J. and S. Bishop (2010a). "Lean healthcare: Rhetoric, ritual and resistance." Social Science & Medicine **71**(7): 1332-1340.

Weaver, S. J., S. M. Dy and M. A. Rosen (2014). "Team-training in healthcare: a narrative synthesis of the literature." BMJ Quality & Safety **23**: 359-372.

Weick, K. E. and K. M. Sutcliffe (2007). Managing the Unexpected. San Francisco, Jossey-Bass.

Weingart, S. N., R. M. Wilson, R. W. Gibberd and B. Harrison (2000). "Epidemiology of medical error." BMJ **320**(7237): 774-777.

Wennberg, J. E., E. S. Fisher, D. C. Goodman and J. S. Skinner (2008). Tracking the Care of Patients with Severe Chronic Illness: The Darthmouth Atlas of Health Care 2008. Lebanon, New Hampshire, Darthmouth Institute for Health Policy and Clinical Practice.

West, E. (2000). "Organisational sources of safety and danger: sociological contributions to the study of adverse events." Quality in Health Care **9**(2): 120-126.

West, E., N. Mays, A. M. Rafferty, K. Rowan and C. Sanderson (2009). "Nursing resources and patient safety outcomes in intensive care: A systematic review of the literature." International Journal of Nursing Studies **46**: 993-1011.

Whyte, S., C. Cartmill, F. Gardezi, R. Reznick, B. A. Orser, D. Doran and L. Lingard (2009). "Uptake of a team briefing in the operating theatre: A Burkean dramatistic analysis." Social Science & Medicine **69**(12): 1757-1766.

Wiig, S. and K. Aase (2007). "Fallible humans in infallible systems? Learning from errors in health care." Safety Science Monitor **11**(3): 1-13.

Wiig, S. and P. H. Lindøe (2009). "Patient safety in the interface between hospital and risk regulator." Journal of Risk Research **12**(3): 411 - 426.

Williams, M. (1998). The social world as knowable. Knowing the Social World. T. May and M. Williams. Buckingham & Philadelphia, Open University Press.

Wolinsky, F. D. (1993). The professional dominance, deprofessionalization, proletarianization, and corporatization perspectives: An overview and synthesis. The Changing Medical Profession: An International Perspective. F. W. Hafferty and J. B. McKinlay. New York & Oxford, Oxford University Press.

Womack, J. and D. Jones (1996). Lean Thinking: Banish the Waste and Create Wealth in Your Organization. New York, Simon and Schuster.

Wright, L., L. Malcolm, P. Barnett and C. Hendry (2001). Clincial leadership and clinical governance: a review of developments in New Zealand and internationally. Wellington, Ministry of Health.

Wu, A. W., A. M. Lipshutz and P. J. Pronovost (2008). "Effectiveness and efficiency of root cause analysis in medicine." The Journal of the American Medical Association **299**(6): 685-687.

Wyszewianski, L. (1988). "Quality of care: past achievements and future challenges." Inquiry **25**(1): 13-22.

Young, T. and S. McClean (2009). "Some challenges facing Lean Thinking in healthcare." International Journal for Quality in Health Care **21**(5): 309-310.

Young, T. P. and S. I. McClean (2008). "A critical look at Lean Thinking in healthcare." Quality and Safety in Health Care **17**(5): 382-386.

Zuiderent-Jerak, T. and M. Berg (2010). The sociology of quality and safety in health care. Handbook of Medical Sociology, Sixth Edition. C. E. Bird, P. Conrad, A. M. Fremont and S. Timmermans. Nashville, TN Vanderbilt University Press.