Organisational and systems factors impacting on patient safety in acute care organisations: lessons from four multi-site research studies

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ORGANISATIONAL AND SYSTEMS FACTORS IMPACTING ON PATIENT SAFETY IN ACUTE CARE ORGANISATIONS

LESSONS FROM FOUR MULTI-SITE RESEARCH STUDIES

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Abstract

Background

Patient safety is concerned with preventable harm in healthcare, a subject that became a focus for study in the UK in the late 1990s. How to improve patient safety, presented both a practical and a research challenge in the early 2000s, leading to the eleven publications presented in this thesis.

Research question

The overarching research question was: What are the key organisational and systems factors that impact on patient safety, and how can these best be researched?

Methods

Research was conducted in over 40 acute care organisations in the UK and Europe between 2006 and 2013. The approaches included surveys, interviews, documentary analysis and non-participant observation. Two studies were longitudinal.

Results

The findings reveal the nature and extent of poor systems reliability and its effect on patient safety; the factors underpinning cases of patient harm; the cultural issues impacting on safety and quality; and the importance of a common language for quality and safety across an organisation.

Across the publications, nine key organisational and systems factors emerged as important for patient safety improvement. These include leadership stability; data infrastructure; measurement capability; standardisation of clinical systems; and creating an open and fair collective culture where poor safety is challenged.

Conclusions and contribution to knowledge

The research presented in the publications has provided a more complete understanding of the organisation and systems factors underpinning safer healthcare.

Lessons are drawn to inform methods for future research, including: how to define success in patient safety improvement studies; how to take into account

external influences during longitudinal studies; and how to confirm meaning in multi-language research. Finally, recommendations for future research include assessing the support required to maintain a patient safety focus during periods of major change or austerity; the skills needed by healthcare leaders; and the implications of poor data infrastructure.

Contents

PART 1		
Section		Page
1.	Introduction	1
1.1	Overview of patient safety	2
1.2	Definition of terms relating to safety in organisations	4
1.3	Context for the research	5
1.4	Summary and rationale for the research presented in this thesis	16
1.5	The research question and aims	17
1.6	Overview of methodology	17
2.	The research studies and publications	18
2.1	Publications arising from the 'Safer Patients Initiative' (SPI) programme, a complex safety intervention in NHS hospitals	18
2.2	Publications arising from a study of the reliability of clinical systems in seven UK NHS organisations (the WISER study)	20
2.3	An analysis of the causes of wrong site and wrong procedure surgery in the NHS in England	22
2.4	Publications arising from an investigation into the factors impacting on quality and safety in ten hospitals in five European countries (the QUASER study)	23
3.	Commentary	26
3.1	Synthesis of the findings	26

3.2	Evaluation of and reflection on the methods used in the research: informing future research in this area	33
3.3	Conclusions	36
Appendix 1	Overview of the history of medical harm, safety and risk management	40
Appendix 2	Definition of terms	65
Appendix 3	Tabulation of research methods used across the studies	71
Glossary of Acronyms in part 1		72
References to part 1		75
PART 2: Portfolio of Publications (not included)		
Paper 1	Burnett, S., Benn, J., Pinto, A., Parand, A., Iskander, S. and Vincent, C. (2010) Organisational readiness: exploring the preconditions for success in organisation-wide patient safety improvement programmes. *Quality and Safety in Health Care,* 19(4): 313-317	
Paper 2	Burnett, S., Parand, A., Benn, J., Pinto, A., Iskander, S. and Vincent, C. (2008) Learning about leadership from Patient Safety WalkRounds. *The International Journal of Clinical Leadership,* 16(4): 185-192	
Paper 3	Benn, J., Burnett, S., Parand, A., Pinto, A., Iskander, S. and Vincent, C. (2009) Studying large-scale programmes to improve patient safety in whole care systems: challenges for research. *Social science & medicine,* 69(12): 1767-1776	

Paper 4	Burnett, S., Franklin, B.D., Moorthy, K., Cooke, M.W. and Vincent, C. (2011) *Evidence: How safe are clinical systems?* London: The Health Foundation	
Paper 5	Burnett, S., Franklin, B.D., Moorthy, K., Cooke, M.W. and Vincent, C. (2012) How reliable are clinical systems in the UK NHS? A study of seven NHS organisations. *BMJ Quality & Safety,* 21(6): 466-472	
Paper 6	Burnett, S.J., Deelchand, V., Franklin, B.D., Moorthy, K. and Vincent, C. (2011) Missing Clinical Information in NHS hospital outpatient clinics: prevalence, causes and effects on patient care. *BMC Health Services Research,* 11(1): 1-7	
Paper 7	Burnett, S., Norris, B., Flin, R. (2012) Never events: the cultural and systems issues that cannot be addressed by individual action plans. *Clinical Risk,* 18(6): 213-216	
Paper 8	Robert, G.B., Anderson, J.E., Burnett, S.J., Aase, K., Andersson-Gare, B., Bal, R., Calltorp, J., Nunes, F., Weggelaar, A.-M., Vincent, C.A. and Fulop, N. (2011) A longitudinal, multi-level comparative study of quality and safety in European hospitals: the QUASER study protocol. *BMC health services research,* 11(1): 285	
Paper 9	Burnett, S., Renz, A., Wiig, S., Fernandes, A., Weggelaar, A.M., Calltorp, J., Anderson, J.E., Robert, G., Vincent, C. and Fulop, N. (2013) Prospects for comparing European hospitals in terms of quality and safety: lessons from a comparative study in five countries. *International journal for quality in health care,* 25(1):1-7	

10	Paper 10: Burnett, S., Mendel, P., Nunes, F., Wiig, S., Van Den Bovenkamp, H., Karltun, A., Robert, G., Anderson, J., Vincent, C. and Fulop, N. (2016) Using institutional theory to analyse hospital responses to external demands for finance and quality in five European countries. *Journal of health services research & policy,* 21(2): 109-117	
11	Paper 11: Wiig, S., Aase, K., von Plessen, C., Burnett, S., Nunes, F., Weggelaar, A.M., Anderson-Gare, B., Calltorp, J., Fulop, N., (2014) Talking about quality: exploring how 'quality' is conceptualized in European hospitals and healthcare systems. *BMC Health Services Research,* 14(1): 1-12	

List of tables and figures in part 1

	Tables	Page
Table 1	Evidence of increasing focus on safety in healthcare in the medical literature	3
Table 2	Timeline of the history of safety and risk related to medicine	50
Table 3	Definition of terms commonly used in relation to safety	65
Table 4	Terms used in patient safety research and in the investigation of errors and adverse events in healthcare	68
Table 5	Tabulation of research methods used across the studies	71
Table 6	Glossary of Acronyms	73
	Figures	
Figure 1	The London Protocol for classifying the contributory factors in healthcare adverse events (Taylor-Adams et al., 2004)	7
Figure 2	Organisational challenges in quality improvement (Bate et al., 2008, Robert et al., 2011)	8
Figure 3	Power structure of fields as characterised by the degree of centralization (adapted from Pache and Santos, 2010)	11
Figure 4	Responses to institutional pressures: strategies and tactics (adapted from Oliver, 1991)	12
Figure 5	Aims of Patient Safety Executive/Leadership WalkRounds	15
Figure 6	Methods of risk management in society	48

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Author declaration:

I declare that all the material contained in this commentary is my own work.

1. Introduction

This thesis brings together eleven publications, including ten peer reviewed journal papers and one published research monograph. The publications are drawn from four research studies, each considering the organisational and systems factors impacting on patient safety. Considered as a whole, the research was conducted in over 40 hospital organisations, between 2006 and 2013.

The research studies are as follows:

1. A longitudinal study of the 'Safer Patients Initiative' (SPI), a large scale intervention to improve patient safety in 24 UK NHS organisations (The Journey to Safety Study: papers 1, 2 and 3) (Burnett et al., 2010, Burnett et al., 2008, Benn et al., 2009)

2. A study of the reliability of clinical systems in seven UK NHS organisations (the Warwick and Imperial Study to Enhance Reliability in Healthcare (WISER): papers 4, 5 and 6) (Burnett et al., 2011a, Burnett et al., 2012a, Burnett et al., 2011b)

3. An analysis of the causes of wrong site and wrong procedure surgery in the NHS in England (paper 7) (Burnett et al., 2012b)

4. An investigation into the factors impacting on quality and safety in ten hospitals in five European countries (the QUASER study: papers 8, 9, 10 and 11) (Robert et al., 2011, Burnett et al., 2013, Burnett et al., 2016, Wiig et al., 2014)

This section sets the context for these publications, beginning with an overview of patient safety, followed by the definition of the terms used and finally a discussion of related research leading to the rationale for the research presented in this thesis.

1.1. Overview of patient safety

Patient safety is concerned with preventable harm in healthcare (World Health Organisation, 2015). Every surgical procedure carries with it the risk of complications and many prescribed drugs have the potential for unwanted and sometimes serious side effects. Some of these risks may be related to the patient's disease process or condition and, as such, may not be preventable. What is and what is not considered preventable harm has changed over time and there are currently numerous definitions. For example, a recent systematic review (Nabhan et al., 2012) found 132 definitions, which largely could be placed in one of the following categories:

1) Presence of an identifiable modifiable cause

2) Reasonable adaptation to a process will prevent future recurrence

3) Lack of adherence to guidelines implies preventability

As medical knowledge has developed, so too has knowledge about what is a 'modifiable cause' and now the term 'patient safety' encompasses harm from, for example missed doses of medication, to failure to adhere to national clinical guidelines (see 3 above).

It has been known throughout history that doctors can harm their patients (Wootton, 2006, Sharpe and Faden, 1998). However, terms such as 'patient harm', 'medical error', 'adverse events' and 'patient safety' only became widely discussed in the medical literature from the 1980s[1] (see table 1). The extent of patient harm did not became a focus for study until the 1990s, when it was found that, in US hospitals, 3.7% of patients were being harmed by their healthcare and, in UK, the corresponding figure was 10%, with much of this harm being preventable (Brennan et al., 1991, Vincent et al., 2001). A timeline and more comprehensive overview of the history of medical harm, safety and risk management is provided in appendix 1.

[1] The term 'patient safety' only became a MESH term in PubMed in 2012

Table 1: Evidence of increasing focus on safety in healthcare in the medical literature

Period	No. of years	Number of articles referring to patient safety		
		BMJ	Lancet	PubMed
1800-1960	160	87	2	2057
1961-1980	20	90	31	12401
1981-1990	10	71	43	20123
1991-2000	10	233	215	39106
2001-2010	10	822	459	85186
2011-2015	5	853	552	76264

Note: Based on a search for (singular and plural)[2] “patient safety”; “medical harm”; “medical error”; and “adverse events” in the title or abstract

In the wider society, the UK government had been intervening to improve safety in other industries for over 160 years (for example, the 1833 Factories Act (UK National Archives, 2016)). Research to understand and improve safety had grown from this, particularly in industries where risks were high and safety was paramount, for example in mines and factories, and later in aviation and nuclear power. In the NHS, concern over the rising costs of claims for clinical negligence (see appendix 1) led the UK government, in the 1990s, to

[2] "medical harm" OR "patient harm" OR "medical error*" OR error* OR "adverse event*" OR “patient safety”

encourage the introduction of risk management into the NHS. During this time, public concern over the quality of care in the NHS continued to grow, following a number of high profile cases of poor care, for example the deaths of children from heart surgery in Bristol (Savage, 1998, Kennedy, 2001). This led to further government intervention with a White Paper in 1997 introducing:

> '..*a new system of clinical governance in NHS Trusts... to ensure that clinical standards are met, and that processes are in place to ensure continuous improvement.'* (Department of Health, 1997, p24).

Then in 2000, the first major report on preventing harm in UK healthcare, entitled 'An Organisation with a Memory' was issued (Department of Health, 2000), at the same time as the seminal report in the USA, 'To Err is Human' (Kohn et al., 2000). This led to considerable attention on how to improve safety in healthcare, drawing on what was known in industries outside healthcare (Shojania et al., 2001, Department of Health, 2000, Kohn et al., 2000, Vincent, 2011, Amalberti et al., 2006, Kennedy, 2001). How to transfer this learning into the NHS and achieve widespread and sustainable organisational change presented both a practical and a research challenge in the early 2000s leading to the research set out in this thesis.

1.2. Definition of terms relating to safety in organisations

The terms used in this thesis relating to safety, errors and accidents are set out in appendix 2, together with the terms used in safety research. Here, the most frequently encountered terms and concepts will be considered in more detail.

1.2.1. Safety

Safety research and improvement in healthcare, as in industry, has required the contribution of a combination of disciplines. Understanding the causes of errors and accidents has involved the study topics such as communication, teamwork, decision making, situation awareness, stress, and fatigue, known collectively as 'human factors' (Flin et al., 2008). The challenge of improving patient safety in

organisations has drawn also on quality improvement (QI) methodologies and an understanding of what underpins high quality care. Furthermore, clinical epidemiology has provided '*a vital empirical understanding of the incidence and characteristics of error and patient harm*' (Walshe and Boaden, 2005. p2). The study of patient safety, therefore, has brought clinical research together with design, engineering, sociology, psychology and research into systems, organisation and change management. All are involved, in varying degrees, in the research presented here.

1.2.2. Quality or safety?

The relationship between quality and safety in healthcare has been debated for many years (Woolf, 2004). In this thesis, the term 'quality' is defined as being made up of a combination of patient safety, clinical effectiveness, and patient experience dimensions (Darzi, 2008). This definition was used in the QUASER study (Robert et al., 2011) (papers 8-11 in this thesis).

1.3. Context for the research

In order to provide focus for the research question, this section begins by considering what is meant by organisational and systems factors in patient safety, and how they can be classified. Previous related research is then discussed, including the knowledge gaps, and why the research set out in this thesis was needed.

1.3.1. Defining and Classifying Organisational and Systems Factors in Patient Safety Research

Organisational and systems factors encompass aspects of an organisation such as culture, leadership, infrastructure, and resources (Vincent et al., 2000, Rundmo et al., 1998, Simard and Marchand, 1995). Here, they are used to describe the internal and external characteristics of an organisation that impact on the quality and safety of patient care, and on efforts to make improvements.

During WW2, for the first time, physiologists and psychologists began working together on the design of aircraft and submarines, described as ‘human factors’ studies of the man-machine interface (Meister, 1999). Rather than focusing just on individuals, these studies began to consider errors as being caused by the systems in which people worked, and that these systems could be designed to reduce or eliminate certain errors (Guarnieri, 1992, Ilan and Fowler, 2005). Findings from this work began to be applied in industries where safety was paramount, such as civil aviation and nuclear power - the so called ‘safety conscious’ or ‘high risk’ industries.

In the late 1990s, the NHS began to draw on this research to provide further understanding of the systems failures underpinning major patient safety failures. In 1997, clinicians and researchers in the UK began to consider how to apply techniques used in other industries to healthcare, to investigate and analyse incidents and accidents (Stanhope et al., 1997). From this, a classification system was developed for the influencing or contributory factors, called ‘the London Protocol’ (Vincent et al., 2000, Taylor-Adams et al., 2004), set out in figure 1. The structuring of these factors provided a basis for understanding systems failures and enabled those investigating adverse events in hospitals to classify problems and begin to develop solutions.

The classification in figure 1 was used to structure the research and analysis of in papers 4-7 in this thesis.

Figure 1: The London Protocol for classifying the contributory factors in healthcare adverse events (Taylor-Adams et al., 2004)

Factor Types	**Influencing/Contributory Factors**
Institutional Context	Economic and regulatory context National health service executive Clinical negligence scheme for trusts
Organisational and Management Factors	Financial resources and constraints Organisational structure Policy standards and goals Safety culture and priorities
Work Environment Factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support
Team Factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership etc.)
Individual (staff) Factors	Knowledge and skills Competence Physical and mental health
Task Factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Patient Factors	Condition (complexity and seriousness) Language and communication Personality and social factors

Building on this, in a study reported in 2008, Bate and colleagues described, and usefully grouped into 'challenges', the organisational factors that had a bearing on success in quality improvement in healthcare organisations (Bate et al., 2008) (figure 2). This classification of organisational factors was updated following a literature review and used to structure the research in papers 8-11 in this thesis.

Figure 2: Organisational challenges in quality improvement (Bate et al., 2008, Robert et al., 2011)

1. Structural – structuring, planning and co-ordinating quality efforts
2. Political – addressing the politics and negotiating the buy-in, conflict and relationships of change surrounding any quality improvement effort
3. Cultural – giving 'quality' a shared, collective meaning, value and significance within the organisation
4. Educational – creating and nurturing a learning process that supports continuous improvement
5. Emotional – inspiring, energizing, and mobilizing people for the quality improvement effort
6. Physical and technological – designing physical systems and technological infrastructures that support improvement and quality of care.

In research into change management, these organisation and systems factors, described collectively as 'context', have been found to be important:

> '..*experience suggests that 'context counts' for how easy it is to implement a safety intervention.'* (Øvretveit et al., 2011. p609)

'Context' has also been described as '*everything that is not the intervention*' (Stevens and Shojania, 2011. p557). In addition to the internal characteristics, these factors may also include the external or macro level system factors within which an organisation operates, for example the

social, political, economic, and regulatory context and the processes or interactions between these features (Paul Bate, 2014, Pettigrew et al., 1992, Pettigrew, 1988).

The research resulting in the publications in this thesis examined these organisational and systems factors in relation to patient safety and to patient safety improvement strategies and initiatives.

1.3.2. Research into the organisational and systems factors underpinning successful change

It is clear from the range of organisational factors found to contribute to accidents and incidents described in the London Protocol (figure 1), that efforts to improve patient safety will involve change across an organisation. In the period leading up to the research in this thesis, little research evidence existed regarding the effectiveness of improvement programs that targeted the whole organisation (Øvretveit et al., 2002, Shojania and Grimshaw, 2005, Mittman, 2004). Therefore, when, in the early 2000s, for the first time in the UK, work began to translate and apply lessons in safety improvement from industry into the NHS, research was needed to capture the lessons and to gain an understanding of the steps needed to develop safer healthcare organisations (papers 1-3).

At that time, studies investigating organisational change in healthcare had reported certain organisational factors as vital prerequisites for success, referred to as 'organisational readiness' (Weiner et al., 2008, Madsen et al., 2005, Weiner, 2009). These readiness factors included: senior management and board commitment, clinicians engagement in quality improvement, quality reporting processes, and fostering processes for improvement that engaged front line staff (Gollop et al., 2004, Vaughn et al., 2006, Walley et al., 2006). Indeed, research had suggested that half of all failures to implement large scale change were due to organisational leaders failing to establish the right conditions within their organisations prior to starting change programmes (Kotter, 1996).

On the negative side, periods of uncertainty, for example trust mergers and management changes, were found to have a detrimental influence on the course and success of change programmes (Wezel and Saka-Helmhout, 2006, Fulop et al., 2005). Pettigrew described these as 'receptive' and 'non-receptive' contexts for change (Pettigrew et al., 1992, Pettigrew, 1988).

In summary, previous research suggested that a better appreciation of an organisation's readiness factors was likely to increase the chance of change succeeding (Jennett et al., 2003, Barrett et al., 2005, Penland, 1997). In addition, the failure of a programme may not be due to the intervention itself, but to the existing conditions in the organisations within which it was introduced. Investigating organisational readiness was therefore important in this thesis to understand the course of an improvement programme. Furthermore, no previous research had been conducted into the factors underpinning success in safety improvement programmes in the NHS.

1.3.3. The impact of the external environment on safety and quality improvement

In the London Protocol (figure 1), the institutional context is one of the factors found in research to contribute to adverse events in healthcare (Taylor-Adams et al., 2004). Hospitals exist within a wider socio-political environment and are influenced in what they do by a range of external organisations (Mendel and Richard, 2010). In the UK, these include the Department of Health; the Care Quality Commission (CQC); the Medical Royal Colleges; and the National Institute for Health and Clinical Excellence (NICE). Each organisation has its own priorities for delivery by healthcare organisations and as such, each puts different demands on hospitals.

Institutional theory provides conceptual frameworks for examining these competing demands, and for assessing the reactions of organisations to these pressures (Scott, 2004). Here, the structure and distribution of power among such institutional actors is considered an important determinant of how hospitals respond to external expectations (see figure 3). Where there are a multiple influential institutions, but where each has insufficient power to clearly dominate,

the leadership task in hospitals is considered even more complex (Ruef and Scott, 1998).

Figure 3: Power structure of fields as characterised by the degree of centralisation (adapted from Pache and Santos, 2010)

Highly centralised fields	Typically rely on one principal constituent whose authority in the field is both formalised and recognised.(Meyer et al., 1987) This principal constituent can resolve disagreements between disparate players and impose relatively coherent demands on organisations
Moderately centralised fields	Characterised by the competing influence of multiple and misaligned players whose influence is not dominant yet is potent enough to be imposed on organisations
Decentralised fields	Institutional pressures are rather weak and, when incompatible, they can be easily ignored or challenged by organisations since the referents have little ability to monitor or enforce them.

Other institutional analysts have highlighted how organisational responses to external institutional pressures and resource dependencies may vary across contexts and how organisational leaders exercise a range of strategic choices (Clemens and Cook, 1999). One model, outlining organisational responses to institutional demands and resource dependencies, identified a continuum that ranged from acquiescence, through to defiance and manipulation (see figure 4) (Oliver, 1991).

Figure 4: Responses to institutional pressures: strategies and tactics (adapted from Oliver, 1991)

- Acquiescence refers to how organisations comply with institutional demands whether consciously or unconsciously arising from habit, imitation or voluntary accession.
- Compromise refers to where an organisation partially conforms to institutional demands by either adjusting those institutional demands and /or adjusting internal organisational responses. Compromise may arise by applying one of three strategies: balancing competing expectations via negotiating with internal groups; allocating energies to pacify those resisting; or, to bargain with external institutions external demands.
- Avoidance strategies involve attempts by the organisation to adjust conditions so as to make it possible for the organisation to comply with institutional demands. Avoidance tactics include: concealing non-conformity by pretending to acquiesce; by preventing technical monitoring of compliance (buffering); or by changing the organisational function so as to make compliance unnecessary (escaping).
- A defiant strategy may occur when the organisation rejects at least one institutional demand and may be manifested as dismissal of a demand, overtly challenging a requirement or aggressively attacking the institutional demand.
- A manipulation strategy refers to the deliberate attempt to actively change the content of institutional demands. Manipulation tactics include: co-opting sources of institutional pressure; influencing norms by active lobbying; and, control of the source of pressure.

With patient safety growing in prominence in the UK, since the publication of ‘Building a Safer NHS’ (Department of Health, 2001) (appendix 1), pressure to improve was placed on hospitals through a range of external organisations (Department of Health, 2009), including the mainstream media (Boyce et al., 2009). In the period from 2010, following the Great Recession, austerity measures were introduced (Jones and Charlesworth, 2013) with hospitals

required to achieve financial balance at the same time as improving patient safety. By then, research had shown the importance of understanding the nature and impact of the external context on healthcare organisations work to improve safety and quality. The QUASER study (papers 8-11) was the first research to examine the impact of the external context on healthcare organisations across European countries. The QUASER research included an analysis of how quality was conceptualised by different external and internal stakeholders, and how external pressures were managed, providing advice to hospitals, payers and policy makers (Robert et al., 2011, Burnett et al., 2013, Burnett et al., 2016, Wiig et al., 2014).

1.3.4. Organisational Culture and Patient Safety

Within the safety literature, a number of organisational characteristics are described as necessary if errors and adverse events are to be minimised, known collectively as a 'safety culture' (Weaver et al., 2013, Morello et al., 2013, Vincent, 2011, Flin et al., 2008). These factors, for example teamwork and communication, form part of the classification within the London Protocol (figure 1), used in the studies set out in papers 4-7. This section provides a brief overview of culture in this context.

Morello et al. (2013) define a patient safety culture as follows:

> *'Patient safety culture... includes the shared beliefs, attitudes, values, norms and behavioural characteristics of employees and influences staff member attitudes and behaviours in relation to their organisation's ongoing patient safety performance*.' (Morello et al., 2013. p11)

The need to shift the culture within healthcare, from individual blame to a collective culture that is open and fair, was recognised in the early work on errors in medicine (Department of Health, 2000, Leape, 1994, Kohn et al, 2000). Here, it was recognised that the culture needed to be one where staff felt able to speak up about adverse events so that the systems factors could be explored and improvements made. This formed part of the early work of the UK National Patient Safety Agency (NPSA) when set up in 2001 (Milligan and Dennis, 2005, NPSA, 2004). It continues to be a challenge in healthcare, in particular in

balancing accountability for safety with the need to move away from an individual blame culture (Wachter and Pronovost, 2009, Vincent, 2011).

1.3.5. Leadership and patient safety

Following the investigation into the sinking of the Herald of Free Enterprise ferry in 1987 (Sheen, 1987), interest in the role of the wider organisation in major accidents began to grow (Reason, 1997, Cox and Flin, 1998, Flin, 2003, O'Dea and Flin, 2001) including the role played by senior leaders (Kennedy and Kirwan, 1995, Quarantelli, 1987).

Several studies outside healthcare had shown management's commitment and involvement in safety work to be the factor of most importance for a satisfactory safety level (Cohen, 1977, Smith et al., 1978):

> *Evidence of a strong management commitment to safety and of frequent, close contacts between workers, supervisors, and management on safety matters loom as the two most influential and dominant factors [in successful occupational safety programmes]*
> (Cohen, 1977. p78)

Leadership engagement had also been found to be important in the success of quality improvement programmes in healthcare (Berwick et al., 1990, Bradley et al., 2003, Walley et al, 2006). However, the Safer Patients Initiative (paper 2 in this thesis (Burnett et al., 2008)) was the first intervention in the UK to directly engage healthcare executive leaders in patient safety at the clinical frontline through ‘patient safety leadership walkrounds’.

Patient safety executive walkrounds had been introduced in 2001 as part of a strategy to improve patient safety across a large integrated health care system in the USA (Frankel et al., 2003) with the aims set out in figure 5:

Figure 5: Aims of Patient Safety Executive/Leadership Walkrounds

- Demonstrate top level commitment to patient safety
- Establish lines of communication about patient safety among employees, executives, and managers
- Provide opportunities for senior executives to learn about patient safety
- Identify opportunities for improving safety
- Encourage reporting of issues, errors and near misses
- Promote a culture for change pertaining to patient safety
- Establish local solutions to minimise risk

Prior to the research set out in this thesis (paper 2) there had been no research in the NHS on Patient Safety Leadership Walkrounds, nor had previous research reported the complex social processes that underpin this intervention.

The importance of the Chief Executive providing clear and committed leadership for patient safety to be an organisational priority was set out by Vincent (2012). However prior to the QUASER study (papers 8-11) there was no previous research on how this might be enacted, particularly at a time of austerity. Hence the role of senior leaders in quality and safety improvement was investigated in the QUASER study, considering their roles in mediating and translating external pressures for quality, safety and financial balance (see section 1.3.4).

Moving from the executive to leadership within clinical micro-systems, local clinical and team leadership has been found in research to be important for new safety practices to be adopted (Greenhalgh et al., 2004). It has also been found to be important for safety procedures to be followed, notably the WHO Safer Surgery Checklist (Vats et al., 2010, Conley et al., 2011, Russ et al., 2015). This aspect of leadership was analysed in the study of wrong site and wrong procedure surgery, reported here in paper 7.

1.3.6. Reliability and Patient Safety

In the safety conscious industries of aviation and nuclear power, the importance of systems reliability for safety was recognised at an early stage and acted

upon, with impressive results (Amalberti et al., 2005). In studies in the USA, the delivery of recommended clinical care had been found to be unreliable (McGlynn et al., 2003, Asch et al., 2006, Resar, 2006). For example, in the McGlynn study patients were found only to receive about half of the recommended care processes required for their treatment. However, in the period leading up to the research set out in papers 4-6 the size and nature of poor reliability in the NHS was not known. Importantly, the impact of poor reliability on patient safety and patient care was also unknown.

1.4. Summary and rationale for the research presented in this thesis

Clearly, patient safety is a topic with a long history, however it was not until the 1990s that the subject came to greater prominence, when hospitals were asked to implement systems of risk management. At this time, research into patient safety began to grow, with lessons being learned from safety in other industries. In the early 2000s, for the first time in the UK, work began to translate these lessons in the NHS. Research was needed to gain an understanding of the steps needed to develop safer healthcare. The findings from this (papers 1-3) indicated that there was relatively poor clinical systems reliability and that this may lead to poor patient safety. Research then ensued to discover the nature, extent and impact of poor clinical systems reliability (papers 4-6). Despite much work to improve patient safety, reports persisted about cases of wrong site and wrong procedure surgery and there was a need to understand why. Using experience gained in the earlier research, an analysis was conducted of the investigation reports of 9 such cases (paper 7). The research was then extended to consider the issues regarding safety and quality in 10 hospitals in 5 European countries (papers 8-11).

1.5. The research question and aims

The overarching research question investigated in the publications in this thesis is: What are the key organisational and systems factors that impact on patient safety, and how can these best be researched?

Specifically, the aims were to:

- Investigate the implementation and impact of patient safety improvement interventions in UK hospitals and the factors associated with successful outcomes
- Explore the nature and extent of poor patient safety in the UK NHS and specifically, the factors contributing to the persistence of cases of wrong site and wrong procedure surgery
- Extend the research to explore and compare safety and quality in hospitals in 5 European countries
- To consider the methodological approaches and the challenges of research in practice to inform future research in this area

1.6. Overview of methodology

The research studies resulting in the publications in this thesis have involved a range of approaches to reflect the multi-dimensional nature and complexity of the interventions and organisations being studied. A multi-method, longitudinal research design was utilised to investigate the implementation and impact of a complex safety intervention in NHS hospitals and which resulted in papers 1-3. Mixed qualitative and quantitative methods were also used in the research into clinical systems reliability and patient safety in papers 4-6. Paper 7 involved a human factors analysis. A multi-method, longitudinal design was used in extending the research from the UK to five European countries (papers 8-11) involving analysis of quantitative aggregated data, semi-structured interviews, non-participant observation and an in-depth, multilevel analysis using institutional theory.

2. The research studies and publications

The publications presented in this thesis consist of 10 peer-reviewed journal papers (papers 1-3, 5-11) and a published research monograph (paper 4). In this section, each publication is described briefly, setting out the role and contribution of the author (SJB) and the contribution to knowledge. A tabulation of the methods for each study is provided in appendix 3. A synthesis of the findings and an evaluation and reflection on the methods is presented in section 3.

2.1. Publications arising from the 'Safer Patients Initiative' (SPI) programme, a complex safety intervention in NHS hospitals

In 2004, the Health Foundation (HF) funded a large scale, four year safety improvement programme in 24 UK hospitals. A multi-method, longitudinal research design was utilised to investigate the implementation and impact of this programme. The papers arising from this research are described below (papers 1, 2, and 3).

Paper 1: Burnett, S., Benn, J., Pinto, A., Parand, A., Iskander, S. and Vincent, C. (2010) Organisational readiness: exploring the preconditions for success in organisation-wide patient safety improvement programmes. *Quality and Safety in Health Care,* 19(4): 313-317.

Brief description: A mixed methods study involving a survey and semi-structured interviews with senior leaders in the NHS

Role and contribution: SJB contributed to the design and management of the study; conducting interviews; analysed the qualitative data for the paper; and contributed towards the quantitative analysis. SJB wrote the paper incorporating comments from co-authors.

Contribution to knowledge: This paper represented the first attempt to understand organisational readiness factors in the UK NHS in the context of a large scale safety improvement programme. It revealed that a better

understanding of the preconditions within an organisation would inform setting realistic expectations of the outcomes of such safety initiatives in future.

Paper 2: Burnett, S., Parand, A., Benn, J., Pinto, A., Iskander, S. and Vincent, C. Learning about leadership from Patient Safety WalkRounds. (2008) *The International Journal of Clinical Leadership.* 16(4): 185-192.

Brief description: a qualitative study involving a purposive sample of 56 clinical, operational or management leads from 20 organisations.

Role and contribution: SJB contributed to the design and management of the study; conducted interviews; and analysed the qualitative data for the paper, with input from a second researcher to ensure consistency of coding. SJB wrote the paper, incorporating comments from co-authors.

Contribution to knowledge: The findings provided an understanding of the concerns of NHS healthcare executives regarding patient safety. It provided evidence of the benefits brought about by leadership engagement in safety, and the need for a structured process to enable leaders to connect with clinicians in their organisations on the subject of patient safety.

Paper 3: Benn, J., Burnett, S., Parand, A., Pinto, A., Iskander, S. and Vincent, C. (2009) Studying large-scale programmes to improve patient safety in whole care systems: challenges for research. *Social science & medicine,* 69(12): 1767-1776.

Brief description: An evaluation of the effectiveness of a multi-method approach to research into complex, patient safety-focused interventions and the challenges encountered.

Role and contribution of SJB: As second author, SJB worked with Dr Benn on the paper, contributing to the ideas and the content of the paper.

Contribution to knowledge: This research was the first time such a complex organisation-wide intervention to improve patient safety had been investigated and the methods reported in this way. Evaluation of the methods

informed recommendations for future research on the impact of long-term, large-scale complex interventions.

2.2. Publications arising from a study of the reliability of clinical systems in seven UK NHS organisations (the WISER study)

Routine data collected during SPI indicated that care was not being delivered reliably and that this was an issue for patient safety. The purpose of the research was to discover the extent and nature of poor reliability in acute care hospitals in the UK; to understand the impact this may have on patient care and patient safety; and to find the organisational factors that contributed to this.

Paper 4: Burnett, S., Franklin, B.D., Moorthy, K., Cooke, M.W. and Vincent, C. (2011) *Evidence: How safe are clinical systems?* London: The Health Foundation.

Brief description: Full research report on an investigation into the effect of clinical systems reliability on patient safety in UK hospitals.

Role and contribution of SJB: SJB contributed to the design, analysis and management of the study, and wrote one chapter in this research report with comments incorporated from co-authors. SJB also provided comments for other chapters in the report, in particular for the discussion section set out in chapter 9.

Contribution to knowledge: This study was the first time reliability had been systematically studied in the UK NHS. It described the nature, type, extent and variation in the reliability of five healthcare systems that have the potential to cause harm to patients in UK hospitals, comparing findings across hospitals. The study revealed the extent to which important clinical systems and processes fail, and the potential these failings have to harm patients.

Paper 5: Burnett, S., Franklin, B.D., Moorthy, K., Cooke, M.W. and Vincent, C. (2012) How reliable are clinical systems in the UK NHS? A study of seven NHS organisations. *BMJ Quality & Safety.* 21(6): 466-472.

Brief description: A prospective, descriptive study of the reliability of four clinical systems involving a mixed method approach (quantitative assessment of data plus semi-structured interviews with key personnel).

Role and contribution of SJB: SJB contributed to the design, analysis and management of the study, and wrote the paper with comments incorporated from co-authors.

Contribution to knowledge: This study was the first time reliability had been studied in the UK NHS, covering different clinical systems and comparing findings across hospitals. It revealed that overall reliability was low for the four systems, but there was significant variation between organisations. One in five reliability failures were linked with threats to patient safety.

Paper 6: Burnett, S.J., Deelchand, V., Franklin, B.D., Moorthy, K. and Vincent, C. (2011) Missing Clinical Information in NHS hospital outpatient clinics: prevalence, causes and effects on patient care. *BMC Health Services Research.* 11(1):114.

Brief description: A prospective, descriptive study of the reliability of clinical information availability in NHS hospital outpatient clinics involving a mixed method approach (quantitative assessment of data plus semi-structured interviews with key personnel).

Role and contribution of SJB: SJB was the lead for this research, contributing to the design and management, and analysing the qualitative and quantitative data. SJB wrote the paper with comments incorporated from co-authors.

Contribution to knowledge: This study was the first time the reliability of clinical information in outpatient clinics had been systematically studied and reported in the UK. It revealed that 1 in 7 of surgical outpatient consultations

had key items of clinical information missing and that a fifth of these had a threat to patient safety. The underlying causes of missing information were reported for the first time.

2.3. An analysis of the causes of wrong site and wrong procedure surgery in the NHS in England

The NHS in England has set out a list of patient safety incidents that cause severe harm or death and where guidance exists to prevent these, called 'Never Events'. Building on the research presented in papers 1-6 above, and now presented in paper 7, research was conducted into the human and organisational factors underpinning two such 'Never Events': wrong site surgery and wrong procedure cases.

Paper 7: Burnett, S., Norris, B. and Flin, R. (2012) Never events: the cultural and systems issues that cannot be addressed by individual action plans. *Clinical Risk,* 18(6): 213-216.

Brief description: A qualitative study of hospital investigation reports into cases of wrong procedure and wrong site surgery in the NHS.

Role and contribution of SJB: SJB conducted the qualitative analysis of the anonymised investigation reports of the root causes of nine cases of wrong site or wrong procedure surgery. SJB wrote the paper incorporating amendments from co-authors.

Contribution to knowledge: This was the first time that reports from investigations into wrong procedure and wrong site surgery (so called 'Never Events') had been analysed, reported, and made widely accessible to frontline clinical teams. The paper discusses the factors that need to be addressed in hospitals to prevent such events in future.

2.4. Publications arising from an investigation into the factors impacting on quality and safety in ten hospitals in five European countries (the QUASER study)

The QUASER study widened the research reported in the papers set out above, to five European countries (England, the Netherlands, Norway, Portugal and Sweden). The aim of study was to explore the relationships between the organisational and cultural characteristics of hospitals and how these impact upon clinical effectiveness, patient safety and patient experience in European countries.

Paper 8: Robert, G.B., Anderson, J.E., Burnett, S.J., Aase, K., Andersson-Gare, B., Bal, R., Calltorp, J., Nunes, F., Weggelaar, A.-M., Vincent, C.A. and Fulop, N. (2011) A longitudinal, multi-level comparative study of quality and safety in European hospitals: the QUASER study protocol. ***BMC health services research,*** **11(1): 285.**

Brief description: The paper describes the research protocol for the QUASER study, setting out the concepts and the methods used.

Role and contribution of SJB: SJB contributed to research design and provided comments to the lead author for this paper.

Contribution to knowledge: see papers below.

Paper 9: Burnett, S., Renz, A., Wiig, S., Fernandes, A., Weggelaar, A.M., Calltorp, J., Anderson, J.E., Robert, G., Vincent, C. and Fulop, N. (2013) Prospects for comparing European hospitals in terms of quality and safety: lessons from a comparative study in five countries. ***International journal for quality in health care.*** **25(1): 1-7**

Brief description: A report on the study to find common process and outcome indicators to compare hospitals for quality and safety in five countries (England, Portugal, The Netherlands, Sweden and Norway).

Role and contribution of SJB: SJB led the research; conducted the analysis; and wrote the paper, incorporating comments from co-authors.

Contribution to knowledge: The paper described the challenges faced across Europe if patients and policymakers are to compare the quality and safety of hospitals, as set out in the 2011 European Union directive on patients rights to cross border health care (European Parliament, 2011). The findings were used to select the hospitals for the QUASER study.

Paper 10: Burnett, S., Mendel, P., Nunes, F., Wiig, S., Van Den Bovenkamp, H., Karltun, A., Robert, G., Anderson, J., Vincent, C. and Fulop, N. (2016) Using institutional theory to analyse hospital responses to external demands for finance and quality in five European countries. *Journal of health services research & policy,* 21(2): 109-117.

Brief description: Using institutional theory, a qualitative analysis of the data drawn from the multilevel analysis of health care quality policies and practices in ten hospitals in five European countries, exploring how hospital leaders manage the competing demands to improve quality and constrain spending.

Role and contribution of SJB: SJB conducted the cross case analysis that led to this paper. SJB wrote the paper working with advice from and incorporating the comments of co-authors.

Contribution to knowledge: This is the first time that institutional theory has been applied in this way to hospitals across Europe. The paper makes recommendations for policy makers and for hospital managers.

Paper 11: Wiig, S., Aase, K., von Plessen, C., Burnett, S., Nunes, F., Weggelaar, A.M., Anderson-Gare, B., Calltorp, J. and Fulop, N. (2014) Talking about quality: exploring how 'quality' is conceptualized in European hospitals and healthcare systems. *BMC Health Services Research*, 14(1): 1-12.

Brief description: A cross-national multi-level qualitative case study in ten hospitals in five European countries with data analysed from the national (macro) level; hospital management (meso) level, and from clinical micro-systems.

Role and contribution of SJB: SJB contributed to QUASER study design, including acquisition of data, within country analysis in England, and verified the cross country analysis and commented on manuscript drafts.

Contribution to knowledge: The paper revealed for the first time, the different ways that quality (defined in the paper as clinical effectiveness, patient safety and patient experience) is conceptualised in Europe at different levels from the national to the local (macro, meso, micro); also among professional groups (nurses, doctors, managers); and between the different micro-systems studied.

3. Commentary

3.1. Synthesis of the findings

This section brings together the findings from the 11 publications, described in section 2, to address the first part of the research question and related aims (see section 1.5), as follows:

What are the key organisational and systems factors that impact on patient safety?

Aims:

- Investigate the implementation and impact of patient safety improvement interventions in UK hospitals and the factors associated with successful outcomes
- Explore the nature and extent of poor patient safety in the UK NHS and specifically, the factors contributing to the persistence of cases of wrong site and wrong procedure surgery
- Extend the research to explore and compare safety and quality in hospitals in 5 European countries

Drawing on the Framework Method (Gale et al., 2013, Dixon-Woods, 2011), the findings from each publication were categorised, tabulated, and collated into themes. Three higher level themes emerged and the findings are grouped and discussed for each of these, as follows: organisational history/readiness for change; organisational culture; and systems and infrastructure.

3.1.1. Organisational history/ readiness for change

Evidence from prior research (see section 1.3.3) had found that a number of organisational conditions were necessary for large scale change programmes to be successful. These were specifically considered in the research in paper 1 but also drawn out in the findings from papers 4, 6 10 and 11.

3.1.1a Involvement in quality improvement work

In the SPI programme (paper 1), hospitals that had been working on quality improvement for several years were described by staff as being 'ready' to engage in the changes required to improve patient safety. This was echoed in the hospitals in the QUASER research (paper 10), where a history of active work on quality and safety improvement was found to enable a more long term strategic approach to embedding these activities in everyday work.

How staff perceived the purpose of the improvement work and how it was aligned with other priorities was found to be particularly important (papers 1, 10 and 11). For example, in some QUASER and SPI hospitals, staff described too many unconnected improvement initiatives underway, which created overload and change fatigue. In some SPI hospitals (paper 1) this overload had led to doctors becoming disengaged, lacking motivation to participate in new improvement programmes, particularly when earlier initiatives had failed to be completed. This echoes the findings from Kotter (Kotter, 1996) where a history of successful change is likely to encourage staff to engage in such change in the future. In the QUASER research (papers 10 and 11) the work of senior leaders was found to be important in (a) negotiating achievable quality goals with external organisations and (b) internally aligning these goals with other targets and priorities.

3.1.1b Managing external pressures

Meeting required external targets, for example for waiting times and cost reduction, was found to be important for quality and safety work (papers 1 and 10). Of particular importance was the degree to which hospitals were under financial pressure and how this was being managed. Findings from the QUASER research (paper 10) grouped hospital responses to financial pressures compared to their work on quality and safety. These ranged from immediate pressure to make savings in the short term to long term approaches to aligning cost and quality. In the hospitals that were in financial difficulties, the measures taken to achieve savings in the short term were often at the expense of work to improve quality and safety, for example staffing levels and training

programmes were cut. Reduced staffing levels were found to be an important factor in creating error provoking conditions in the WISER and the Never Events studies (papers 4, 5, 6, and 7). In the WISER study (papers 4, 5, and 6), staff shortages led to locum staff working in services where they were not familiar with the existing systems. In the Never Events study (paper 7), staff shortages were found to create unrealistic work pressures, giving rise to short-cuts and work-arounds.

3.1.1c Mergers and restructuring

In the WISER and QUASER studies (papers 4, 5, 6 and 10), organisational restructuring and hospital mergers were found to have an impact on safety and quality. These reorganisations had often led to leadership instability where staff described quality as slipping off the agenda in the face of other pressures (paper 10). Having a stable management team that had been in post for several years was associated with increased attention on quality and safety work (papers 1, 6, 10). For example, in the SPI sites, organisational stability was described as enabling leaders to focus their attention on patient safety and on improvement work, rather than being distracted by other more pressing priorities (paper 1).

In addition hospitals that had gone through mergers often had not adequately merged key systems. For example, in the WISER research (papers 4, 5 and 6) after mergers, hospitals were left with multiple IT systems, not communicating with each other and hence not transmitting key patient information in a timely manner. This made information retrieval difficult and surgeons were faced with making important clinical decisions in the absence of key patient information (paper 6).

3.1.2. Organisational Culture

The culture of an organisation is defined by the systems, assumptions, values, and beliefs, which govern how staff behave (see section 1.3.4). Various aspects of organisational culture were found to have an impact on the safety of care in all the publications presented here, and these factors are now described.

3.1.2a Leadership and management

Leadership engagement in quality and safety was found to be an important organisational factor in papers 1, 2, 7, 10 and 11. Where senior leaders were in contact with frontline staff on a regular basis, staff described being able to discuss safety issues with them, and this in turn was found to influence top level decision making. Influencing how leaders conceptualise quality was found to be important in the QUASER study (paper 11).

In organisations where improving quality and safety was delegated to the frontline, described as a 'bottom up' or empowering environment (papers 1,2,10,11), staff described feeling able to implement change and, in these hospitals, change was more likely to succeed. In the QUASER study (paper 10), having a culture where quality and safety was everyone's business was found to lead to safety being embedded in everyday work. By contrast in hospitals with a top-down style of leadership, middle managers described how this limited staff engagement in quality and safety improvement work, particularly the involvement of doctors.

3.1.2b Accountability versus blame

In the WISER study (papers 4, 5 and 6) where poor reliability was evident in clinical systems, the culture was one where staff blamed others for the failures and by doing so accepted the systems failures as normal in everyday work. This resulted in reluctance to report the failures, rather staff developed ways to work around the problems. These systems failures and the work arounds created error producing conditions. Similarly, in the studies of unsafe surgery in 'Never Events' (paper 7), acceptance of failures or problems in the system led to errors. Notably shortcuts to save time meant procedures designed for safe surgery were not followed and over time these shortcuts had become normal working practices which no one questioned.

Staff may not speak up for fear of blame or due to the attitude of those in senior positions towards their juniors (Helmreich and Davies, 2004). This was found to be a factor in the causes of unsafe surgery, for example junior staff often felt

unable to challenge those in senior positions when safety procedures were not followed (paper 7).

3.1.2c Training

Training was found to be important for safety and quality in the WISER and QUASER studies (papers 4, 5, 10). For clinical systems reliability, it was found to be important for staff to be trained and given a good induction into new areas where they were to work. Without this training and without familiarity in how the hospital systems worked, clinical systems were more likely to be unreliable. For example, untrained staff did not know where to find clinical information on computer systems and, in theatres, were unaware of the location of vital equipment.

At the level of the whole hospital, in the QUASER research (paper 10), training in quality improvement methods for all staff was found to be important for ongoing QI work, and for the development of a learning culture. In hospitals that had invested in training staff in QI over many years, quality work was considered everybody's business. By contrast, in hospitals where training was cancelled to save money, staff were found to have no external links to help with QI work and no 'slack time' to consider or undertake improvement activities.

3.1.2d Teamwork and Communication

The importance of good communication and the effects of poor communication on patient safety were reported in papers 1, 2, 3, 6, 7 and 11. For patient safety improvement to be seen as a priority in an organisation, this needs to be communicated from the board to the ward (papers 1, 2 and 11). For good decision making at board level about patient safety, it is important for those present to have a good understanding of the day to day safety concerns of frontline staff. Leadership walkrounds were found to be an effective mechanism for such communication (papers 2 and 11).

Poor communication was found to lead to poor reliability and hence poor patient safety (papers 3, 6, 7). Examples here included poor documentation in medical

records, the use of abbreviations that were misunderstood, medical information not being available, and poor communication with patients. Poor communication within clinical teams was found to lead to errors in the work to understand the root causes of Never Events (paper 7). Examples of this included poor teamwork, and failures to speak up when known safety procedures were not followed.

3.1.3. Systems and Infrastructure

As set out in section 1.3.1, the systems and infrastructure of an organisation are potential contributory factors to poor safety. Papers 1, 4-7, and 10, provided further detail about how these factors impact on safety in healthcare.

3.1.3a Complexity of processes versus standardisation

In the paper on Leadership Walkrounds (paper 2), chief executives reported finding overly complex or bureaucratic processes for simple things within their organisation, that were previously unknown at a senior level.

Both a lack of standardisation and overly complex processes were found to lead to poor clinical systems reliability and poor safety, in the WISER study (papers 4 - 6) and the study of the causes of Never Events (paper 7). For example, in the study of missing clinical information (paper 6), overly complex processes for arranging and reporting tests (X-rays, CT and MRI scans, biopsies etc) meant that often these important results were not available when a patient returned to clinic for a decision about future treatment.

Often standardisation has been introduced through new policies and procedures (paper 7). How these were introduced and how they related to other existing policies and procedures was found to be important in whether they were followed , echoing other studies (Carthey et al., 2011). Not following these policies and procedures was at the root of several of the Never Events. Examples included not following procedures to mark an operation site; and not using the World Health Organisation safer surgery checklist.

3.1.3b Data Infrastructure and the Use of Measurement

Poor data infrastructure was found to create error provoking conditions in the WISER study on the reliability of clinical systems (papers 4 and 6). Examples included key clinical information being unavailable at surgical outpatient appointments and for multi-disciplinary meetings to decide surgical options for cancer patients.

In the SPI programme (paper 1), measures were introduced for all aspects of the change programme to enable participants to demonstrate success, or not, over time. Information systems for measurement were found to be inadequate at the start of the programme (paper 1). In addition staff described their knowledge and capacity to undertake the required measurement tasks as weak, at the start of the programme. This is important since the ability to demonstrate success has been found to be important for future success in change programmes (see section 1.3.2). Hospitals ability to demonstrate success in the delivery of high quality, safe care was examined as part of the QUASER study (papers 9, 10 and 11). A wide variation was found between countries in the data that was available to the public about care in hospitals. This ranged from Portugal where there was no public data available to the Netherlands and the England where there was a plethora of information available for the purposes of patient choice (paper 10).

3.1.4. Summary of the organisational and systems factors underpinning safety improvement in healthcare

In synthesising the findings across the eleven publications, the organisational and systems factors underpinning safety improvement in healthcare emerged, as follows:

- leadership stability:
- financial balance:
- alignment of external and internal priorities:

- data infrastructure:
- measurement capability:
- standardisation of clinical systems:
- creating an open and fair collective culture where poor safety is challenged:
- training and induction:
- teamwork and communication:

This synthesis extends our understanding of the contributory factors of adverse events, as set out in the London Protocol (figure 1), specifically the institutional context and the organisation and management factors. It also adds to our understanding of the organisational challenges described by Bate et al (2008) (figure 2), in particular the cultural, educational, and the physical/technological challenges.

3.2. Evaluation of and reflection on the methods used in the research: informing future research in this area

In addition to the contribution to knowledge from the findings of the submitted publications, the research conducted also contributes to knowledge of how to investigate and capture relevant data for assessing implementation and impact of complex patient-safety and quality improvement programmes. This has been achieved through the publication in full of the research protocol for the large, European study (paper 8) and through the analysis of a multimodal, longitudinal approach as presented in paper 3. This paper analysed the specific challenges encountered and proposed recommendations for similar research programmes. In setting out the challenges, the paper has informed the methods for future studies (Krein et al., 2010, Øvretveit, 2009).

In this section the main research challenges, encountered across the studies are discussed, with the specific aim (as set out in section 1.5) as follows:

- To consider the methodological approaches and the challenges of research in practice to inform future research in this area

3.2.1a Defining and measuring success

Defining and measuring success in patient safety presented a challenge for the research in three of the studies (papers 3, 4, and 10). In the SPI study (papers 1, 2, 3) the 24 sites involved all had different starting positions, some being further ahead with quality improvement work and familiar with the data collection methods to be used during the intervention. As a result baseline measurement was more reliable in these hospitals, whilst being absent in others. This was a complex intervention across different clinical teams, involving different clinical areas and including senior leaders. As such there was no one definition of success for the intervention.

In the WISER study (papers 4, 5, 6) the challenge was to define success in terms of clinical systems reliability for five different systems. This was the first time that reliability had been measured for these systems and hence the first time that reliability had to be defined for each.

In the QUASER study (papers 8-11) there was inconsistency in the data available to assess healthcare organisations performance in quality and safety across the five different countries involved. In some countries also, there was variability and inconsistency in the methods, and robustness, of data collection in different hospitals, making comparisons between sites difficult. The challenges of this and how they were overcome are reported in paper 9.

In each study, success had to be defined by the research team and in consensus with participants where appropriate. In the SPI study success was defined as to whether the programme continued to be rolled out and whether safety improvement data were still being collected and used. In the reliability study, consensus was reached with participants in each clinical system, applying the definition of reliability used in industry. In the QUASER study consensus was reached on the definition of quality in hospitals through

discussion between research teams, based on the data available in each country.

In summary, success is not easy to define in safety and quality improvement research. Research teams need to take this into consideration when planning interviews and survey measures and where possible agree this in consensus with participants.

3.2.1b Conducting longitudinal research

Both the SPI (papers 1-3) and the QUASER (papers 8-11) studies involved longitudinal research at two time periods. In the first study the requirement was to re-survey and re-interview the same sample as at the first time point, over a year earlier. Multiple staff changes across all sites made this task difficult. In particular, those staff that had been successful in delivering the safety interventions had often been promoted to positions outside the organisation to assist others in similar work.

In both studies, in the intervening period between the two time points, the sites had multiple external influences to improve quality and safety. Therefore, attribution of changes during this period to any one influence or intervention had to be considered. The design of the SPI study took this into account by focusing the interviews on the specific aspects of the interventions. In addition the survey measure asked specific questions about the intervention and was administered at each time point to the same cohort of people directly involved in the intervention. In the QUASER study, similarly the interview participants and questions were unchanged between time points, however here there were specific questions about external influences. In addition, a ‘tracer’ project related to infection control was tracked throughout the period of the research to capture and understand both the external and internal influences on improvement work. This included specific questions to participants and the tracking of guidance from external stakeholders, such as NICE.

In summary, it is important to consider how external influences will be captured and taken into consideration in longitudinal research into safety and quality improvement work. This may be through specific questions related to such influences, through the tracking of a specific issue, or through analysis of guidance issued by external stakeholders.

3.2.1c Cross country research

The QUASER study (papers 8-11) involved research teams in working in 5 languages. This posed a challenge for the consistency and reliability of the fieldwork. Overcoming this required regular meetings, emails and phone calls between researchers. The analysis of the fieldwork and interviews was conducted in the language of the research team and the resulting country reports were translated into English as the working language. Additional work was required, between the research teams, to understand the key findings from each country report and to ensure they were correctly translated. Confirming meaning within the translated reports required work between research teams by email and at a research meeting, before the cross case analysis could begin. A wider advisory board and translational workshops also helped to test the emerging findings. From this it is evident that when conducting cross country research, time has to be built in to the study to allow for discussion between research teams, particularly during the analysis phase.

3.3. Conclusions

The publications presented in this thesis, reporting a series of research studies conducted in over 40 healthcare organisations, using mixed methods, have provided a better and more complete understanding of the organisation and systems factors underpinning safer healthcare. This includes the nature and extent of poor systems reliability and its effect on patient safety; the factors underpinning cases of patient harm; and the cultural issues impacting on safety and quality. The findings in the publications highlight the importance of a

common language for quality and safety across an organisation, and the how this can be achieved when healthcare leaders engage with frontline staff using a structured approach. The impact of external pressures on healthcare organisations have been described, with recommendations to policy makers relating to consideration of the difficulties experienced by hospitals in maintaining a focus on safety when in financial difficulty. The importance of aligning both external and internal requirements into an overarching safety strategy have been described, to ensure that staff are not overwhelmed by multiple, conflicting requirements. Finally the specific cultural and systems factors underpinning poor reliability and hence poor safety have been described, including the need for organisations to focus on improving teamwork, communications and data infrastructure.

Considered together, the findings address the overarching question: What are the key organisational and systems factors that impact on patient safety, and how can these best be researched? The synthesis has also addressed the specific aims (section 1.5) as follows:

- Investigate the implementation and impact of patient safety improvement interventions in UK hospitals and the factors associated with successful outcomes

- Explore the nature and extent of poor patient safety in the UK NHS and specifically, the factors contributing to the persistence of cases of wrong site and wrong procedure surgery

- Extend the research to explore and compare safety and quality in hospitals in 5 European countries

- Consider the methodological approaches and the challenges of research in practice to inform future research in this area

Each research study, and the associated analysis, required the development of appropriate methods to answer the research questions. The methods incorporated a range of approaches, both qualitative and quantitative, including interviews, surveys, documentary analysis and observation. One study involved

translation from 4 languages into English. Two studies were longitudinal. Analysis of the effectiveness of the methods used in practice revealed a number of challenges, including how to measure success in research across multiple organisations with different starting positions; how to assess ongoing external influences on organisations during longitudinal research into specific interventions; and how to ensure correct meaning and interpretation in translated research reports.

3.3.1. Implications and impact in practice

Each publication has had implications in practice. The SPI research (papers 1-3) informed the next stage of work on patient safety by the Health Foundation as funders. Each of the subsequent national safety programmes included a component aimed at leaders of healthcare organisations, and the use of measurement for safety improvement (Department of Health, 2009, Welsh-Government, 2008, Healthcare Improvement Scotland, 2008). The study of the reliability of clinical systems (papers 4-6) informed improvement work in each of the participating organisations, and a major programme of work to improve reliability in healthcare (The Health Foundation, 2014). The study of Never Events (paper 7) informed a national initiative in England to develop standards to prevent such events in future (NHS England, 2015a). Finally two guides were produced from the translational research in 5 European countries (papers 8-11), to aide hospital managers and commissioners to improve the quality and safety of healthcare (Fulop, 2013a, Fulop, 2013b).

3.3.2. Implications for and impact on future research

Synthesising the findings of the published papers presented in this thesis has revealed some potentially rewarding aspects for future research. For example:

- Assessing the support required by hospital organisations to maintain focus on patient safety when going through periods of major change, or austerity (papers 4, 6 and 10).

- Assessing the skills needed for healthcare leaders to negotiate, align and translate multiple external and internal pressures into a coherent strategy for safe services (papers 10 and 11).

- Understanding the extent and nature of poor data infrastructure in healthcare organisations and assessing the implications for patient safety (papers 1-7).

The research methods used in the publications described in this thesis provide practical recommendations for these potential studies. For example, how to define 'success' when considering whether a hospital has maintained a focus on patient safety, during a period of major change, will require an assessment of the organisational pre-conditions (paper 1); reaching consensus with participants (papers 4-6); and from this the establishment of a baseline set of measures that can be tracked over time (papers 3, 4 and 9).

3.3.3. Overall original contribution to knowledge

The extent of patient harm from healthcare did not become a focus for study until the 1990s with the first major report on preventing harm in healthcare issued in 2000 (Department of Health, 2000). This led to considerable attention and effort to translate learning from the 'safety conscious' industries into the NHS. How to transfer this knowledge and achieve widespread, sustainable change was a challenge in the early 2000s and led directly to the research presented in this thesis. The publications have provided a better understanding of the key organisational and systems factors impacting on patient safety in acute care organisations. Moreover, the findings have since been used in practice to inform both local and national efforts to improve patient safety. Consideration and analysis of the research methods has provided insight into the application of different research methods in multi-site and longitudinal research in patient safety. Setting out the challenges encountered in this research, will inform future research in this area.

APPENDIX 1

Overview of the history of risk, safety and patient safety

The concept of medical harm is known to date back to 1754 BC when the Babylonian Code of Hammurabi set out the law that, if a surgeon killed a patient, his hand would be cut off (Wootton, 2006). The Hippocratic Oath, first sworn by doctors in the 5th Century BC, contained the clause

> *I will apply dietetic measures for the benefit of the sick according to my ability and judgement; I will keep them from harm and injustice* (Edelstein, 1943, in Veatch, 2000. p3)

The concept of physicians as potential "poisoners", for example, appears in Roman and early Islamic literature (Sharpe and Faden, 1998) and has been a topic in plays and books ever since, most notably in Shakespeare (1623), and Moliere (1667) (Wootton, 2006).

Medical historians acknowledge that doctors had very little to offer patients until the late 19th century (Sharpe and Faden, 1998, Wootton, 2006). Indeed, it is known that the treatments that were available, such as mercury, arsenic, phosphorous and bloodletting, actually caused harm and patients died as a result. In the book *Medical Harm,* Sharpe and Faden (1998. p7) describe a treatise published in 1728, entitled "*Doctors as the Cause of Illness",* where case studies were presented demonstrating the harmful effects of bloodletting. Nevertheless, with little else to offer, and with little understanding of the causes of illness, doctors continued to use it as a treatment until the end of the 19th century (Wootton, 2006).

It was not until the discoveries of germs and germ theory by Lister and Pasteur (circa 1860) that historians acknowledge that medicine became more effective (Sharpe and Faden, 1998, Wootton, 2006). 'Germ theory' provided an understanding of the cause of infections and this led directly to the adoption of antiseptic techniques in surgery. This combined with the introduction of anaesthesia and later, the discovery, and wider use, of penicillin, gave rise to an increase in surgery. From 1900 onwards in the UK, more hospitals began to

open and gradually medicine began to be organised within and around these institutions.

Historically, most accidents were seen as ‘acts of God’ (Loimer and Guarnieri, 1996). However, in the 19th century, the prevailing view was that individuals were responsible for their own safety and, hence, guilty if injured by an accident and blamed if an error occurred (Ilan and Fowler, 2005, Guarnieri, 1992). Research into the causes of accidents until the 1930s was focussed on finding the psychological causes of accidents.(Guarnieri, 1992) As a result, many of those who spoke out about patients being harmed by their care were vilified by the medical profession since it was understood that they were laying the blame at the door of individual doctors.

With the growth of surgery in the early part of the 20th century the first documented attempt was made to study the outcomes of surgery, including surgical errors. A well known American surgeon, Ernest Amory Codman began to collect data on the outcome of his surgery, called ‘end results’ which he published in a book (Codman, 1915b). He defined ’end results’ as:

> *The common sense notion that every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire, “If not, why not?” with a view to preventing similar failures in the future.* (Codman,1915a. In Gerrand and Rankin, 2014. p473-474)

Codman’s efforts to understand surgical failures and to develop standards for operating theatres and hospitals performing surgery were rejected at the time. In the early part of the 20th century, medical harm was not on the agenda and certainly not for public discussion:

> *E. Amory Codman received no appreciation in his lifetime. His efforts to reform medical science by starting the field of outcome studies and evidence-based medicine brought him mostly ridicule, censure and poverty.* (Mallon, 2015)

Prior to the formation of the NHS, each hospital and local authority dealt with their own litigation and complaints. As such, there was no overall knowledge about patient harm in the UK. This continued after the establishment of the NHS in 1948, when systems for collecting national data about the use of hospital services developed, but these were limited (MacFaul, 1988) and focussed on throughput and performance.

The first high profile case of widespread harm from healthcare in the UK occurred in 1961, when the drug Thalidomide was withdrawn from use following the discovery that it caused birth defects. Following this, there were a series of high profile public inquiries into poor quality care in hospitals such as at Ely, Farleigh, and South Ockenden (Walshe and Higgins, 2002, Mold, 2012). Then in 1976, Ivan Illich published 'Limits to Medicine, Medical Nemesis: the Expropriation of Health' (Illich, 1976b), setting out a reasoned argument that the medical establishment had become a major threat to the health of the population. In his critique, Illich (1976) cited the lack of evidence for high technology medicine, and doctor inflicted injuries, saying:

> *The pain, dysfunction, disability, and anguish resulting from technical medical intervention now rival the morbidity due to traffic and industrial accidents and even war-related activities, and make the impact of medicine one of the most rapidly spreading epidemics of our time* (Illich 1976; p.35)

Interest in medical harm began to grow and in 1980, the BBC screened a play entitled 'Minor Complications' about a real life story of a woman who had gone into hospital for a routine sterilisation by keyhole surgery (Ransley, 2015, Watts, 2003) but had her bowel damaged during the procedure. The hospital had denied liability but, after persisting for years, the woman won compensation. Following this broadcast, the charity Action for Victims of Medical Accidents was set up in the UK and began to campaign on behalf of patients who had been harmed by their healthcare. Soon after in 1983, in the UK, the BBC broadcast a series of Reith lectures by Ian Kennedy, subsequently published in 'The Unmasking of Medicine' (Kennedy, 1981). In their review of the book, the New Statesman magazine described the lectures and the book as a '*hard hitting and*

penetrating investigation behind the facade of contemporary medicine' (Kennedy, 1981, book cover). By the mid 1980s, the potential for harm caused by healthcare was firmly on the public agenda in the UK.

Public trust in the medical profession, in the UK, was dealt a further blow in the mid 1990s with the arrest of GP Dr Harold Shipman, for the murder of many of his patients, and the revelations about the high number of deaths of children from heart surgery in Bristol (Savage, 1998, Kennedy, 2001). This led to government intervention with a White Paper issued in 1997 introducing:

> '*a new system of clinical governance in NHS Trusts and primary care to ensure that clinical standards are met, and that processes are in place to ensure continuous improvement, backed by a new statutory duty for quality in NHS Trusts'* (Department of Health London, 1997. p24)

This White Paper also led to risk management being introduced across the NHS (see later section on risk management in this overview).

The outcome of the Bristol Inquiry (Kennedy, 2001) and the surrounding publicity was said in a BMJ editorial to have:

> *... thrown up a long list of important issues that British medicine will take years to address. At the heart of the tragedy, which has been Shakespearean in its scale and structure, is, as the GMC said, "the trust that patients place in their doctors." That trust will never be the same again, but that will be a good thing if we move to an active rather than a passive trust, where doctors share uncertainty.* (Savage, 1998, p1917)

Following a rise in medical negligence claims in the USA, in the 1980s, investigations began into the cause (Sharpe and Faden, 1998). A paper in 1994 by a leading American physician, Lucian Leape, entitled *Error in Medicine (Leape, 1994)* brought the extent of medical harm in the USA to the fore. Leape had been involved in the Medical Practice Study (Brennan et al., 1991) in the USA, which uncovered the extent of medical harm through retrospectively reviewing patients' case notes. Importantly, Leape's paper described how the preventable harm, largely, was not the fault of individual doctors but required a

review of the whole healthcare system (a 'whole systems approach') to foster improvements and prevent similar events happening again. This meant moving away from blaming individuals to considering the role of the wider healthcare system in provoking errors (Kast and Rosenzweig, 1972, Von Bertalanffy, 1972).

Not long after Leape's publication, Betsy Lehman, the respected health reporter at the Boston Globe newspaper, died from a medical error and the paper ran the headline '*Doctors orders killed cancer patient'*. This had occurred at one of the USA's leading cancer institutions and *'spread shockwaves far beyond its walls* (Millenson, 2002, p59). The news outlets in the USA soon began reporting other cases. As Millenson (2002) says, the Lehman incident became:

> *'..the unavoidable anomaly that finally subverted the existing tradition. The proud Boston medical community reacted with "profound shock and dismay..." The reason it was not 'circle the wagons and defend ourselves' was because it was so irrevocably bald.'* (Millenson, 2002. p59)

Following this, many medical groups in the US began to acknowledge that errors in medicine were pervasive. This led, in 1999, to the Institute of Medicine (IOM) in the USA publishing a report entitled *To Err is Human* (Kohn et al., 2000). This report described how between 44,000-98,000 people every year died from preventable medical harm in the USA. Following Leape (Leape, 1994), the report also highlighted how most of these errors were caused by failures within the system of care, rather than by individuals themselves.

Since the 2000, in the UK and internationally, considerable attention has been paid to the ways to reduce harm in healthcare (Shojania et al., 2001, Department of Health, 2000, Kohn et al., 2000, Vincent, 2011, Amalberti et al., 2006, Kennedy, 2001).

The Rise of Patient Safety in the UK

During the 1990s, the antibiotic infection MRSA began to rise in UK hospitals from 2% in 1990 to over 40% in the early 2000s (Johnson et al., 2005), becoming a frequent topic in the news media and of great public concern

(Holmes, 2015). In 1999, Vincent et al (2001) repeating the MPS study in the USA, found that 10% of patients in British hospitals were harmed by their healthcare, and that half of these adverse events were preventable. Together with events in the USA (see previous section) the growing concern about poor safety in UK hospitals led, in 2000, to the UK Chief Medical Officer's report *An Organisation with a Memory* (Department of Health, 2000). This report set out the scale of harm from medical error in the UK and described how healthcare organisations could learn from these events and make improvements. This report also drew on lessons from other industries that were particularly conscious of safety (such as nuclear power and aviation). Following publication of the report, the government responded (Department of Health London, 2001), setting up the National Patient Safety Agency (NPSA), discussed in the next section.

Often a public outcry has prompted government intervention to improve safety in society and this has certainly been the case with regard to patient safety (Bennett, 2010, Pidgeon et al., 2003, Millenson, 2002, Holmes, 2015). As each case began to unfold, increasingly the public began to comprehend the impact of patient harm. The effects of Thalidomide were evident in the disabilities of the children; and during the Bristol enquiry parents described the effects on the families of those left behind. This led to the realisation that more fundamental organisational changes were needed in the NHS, not only to tasks and processes but also to the culture within hospitals to make them more open and safety conscious. This was a call to action across the UK NHS, and with the establishment of the NPSA in 2001, work began to understand and find ways to improve patient safety, with funding allocated, for the first time, to research (Lilford, 2002). What changes were needed to improve patient safety, and how to embed these into systems wide change, presented both a practical and a research challenge in the early 2000s.

The National Patient Safety Agency (NPSA)

The UK National Patient Safety Agency (NPSA) was set up in 2001 with the remit of establishing a national reporting and learning system (NRLS) for adverse events, training staff in incident investigation techniques, and issuing

alerts and guidance to the NHS. The total number of patient safety incidents reported by English healthcare organisations to the NPSA by the end of March 2015 was 11,209,663 (NHS England, 2015b). Early guidance issued by the NPSA dealt with specific safety issues, for example preventing accidental overdose of potassium chloride concentrate by providing ready-diluted solutions (NPSA, 2002) and reducing transfusion errors through standardising medical devices in hospitals. Later alerts provided supporting material to aide implementation and this developed into wider campaigns, for example the 'Clean Your Hands' campaign to improve hand hygiene and reduce healthcare acquired infections (Holmes, 2015)

In 2004 the NPSA published *Seven Steps to Patient Safety* (Woodward, 2004). This set out the range of areas that healthcare organisations needed to deal with, in order to improve patient safety:

1. Developing a safety culture
2. Establishing a strong focus on patient safety throughout the organisation
3. Integrating risk management systems
4. National and local reporting requirements
5. Patient and public involvement in safety
6. Root cause analysis for incident investigation
7. Transferring lessons from investigations to solutions

From this and from work in the USA at that time (Berwick et al., 2006, Gosfield and Reinertsen, 2005), it was clear that more fundamental work was required to embed these steps throughout healthcare organisations. This led to the Health Foundation funding the 'Safer Patients Initiative' (SPI), a major improvement programme in 24 UK hospitals over 4 years. SPI was designed to impact at all levels, with a mix of interventions drawn from other industries (including the US Navy) and from clinical effectiveness research. Since the completion of this programme in 2008 there have been many other initiatives and campaigns to

improve patient safety in UK hospitals, most recently the 'Sign Up to Safety' campaign (NHS England, 2012).

An overview of the history of risk management and incident reporting

The idea that risk could be calculated developed from the gambling tables in the 17th century (Bernstein, 1996, Wootton, 2006). From this developed the mathematics of probability which began to be applied in commerce to calculate financial and other business risks, particularly for the purposes of insurance. For example in 1662 it was used to predict mortality in London for the purposes of selling life insurance (Bernstein, 1996). Once risks could be calculated and insured against, the thought of accidents being 'acts of God' began to be questioned (Loimer and Guarnieri, 1996, Guarnieri, 1992, Bernstein, 1996). The German sociologist Ulrich Beck (Beck, 1992, Elliott, 2002) describes this as the time when a shift began towards a risk society (Beck, 2006):

> *...from now on human beings must find (or invent) their own explanations and justifications for the disasters which threaten them* (Beck, 2006, p333).

With the ability to calculate risks, strategies began to be developed to identify, analyse and control or reduce these risks, known as risk management (Walshe, 2001. p45). In their paper examining the history of risk analysis and risk management Covello and Mumpower (1985) set out the variety of ways in which society has traditionally managed or controlled identified risks (see figure 6).

Figure 6: Methods of risk management in society (Covello and Mumpower, 1985)

- Avoiding or eliminating the risk, such as prohibiting the use of a potentially dangerous object or substance
- Regulating or modifying the activity to reduce the magnitude and/or frequency of adverse health effects, e.g., by constructing dams, levees, and seawalls
- Reducing the vulnerability of exposed persons and property, e g, by requiring the use of safety devices, by elevating buildings in floodplains, by immunizing the population, by implementing quarantine laws, or by establishing disaster warning systems
- Developing and implementing post-event mitigation and recovery procedures, e.g., by establishing search and rescue teams, stockpiling food, providing first aid training, or providing fire extinguishing equipment and services
- Instituting loss-reimbursement and loss-distribution schemes through such mechanisms as insurance systems or incentive pay schedules for high risk activities

Fundamental to risk management is the identification or detection of risks (Dückers et al., 2009. p.6). With developments in technology, alerts and alarms are often used for hazard detection. However these only provide detection where technology is in place or where technology is the cause of the failure:

> *Despite the great advances in aviation technology over the last decade or so we do not see any real improvement in the global accident rate. .... as*

> *technical fixes made aircraft more reliable the more obvious became the crew failures.* (O'Leary, 2002. p245)

Incident reporting arose from the Aviation Psychology Program in the US Air Force during the Second World War (Flanagan, 1954). Since then it has developed and spread into many, if not all industries. For example, in the UK, it is a required part of health and safety at work legislation, that workplace injuries are recorded and reported (Health and Safety Executive, 2013). The purpose of incident reporting is to understand the size or extent of safety problems, to enable prioritisation of resources towards prevention, and to help organisational learning (Secker-Walker and Taylor Adams, 2001b, p 419).

Whilst being firmly established in business, methods of managing and reducing risks did not exist in the NHS until the mid 1990s when the UK government became concerned about the rising costs of medical negligence claims:

> *It has been estimated that during the 1980s, the frequency of claims rose fivefold, while the costs of each claim went up by 250%... By 1996 claims for clinical negligence cost the NHS about £200 million.* (Walshe, 2001. p.47)

Management consultants were hired by the Department of Health to advise and develop risk management methods for the NHS. An ‘Executive Letter’ was issued (NHS-Management-Executive, 1994) encouraging NHS trusts to introduce systems for managing risk. Fundamental to these systems was knowledge about the risks that existed and soon hospitals began to introduce incident reporting systems for adverse events, using the findings from investigations into serious adverse events to make safety improvements. Risk management was firmly introduced across the NHS in the 1997 White Paper entitled ‘The New NHS: modern, dependable’ (Department of Health London, 1997).

When research was conducted into the effectiveness of the new risk management systems, their shortcomings were highlighted. These included clinical staff being reluctant to report adverse events (Lawton and Parker, 2002), resulting in managers only being aware of a fraction of the adverse events that were taking place in their hospitals (Bates et al., 1995, Sari et al.,

2007). It was evident from this, and from research into the factors underpinning safety improvements in other industries (Reason, 1997, Reason, 1990, Cox and Cheyne, 2000, Glendon and Stanton, 2000, Fleming, 2001), that further organisational changes were needed in the NHS, including changes to the culture to make it more open and fair (Department of Health, 2000, Kohn et al., 2000).

Table 2: Timeline of the history of safety and risk related to medicine

Date	***History***	***Reference***
BC	• Code of Hammurabi (1750 BC) • Hippocrates (5th Century BC)	Wootton, 2006.
	Doctors have little to offer in terms of effective treatments (apart from bone setting and amputations) until the mid 19th century	Wootton, 2006.
	Many examples in literature through the ages of doctors doing harm – Shakespeare, Moliere etc	Shakespeare, 1623, Moliere, 1667.
1421	The earliest reference to medical regulation in the UK dates from 1421, when physicians petitioned parliament to ask that nobody without appropriate qualifications be allowed to practise medicine. The doctors said that unqualified practitioners caused "great harm and slaughter of many men" (see note 1 to table)	Raach, 1944. English Medical Licensing

1500s	1511 Statute placed regulation of the medical profession in the hands of the bishops – medicine and religion intertwined – aim to suppress quacks 1518 College of Physicians set up and takes over licensing	Raach, 1944.
17th C	Probability theory develops mainly applied to gambling and to risks in finance and commerce but in 1662 used to predict mortality for life insurance. Start of the industrial revolution and establishment of factories and organised labour (Trades Unions)	Wootton, 2006.
1800-1850	Period of government legislation for the safety of the workforce, followed up with inspection and regulation: • Factories Act and start of Factories Inspectorate (established 1833). • Mines Inspectorate established in 1843	Health and Safety Executive, 2015. UK National Archives, 2016.
	Many accidents seen as 'acts of god' – religion important in people's lives	Guarnieri, 1992.
	Temperance movement – support for the view that alcohol is primary cause of accidents at work View prevailed that people were responsible	Ilan and Fowler, 2005.

	for their own safety and therefore guilt if injured.	
	Growth in insurance and workmen's compensation schemes – insurance companies begin to question high rates of accidents and the notion that these are all the responsibility of the individual	
1847	Ignaz Semelweis proposes that hand washing with chlorinated lime solution would reduce maternal mortality – doctors were offended by the suggestion that they were unclean. In 1861 he publishes a book lamenting the slow adoption of his ideas and dies the same year.	Semmelweis, 1861 (republished 1983)
1854	Florence Nightingale goes to Crimea with a group of nurses and begins her campaign to improve nursing and to improve conditions in army and other hospitals – her campaigning continues until her death in 1910	Nightingale, 1863.
1858	Medical Act empowered the medical profession to create and enforce own professional standards - GMC set up. Professional code states that Drs cannot criticise each other	Chacko, 2009.
1870s-1890s	Increase in numbers entering workhouses when regions cut benefits to the poorest. Workhouse medical officers and nurses	Price, August 17, 2012.

	unprepared and many tragic cases of starvation and neglect of vulnerable people. Local Government sought to blame individual doctors for cases of medical neglect	
1850 - 1914	Start of use of anaesthesia 1865 Lister demonstrates principles of antiseptic surgery – and germ theory. Development and more acceptance of germ theory and asepsis	Wootton, 2006.
	Move towards a more secular society with explanations required for incidents, with less use of the term ‘acts of God’.	Beck, 2006.
1900-1940	The establishment and growth in the number of hospitals – services being organised around doctors Ernest A Codman sets out to improve the outcome of surgery in the USA through recording ‘end results’ and setting standards for operating theatres and surgical hospitals – his ideas are ridiculed and thrown out and he dies in poverty	Mallon, 2015, Vincent, 2011.
1900-1914	Pickstone’s first phase of healthcare development: Productionist – healthcare oriented towards developing and maintaining a strong and healthy workforce and army	Cooter and Pickstone, 2000.

	• Public Health • Poor Laws • Ante natal care starts; registration of midwives; maternity hospitals	
1918 – 1950s	Pickstone's second phase of health care development: Communitarianism – social solidarity; risks become shared (contributions to pay for care when needed)	Cooter and Pickstone, 2000.
	Growth in what doctors can offer in terms of effective treatment	Sharpe and Faden, 1998
	Shift from a social to a medical model of health (especially in maternity care)	Bryers and Van Teijlingen, 2010.
	Drs retain a high level of professional autonomy and are held in high regard by the public	Willis, 2006.
1928	Committee established in the UK to investigate maternal deaths	Ngan Kee, 2005.
	UK Road Safety legislation and start of Royal Society for the Prevention of Accidents	ROSPA, 2016.
	View prevails that accidents are caused by individuals – psychology research into 'accident prone' people	Guarnieri, 1992.

1930s	The term ‘accident’ is questioned – Gibson and Haddon suggest that ‘causes of injury’ should be adopted in research.	Ilan and Fowler, 2005, Guarnieri, 1992.
1940s	WW2 and rise of ergonomics as a subject area for research – from war research into man-machine interface; goes on to be applied in civilian life. Physiologists and psychologists form the Ergonomics Research Society (2009 name change to Ergonomics and Human Factors)	Human Factors and Ergonomics Society - HFES
1948	NHS established – healthcare becomes more of an industry and more organised	Klein, 1995.
	Health and safety embedded in NHS to prevent workplace accidents – all falls reported to HSE; any staff off work for more than a set period due to work injury reported.	HSE, 2015.
1950s	The 1950 Medical Act introduced disciplinary boards and a right of appeal to the General Medical Council	BMJ, “The Medical Act, 1950”
1952	Confidential enquiry into maternal deaths set up	Ngan Kee, 2005.
1960s	Thalidomide prescribed to pregnant women causing birth defects – 1963 Safety in Drugs Committee set up – drugs begin to be licensed	Emanuel et al., 2012.

1966	Health Memorandum published by DHSS recommended adopting standardized complaints procedures. Guidelines suggested complaints be handled by physicians and unnecessary for most complaints to be considered by someone outside the medical organisation – conflicting with main principles of effective regulation that it be conducted by independent agents. Doctors still held in high regard so thinking was that they would want to resolve their own complaints to serve the patients best interests.	Mulcahy, 2003, Mulcahy and Tritter, 1998, Chacko, 2009.
1969 - 1980	1969 Ely Hospital public inquiry over the scandal of patients being mistreated – there then followed 18 more inquiries up to 1980 – all about mistreatment of patients. The public began to lose confidence in the medical profession.	Walshe and Higgins, 2002, Walshe and Shortell, 2004.
1970s	Hospital Advisory Service set up – developed into the Commission for Healthcare Improvement (CHI) and now the Care Quality Commission (CQC)	
1973	Davies Committee report on the NHS Complaints procedures – recommended external involvement – recognised that doctors have professional bias to cover up errors.	Chacko, 2009

1974	Don Harper Mills conducts first comprehensive case note review in a study of medical error in Californian hospitals – motivated by economic and legal concerns – didn't lead to any changes	Mills, 1978, Millenson, 2002.
	Office of the Health Service Commissioner (later the Ombudsman) set up as independent investigator of complaints – although could not investigate complaints relating to the 'consequence of the exercise of clinical judgement'.	Chacko, 2009.
1976	Ivan Illich publishes Limits to Medicine – arguing that medicine was now a danger to our health, causing more deaths and injuries than it was curing. This is followed in 1981 by Ian Kennedy's 'The Unmasking of Medicine' - initiates debate about patients as consumers, involved in decisions about their care	Illich, 1976a, Kennedy, 1981.
1975	Litigation – around 500 claims in the year - value circa £1m – starts to grow	Walshe, in Vincent 2001 p. 47
1980s	MRSA begins to be recognised as a problem in NHS hospitals (personal experience)	Holmes, 2015
1982	Action for Victims of Medical Accidents set up following public reaction to the television play 'Minor Complications'	Ransley, 2015.

1983	National Health Service Management Enquiry introduces managerialism into NHS – doctors begin to be managed by managers 1989 split between purchasers and providers and the creation of NHS Trusts – 10 years later CEO's of Trusts given statutory duty of quality	Griffiths, 1983.
1984	Harvard Medical Practice Study undertaken	Brennan et al., 1991, Millenson, 2002.
1985	Hospital Complaints Procedures Act passed – an MP developed septicaemia due to his treatment – frustrated at complaints procedures he instigated the bill requiring all hospitals to have proper complaints procedures and to tell patients about them	Chacko, 2009.
1985	Birmingham bone tumour service inquiry demonstrates service failings – misdiagnosis of cancer in many cases	Jones and Hall, 1993.
1980s	Chernobyl 1988; Pipa Alpha 1989; Kings Cross Fire; Herald of Free Enterprise; These inquiry reports begin to enunciate the failures of management and the board.	James Reason in Vincent, 2001
Late 80s	Medical audit becomes requirement for hospital doctors	Secker-Walker and Donaldson, 2001a, Stern and Brennan,

		1994.
1990s	Clinical effectiveness gains credence John Major's Patients Charter – idea of an 'empowered patient' set out what patients could expect – raised public awareness of rights and standards.	Secker-Walker and Donaldson, 2001a
1990s	Crown indemnity for clinical negligence introduced and NHS assumes all liability. Risk management begins to grow in NHS – mainly due to costs of litigation – prior to this most hospitals had litigation and complaints systems plus health and safety committees and incident reporting for staff injuries. Also some pharmacists collected reports on medication errors for internal learning. Little ownership corporately and functions not linked together. 1992 DH commission risk management consultants to develop manual for NHS – published 1993 1995 Clinical Negligence Scheme for Trusts set up – and the NHS Litigation Authority - incentivises trusts to develop risk management systems	Walshe, 2001 p.49 NHS Management Executive, 1994.

	Bristol Paediatric Cardiac deaths and public inquiry	Kennedy, 2001, Savage, 1998.
	GP Harold Shipman arrested for murder of 15 patients	Smith, 2002-2005, Mohammed et al., 2001
	Growth in media interest in MRSA associated with unclean hospitals. 2880 articles on MRSA published in 12 UK newspapers between 1994 and 2005(Boyce et al., 2009)	Boyce et al., 2009
	Questioning of role of GMC in regulating doctors – no doctors struck off for failing to attend to patients but several struck off for actions that disgrace the profession.	Chacko, 2009
1994	Lucien Leape's paper in JAMA – Error in Medicine Washington Post article gains national attention (role of media important from now)	Leape, 1994, Millenson, 2002.
1994	Being Heard report published by Department of Health – patients expressed fear that professional loyalties may override fair play in handling complaints – you complain to a person you are complaining about.	Department of Health London, 1994.
1995	Boston Globe reporter Betsy Lehman dies from medication error in USA's most	Millenson, 2002, Gosfield and Reinertsen, 2005,

	prominent cancer institutions, Dana-Faber Newspaper investigates and many other stories begin to be published around the USA. Boston medical community respond with shock and dismay, not 'circling the wagons' IHI begin to get involved in reducing errors in medicine	Berwick et al., 2006.
1995	Quality in Australian Healthcare Study published setting out scale of medical harm	Wilson et al., 1995
1996	Value of negligence claims circa £200m per year Number of claims had risen from 500 per year in 1975 to 6000 in 1992 and 10,000 in 1999	Walshe, 2001 p.47 Chacko, 2009
1997	American Medical Association form the National Patient Safety Foundation following public response to Leape's paper and subsequent media furore	Millenson, 2002.
1997	UK Government White Paper 'The New NHS: modern ● dependable', introduces: '*a new system of clinical governance in NHS Trusts and primary care to ensure that clinical standards are met, and that processes are in place to ensure continuous improvement, backed by a new statutory duty for quality in*	Department of Health London, 1997.

	NHS Trusts. (p24)	
1998	Bristol Inquiry into deaths of children from heart surgery – interim report published	Kennedy, 2001, Savage, 1998.
1998	GMC publish new guidelines on Good Medical Practice and Maintaining Good Medical Practice – sent to every registered doctor – laying explicit individual responsibilities on medical staff, and strongly supporting the philosophy of clinical governance. DH publishes *A First Class Service: Quality in the NHS* – includes risk reduction programmes and incident reporting.	Irvine, 2006. NHS Executive, 1998.
1999	Institute of Medicine releases 'To Err is Human' stating that between 48-98,000 Americans die in hospitals every year due to preventable medical errors.	Kohn et al, 2000.
1999	UK Health Act places statutory duty of quality on NHS Trusts to assure and improve the quality of care they deliver	Secker-Walker and Donaldson, 2001a
1999	UK Dept of Health consultation paper issued to improve the management of poorly performing doctors.	Department of Health London, 1999.
2000	British Medical Journal devotes whole issue to medical error:	Leape and Berwick, 2000.

2000	An Organisation With a Memory published in UK	Department of Health, 2000.
2001	Death of Wayne Jowett from medication error in Nottingham hospital – first independent investigation using techniques used in airline industry. The report described over 40 examples of barriers and defences in the hospital's systems and procedures that had been breached.	Toft, 2001.
2001	The Pursuing Perfection Demonstration Programme funded by Robert Wood Johnson Foundation starts in 13 hospital organisations across the US and Europe (including the UK), supported by IHI	Kabcenell et al., 2010.
2004	IHI announce launch of 100,000 Lives Campaign in US hospitals	Berwick et al., 2006.
2004-2008	Health Foundation announce Safer Patients Initiative – calling for applicant NHS Trusts to work with IHI Once the programme starts, the research in this thesis begins.	

Note 1:

Medical Regulation: One of the earliest reference to action to reduce the risk of patient harm appeared in 1421 (Raach, 1944) when physicians petitioned parliament to outlaw unqualified practitioners who the doctors described as causing 'great harm and slaughter of many men'. Thus the regulation of the

medical profession was established. In 1518 the College of Physicians was set up and this took over the licensing of medical practitioners (Raach, 1944). In 1858 the Medical Act was passed setting up the General Medical Council (GMC) (Chacko, 2009) empowering the medical profession to create and enforce its own professional standards. With the rise in cases of patient harm in the media in the UK, often blaming individual doctors, the government issued a consultation paper leading to the establishment of the National Clinical Assessment Service (NCAS) to help trusts deal with doctors who were not performing to standard, or who were seen as a danger to patient safety (Department of Health London, 1999). Further changes were made in the management and regulation of the medical profession to assure the safety of patients. The regulation of healthcare professions is now embedded in the UK as one of the cornerstones of patient safety, with the aim of ensuring that all those caring for patients are qualified with their knowledge kept up to date (Allsop and Saks, 2002, Dixon-Woods et al., 2011).

APPENDIX 2

DEFINITION of TERMS

Table 3: Definition of terms commonly used in relation to safety

	Definitions from the online Oxford Dictionary (Oxford Dictionaries, 2016)	**Definitions used in healthcare**
Harm:	Physical injury, especially that which is deliberately inflicted; Material damage; Actual or potential ill effects or danger	Difficult to define – many definitions in use (see section 1). The simplest definition of harm in healthcare is a negative effect, whether or not it is evident to the patient. (The Evidence Centre, 2011, p.3)
Accident	An unfortunate incident that happens unexpectedly and unintentionally, typically resulting in damage or injury	As the Oxford Dictionary.
Error	A mistake	The failure to complete a planned action as intended, or the use of an incorrect plan of action to achieve a given aim (Department of Health, 2000, p.xii)
Complication	Something that complicates or adds difficulties; a complicating factor.	As the Oxford Dictionary.

	Also (*Med.*), an additional disorder or condition that develops during the course of an existing one; frequently in plural, complication of diseases:	
Adverse event	Term not in the Oxford Dictionary	Any injury caused as a result of treatment and care (World Health Organisation, 2015, p.107) An event or omission arising during clinical care and causing physical or psychological injury to a patient (Department of Health, 2000 p.xii)
Near Miss	*(a)* A shot that only just misses a target; also in extended use; *(b)* A situation in which a collision is narrowly avoided.	An event or situation that did not produce patient injury, but only because of chance (World Health Organisation, 2015, p107) A situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as the result of compensating action, thus preventing injury to a patient (Department of Health, 2000 p.xii)

Safety	The condition of being protected from or unlikely to cause danger, risk, or injury	As the Oxford Dictionary
Risk	A situation involving exposure to danger	The likelihood, high or low, that somebody or something will be harmed by a hazard, multiplied by the severity of the potential harm (Department of Health, 2000 p.xii)
Risk Management	The forecasting and evaluation of risks in business and commerce, combined with the identification of procedures to avoid or minimize the impact of such risks	The activities, including planning, organizing, directing, evaluating and implementing, which are involved in reducing the risk of injury to patients and health care workers. (World Health Organisation, 2015, p107)
Patient safety	Term not in OED	Freedom from accidental or preventable injuries produced by medical care. Practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events (World Health Organisation, 2015, p107)
Patient safety incident	Term not in OED	A patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient

		(Runciman et al., 2009)

Table 4: Terms used in patient safety research and in the investigation of errors and adverse events in healthcare

Term	**Definition and reference**
Barriers and defences	Measures put in place to prevent or reduce the risk of error or accident and its impact, including (Reason, 1997): • Alarms and warnings • Guidance and guidelines • Training and awareness • Measures for containment, escape and rescue
Active failures	Those made by people. They may include incorrect choices due to inexperience; lack of training; over-confidence; lapses in concentration due to tiredness or competing demands; and violations (see below) (Reason, 1997)
Latent conditions	Latent: Lying dormant or hidden until circumstances are suitable for development or manifestation (Oxford Dictionaries, 2016) The underlying conditions that unless addressed, are likely to lead to an error or accident happening. Usually they are only revealed when the accident takes place. Latent conditions may include poor design of equipment; ineffective leadership; poor communication; the lack of suitable safety procedures; and poor or no training.
Error provoking	The combined effect of the underlying causes of active

conditions	failures and latent conditions described above.
Violations	Deliberate acts that circumvent rules and procedures (such as exceeding the speed limit in a car). Violate: to break or fail to comply with (a rule or formal agreement) (Oxford Dictionaries, 2016)
Organisational accident	Comparatively rare but often catastrophic events that occur within complex organisations. They have multiple causes involving many people operating at different levels within the organisation (Reason, 1997).
Organisational culture	Shared basic assumptions about the way things are done in an organisation: 'how we do things around here' (Vincent, 2011, p.272)
Safety Culture	The product of individual and group values, attitudes, competencies and patterns of behaviour that determine commitment to, and the style and proficiency of, an organisations health and safety programmes (Vincent, 2011 p.273)
System	A set of things working together as parts of a mechanism or an interconnecting network; a complex whole (Oxford Dictionaries, 2016)
Systems theory	Understanding an organisation as a total system including the configuration of sub-systems (Kast and Rosenzweig, 1972, Von Bertalanffy, 1972)
Safety conscious	Industries where safety is considered paramount such as

industries	nuclear power; aviation; and petro-chemicals.
Human Factors	“Ergonomics (or Human Factors) is 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 optimise human well-being and overall system performance.” (International Ergonomics Association, 2016)
Clinical Human Factors	“Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture, organisation on human behaviour and abilities, and application of that knowledge in clinical settings.” (Clinical Human Factors Group (CHFG), 2016)
Non-technical skills	Cognitive and social skills that complement a workers technical skills (Flin et al., 2008). These include: • Situation awareness • Decision making • Communication • Teamwork • Leadership • Managing stress • Coping with fatigue

Appendix 3:

Table 5: Tabulation of research methods used across the studies

Study	1. SPI	2. WISER	3. Never Events	4. QUASER
Papers	1, 2, 3	4, 5, 6	7	8, 9, 10, 11
Semi structured interviews	yes	yes		yes
Survey	yes	yes		
Observation				yes
Documentary analysis	yes			yes
Framework Analysis		yes	yes	yes
Cross case analysis	yes	yes		yes
Content analysis	yes	yes	yes	yes
Constant comparative technique for open coding	yes			yes
Longitudinal study	Data collected at 2 time points			Data collected at 2 time points
Number of organisations	24	7	9	10

Table 6: Glossary of Acronyms

Acronym	Full description	Country
BMJ	British Medical Journal	UK
CHFG	The Clinical Human Factors Group	UK
CHI	Commission for Healthcare Improvement (CHI) - now the Care Quality Commission (CQC)	UK
CNST	Clinical Negligence Scheme for Trusts	UK
CQC	The Care Quality Commission	UK
CT	Computerised Tomography	
DH	The Department of Health	UK
DHSS	Department of Health and Social Security (now DH)	UK
EU	European Union	European
FP7	Framework 7 research programme of the European Union	European
GMC	The General Medical Council	UK

GP	General Practitioner	UK
HF	The Health Foundation	UK
HFES	Human Factors and Ergonomics Society	USA
HSE	The Health and Safety Executive	UK
IHI	The Institute of Healthcare Improvement	USA
IOM	The Institute of Medicine	USA
JAMA	Journal of the American Medical Association	USA
MeSH	Medical Subject Heading	
MRI	Magnetic Resonance Imaging	
MRSA	Methicillin-resistant Staphylococcus aureus	
NCAS	National Clinical Assessment Service	UK
NHS	National Health Service	UK
NHSI	National Institute for Innovation and Improvement	UK
NICE	The National Institute for Clinical Excellence	UK
NPSA	National Patient Safety Agency	UK

NRLS	The National Reporting and Learning System	UK
QI	Quality Improvement	
QUASER	Quality and Safety in Europe by Research	
ROSPA	Royal Society for the Prevention of Accidents	UK
SJB	The author: Susan J Burnett	
SPI	The Safer Patients Initiative	UK
WHO	The World Health Organisation	International
WISER	The Warwick and Imperial study to Enhance Reliability	UK

References to Part 1

ALLSOP, J. and SAKS, M. (ed.) (2002). *Regulating the health professions.* London: Sage Publications.

AMALBERTI, R., AUROY, Y., BERWICK, D. and BARACH, P. (2005). Five system barriers to achieving ultrasafe health care. *Annals of internal medicine,* 142(9): 756-764.

AMALBERTI, R., VINCENT, C., AUROY, Y. and DE SAINT MAURICE, G. (2006). Violations and migrations in health care: a framework for understanding and management. *Quality and Safety in Health Care,* 15(Supplement 1): i66-i71.

ASCH, S. M., KERR, E. A., KEESEY, J., ADAMS, J. L., SETODJI, C. M., MALIK, S. and MCGLYNN, E. A. (2006). Who is at greatest risk for receiving poor-quality health care? *New England journal of medicine,* 354(11): 1147-1156.

BARRETT, J. H., HASLAM, R. A., LEE, K. G. and ELLIS, M. J. (2005). Assessing attitudes and beliefs using the stage of change paradigm—case study of health and safety appraisal within a manufacturing company. *International Journal of Industrial Ergonomics,* 35(10): 871-887.

BATE, P., MENDEL, P. and ROBERT, G. (2008). *Organizing for quality: the improvement journeys of leading hospitals in Europe and the United States,* Abingdon, Radcliffe Publishing.

BATE, P., ROBERT, G., FULOP, N., ØVRETVEIT, J. and DIXON-WOODS, M. (2014). *Perspectives on context: A selection of essays considering the role of context in successful quality improvement*. London: The Health Foundation.

BATES, D.W., CULLEN, D.J., LAIRD, N., PETERSEN, L.A., SMALL, S.D., SERVI, D., LAFFEL, G., SWEITZER, B.J., SHEA, B.F. and HALLISEY, R. (1995). Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA,* 274(1): 29-34.

BECK, U. (1992). *Risk society: Towards a new modernity,* London: Sage Publications Ltd in association with Theory, Culture & Society.

BECK, U. (2006). Living in the world risk society: A Hobhouse Memorial Public Lecture given on Wednesday 15 February 2006 at the London School of Economics. *Economy and society,* 35(3): 329-345.

BENN, J., BURNETT, S., PARAND, A., PINTO, A., ISKANDER, S. and VINCENT, C. (2009). Studying large-scale programmes to improve patient safety in whole care systems: challenges for research. *Social science & medicine,* 69(12): 1767-1776.

BENNETT, P. (2010). *Risk communication and public health,* Oxford: Oxford University Press.

BERNSTEIN, P. L. (1996). The new religion of risk management. *Harvard Business Review,* 74(2): 47-52.

BERWICK, D., GODFREY, A. and ROESSNER, J. (1990). *Curing Health Care: New Strategies for Quality Improvement.* San Francisco. Jossey-Bass..

BERWICK, D.M., CALKINS, D.R., MCCANNON, C.J. and HACKBARTH, A.D. (2006). The 100 000 lives campaign: setting a goal and a deadline for improving health care quality. *JAMA,* 295(3): 324-327.

BMJ: BRITISH MEDICAL JOURNAL (1950). "The Medical Act, 1950." (no author) 5th August. *BMJ: British Medical Journal* 2(4674):337-338 [Online] Available at: http://www.bmj.com/content/2/4674/337 [Accessed 23rd June 2016]

BOYCE, T., MURRAY, E. and HOLMES, A. (2009). What are the drivers of the UK media coverage of meticillin-resistant Staphylococcus aureus, the inter-relationships and relative influences? *Journal of Hospital Infection,* 73(4): 400-7.

BRADLEY, E.H., HOLMBOE, E.S., MATTERA, J.A. and ROUMANIS, S.A. (2003). The roles of senior management in quality improvement efforts: What are the key components? *Journal of Healthcare Management,* 48(1): 15-28.

BRENNAN, T.A., LEAPE, L.L., LAIRD, N.M., HEBERT, L., LOCALIO, A.R., LAWTHERS, A.G., NEWHOUSE, J.P., WEILER, P.C. and HIATT, H.H. (1991). Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *New England journal of medicine,* 324(6): 370-376.

BRYERS, H.M. and VAN TEIJLINGEN, E. (2010). Risk, theory, social and medical models: a critical analysis of the concept of risk in maternity care. *Midwifery,* 26(5):488-496.

BURNETT, S., BENN, J., PINTO, A., PARAND, A., ISKANDER, S. and VINCENT, C. (2010). Organisational readiness: exploring the preconditions for success in organisation-wide patient safety

improvement programmes. *Quality and Safety in Health Care,* 19(4): 313-7.

BURNETT, S., COOKE, M.W., DEELCHAND, V., FRANKLIN, B.D., HOLMES, A., MOORTHY, K., SAVARIT, E., SUJAN, M.-A., VATS, A. and VINCENT, C. (2011a). *How safe are clinical systems? Primary research into the reliability of systems within seven NHS organisations*. London: The Health Foundation.

BURNETT, S.J., DEELCHAND, V., FRANKLIN, B.D., MOORTHY, K. and VINCENT, C. (2011b). Missing Clinical Information in NHS hospital outpatient clinics: prevalence, causes and effects on patient care. *BMC Health Services Research,* 11(1): 1-7.

BURNETT, S., FRANKLIN, B.D., MOORTHY, K., COOKE, M.W. and VINCENT, C. (2012a). How reliable are clinical systems in the UK NHS? A study of seven NHS organisations. *BMJ Quality & Safety,* 21(6): 466-472.

BURNETT, S., MENDEL, P., NUNES, F., WIIG, S., VAN DEN BOVENKAMP, H., KARLTUN, A., ROBERT, G., ANDERSON, J., VINCENT, C. and FULOP, N. (2016). Using institutional theory to analyse hospital responses to external demands for finance and quality in five European countries. *Journal of health services research & policy,* 21(2): 109-117.

BURNETT, S., NORRIS, B. and FLIN, R. (2012b). Never events: the cultural and systems issues that cannot be addressed by individual action plans. *Clinical Risk,* 18(6): 213-216.

BURNETT, S., PARAND, A., BENN, J., PINTO, A., ISKANDER, S. and VINCENT, C. (2008). Learning about leadership from Patient Safety WalkRounds™. *International Journal of Clinical Leadership, 16*(4): 185-192.

BURNETT, S., RENZ, A., WIIG, S., FERNANDES, A., WEGGELAAR, A.M., CALLTORP, J., ANDERSON, J.E., ROBERT, G., VINCENT, C. and FULOP, N. (2013). Prospects for comparing European hospitals in terms of quality and safety: lessons from a comparative study in five countries. *International Journal for Quality in Health Care,* 25(1): 1-7.

CARTHEY, J., WALKER, S., DEELCHAND, V., VINCENT, C. and GRIFFITHS, W.H. (2011). Breaking the rules: understanding non-compliance with policies and guidelines. *BMJ: British Medical Journal ,* 343(3): d5283.

CHACKO, D. (2009). Medical Liability Litigation: An Historical Look at the Causes for Its Growth in the United Kingdom. *Discussion Papers in Economic and Social History, University of Oxford, 77: 1-29*. [Online] Available at:

http://www.nuff.ox.ac.uk/Economics/History/Paper77/77chacko.pdf [Accessed 21st June 2016]

CLEMENS, E.S. and COOK, J. M. (1999). Politics and institutionalism: Explaining durability and change. *Annual review of sociology,* 25**:** 441-466.

CLINICAL HUMAN FACTORS GROUP (CHFG) (2016). Clinical Human Factors Group. [Online] Available at: http://chfg.org/ [Accessed 22nd June 2016]

CODMAN, E. A. (1915a). The Registry of Bone Sarcomas as an Example of the End-Result Idea in Hospital Organization. In*:* GERRAND, C.H. and RANKIN, K., (ed.) (2014). *Classic Papers in Orthopaedics.* London: Springer London.

CODMAN, E. A. (1915b). *A study in hospital efficiency*. Boston, MC: Th.Todd Co

COHEN, A. (1977). Factors in successful occupational safety programs. *Journal of Safety Research,* 9(4): 168-178.

CONLEY, D.M., SINGER, S.J., EDMONDSON, L., BERRY, W.R. and GAWANDE, A.A. (2011). Effective Surgical Safety Checklist Implementation. *Journal of the American College of Surgeons,* 212(5): 873-879.

COOTER, R. and PICKSTONE, J., (ed.) (2000). *Medicine in the Twentieth Century,* Oxford: Taylor & Francis.

COVELLO, V.T. and MUMPOWER, J. (1985). Risk analysis and risk management: an historical perspective. *Risk Analysis,* 5(2): 103-120.

COX, S. and CHEYNE, A. (2000). Assessing safety culture in offshore environments. *Safety science,* 34(1): 111-129.

COX, S. and FLIN, R. (1998). Safety culture: philosopher's stone or man of straw? *Work & Stress,* 12(3): 189-201.

DARZI, A. (2008). *High quality care for all: NHS next stage review final report*. London, Department of Health.

DEPARTMENT OF HEALTH (1994). *Being heard The report of a review committee on NHS complaints procedures*. London, Department of Health.

DEPARTMENT OF HEALTH (1997). *The New NHS: Modern, Dependable*. London: HMSO.

DEPARTMENT OF HEALTH (1999). *Supporting doctors, protecting patients.* London, Department of Health

DEPARTMENT OF HEALTH, (2000). *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer.* London: The Stationery Office.

DEPARTMENT OF HEALTH (2001). *Building a Safer NHS for Patients: Implementing an Organisation with a Memory.* London, Department of Health.

DEPARTMENT OF HEALTH (2009). *Patient Safety First Campaign. Sponsored by the NPSA, NHSI and The Health Foundation.* [Online]. Available at: http://webarchive.nationalarchives.gov.uk/20090518092554/http://www.patientsafetyfirst.nhs.uk/ [Accessed 22nd June 2016].

DIXON-WOODS, M. (2011). Using framework-based synthesis for conducting reviews of qualitative studies. *BMC medicine,* 9:39.

DIXON-WOODS, M., YEUNG, K. and BOSK, C.L. (2011). Why is UK medicine no longer a self-regulating profession? The role of scandals involving "bad apple" doctors. *Social science & medicine,* 73(10): 1452-1459.

DÜCKERS, M., FABER, M., CRUIJSBERG, J., GROL, R., SCHOONHOVEN, L. and WENSING, M. (2009). Safety and Risk Management Interventions in Hospitals: A Systematic Review of the Literature. *Medical Care Research and Review,* 66(6 Suppl): 90S-119S.

EDELSTEIN, L. (1943). The Hippocratic Oath: Text; Translation, and Interpretation. In*:* VEATCH, R. M. (ed.) 2000. *Cross Cultural Perspectives in Medical Ethics. Second edition.* London: Jones & Bartlett

ELLIOTT, A. (2002). Beck's sociology of risk: a critical assessment. *Sociology,* 36(2): 293-315.

EMANUEL, M., RAWLINS, M., DUFF, G. and BRECKENRIDGE, A. (2012). Thalidomide and its sequelae. *The Lancet,* 380(9844): 781-783.

EUROPEAN PARLIAMENT, (2011). *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.* Brussels: European Parliament [Online] Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024 [Accessed 23rd June 2016]

FLANAGAN, J.C. (1954). The critical incident technique. *Psychological Bulletin,* 51(4): 327-358.

FLEMING, M. (2001). *Safety culture maturity model*. Norwich: Health and Safety Executive (Stationary Office)

FLIN, R. (2003). “Danger—men at work”: Management influence on safety. *Human Factors and Ergonomics in Manufacturing & Service Industries,* 13(4): 261-268.

FLIN, R.H., O'CONNOR, P. and CRICHTON, M. (2008). *Safety at the sharp end: a guide to non-technical skills,* Farnham: Ashgate Publishing Ltd.

FRANKEL, A., GANDHI, T.K. and BATES, D.W. (2003). Improving patient safety across a large integrated health care delivery system. *Int J Qual Health Care,* 15(Suppl 1): i31-40.

FULOP, N. (2013a). *Quality and Safety in European Hospitals (QUASER): A guide for senior leadership teams to help improve and sustain hospital quality* [Online]. Available at: https://www.ucl.ac.uk/dahr/news-events/events-publication/quaser [Accessed 16th May 2016].

FULOP, N. (2013b). *Quality and Safety in European Hospitals (QUASER): The guide for Payers. A research based tool to assess and facilitate quality improvement strategies in hospitals* [Online]. Available at: https://www.ucl.ac.uk/dahr/news-events/events-publication/quaser [Accessed 16th May 2016].

FULOP, N., PROTOPSALTIS, G., KING, A., ALLEN, P., HUTCHINGS, A. and NORMAND, C. (2005). Changing organisations: a study of the context and processes of mergers of health care providers in England. *Social Science & Medicine,* 60(1): 119-130.

GALE, N.K., HEATH, G., CAMERON, E., RASHID, S. and REDWOOD, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC medical research methodology,* 13(1): 117.

GERRAND, C.H. and RANKIN, K. (2014). The Registry of Bone Sarcomas as an Example of the End-Result Idea. In *Hospital Organization. Classic Papers in Orthopaedics:* 473-474. London, Springer.

GLENDON, A.I. and STANTON, N.A. (2000). Perspectives on safety culture. *Safety science,* 34(1): 193-214.

GOLLOP, R., WHITBY, E., BUCHANAN, D. and KETLEY, D. (2004). Influencing sceptical staff to become supporters of service improvement: a qualitative study of doctors’ and managers’ views. *Quality and Safety in Health Care*, *13*(2): 108-114.

GOSFIELD, A.G. and REINERTSEN, J.L. (2005). The 100,000 lives campaign: crystallizing standards of care for Hospitals. *Health Affairs,* 24(6): 1560-1570.

GREENHALGH, T., ROBERT, G., MACFARLANE, F., BATE, P. and KYRIAKIDOU, O. (2004). Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q,* 82(4): 581-629.

GRIFFITHS, R. (1983). *Report of the NHS management enquiry.* London: Department of Health and Social Services.

GUARNIERI, M. (1992). Landmarks in the history of safety. *Journal of Safety Research,* 23(3): 151-158.

HEALTH AND SAFETY EXECUTIVE (HSE) (2013). *RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations*. [Online] Available at: http://www.hse.gov.uk/riddor/index.htm [Accessed 22nd June 2016]

HEALTH AND SAFETY EXECUTIVE (HSE). (2015). *History of the Health and Safety Executive* [Online]. Available: http://www.hse.gov.uk/aboutus/timeline/index.htm [Accessed 23rd November 2015].

HEALTHCARE IMPROVEMENT SCOTLAND. (2008). *Scottish Patient Safety Programme* [Online]. Available at: http://www.scottishpatientsafetyprogramme.scot.nhs.uk/ [Accessed 22nd June 2016].

HELMREICH, R.L. and DAVIES, J.M. (2004). Culture, threat, and error: lessons from aviation. *Canadian Journal of Anesthesia,* 51(1): R1-R4.

HOLMES, A., DIXON-WOODS, M., AHMAD, R., BREWSTER, E., CASTRO-SANCHEZ, E., SECCI, F. and ZINGG, W. (2015). *Infection prevention and control: lessons from acute care in England.* London, The Health Foundation

HUMAN FACTORS AND ERGONOMICS SOCIETY (HFES). *History of the Human Factors and Ergonomics Society* [Online]. Available: https://hfes.org/web/AboutHFES/history.html [Accessed 23rd November 2015].

ILAN, R. and FOWLER, R. (2005). Brief history of patient safety culture and science. *Journal of critical care,* 20(1): 2-5.

ILLICH, I. (1976a). *Limits to Medicine,* London, Marion Boyars Publishers Ltd.

ILLICH, I. (1976b). *Medical nemesis: The expropriation of health. Marion Boyars Ideas in Progress Series*, London: Calder & Boyars Ltd.

INTERNATIONAL ERGONOMICS ASSOCIATION. (2016). *International Ergonomics Association,* [Online]. Available at: http://www.iea.cc/whats/ [Accessed 16th May 2016].

IRVINE, D. (2006). A short history of the General Medical Council. *Medical Education,* 40(3): 202-211.

JENNETT, P., YEO, M., PAULS, M. and GRAHAM, J. (2003). Organizational readiness for telemedicine: implications for success and failure. *Journal of Telemedicine and Telecare,* 9(Suppl 2): 27-30.

JOHNSON, A.P., PEARSON, A. and DUCKWORTH, G. (2005). Surveillance and epidemiology of MRSA bacteraemia in the UK. *Journal of Antimicrobial Chemotherapy,* 56(3): 455-462.

JONES, J. and HALL, C. (1993). *Pathology service first raised doubt in 1985.* The Independent Newspaper. 26th August. [Online]. Available at: http://www.independent.co.uk/news/uk/pathology-service-first-raised-doubt-in-1985-bone-cancer-surgeons-felt-they-were-getting-nowhere-1463611.html [Accessed 8th June 2016].

JONES, N. and CHARLESWORTH, A. (2013). *The anatomy of health spending 2011/12.* London: Nuffield Trust.

KABCENELL A, NOLAN, T., MARTIN, L.A. and GILL, Y. (2010). The Pursuing Perfection Initiative: Lessons on Transforming Health Care. *IHI Innovation Series white paper.* Cambridge, MA: Institute for Healthcare Improvement.

KAST, F.E. and ROSENZWEIG, J.E. (1972). General systems theory: Applications for organization and management. *Academy of management journal,* 15(4): 447-465.

KENNEDY, I. (1981). *The unmasking of medicine.* London: George Allen & Unwin Ltd.

KENNEDY, I. (2001). *The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*, London: Stationery Office.

KENNEDY, R. and KIRWAN, B. (1995). The failure mechanisms of safety culture. In: CARNINO, A., and WEIMANN, G. (eds.). *Proceedings from the International Topical Meeting on Safety Culture in Nuclear Installations*. 24-28 April, Vienna: Published by ANS-ALS, Vienna in cooperation with ARCS, Seibersdorf. [Online] Available at:

http://www.iaea.org/inis/collection/NCLCollectionStore/_Public/27/036/27036465.pdf?r=1 [Accessed 22nd June 2016]

KLEIN, R. (1995). *The New Politics of the National Health Service: Third Edition.* Harlow: Longman.

KOHN, L.T., CORRIGAN, J.M., DONALDSON, M.S. (eds) (2000). *To Err Is Human: Building a Safer Health System*, Washington: Institute Of Medicine, National Academies Press.

KOTTER, J.P. (1996). *Leading change,* Boston: Harvard Business Press.

KREIN, S.L., DAMSCHRODER, L.J., KOWALSKI, C.P., FORMAN, J., HOFER, T. P. and SAINT, S. (2010). The influence of organizational context on quality improvement and patient safety efforts in infection prevention: A multi-center qualitative study. *Social science & medicine,* 71(9): 1692-1701.

LAWTON, R. and PARKER, D. (2002). Barriers to incident reporting in a healthcare system. *Quality and Safety in Health Care,* 11(1): 15-18.

LEAPE, L.L. (1994). Error in medicine. *JAMA,* 272(23): 1851-1857.

LEAPE, L.L. and BERWICK, D.M. (2000). Safe health care: are we up to it?: We have to be. *BMJ: British Medical Journal,* 320(7237): 725-6.

LILFORD, R.J. (2002). Patient safety research: does it have legs? *Quality and Safety in Health Care,* 11(2): 113-114.

LOIMER, H. and GUARNIERI, M. (1996). Accidents and acts of God: a history of the terms. *American Journal of Public Health,* 86(1): 101-107.

MACFAUL, R. (1988). Much data but limited information in the NHS. *Archives of disease in childhood,* 63(10): 1276-1280.

MADSEN, S.R., MILLER, D. and JOHN, C. R. (2005). Readiness for organizational change: Do organizational commitment and social relationships in the workplace make a difference? *Human Resource Development Quarterly,* 16(2): 213-233.

MALLON, W.J. (2015). *E. Amory Codman*. [Online] Available at: http://www.aaos.org/news/bulletin/janfeb07/research1.asp [Accessed 22nd June 2016].

MALLON, W.J. (2000). *Ernest Amory Codman: the end results of life in medicine.* Philadelphia: WB Saunders Company.

MCGLYNN, E.A., ASCH, S.M., ADAMS, J., KEESEY, J., HICKS, J., DECRISTOFARO, A. and KERR, E.A. (2003). The quality of health care

delivered to adults in the United States. *New England journal of medicine,* 348(26): 2635-2645.

MEISTER, D. (1999). *The history of human factors and ergonomics,* New Jersey: Lawrence Erlbaum Associates.

MENDEL, P.S. and RICHARD W. (2010). Institutional Change and the Organization of Healthcare: The Dynamics of 'Muddling Through'. *In:* BIRD, C.E.,CONRAD, P. FREMONT, A.M. and TIMMERMANS, S. (ed.) *Handbook of Medical Sociology. Sixth Edition*. Nashville: Vanderbilt University Press. 249-269

MEYER, J., SCOTT, W.R. and STRANG, D. (1987). Centralization, fragmentation, and school district complexity. *Administrative Science Quarterly***,** 32(2):186-201.

MILLENSON, M. (2002). Pushing the profession: how the news media turned patient safety into a priority. *Quality and Safety in Health Care,* 11(1): 57-63.

MILLIGAN, F. and DENNIS, S. (2005). Building a safety culture. *Nursing Standard,* 20(11): 48-52.

MILLS, D.H. (1978). Medical insurance feasibility study: a technical summary. *Western Journal of Medicine,* 128(4): 360-365.

MITTMAN, B.S. (2004). Creating the evidence base for quality improvement collaboratives. *Annals of internal medicine,* 140(11): 897-901.

MOHAMMED, M.A., CHENG, K., ROUSE, A. and MARSHALL, T. (2001). Bristol, Shipman, and clinical governance: Shewhart's forgotten lessons. *The Lancet,* 357(9254): 463-467.

MOLD, A. (2012). Patients´ Rights and the National Health Service in Britain, 1960s–1980s. *American Journal of Public Health,* 102(11): 2030-2038.

MOLIERE (1667). *Le Médecin malgré lui (The Doctor despite himself).* In COWARD, D. (ed) (2000). *The Misanthrope and Other Plays by Jean-Baptiste Moliere.* London: Penguin Books.

MORELLO, R.T., LOWTHIAN, J.A., BARKER, A.L., MCGINNES, R., DUNT, D. and BRAND, C. (2013). Strategies for improving patient safety culture in hospitals: a systematic review. *BMJ Quality & Safety,* 22(1): 11-18.

MULCAHY, L. (2003). *Disputing doctors: the socio-legal dynamics of complaints about medical care,* Maidenhead: Open University Press.

MULCAHY, L. and TRITTER, J.Q. (1998). Pathways, pyramids and icebergs? Mapping the links between dissatisfaction and complaints. *Sociology of health & illness,* 20(6): 825-847.

NABHAN, M., ELRAIYAH, T., BROWN, D.R., DILLING, J., LEBLANC, A., MONTORI, V.M., MORGENTHALER, T., NAESSENS, J., PROKOP, L., ROGER, V., SWENSEN, S., THOMPSON, R. L. and MURAD, M.H. (2012). What is preventable harm in healthcare? A systematic review of definitions. *BMC Health Services Research,* 12(1): 1-8.

NGAN KEE, W.D. (2005). Confidential Enquiries into Maternal Deaths: 50 years of closing the loop. *British Journal of Anaesthesia,* 94(4): 413-416.

NHS ENGLAND. (2012). *The "never events" list 2012/13* [Online]. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132352.pdf [Accessed 16th May 2016].

NHS ENGLAND. (2015a). *The National Safety Standards for Invasive Procedures (NatSSIPs).* [Online] Available at: https://www.england.nhs.uk/2015/09/natssips/ [Accessed 4th September 2015].

NHS ENGLAND (2015b). *Quarterly Dataset Summary (QDS) workbook: Jan to Mar 2015 – Commentary.* [Online] Available at: http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/?entryid45=135507 [Accessed 22nd June 2016]

NHS EXECUTIVE (1998). *A first class service: quality in the new NHS.* London: Department of Health

NHS MANAGEMENT EXECUTIVE (1994). *Risk Management in the NHS*. London: Department of Health .

NIGHTINGALE, F. (1863). *Notes on hospitals*, London: Longman, Green, Longman, Roberts, and Green.

NPSA: NATIONAL PATIENT SAFETY AGENCY (2002). *Potassium Chloride Alert.* [Online] Available at: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59882 [Accessed 22nd June 2016]

O'DEA, A. and FLIN, R. (2001). Site managers and safety leadership in the offshore oil and gas industry. *Safety science,* 37(1): 39-57.

O'LEARY, M. (2002). The British Airways human factors reporting programme. *Reliability Engineering & System Safety,* 75(2): 245-255.

OLIVER, C. (1991). Strategic responses to institutional processes. *Academy of Management Review,* 16(1): 145-179.

OVRETVEIT, J. (2009). The contribution of new social science research to patient safety. *Social science & medicine,* 69(12): 1780-1783.

ØVRETVEIT, J., BATE, P., CLEARY, P., CRETIN, S., GUSTAFSON, D., MCINNES, K., MCLEOD, H., MOLFENTER, T., PLSEK, P. and ROBERT, G. (2002). Quality collaboratives: lessons from research. *Quality and Safety in Health Care,* 11(4): 345-351.

ØVRETVEIT, J.C., SHEKELLE, P.G., DY, S.M., MCDONALD, K.M., HEMPEL, S., PRONOVOST, P., RUBENSTEIN, L., TAYLOR, S.L., FOY, R. and WACHTER, R.M. (2011). How does context affect interventions to improve patient safety? An assessment of evidence from studies of five patient safety practices and proposals for research. *BMJ Quality & Safety,* 20(7): 604-610.

OXFORD DICTIONARIES. (2016). *Oxford Dictionaries,* Oxford: Oxford University Press. [Online] Available at: http://www.oxforddictionaries.com/definition/english/harm [Accessed 11th January 2016].

PACHE, A.-C. and SANTOS, F. (2010). When Worlds Collide: The Internal Dynamics of Organizational Responses to Conflicting Institutional Demands. *Academy of Management Review,* 35(3): 455-476.

PENLAND, T. (1997). A model to create “organizational readiness” for the successful implementation of quality management systems. *International Journal for Quality in Health Care,* 9(1): 69-72.

PETTIGREW, A., FERLIE, E. and MCKEE, L. (1992). Shaping strategic change-The case of the NHS in the 1980s. *Public Money & Management,* 12(3): 27-31.

PETTIGREW, A.M. (1988). *The management of strategic change.* University of Warwick. Centre for Corporate Strategy Change: B. Blackwell.

PIDGEON, N., KASPERSON, R.E., SLOVIC, P. (2003). *The social amplification of risk,* Cambridge, Cambridge University Press.

PRICE, K. (2012). *Reaching out: engaging with medical neglect before the NHS.* [Online] Available at: https://wellcomehistory.wordpress.com/2012/08/17/reaching-out-engaging-with-medical-neglect-before-the-nhs/ [Accessed 16th May 2016].

QUARANTELLI, E.L. (1987). *Disaster studies: An analysis of the social historical factors affecting the development of research in the area.* [Online] Available at: http://udspace.udel.edu/handle/19716/1335 [Accessed 22nd June 2016]

RAACH, J.H. (1944). English Medical Licensing in the Early Seventeenth Century. *Yale J Biol Med.,* 16(4): 267-88.

RANSLEY, P. (2015). *How it all began.* Action for Victims of Medical Accidents. [Online] Available at: http://www.avma.org.uk/about-us/history/how-it-all-began/ [Accessed 11th January 2016].

REASON, J. (1990). *Human error.* Cambridge: Cambridge University Press.

REASON, J. T. (1997). *Managing the risks of organizational accidents*. Aldershot: Ashgate.

RESAR, R. K. (2006). Making Noncatastrophic Health Care Processes Reliable: Learning to Walk before Running in Creating High-Reliability Organizations. *Health services research,* 41(4p2): 1677-1689.

ROBERT, G.B., ANDERSON, J.E., BURNETT, S.J., AASE, K., ANDERSSON-GARE, B., BAL, R., CALLTORP, J., NUNES, F., WEGGELAAR, A.-M., VINCENT, C.A. and FULOP, N. (2011). A longitudinal, multi-level comparative study of quality and safety in European hospitals: the QUASER study protocol. *BMC Health Services Research,* 11(1): 285.

ROYAL SOCIETY FOR THE PREVENTION OF ACCIDENTS (ROSPA). (2016). *History of the Royal Society for the Prevention of Accidents* [Online]. Available at: http://www.rospa.com/about/history/ [Accessed 16th November 2015].

RUEF, M. and SCOTT, W.R. (1998). A multidimensional model of organizational legitimacy: Hospital survival in changing institutional environments. *Administrative Science Quarterly*. p 877-904.

RUNDMO, T., HESTAD, H. and ULLEBERG, P. (1998). Organisational factors, safety attitudes and workload among offshore oil personnel. *Safety science,* 29(2): 75-87.

RUSS, S.J., SEVDALIS, N., MOORTHY, K., MAYER, E.K., ROUT, S., CARIS, J., MANSELL, J., DAVIES, R., VINCENT, C. and DARZI, A. (2015). A qualitative evaluation of the barriers and facilitators toward implementation of the WHO surgical safety checklist across hospitals in England: lessons from the “Surgical Checklist Implementation Project”. *Annals of surgery,* 261(1): 81-91.

SARI, A. B.-A., SHELDON, T. A., CRACKNELL, A., TURNBULL, A. (2007). Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ: British Medical Journal,* 334(7584): 79.

SAVAGE, R. (1998). All changed, changed utterly: British medicine will be transformed by the Bristol case. *BMJ: British Medical Journal,* 316(7149): 1917-19.

SCOTT, W.R. (2004). Institutional theory. In RITZER, G. (ed) *Encyclopedia of social theory.* Thousand Oaks: Sage p408-14.

SECKER-WALKER, J. and DONALDSON, L., (2001a). Clinical Governance: the context of risk management. *In:* VINCENT, C. (ed.) *Clinical Risk Management - second edition.* London: BMJ Books.

SECKER-WALKER, J. and TAYLOR-ADAMS, S. (2001b). Clinical Incident Reporting. *In:* VINCENT., C. (ed.) *Clinical Risk Management - second edition.* London: BMJ Books.

SEMMELWEIS, I. (1861) *The Cause, Concept, and Prophylaxis of Childbed Fever*. In: CODELL CARTER, K. (ed) (1983). Madison: University of Wisconsin Press.

SHAKESPEARE, W. (1623). *Timon of Athens*, First Folio.

SHARPE, V.A. and FADEN, A.I. (1998). *Medical Harm: Historical, conceptual and ethical dimensions of iatrogenic illness,* Cambridge: Cambridge University Press.

SHEEN, B. (1987). *MV Herald of Free Enterprise, Report of Court 8074–Formal Investigation, September 1987, Department of Transport*. London: HMSO

SHOJANIA, K.G., DUNCAN, B.W., MCDONALD, K.M., WACHTER, R.M. and MARKOWITZ, A.J. (2001). Making health care safer: a critical analysis of patient safety practices. *Evidence Report/Technology Assessment, Number 43(1): 668.* Rockville: Agency for Healthcare Research and Quality. [Online] Available at: http://somaaccess.net/ptsafety.pdf [Accessed 22nd June 2016]

SHOJANIA, K.G. and GRIMSHAW, J.M., (2005). Evidence-based quality improvement: the state of the science. *Health Affairs,* 24(1): 138-150.

SIMARD, M. and MARCHAND, A. (1995). A multilevel analysis of organisational factors related to the taking of safety initiatives by work groups. *Safety science,* 21(2): 113-129.

SMITH, Dame J. (2002-2005). *The Shipman Enquiry Reports.* London, Department of Health, HMSO.

SMITH, M.J., COHEN, H.H., COHEN, A. and CLEVELAND, R.J. (1978). Characteristics of successful safety programs. *Journal of Safety Research*. 10(1): 5-15.

STANHOPE, N., VINCENT, C., TAYLOR-ADAMS, S.E., O'CONNOR, A.M. and BEARD, R. (1997). Applying human factors methods to clinical risk management in obstetrics. *British Journal of Obstetrics & Gynaecology,* 104(11): 1225-1232.

STERN, M. and BRENNAN, S. (1994). *Medical Audit in the Hospital and Community Health Service (HCHS).* London: Health Publications Unit, Department of Health.

STEVENS, D.P. and SHOJANIA, K.G. (2011). Tell me about the context, and more. *BMJ Quality & Safety,* 20(7): 557-559.

TAYLOR-ADAMS, S., VINCENT, C. and STREET, P. (2004). Systems analysis of clinical incidents: the London protocol. *Clinical Risk,* 10(6): 211-220.

THE EVIDENCE CENTRE (2011). *Levels of Harm: Evidence scan*. London: The Health Foundation. [Online] Available at: http://www.health.org.uk/publication/levels-harm [Accessed 22nd June (2016]

THE HEALTH FOUNDATION. (2014). *Safer Clinical Systems* [Online]. Available at: http://www.health.org.uk/programmes/safer-clinical-systems [Accessed 22nd June 2016].

TOFT, B. (2001). *External Inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, 4th January 2001.* London: Department Of Health

UK NATIONAL ARCHIVES. (2016). *The Factories Act of 1833.* [Online]. Available: http://www.nationalarchives.gov.uk/education/resources/1833-factory-act/ [Accessed 16th November 2015].

VATS, A., VINCENT, C., NAGPAL, K., DAVIES, R., DARZI, A. and MOORTHY, K. (2010). Practical challenges of introducing WHO surgical checklist: UK pilot experience. *BMJ: British Medical Journal,* 340:b5433.

VAUGHN, T., KOEPKE, M., KROCH, E., LEHRMAN, W., SINHA, S. and LEVEY, S., (2006). Engagement of leadership in quality improvement initiatives: executive quality improvement survey results. *Journal of Patient Safety*, *2*(1): 2-9.

VEATCH, R.M. (2000). *Cross-cultural perspectives in medical ethics,* Sudbury, USA: Jones & Bartlett Learning.

VINCENT, C. (ed.) (2001). *Clinical risk management: Enhancing patient safety.* London: BMJ Books.

VINCENT, C. (2011). *Patient Safety: second edition.* Oxford: John Wiley & Sons.

VINCENT, C., NEALE, G. and WOLOSHYNOWYCH, M. (2001). Adverse events in British hospitals: preliminary retrospective record review. *BMJ: British Medical Journal,* 322(7285): 517-519.

VINCENT, C., TAYLOR-ADAMS, S., CHAPMAN, E.J., HEWETT, D., PRIOR, S., STRANGE, P. and TIZZARD, A. (2000). How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management protocol. *BMJ: British Medical Journal,* 320(7237): 777-781.

VON BERTALANFFY, L. (1972). The history and status of general systems theory. *Academy of management journal,* 15(4): 407-426.

WACHTER, R.M. and PRONOVOST, P.J. (2009). Balancing “no blame” with accountability in patient safety. *New England Journal of Medicine,* 361(14): 1401-1406.

WALLEY P., RAYMONT. J., COOKE M. (2006). *Clinical Systems Improvement in NHS Hospital Trusts and their PCTs: A snapshot of current practice.* Warwick: NHS Institute for Innovation and Improvement & The University of Warwick

WALSHE, K. (2001). The Development of Risk Managment. In*:* VINCENT, C. (ed.) *Clinical Risk Management - second edition.* London: BMJ Books.

WALSHE, K. and BOADEN, R. (eds.) (2005). *Patient safety: research into practice.* Maidenhead: McGraw-Hill Education (UK).

WALSHE, K. and HIGGINS, J. (2002). The use and impact of inquiries in the NHS. *BMJ: British Medical Journal,* 325(7369): 895-900.

WALSHE, K. and SHORTELL, S.M. (2004). When things go wrong: how health care organizations deal with major failures. *Health Affairs,* 23(3): 103-111.

WATTS, G. (2003). Is this journalism that makes a difference? *BMJ: British Medical Journal,* 326(7398): 1093.

WEAVER, S.J., LUBOMKSI, L.H., WILSON, R.F., PFOH, E.R., MARTINEZ, K.A. and DY, S.M. (2013). Promoting a Culture of Safety as a Patient Safety Strategy - A Systematic Review. *Annals of internal medicine,* 158(5_Part_2): 369-374.

WEINER, B., AMICK, H. and LEE, S.-Y. (2008). Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. *Medical Care Research and Review* 65(4): 379-436.

WEINER, B.J. (2009). A theory of organizational readiness for change. *Implementation Science,* 4:67 [Online] Available at: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-4-67 [Accessed 23rd June 2016]

WELSH GOVERNMENT. (2008). *1000 Lives Campaign* [Online]. Available: http://www.1000livesplus.wales.nhs.uk/home [Accessed 4th Sept 2015].

WEZEL, F.C. and SAKA-HELMHOUT, A. (2006). Antecedents and consequences of organizational change:'Institutionalizing'the behavioral theory of the firm. *Organization Studies,* 27(2): 265-286.

WIIG, S., AASE, K., VON PLESSEN, C., BURNETT, S., NUNES, F., WEGGELAAR, A.M., ANDERSON-GARE, B., CALLTORP, J. and FULOP, N. (2014). Talking about quality: exploring how 'quality' is conceptualized in European hospitals and healthcare systems. *BMC Health Services Research,* 14(1): 1-12.

WILLIS, E. (2006). Medical dominance then and now: critical reflections. *Health Sociology Review,* 15(5): 432-443.

WILSON, R.M., RUNCIMAN, W.B., GIBBERD, R.W., HARRISON, B.T., NEWBY, L. and HAMILTON, J.D. (1995). The quality in Australian health care study. *Medical Journal of Australia,* 163(9): 458-471.

WOODWARD, S. (2004). *Seven Steps to Patient Safety* London: NPSA [Online]. Available at: http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/ [Accessed 10th February 2016]

WOOLF, S.H. (2004). Patient Safety Is Not Enough: Targeting Quality Improvements To Optimize the Health of the Population. *Annals of internal medicine,* 140(1): 33-36.

WOOTTON, D. (2006). *Bad medicine: doctors doing harm since Hippocrates,* Oxford, Oxford University Press.

WORLD HEALTH ORGANISATION. (2015). *Patient Safety Toolkit* Cairo: World Health Organization [Online]. Available at: http://apps.who.int/iris/handle/10665/195709 [Accessed 4th April 2016].

WORLD HEALTH ORGANISATION. (2015). *Patient Safety* [Online]. Available: http://www.who.int/patientsafety/about/en/ [Accessed 22nd June 2016].