Using a national repository of error reports to obtain insights into the safety of orthopaedic surgery

Sukhmeet S. Panesar

BSc (Hons.) MBBS AICSM MPH DIC FRSPH

Centre for Population Health Sciences

The University of Edinburgh

Medical School, Teviot Place

Edinburgh

EH8 9AG

Thesis presented in fulfilment of the requirement of the degree of Doctor of Medicine (MD)

The University of Edinburgh

March 2014

Signed Declaration

I hereby state:

(a) that the thesis has been composed by myself, and

(b) that the work is my own

(c) that the work has not been submitted for any other degree or professional qualification except as specified.

_____

Sukhmeet S. Panesar

March 2014

Table of contents

List of tables and figures

Tables

Figures

Abbreviations

AAOS	American Academy of Orthopedic Surgeons
AHRQ	Agency for Healthcare Research and Quality
AIMS	Australian Incident Monitoring System
APSF	Australian Patient Safety Foundation
ASA	American Society of Anesthesiologists
BOA	British Orthopaedic Association
C.diff	Clostridium difficile
CAST	Commercial Aviation Safety Team
CORESS	Confidential Reporting System for Surgery
CI	Confidence Interval
EPR	Electronic Patient Record
EWS	Early Warning Scores
GCC	Gulf Cooperation Council
GCS	Glasgow Coma Scale
GMC	General Medical Council
HCAI	Healthcare Associated Infection
HES	Hospital Episode Statistics
HR	Hazard Ratio
HSMR	Hospital Standardised Mortality Ratio
ICU	Intensive Care Unit
ICUSRS	Intensive Care Unit Safety Reporting System
INR	International Normalised Ratio
IOM	Institute of Medicine
IPW	Inverse Probability Weights
IT	Information Technology
M&M	Morbidity and Mortality
MHRA	Medicines and Healthcare products Regulatory Agency
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
NHFD	National Hip Fracture Database
NHS	National Health Service
NHSLA	NHS Litigation Authority
NICE	National Institute for Health and Care Excellence
NOTSS	Non-Technical Skills for Surgeons
NPSA	National Patient Safety Agency

NRLS	National Reporting and Learning System
OEI	Orthopaedic Error Index
OR	Odds Ratio
PIAA	Physician Insurers Association of America
PSI	Patient Safety Incident
PSRS	Patient Safety Reporting System
QIPP	Quality, Innovation, Productivity, Prevention
RCT	Randomised Controlled Trial
RR	Relative Risk
RRR	Rapid Response Report
SD	Standard Deviation
SIGN	Scottish Intercollegiate Guidelines Network
SMR	Standardised Mortality Ratio
SSI	Surgical Site Infection
UK	United Kingdom
US	United States
VTE	Venous Thromboembolism
WHO	World Health Organization

Acknowledgements

As a medical student, the idea of cutting-edge technologies in orthopaedic surgery fascinated me. This led to my earlier research pursuits on synthesising evidence for the uptake and efficacy of these technologies. An 'accidental' placement at the National Patient Safety Agency via the Chief Medical Officer for England's Clinical Adviser Scheme opened up a new avenue for research. I was alarmed to hear that approximately one in 10 patients experience a medical error; in some high-risk specialties such as orthopaedic surgery, the figure is much higher. At the time, the science of patient safety was, and still is, an emerging discipline of health services research. This work is a product of numerous encounters with leaders in patient safety – Professor Rajan Madhok (Manchester), Professor Mohit Bhandari (McMaster), Dr Gopalakrishnan Netuveli (Imperial) and Dr Kevin Cleary (East London) – whom I incessantly troubled for their time and expertise to discuss the novel methods in this thesis; very little is known about patient safety in orthopaedics and the hope is that this work will help to further the discipline.

I remain most grateful to Professor Sir Liam Donaldson (Imperial), one of the founding fathers of patient safety, for his constant mentorship, guidance and encouragement when I explored the use of challenging methods. My supervisor, Professor Aziz Sheikh (Edinburgh), deserves the utmost thanks. I remain indebted to him for his constant support, guidance and patience. Very rarely does one find such a mentor and I am most grateful for our first encounter at a lecture that I had not originally planned to attend. He has certainly been responsible for developing what is certainly now going to be my area of further academic research. In these academic pursuits, my parents, especially my mother, has been my rock; for all the times I could not be home due to my research, you have been most patient and understanding.

Several sections of this thesis have already been published in peer-reviewed papers, as shown in Appendix 1.

Sukhmeet S. Panesar

December 2013

Dedication

To my mother and father who have felt my absence on numerous occasions as I pursued my academic interests. An equally important dedication is necessary to Professor Aziz Sheikh, who has been a constant beacon of support and reminded me to strive for academic excellence in this offering.

Ethical considerations and permissions

Permission to use the database, the National Reporting and Learning System, was kindly provided by the Medical Director, Dr Kevin Cleary and the Chairman, Lord Naren Patel, both of whom worked at the National Patient Safety Agency until July 2010. No additional permissions were required as I was an internal member of staff at the Agency. The work undertaken focuses on four key studies, set out in the following chapters, that aim to further the understanding of errors in orthopaedic surgery through the lens of the National Reporting and Learning System.

Glossary

Patient safety
"Patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment."
[WHO 2009]

Harm
"Harm implies impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological. Disease is a physiological or psychological dysfunction. Injury is damage to tissues caused by an agent or event and suffering is the experience of anything subjectively unpleasant. Suffering includes pain, malaise, nausea, depression, agitation, alarm, fear and grief. Disability implies any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm."
[WHO 2009]

Errors of commission*
"The Institute of Medicine's (IOM) 1999 report *To Err Is Human* reported that medical error accounted for between 44,000 and 98,000 deaths per year in the United States. To many, this was not a surprise and even underreported. The fact is that this study was based on errors of commission only. Errors of commission would include situations in which inappropriate actions were taken that resulted in something other than what was intended."

Errors of omission*
"On the flip side, errors of omission (which were not included in the IOM report) are situations in which inaction contributed to a deviation from an intended path and outcome. Inactions may involve mistakes, slips, and lapses."

Three error types*
The three error types are:

Mistakes:
"Mistakes occur when an intended outcome is not achieved even though there was adherence to the steps in the plan. This is usually a case in which the original plan was wrong, was followed, and resulted in an unintended outcome. For instance, a facility purchases a new type of IV pump from a new manufacturer. A nurse is not present for the inservice training to learn the new procedures on how to use the pump. The nurse begins her shift and is put in a position to use the new IV pump. Acting on previous experience, she operates the new pump using the old procedure. As a result, a patient is overmedicated and slips into a coma."

Lapses:
"Lapses are associated with our memories (e.g., lapses of memory, 'senior moments', etc.). These are generally not observable events."

Slips:
"Slips are generally externalized, observable actions that are not in accordance with a plan. These are often referred to as Freudian slips, in which a person may be thinking something but inadvertently says it so that someone else can hear it. Slips are most often associated with the execution phase of cognition."

* Taken from: http://www.reliability.com/healthcare/articleshcp/nov_07_Defining%20and%20Reducing%20Human%20Error.pdf

Abstract

Introduction

Almost a decade ago, there was a call to establish patient safety reporting systems that would operate at local, regional and national levels; it was envisaged that these would help healthcare professionals and organisations to learn from mistakes and lead to the development of interventions aimed at mitigating against these errors. This policy call led to the creation of the National Reporting and Learning System (NRLS). It however remains unclear whether reporting systems result in safer care. Specialties such as orthopaedics pose a high potential risk of iatrogenic harm, and this clinical area therefore represents a useful exemplar in which to study the opportunities offered by this national repository of errors to improve the safety of orthopaedic care provision.

Aims

The aims of this thesis were to:

- understand the opportunities offered by the NRLS to ascertain the frequency, types and causes of errors in orthopaedic surgery
- develop the risk prediction potential of the system
- offer critical reflections on the role of reporting systems for improving the care received by orthopaedic patients.

Methods

Data on orthopaedic entries over the time period 2005–2008 were extracted from the National Patient Safety Agency's NRLS. Given the high volume of orthopaedic error reports, an approach was developed to prioritise areas most likely to result in patient harm. This approach was used to select four key areas, and examples of work undertaken to reduce the harm associated with orthopaedic surgery in these areas are presented. A detailed assessment of all orthopaedic deaths was

also undertaken using an inductive approach of content analysis. A key aspect of this thesis was the creation of the Orthopaedic Error Index for hospitals, which allows a national assessment of the relative safety of provision of orthopaedic surgery. It uses existing principles of benchmarking to identify outlier hospitals where a large proportion of harm occurs compared to other hospitals.

Results

There were 48,971 free-text reports of orthopaedic errors made available for analyses. These reports were grouped into 15 categories, which have been used since inception of the NRLS. A method of prioritising these categories of errors was developed which yielded an odds ratio of the most harmful category of errors compared to the others; these included errors associated with implementation of care and on-going monitoring/review [OR = 2.55 (95% CI 2.49, 2.62)]; self-harming behaviour [OR = 1.60 (95% CI 1.30, 1.96)]; infection control [OR = 1.50 (95% CI 1.41, 1.61); treatment, procedure [OR = 1.31 (95% CI 1.22, 1.42)]; and patient accidents [OR = 1.02 (95% CI 0.99, 1.05)]. In each of these error categories, where possible, topics were selected where there was a paucity of national guidelines on delivering safer orthopaedic care. All the deaths (n = 257) were also reviewed (2005–2009). Four main thematic categories emerged: (1) stages of the surgical journey – 62% of deaths occurred in the post-operative phase; (2) causes of patient death – 32% were related to severe infections; (3) reported quality of medical interventions – 65% of patients experienced minimal or delayed treatment; and (4) skills of healthcare professionals – 44% of deaths had a failure in non-technical skills. A single error could have multiple themes, hence all errors did not add up to 100%. National alerts were then produced to mitigate risks associated with the use of digital tourniquets, hip cement, and slips, trips and falls. Data from 155 hospitals were used to create an Orthopaedic Error Index (OEI) which was normally distributed. The mean OEI was 7.09/year (SD 2.72); five hospitals were identified as outliers, lying three standard deviations above the mean OEI. This is the first time that a direct measure of patient safety has been created and used.

Discussion

Reporting systems such as the NRLS offer a potentially important approach for orthopaedic surgeons to better understand the safety considerations of their work. This work has shown that content analyses and prioritisation of errors can be beneficial for large databases and can alert orthopaedic surgeons to practices of unsafe care. Subsequent solutions to mitigate against these errors can furthermore be developed. It is also possible to use the NRLS for risk prediction and identify, earlier on, any hospitals that have significant variation in the severity and propensity of errors. It is hoped that this work will catalyse efforts by a few in orthopaedic surgery to recognise that unsafe care is a problem and needs to be better understood and appropriate solutions developed.

1. Patient safety literature and what it reveals

1.1. Introduction

Understanding of, and commitment to, patient safety worldwide has grown since the late 1990s. This was prompted by two influential reports: *To Err is Human* [Kohn 1999] produced by the Institute of Medicine (IOM) in the United States (US) and *An Organisation with a Memory* [Department of Health 2000] produced by the United Kingdom (UK) Government's Chief Medical Adviser. Both reports recognised that error was routine during the delivery of healthcare: affecting something like one in 10 of all hospital patients. In a proportion of cases the harm produced was serious, even fatal.

The reports also drew attention to the poor performance of healthcare, as a sector, worldwide, on safety compared to most other high-risk industries. Notably, aviation has shown remarkable and sustained improvements in the risk to passengers of air travel over four decades. Both reports called for greater focus on, and commitment to, reducing the risks of healthcare.

Since then, the quest to improve the safety of care for patients has become a global movement. Important bodies such as the World Health Organization (WHO) [World Health Assembly Resolution], the Gulf Cooperation Council (GCC) [Cooperation Council for the Arab States of the Gulf], the Agency for Healthcare Research and Quality (AHRQ) [Agency for Healthcare Research and Quality] and the European Commission [European Commission] have produced strategic documents, initiated programmes of action, and galvanised the support of political and health leaders worldwide.

This has led to a remarkable transformation in the way that patient safety is viewed. Having been a subject of minority academic interest, it is now a firm priority for most healthcare systems. Yet, the

current state of patient safety worldwide is still a source of deep concern. As data on the scale and nature of errors and adverse events have been more widely gathered, it has become apparent that unsafe actions are a feature of virtually every aspect of healthcare. Reports of the deaths of patients regularly feature in media reports in many countries and undermine public confidence in the health services available to citizens. Moreover, many events recur with efforts to prevent them ineffective. These could be in part due to a punitive culture of individual blame and system failures in ensuring safer care.

Various definitions have been used throughout this review, details of which can be found in the Glossary.

Unsafe care is responsible for a substantial disease burden, and this has been studied extensively in hospitals for the past decade; the prevalence of harm due to all episodes of secondary care has been estimated at around one in 10 patients. [Baker GR 2004, Brennan TA 1991, Davis P 2002, Schioler T 2001, Thomas EJ 2000, Vincent C 2001] In Colorado and Utah hospitals, 6.6% of adverse events led to death; compared with 13.6% in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented. [Brennan TA 1991, Leape LL 1991] This figure, when extrapolated for the entire US system, which constitutes in excess of 30 million admissions annually, would imply that 44,000 Americans die as a result of medical errors per year. The total national cost in the US of preventable adverse events associated with a surgical procedure could be as high as $30 billion. [Kohn LT 1999] In the UK, a review of 1,010 records found an adverse error rate of 10.8%. Half of these errors were also deemed preventable. [Vincent C 2001]

The Harvard study [Brennan TA 1991] found 47.7% and the Australian study [Wilson RL 1995] found 50.4% of adverse events were associated with a surgical operation. The Utah Colorado

Medical Practice Study provided additional data on operative events. The annual incidence rate of adverse events among hospitalised patients who received an operation was 3.0%. Among all surgical events, 54% were deemed to be preventable. Eight operations were 'high risk', based upon their preventable adverse event rate: lower extremity bypass graft (11.0%); abdominal aortic aneurysm repair (8.1%); colon resection (5.9%); coronary artery bypass graft/cardiac valve surgery (4.7%); transurethral resection of the prostate or of a bladder tumour (3.9%); cholecystectomy (3.0%); hysterectomy (2.8%); and appendectomy (1.5%). Technique-related complications, wound infections and post-operative bleeding produced nearly half of all surgical adverse events.

1.1.1. Typologies of errors

The link between complication and error was analysed in 9,830 surgical procedures. [Fabri PJ 2008] Major complications occurred in 3.4% of patients, with errors in four out of five complications; with those errors forming the major part in three-quarters of those complications. In other words, of 322 complications, about 60% were predominantly due to human error, reflecting the view that, if these can be addressed, about half of surgical complications are avoidable. [Leape LL 1991, Neale G 2001] These errors were related to surgical technique (63.5%), judgement errors (29.6%), inattention to detail (29.3%) and incomplete understanding (22.7%). In contrast to other studies, system errors (2%) and communication errors (2%) were infrequently identified. Of these complications, 16% resulted in death. The epidemiology of error in medicine which can quite easily be extrapolated to surgery and, indeed, orthopaedic surgery has shown that safety is a major concern in six main areas – problems of: (1) access; (2) communication leading to breakdown in patient/clinician relationships; (3) diagnostic errors; (4) prescribing errors; (5) errors in organisational systems; and (6) technological failures. [Wilson T 2002] Authors have attempted to categorise the causes of, and solutions to, errors in patient care. Vincent suggested that error occurs at the different levels of: institution; organisational management; the workplace environment; the team; the individual staff member; the

specific task; and the patient. [Vincent C 2003] This concurs with much of the literature which recognises that errors may be a result of a number of co-existing human and systems factors.

In the UK, complication rates for some of the major operations are 20–25%. [Gordon NLM 1993] However, at least 30–50% of major complications occurring in patients undergoing general surgical procedures are thought to be avoidable. [Healey MA 2002] The wide variation in surgical complication rates between different centres and different surgeons would support this view. Many adverse events classified as operative are, on closer examination, found to be due to problems related to ward management rather than intra-operative care. For instance, Neale and colleagues [Neale G 2001] identified preventable pressure sores, chest infections, falls and poor care of urethral catheters in their study of adverse events, together with a variety of problems with the administration of drugs and intravenous fluids.

A recent survey of 917/5,540 American Academy of Orthopedic Surgeons (AAOS) fellows revealed the top 10 errors (Table 1.1). By location, 78% of errors occurred in the hospital (54% in the surgery suite and 10% in the patient room or floor). The reporting orthopaedic surgeon was involved in 60% of the errors; a nurse in 37%; another orthopaedic surgeon in 19%; other physicians in 16%; and house staff in 13%. [Wong DA 2009]

Table 1.1: Top 10 errors in orthopaedic surgery according to American Academy of Orthopedic Surgeons survey

Type of error	**Percentage reported by responders (n=917)**
Communication failure	24.7
Equipment and/or instrumentation problem in operating room	20.0
Improper technique and/or physician impairment	12.7
Patient injury event	10.6
Equipment problem with implants	9.0
Wrong site surgery	8.2
Medication error	8.2
Transition of care problem	6.3
Imaging studies problem	6.1
Blood or tissue event	5.5

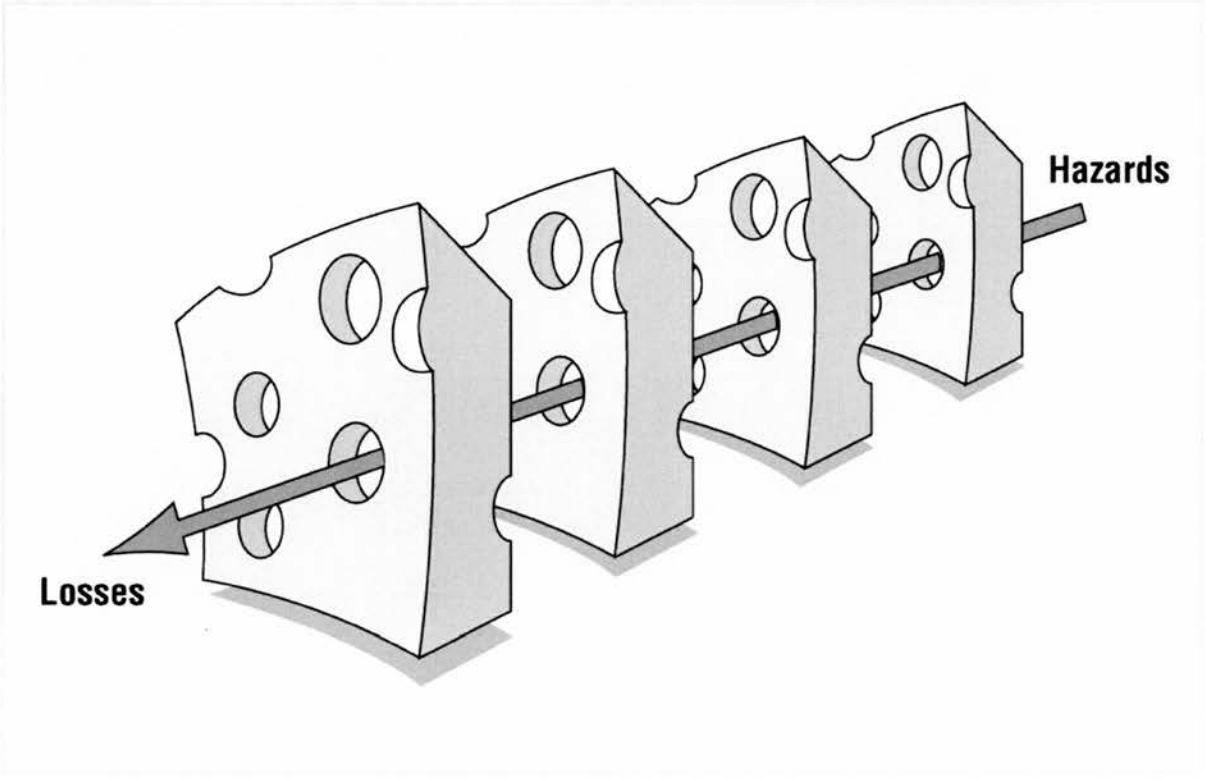
Source: Wong DA 2009

1.1.2. Why do errors occur?

Surgical competency involves a combination of good decision-making (pre-operatively, operatively and post-operatively), team performance and communication (surgical, anaesthetic, nursing and other essential staff members), and technical skills. [Birkmeyer JD 2002, Begg CB 2002] It is unlikely that no errors occur throughout the surgical process, even for the most simple of cases. Taking the example of the lead surgeon, he or she will be: constantly checking and re-checking documentation (salient communications); re-appraising the clinical and theatre setting; and constantly re-evaluating the patient's care and the progress of the operation. This is done with the aim of reducing the error rate occurring during this process to a bare minimum. But errors still happen. However, the occurrence of surgical error is part of a multifaceted phenomenon and adhering to protocols is only part of the answer. This is because a cascade of glitches from various elements, with different controlling factors, can/may culminate in a catastrophe or adverse event.

The 'Swiss cheese' model (Figure 1.1) characterises healthcare in that the system may look robust, but with a closer look, it is full of holes. [Reason J 2000; see Appendix 2]

Figure 1.1: The 'Swiss cheese' model of how defences, barriers and safeguards may be penetrated by an accident trajectory



To understand why errors occur generally, the psychologist Rasmussen developed the Skill, Knowledge & Rule Error Model. [Rasmussen J 1983] At the skill level, actions are automatic and are enacted by way of "stored patterns of pre-programmed instructions". These actions are frequently performed and are often said to 'come naturally' to the operator. However, these skills can be acquired with practice. On a rule level, tasks are completed using stored sets of rules. These rules consist of familiar, rehearsed patterns of actions. Tasks which use rule-based cognitive mechanisms require a greater degree of thought than skill-based tasks, as the rules which need to be applied to complete the situation must be selected. On a knowledge level, unfamiliar tasks are performed with

a high degree of conscious thought as the operator attempts to devise a novel solution to a situation which has not previously been encountered. Reason used Rasmussen's classification as a framework for his categorisation of errors, attaching a specific type of error to the three levels of cognitive performance: errors in execution of skill-based tasks were termed lapses, and errors in execution of rule and knowledge-based behaviours were termed mistakes in his Generic Error-Modelling System.

Lapses characteristically relate to an error in the actual execution of the task, whilst mistakes are more abstract errors, relating to errors in planning (where a strategy not suitable for the situation is carried out), or in problem-solving. In the case of lapses, the plan is correct but the actions are carried out incorrectly, leading to an error; whereas in the case of mistakes, the actions are carried out correctly, but it is instead the plan which is incorrect.

Training in healthcare and surgery *par excellence* focuses on technical skills. Whilst essential, this fails to recognise that surgeons cannot perform to the best of their technical ability unless they are in a well-functioning team. Every surgeon will have experienced the frustrations of a list that is full of delays and appears poorly prepared. These lists are often performed amidst growing friction and failing communication. Most surgeons will also have experienced a very good list, where things flow smoothly and everything falls into place. The work is completed quicker, with less effort and better outcomes. The rest of the team feel the same way and are equally aware of the impact of poor teamwork on the patient. Staff turnover and sickness rates are inversely related to the perception of team performance. The most discerning element of team performance is how safe team members feel to speak up if they see something going wrong. In many cases of wrong site surgery, someone in theatre knew it was happening but felt unable to say so.

The theme of teamwork and communication frequently arises in studies of surgical performance and patient safety, in part because care is delivered in multi-professional teams, and because teamwork

can mediate the relationship between system threats and human errors. In principle, good teamwork results in better avoidance of error-inducing situations (through anticipation and workload management); an improved ability to detect mistakes (through mutual monitoring and support); and better response in a crisis.

Catchpole and colleagues examined teamwork skills in relationship to process problems. [Catchpole K 2008a] They found that in some operations, operating time increased significantly with better anaesthetic leadership, but decreased with better surgical leadership. There are two explanations for this: either that longer and more difficult operations require better leadership from the anaesthetist; or that stronger leadership from an anaesthetist might help surgeons (who often pride themselves on how quickly they can perform an operation) to consider safety over speed. The study also found that errors in surgical technique had a strong association with surgical situation awareness, while most other process problems were related to the leadership and management skills of the nurses. ElBardissi and colleagues also found a strong correlation between technical error and teamwork failure, this time suggesting familiarity is important. [ElBardissi AW 2008] Lingard has also produced an excellent sequence of studies looking specifically at communication in operating teams. In this study, [Lingard L 2004] the researchers noted that the dominant themes of communication were time, safety and sterility, resources, roles and situation. At least one instance of tension from these communications was found in every one of the 35 procedures, which had a negative impact on teamwork and other aspects of performance. Surgical trainees' propensity to either not communicate, or to simply mimic the senior surgeon, appear to make these conflicts worse. Communication failures were found to occur in 30% of team exchanges, with a third of these leading to process problems, increased cognitive load, interruptions or increased tension; thus jeopardising patient safety. Poor timing, missing information, unclear purpose and wrong audience were cited as the sources of these failures. [Lingard L 2004]

Formal methods of communication deliver improved team performance as they help to remove hierarchy and the fear of speaking up, and they prepare team members for the expected as well as the unexpected, and ensure everyone is 'singing from the same hymn sheet'. Sporting teams spend many hours practising together to ensure players know what is expected of them, what the plan is and how to react if it goes wrong. Surgeons tend to assume the scrub nurse remembers what might happen; that the system has delivered the appropriate amount of cross-matched blood and the right antibiotics; that the images are ready and available; and that everyone else knows what they are thinking. It truth, these systems function correctly less than 75% of the time and many patients simply don't get what is expected. The human mind can store, at best, seven or eight items in the short-term memory. That's why telephone numbers are seven or eight digits long. Stress, which is part of our everyday work, makes this even less reliable. Staff members who work in theatres are regularly trying to remember 20–25 things, are interrupted in their work 10–15 times an hour, and interact with numerous different teams during the working day. Some of this is frustrating, but not ultimately harmful, for our patients. Many, however, are, and a significant numbers of these 'errors' lead to significant harm or even death. [Emerton M 2009]

Fatigue is amongst the most well recognised contributors to the potential for error. When examining the effects of time of day on adverse events, Wright found that an adverse event was four times more likely in an operation that started at 4pm than 9am, although they admit this may be due to patient-related factors (and may also be related to time pressure on operating lists, which is discussed in detail later). [Wright MC 2006] A web survey of 2,737 US resident doctors also found that long work shifts were associated with an increased risk of significant medical errors, adverse events and attention failures in trainees. [Barger LK 2006] Most recently, a large retrospective analysis found decreased mortality and morbidity in trauma patients when doctors were limited to an 80-hour working week. [Morrison CA 2009]

The problem of unsafe care in orthopaedic surgery is a real one. It can no longer be neglected; understanding the frequency and types of errors, coupled with developing solutions to unsafe practices is a good start to delivering harm-free orthopaedic care. A key starting point in this journey is the use of a patient safety reporting system.

1.2. Patient safety reporting systems: an opportunity to understand the frequency and causes of healthcare errors in orthopaedic surgery

1.2.1. A global perspective: taking stock of databases of errors

The key output from patient safety initiatives is to prevent harm to the patient, and key tools in this respect are patient safety reporting systems (PSRSs), which help us learn from mistakes and should lead to the development of interventions aimed at mitigating against these errors. Reporting must be coupled with measures of action and there are several methods by which PSRSs can achieve success: generation of alerts on complications of new drugs; dissemination of lessons learned by healthcare organisations experiencing serious patient safety incidents (PSIs); and revelation of unrecognised trends. [Leape LL 2002]

Methods of identification of incidents vary significantly between countries. Physicians, safety officers, and patients and their families may be involved. Some systems centre on certain types of events (e.g. medication error); whereas others focus on events where serious harm occurred; and some are more all-encompassing. Methods of analysis and prioritisation of risk also vary widely between different systems. A common approach is an in-depth root cause analysis of one event, with production of a report that is then widely disseminated. Other approaches include online publication of the virtually unaltered description of the incident. Rates of harm are also calculated in different ways, making summation of data problematic. Use of checklist reporting forms versus free-text; web-based versus paper recording; and inconsistent approaches to prioritising the significance

of events, further confound data problems. In general, proving reduction in harm resulting from the use of reporting system data is not yet feasible. Methods of incident mitigation range from individual feedback, local educational meetings, production of national alerts, and media or web-based releases. Determining the best level for a risk reduction intervention (local, regional, national or international) is at a rudimentary stage of development. Evaluation of the effectiveness of systems is also under-developed, and in many cases not present. Although a belief is often present that things are getting better, data supporting this are lacking. In fact, due to the increased number of reports collected, data often suggest the opposite. [Noble DJ 2011]

Additionally, the number of different systems in existence encourages bureaucracy and lack of clarity regarding taxonomies, [Arah OA 2004] as well as potentially stifling local, regional, national and international learning and change. [Donaldson L 2004] Overall, national systems are better developed than regional and local systems.

1.2.2. Reporting systems operating at multiple levels

Following are four examples of reporting systems from different countries:

1. Osaka University Hospital introduced a voluntary and anonymous online reporting system which allows capture of electronic information about adverse events. This information is subject to daily analysis by a member of the clinical risk management committee. Findings and lessons learned are shared at regular educational staff meetings. The programme has driven the development of several risk reduction initiatives. Their experience has led them to believe that web-based models with effective sharing of information have led to a reduction in physician under-reporting compared to previous studies in Japan. [Nakajima K 2005]

2. The Intensive Care Unit Safety Reporting System (ICUSRS) has been used in 18 different intensive care units (ICU) in the US. It was created at Johns Hopkins Hospital for use in ICUs to provide an anonymous, voluntary and confidential system for incident reporting. It focuses on collecting web-based reports from all healthcare workers in an ICU and producing a monthly report which is fed back to the individual ICU and also includes comparative data from other ICUs. It includes a built-in evaluation section for the reporter. [Thompson DA 2005]

3. The Pennsylvania PSRS receives reports of serious events and incidents from 528 healthcare facilities within the region. It also collects data on healthcare associated infections (HCAI), which come from 700 nursing homes. There is a legal requirement for these healthcare facilities to report to this reporting system. Like most PSRSs, the aim is to collect data, identify trends, learn from reports and recommend changes in healthcare practices and procedures that may be instituted to reduce the number and severity of future serious events and incidents. There have been 528 hospitals, ambulatory surgical facilities, abortion facilities and birthing centres who have submitted 226,670 reports of serious events and incidents to the authority in 2009; an increase of 6,796 reports from 2008. In 2009, the authority received 18,889 reports per month on average; an increase of 3% from 2008. Approximately 96% of all reports submitted by these facilities in 2009 were near-miss incidents, or did not cause harm to the patient. Approximately 4% of all reports were submitted as serious events, indicating that the patient suffered some level of harm, ranging from minor, temporary harm to death. [Pennsylvania Patient Safety Authority 2010]

4. Jeder Fehler Zaehlt is an online reporting system for general practitioners in Germany. Data are entered anonymously and voluntarily, and reports of key incidents are published on the website,

where users can learn and comment. It is one of the few systems solely focused on primary care. [Jeder Fehler Zaehlt 2010]

Various medical specialties have enjoyed varying degrees of success with different types of reporting systems. A voluntary and anonymous online system for neonatal units in 54 hospitals was studied amongst 739 healthcare workers from the Vermont Oxford Network. It revealed a typical pattern of incident epidemiology, the most frequent type of incident being medication errors. [Suresh G 2004]

National systems have been more ambitious in their aims; the most well-known being the National Reporting and Learning System (NRLS). However, the oldest national system is the Australian Incident Monitoring System (AIMS), which has been used in Australia for over 20 years, having originated from an adverse event reporting system in anaesthesia in the 1980s. AIMS was engineered by the Australian Patient Safety Foundation (APSF), who were given the responsibility of developing a system for reporting adverse events and near misses in Australia in 1996 for public sector hospitals.

The system of reporting used by AIMS has specific software for collecting confidential data, and for classifying and producing reports to prevent future error. The software allows individual units to compare frequency of incidents with other providers. [Australian Patient Safety Foundation 2010] AIMS was recently renamed as the Advanced Incident Monitoring System and is marketed internationally by Patient Safety International. [Patient Safety International 2010] Other countries such as New Zealand, as well as the UK, have benefited from this early work. Data are anonymous and are used to identify trends which can be compared nationally, as well as communicated through reports produced by the APSF. Under-reporting from medical practitioners has been a criticism, as has the omission of the most serious incidents.

England and Wales have been spearheading the patient safety agenda, initially through the creation of the National Patient Safety Agency (NPSA) in 2003 as a specially-designated strategic health authority, and this in turn led to the development of the NRLS database of patient safety incidents. This database is now the largest of its kind in the world, having already received (as of 1 January 2013) over seven million reports of episodes of care that could or did result in iatrogenic harm. Reports continue to accrue at an accelerating rate, with the database currently receiving approximately a quarter of a million cases per quarter. [Panesar SS 2009a]

Data are arranged categorically, comprising of 75 data fields, including: incident categories at two levels; specialty and location of the incident; and free-text description of the event. The largest proportion of incidents originates from medical specialties (34%), surgical specialties (16%), mental health (13%), and obstetrics and gynaecology (10%). Of note is that the proportion of reports from primary care has been particularly low (5%), for reasons that as yet remain poorly understood. [Panesar SS 2009a] Data from the NRLS are published in a number of formats including summative quarterly reports for England and Wales. Individual organisational reports have also been released showing reporting rates benchmarked against other similar organisations. [Panesar SS 2009a] This allows for a middle-ground approach; allowing for a certain degree of disclosure, and yet also maintaining a certain degree of disclosure, which ensures anonymity and allows both patients and clinicians to appreciate the results.

The gross under-reporting to the database has been cited as its Achilles heel, and opponents of its use have cited its use to warning, communication and detection of rare patient safety incidents. [Vincent C 2008] Whilst this may be a valid criticism, it is clear that reporting is increasing as clinicians become more aware of the presence of the NRLS and develop confidence that there will

not be any personal repercussions to making reports. Convincing clinicians of the usefulness of the data they contribute should in due course further increase the frequency and quality of reporting.

Medication errors have frequently been cited as the common type of adverse event. Reporting systems, such as the anonymous MEDMARX system, have been very successful in quantifying and responding to incidents. Almost 900 hospitals have taken part in submitting information and over one million reports have been received – one of the few systems with a similar number of overall reports to the NRLS. The system provides a way of sharing data between healthcare providers and has contributed information in specific areas, such as operating theatre medication errors. [Santell JP 2003, Beyea SC 2003] Such a defined database in a specific area is likely to reveal important lessons for more comprehensive reporting systems, for example, using targeted reporting when something new is introduced into the system; understanding that the most significant errors are only a signpost to the vast majority; and unravelling their detail, even in the face of vast quantities of reports (not necessarily a waste of time as it may lead to increased predictive powers to detect error). [MEDMARX 2002]

Some specialties have opted for specialty-specific reporting systems. A good example of this is the Confidential Reporting System for Surgery (CORESS), which relies on surgical trainees and consultants reporting untoward incidents on a data sheet. These 'stories' then undergo editorial review and are published in the form of quarterly reports with advice on preventing the error from occurring again. Anonymity of the patient and the clinician is maintained throughout the process. The person who submitted the case receives a certificate. To date, less than 100 incidents have been reported. [CORESS 2010]

1.2.3. The role of the World Health Organization

WHO has a key role to play in reporting and learning systems. Guidelines developed in 2005, which are readily available, were developed by the WHO Patient Safety Programme [WHO 2005] and present information for countries on areas such as the purpose and methods of reporting, components of a reporting system, and a guide and checklist to setting up a national system. [Donaldson L 2006] These are at a conceptual rather than operational level. Controversial issues such as voluntary versus mandatory reporting, anonymous or confidential reporting, and resource allocation are covered. To date, WHO has released information in a selection of areas to improve patient safety, such as in surgery and reducing errors in the delivery of chemotherapy. However, realising an orange-wire system, that translates critical information internationally, as advocated in the guideline, is, as yet, a far-reaching goal. [Donaldon L 2004] This is in part due to the lack of regulatory authority that WHO has over countries, and that at present most country's reporting systems are hosted by governmental agencies.

One future approach may be to imitate the aviation industry's approach to such a problem: following a number of airline crashes some years ago, the aviation industry brought together all relevant partners (including regulatory bodies and technical experts) under one banner: Commercial Aviation Safety Team (CAST). This body has been able to demonstrably reduce fatalities in aviation, and recently the creation of a similar body in healthcare has been advocated. [Pronovost PJ 2009]

1.2.4. Translating reporting into action

WHO holds the following hope for reporting systems:

> *"The currency of patient safety can only be measured in terms of harm prevented and lives saved. It is the vision of the [WHO] that effective patient safety reporting systems will help to make this a reality for future patients worldwide." [WHO 2005]*

The true value of a reporting system is dependent on its input and if clinicians fail to supply useful information, the outputs will be meaningless. Reporting systems can be classed according to incident identification, analysis and prioritisation of incidents, methods of risk mitigation and evaluation mechanisms. National systems are better developed than regional and local systems, but evaluation of effectiveness and translatability into action is significantly under-developed.

1.3. The National Reporting and Learning System: an opportunity for orthopaedic surgeons to understand the level of harm in the specialty

The NRLS was initially a voluntary, national reporting system set up in 2003 for the National Health Service (NHS) in England and Wales. In April 2010, reporting of serious untoward incidents (those that constituted severe harm and death) became mandatory. [NPSA 2010a] One of the largest and most comprehensive reporting systems in the world, the number of incidents reported to it increases year on year. [Lamont T 2009] All staff working within the NHS can report incidents through their parent institution to ensure local action can be taken when needed. A representative from each parent institution is responsible for uploading records to the national database. In addition, healthcare staff, patients and members of the public can report incidents independently through the NRLS website. [NRLS]

Each NRLS report refers to an unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded care. It also includes the reporting of incidents that reached the patient but did not lead to harm, and those which did not lead to harm because an incident was prevented from reaching the patient. These incidents are further stratified into different levels of harm. When a patient safety incident report is made, a record of it is stored digitally in a safety management system in the NHS organisation. The information is gathered, de-identified and stored in the NRLS. Incidents can be directly reported to the NRLS via a web-based

open-access system, but they are usually entered into a local database by administrative staff or the local clinical risk manager, who transcribes a paper-based primary critical incident report. In order to integrate the wide variety of local safety management systems and software, the NRLS has 75 data fields (see Appendix 3), including incident categories at two levels, specialty and location of the incident, and free-text descriptions of the events. [Catchpole K 2008b] Each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff and a range of outputs are produced to provide solutions to patient safety problems. These include one-page reports called Rapid Response Reports (RRR), quarterly data summaries and topic-specific information on topics such as preventing inpatient falls in hospitals. There is constant consultation with subject-matter experts, including professional organisations such as the Royal Colleges. NHS organisations also have deadlines imposed on them by which time they should have implemented any findings from these reports (see section 1.4.1).

1.4. The National Reporting and Learning System

1.4.1. Background

A decade ago, there was a call for the urgent development of a national database of medical error in England and Wales; the vision was that this would help the medical fraternity better understand the epidemiology of errors that caused harm and those that did not; define research priorities in this area; and develop error reduction strategies. [Sheikh A 1999] This call arose out of the recommendations of two key reports from the US and Australia, which highlighted the need for patient safety to be an integral part of health policy considerations. [Wilson RL 1995, Kohn LT 1999] The scope of this chapter is to critically reflect on the progress that has been achieved with respect to the creation of the NRLS.

Domestic and international health policy has prioritised the importance of reducing the burden of iatrogenic harm, the latter mandate coming through the WHO World Alliance for Patient Safety. [WHO 2008] One of the initiatives consistently identified as of highest priority in such deliberations has been the need for the creation of PSRSs – this favourable policy climate has enabled several such systems to have been created in countries such as Australia, Germany, some states in the US, and England and Wales. [Clinton HR 2006]

When first envisioned, the underlying model for the NRLS was simple: it would be a fully mandatory reporting scheme for medical errors. [Department of Health 2000] The main arguments for mandatory systems is that these allow a truly comprehensive picture of the patient safety landscape to emerge and, furthermore, that these improve healthcare professionals' sense of accountability. It has, however, subsequently been noted that mandatory systems deter practitioners and hospitals from reporting incidents as they fear public disclosure will lead to possible comeback for the reporting physician or trust. [Leape LL 2002]

The NPSA did consider a mandatory reporting model, but in the end opted for a voluntary, anonymised reporting structure in the hope of enabling fuller disclosure of incidents without fear of reprisal on the part of the individual making the report. [Department of Health 2000] The approach used allows patient safety incidents to be reported via a web-based open access system, or the more popular system whereby reports are submitted in an anonymised fashion via the individual organisation's local risk management system.

Analysis of the reported incidents by the NPSA has helped lead to the identification of possible solutions to these problems (see Table 1.2 for details of published RRRs). Whilst these have proved useful, there remain several challenges associated with the analysis and interpretation of data, which largely reflect issues with the architecture of the NRLS. The approaches used for analyses of reports

include stratified sampling of frequently occurring incident types and free-text data mining for specific topics. The very large number of case reports being received renders it difficult to undertake detailed analysis of all incidents. [Panesar SS 2009a] Such analysis is also compromised by the lack of detail in many of the reports received and, because reports are anonymised, the lack of opportunity to easily go back to those making the reports or to case notes to identify further information.

The gross under-reporting to the database has been a cause for concern and, as such, its use is often limited to warning, communication and detection of rare patient safety incidents. [Vincent C 2008]. Whilst this may be a valid criticism, it is clear that reporting is increasing as clinicians become more aware of its presence and furthermore develop confidence that there will not be any personal repercussions to making reports.

Also of relevance in this context is the varying degree of engagement by different professional groups. Nurses in particular are good reporters; in contrast, consultants are very poor reporters. Convincing clinicians of the usefulness of the data they contribute should, in due course, further increase the frequency and quality of reporting.

Consequently, clinical problems tend to be under-reported, whilst other potentially less serious, non-clinical problems are perhaps over-represented. It is still proving difficult to engage senior clinicians in a generic reporting system. In order to try and overcome these problems, the NPSA engaged frontline and senior clinicians, and undertook two pilot projects aimed at improving reporting from general practice and anaesthesia. Working with the Royal College of Anaesthetists and the Royal College of General Practitioners, two bespoke reporting systems have been developed. These are incorporated into the architecture of the NRLS. Encouragingly, the former has been a success and there has been a significant improvement in the level of reporting from anaesthetists. [NPSA 2008a]

The impact of the latter work with the Royal College of General Practitioners is currently being assessed.

Initially, the NPSA produced detailed patient safety solutions that, when evaluated, proved difficult for organisations to implement. Simpler solutions were then developed using a one-page format which outlines the problems and describes actions that can be taken to help prevent other patients being similarly harmed. NHS organisations are now also provided with supporting information that describes in considerable detail the relevant contextual data from the reporting system, together with advice on implementation considerations. These RRRs cover a wide range of issues, from resuscitation in mental health and the risks of amphotericin toxicity, to the risk of bone cement implantation syndrome in hip fracture surgery (see Table 1.2).

The challenges of improving patient safety in healthcare remain significant. The national database represents an important step, and is an important resource in ensuring that information about adverse events are both learned from and shared throughout the NHS. All clinicians, regardless of specialty can contribute to these efforts by reporting patient safety incidents to the NRLS. Whilst important challenges remain in relation to encouraging fuller, franker and more comprehensive reporting, and then meaningfully analysing these data, it is fair to conclude that substantial progress has been made. As a clear leader in reporting systems, the successes and failures of the NRLS are likely to have major implications on reporting systems in other parts of the UK and internationally, and so it is very much in the collective interests of patients nationally and internationally that healthcare professionals engage with, report to and make use of this resource to the best of their ability.

1.4.2. How are national outputs developed?

Within an NHS trust, patient safety incidents reported on the ward are forwarded to the risk manager. These should then be reviewed locally to identify any areas where action can be taken to make services safer – for instance, a ward reporting repeated errors with certain high-risk injectable medicines. But they are also uploaded to the NRLS. This has been designed as the push of a button by local risk managers, to minimise burden on trusts – this means that at a national level, all incidents are received, however trivial. These are mapped against data fields, which are being updated to align with international patient safety classification terms.

Most incidents come from locally uploaded data, as described above. A minority (less than 1%) are received from web-based reports from individual clinicians. Some also come through particular specialty-specific initiatives, such as the reporting scheme set up in partnership with the Royal College of Anaesthetists (as described in section 1.4.1). This includes more detailed taxonomy around particular areas of clinical interest, such as difficult airways.

The challenge is to identify the most pressing risks and issues from the vast database of over seven million incidents. In addition to wider trends and patterns, each incident reported as resulting in severe harm or death is now scrutinised by clinical staff, in particular the free-text description of the incident. These are screened to focus on the incidents which suggest wider system problems that could affect a number of trusts. Over 300 serious incidents are carefully reviewed in this way each month and a few are selected for further work. They are discussed at a weekly multidisciplinary meeting. More evidence from the wider database is sought at this stage, together with data from other sources such as litigation as well as international sources (such as the Pennsylvania Safety Agency). NRLS staff may also go back to trusts reporting serious harm events at this stage for more

information about what action was taken locally. A wide range of clinical advice is sought for further understanding of the problem and possible actions to reduce harm.

Criteria for urgent action are:

- evidence of substantive harm from incident data or other sources
- risks not well recognised by staff
- clear actions available to prevent harm.

Issues which meet these criteria are developed as RRRs (see Table 1.2). These are usually produced within two to four months of the incident report, although some are produced in a matter of weeks when swift action is needed (for instance, to prevent risks to haemodialysis patients from additives to hospital water supply).

The NRLS is the largest database of patient safety incidents around the world. To date, there has been a lack of a systematic approach to identify errors that cause the greatest degree of harm. The approach has also been reactive and most solutions have been developed after these incidents have occurred. The sheer volume of incidents makes prioritisation and analyses challenging. In subsequent chapters, I will use the example of orthopaedic surgery to assess the potential of the system for better understanding the frequency, typology and causes of errors, and test the risk prediction-ability of the database.

Table 1.2: Rapid Response Reports to date

Date	Topic	Title
22 Mar 2012	Nasogastric feeding tubes	Harm from flushing of nasogastric tubes before confirmation of placement
28 Nov 2011	Intravenous equipment	Minimising risks of mismatching spinal, epidural and regional devices with incompatible connectors
26 Oct 2011	Medium-chain acyl-CoA dehydrogenase deficiency	Keeping newborn babies with a family history of MCADD safe in the first hours and days of life
20 Mar 2011	Insulin	The adult patient's passport to safer use of insulin
10 Mar 2011	Nasogastric feeding tubes	Reducing the harm caused by misplaced nasogastric feeding tubes in adults, children and infants
31 Jan 2011	Intrathecal, epidural and regional medicines	Safer spinal (intrathecal), epidural and regional devices
13 Jan 2011	Falls	Essential care after an inpatient fall
16 Dec 2010	Ambulatory syringe drivers	Safer ambulatory syringe drivers
25 Nov 2010	Loading doses	Preventing fatalities from medication loading doses
21 Oct 2010	Blood transfusion	The transfusion of blood and blood components in an emergency
23 Sept 2010	Laparoscopic surgery	Laparoscopic surgery: Failure to recognise post-operative deterioration
26 Aug 2010	Intravenous fluids and medicines	Prevention of over infusion of intravenous fluid and medicines in neonates
30 July 2010	Low molecular weight heparins	Reducing treatment dose errors with low molecular weight heparins
16 June 2010	Insulin	Safer administration of insulin
26 May 2010	Retained swabs	Reducing the risk of retained swabs after vaginal birth and perineal sutering
28 Apr 2010	Surgery	Checking pregnancy before surgery
31 Mar 2010	Gastrostomies	Early detection of complications after gastrostomy
24 Feb 2010	Omitted or delayed medicines	Reducing harm from omitted and delayed medicines in hospital
9 Feb 2010	Intravenous gentamicin	Safer use of intravenous gentamicin for neonates
21 Jan 2010	Immunisation	Vaccine cold storage
9 Dec 2009	Tourniquets	Reducing the risk of tourniquets left on after finger and toe surgery
1 Dec 2009	Lithium	Safer lithium therapy
19 Nov 2009	Being open	Being open: Communicating patient safety incidents with patients, their families and carers
29 Sept 2009	Oxygen	Oxygen safety in hospitals
29 July 2009	Catheter insertion	Minimising risks of suprapubic catheter insertion (adults only)
24 June 2009	NHS Number	Risk to patient safety of not using the NHS Number as the national identifier for all patients

11 June 2009	Glaucoma	Preventing delay to follow-up for patients with glaucoma
28 May 2009	Mental health	Preventing harm to children from patents with mental health needs
30 Apr 2009	Urinary catheters	Female urinary catheters causing trauma to adult males
28 Apr 2009	Throat packs	Reducing the risk of retained throat packs after surgery
11 Mar 2009	Hip cement	Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur
19 Feb 2009	Bowel cleansing solutions	Reducing risk of harm from oral bowel cleansing solutions
09 Dec 2008	Midazolam	Reducing risk of overdose with midazolam injection in adults
26 Nov 2008	Resuscitation, mental health, learning disability	Resuscitation in mental health and learning disability settings
12 Nov 2008	Craniotomy, burr holes, neurosurgery	Avoiding wrong side burr holes / craniotomy
21 Oct 2008	Hib vaccine, Infanrix, immunisation	Risks of omitting Hib when administering Infanrix-IPV+Hib
30 Sep 2008	Haemodialysis, water supply	Risks to haemodialysis patients from water supply (hydrogen peroxide)
11 Aug 2008	Vinca alkaloid, minibag	Using Vinca Alkaloid Minibags (adult/adolescent units)
28 Jul 2008	Infusions, arterial lines	Problems with infusions and sampling from arterial lines
19 May 2008	Chest drain, chest tube	Risks of chest drain insertion
24 Apr 2008	Intravenous, heparin flush	Risks with intravenous heparin flush solutions
22 Jan 2008	Oral anti-cancer medicines	Risks of incorrect dosing of oral anti-cancer medicines
26 Nov 2007	Paraffin skin products	Fire hazard with paraffin based skin products on dressings and clothing
10-Sep-2007	Haemorrhage	Emergency support in surgical units: Dealing with haemorrhage
03 Sep 2007	Injectable amphotericin	Risk of confusion between non-lipid and lipid formulations of injectable amphotericin
18 Jun 2007	Cytarabine	Risk of confusion between cytarabine and liposomal cytarabine (Depocyte®)

2. Aims and objectives

Given the proliferation of orthopaedic patient safety incidents reported to the NRLS, this is the first systematic attempt at understanding the aetiology of unsafe care in the specialty.

The aims of this thesis are to:

- understand the opportunities offered by the NRLS to ascertain the frequency, types and causes of errors in orthopaedic surgery
- develop the risk prediction potential of the system
- offer critical reflections on the role of reporting systems for improving the care received by orthopaedic patients.

The specific objectives are to explore the following aspects of safety in orthopaedic surgery:

- Critically appraising the roles of reporting systems in understanding the aetiology of healthcare errors.
- Using the NRLS to understand the frequency and types of errors in orthopaedic surgery.
- Developing a method to prioritise the types of errors likely to cause the greatest harm in the above specialty, as reported to the NRLS.
- Using examples from the above prioritisation exercise to develop national solutions to minimising certain types of orthopaedic errors.
- Assessing the feasibility of developing an index of harm which will identify outlier hospitals that appear to be particularly dangerous for patients receiving orthopaedic care.
- Reflecting on the limitations of the NRLS in better understanding errors from orthopaedic care and offering solutions to further the delivery of safer orthopaedic care.

3. Experimental studies

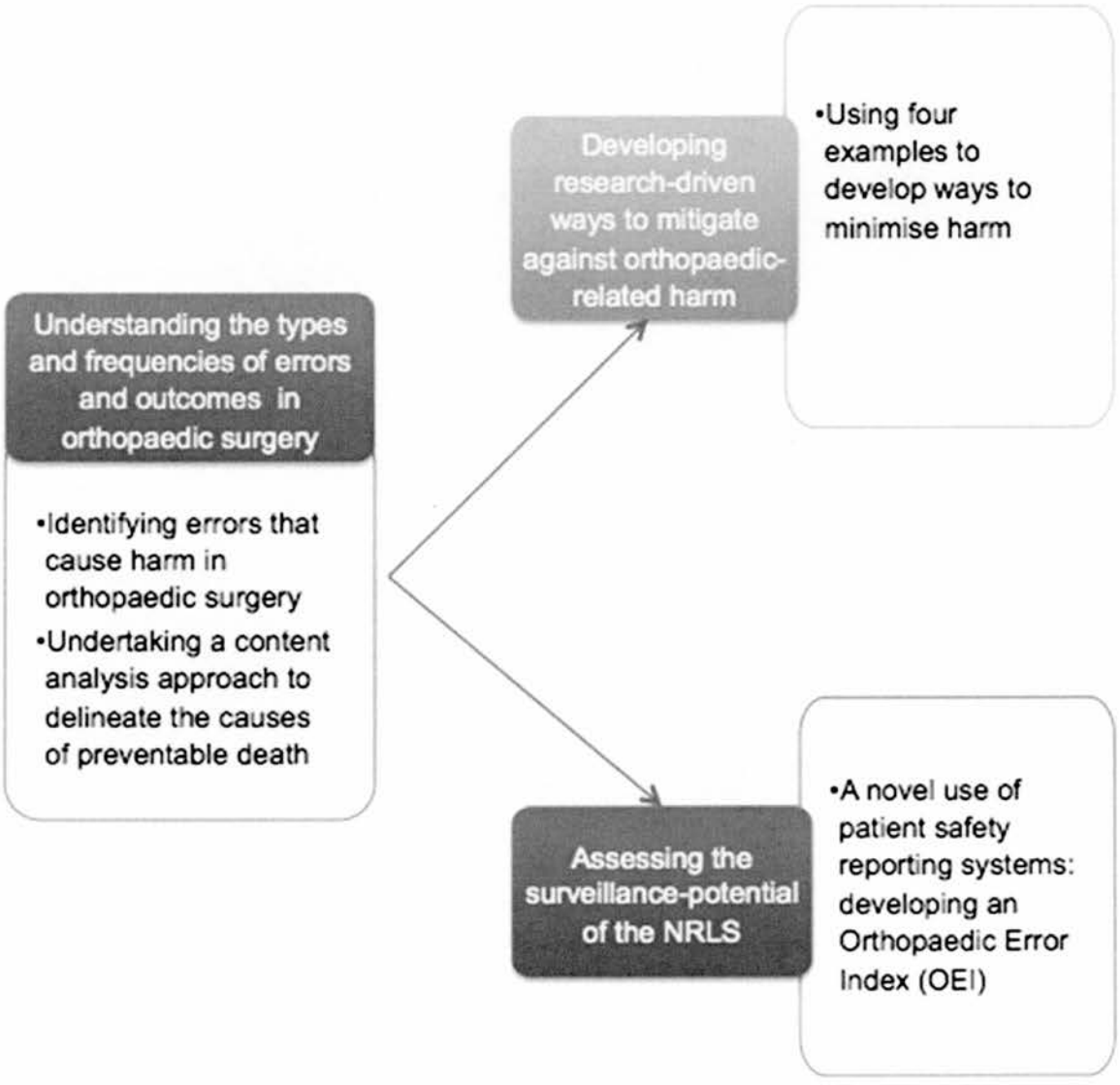
The work undertaken focuses on four key studies, set out in Chapter 3, which aim to further the understanding of errors in orthopaedic surgery through the lens of the NRLS. A conceptual framework has been used which has been adapted from the one proposed by Donabedian [Donabedian 2005], as shown in Figure 3.1. Specifically, the three components of my framework are:

(i) **Understanding the types and frequencies of errors and outcomes in orthopaedic surgery**. In order to learn from errors, I sought to categorise the orthopaedic-related errors. [Noble DJ 2011] Death, in terms of absolute numbers, being the most severe category of harm, was explored further to delineate the causes of a sub-set of preventable deaths.

(ii) **Developing research-driven ways to mitigate orthopaedic-related harm.** These were derived from the underlying principles enshrined within the national guidance suggested in *The Seven Steps to Patient Safety,* in which it is stipulated that an organisation must learn from errors and provide solutions to minimise harm resulting from these errors. [NPSA 2004]

(iii) **Assessing the surveillance potential of the NRLS.** My aim was to understand the risk posed by hospitals that carry out orthopaedic surgery. This work built on the concept behind system-wide outlier analyses or hospital standardised mortality ratios (HSMRs). As these have come under increasing scrutiny, [van Gestal YR 2012] I sought to undertake exploratory work and assess whether organisations could be compared at a systems-level using the NRLS.

Figure 3.1: Conceptual framework for thesis



3.1. *Study 1:* Identifying errors that cause the greatest harm in orthopaedic surgery

With scientific and technological advances, the practice of orthopaedic surgery has transformed the lives of millions worldwide. Such successes, however, have a downside; not only is the provision of comprehensive orthopaedic care becoming a fiscal challenge to policy-makers and funders, concerns are also being raised about the extent of the associated iatrogenic harm. The NRLS in England and

Wales is an under-used resource which collects intelligence from reports about healthcare error. Using methods akin to case-control methodology, I have identified a method of prioritising the areas of a national database of errors that have the greatest propensity for harm. My findings are presented using odds ratios (ORs) and 95% confidence intervals (CIs). The largest proportion of surgical patient safety incidents reported to the NRLS was from the trauma and orthopaedics specialty; 48,095/163,595 (29.4%). Of those, 14,482/48,095 (30.1%) resulted in iatrogenic harm to the patient and 71/48,095 (0.15%) resulted in death. The leading types of errors associated with harm involved the implementation of care and on-going monitoring (OR 5.94, 95% CI 5.53 to 6.38); self-harming behaviour of patients in hospitals (OR 2.14, 95% CI 1.45 to 3.18); and infection control (OR 1.91, 95% CI 1.69 to 2.17). I analysed these data to quantify the extent and type of iatrogenic harm in the specialty, and make suggestions on the way forward. Despite the limitations of such analyses, it is clear that there are many proven interventions which can improve patient safety and need to be implemented. Avoidable errors must be prevented, lest we be accused of contravening our fundamental duty of *primum non nocere.*

3.1.1. Introduction

The high frequency of medical errors and the associated disease burden resulting from iatrogenic harm remains an important challenge for healthcare systems globally. [Hurwitz B 2009] Surgical specialties have been a focus of scrutiny given the large volumes of procedures carried out. More than 234 million people require surgical treatment every year globally, and more than half of these occur in developed countries. [Weiser TG 2008] By the sheer numbers of procedures, both for emergency and elective problems, trauma and orthopaedics as a specialty could be deemed more 'risky', as partly evidenced by the fact that 20% of wrong site surgery incidents occurred in the specialty in 2006–2007. [Robinson PM 2009]

As well as additional morbidity and mortality, there are direct financial implications of unsafe care. A measure of the problem could be the amount paid out for clinical negligence claims against the NHS, which stood at approximately £860 million in the financial year 2010/11; a 9% increase from the previous year. The specialty with the highest number of clinical number claims was orthopaedic surgery. [NHS Litigation Authority 2011]

In their follow up report to *To Err is Human*, *Crossing the Quality Chasm*, the IOM highlighted the poor use of incident reporting systems, which are necessary to help inform actions to improve patient safety. PSRSs help us understand the extent and nature of the problems and should lead to the development of interventions aimed at mitigating against these errors. National databases of errors have been created in many parts of the world, including now in the US. [Sheikh A 1999, Panesar SS 2009a, Hickner J 2010] These have offered important insights that have helped to shape national policy, for example, the recognition of the risks of bone cement implantation syndrome associated with use of cement in hip fracture surgery, and the potential for information technology (IT)-based interventions to reduce many cases of drug allergy-related morbidity. [Panesar SS 2009b, Cresswell KM 2008]

The aim of this study was to understand the burden of harm in trauma and orthopaedics using a cross-sectional methodology. As such, I wanted to ascertain what types of errors are associated with the greatest degree of harm in orthopaedic patients.

3.1.2. Methods

3.1.2.1. Study design and data collection

Data from the NRLS database were obtained, cleaned and then analysed for all incidents reported in the specialty of trauma and orthopaedics from January 2009 to December 2009. The domains

searched were 'acute/general hospital' and 'trauma and orthopaedics' and it was limited to England. Characteristics of the medical incident such as cause (data element IN011), contributing factor (IN06), incident type (IN05), work area (IN03), extent of harm (PD09 and PD16), preventability and mitigating circumstances (PD12 and PD14), staff involved (ST01), and patient characteristics (PD02 and PD11) were abstracted. There are 16 types of incident categories (INO5), with further subdivisions. Free-text descriptions of all the PSIs were also abstracted. Harm was defined by the user's self-report using variable PD16. Level of harm was classified as no harm, low harm (minimal harm – patient(s) required extra observation or minor treatment), moderate harm (short-term harm – patient(s) required further treatment, or procedure), severe harm (permanent or long-term harm) or death. All incidents causing harm (low, moderate, severe and death) were grouped together. Further details of these categories of harm are given in Panel 1 below.

Panel 1: Descriptions of categories of harm [NPSA 2011a]

These categories of harm were developed by the NPSA and have been quoted directly.

"No harm:

Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care.

Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.

Low harm: Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.

Moderate harm: Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

Severe harm: Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.

Death: Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care."

3.1.2.2. Statistical approach

The null hypothesis was that the propensity of harm in all categories was equal. A 'case' was one where an error resulted in harm. The 'controls' were defined as errors where no harm occurred or 'near-misses.' Errors were clustered into 15 discrete categories called 'incident types'. I sought to evaluate the degree of association between different types of errors and resultant harm to the patient. Measures of relative effect express the outcome in one group relative to that in the other. Two commonly-used methods are the relative risk (RR) and the OR. The OR is the probability that a particular event will occur, to the probability that it will not occur, and can be any number between zero and infinity. In gambling, the odds describe the ratio of the size of the potential winnings to the gambling stake; in healthcare it is the ratio of the number of people with the event to the number without. Risk is the concept more familiar to patients and health professionals. Risk describes the probability with which a health outcome (usually an adverse event) will occur. Measures of relative effect express the outcome in one group relative to that in the other. Hence, the RR is the ratio of the risk of an event in the two groups, whereas the OR is the ratio of the odds of an event. For treatments that increase the chances of events, the OR will be larger than the RR, so the tendency will be to misinterpret the findings in the form of an overestimation of treatment effect, especially when events are common (with, say, risks of events more than 20). For treatments that reduce the chances of events, the OR will be smaller than the RR, so that again misinterpretation overestimates

the effect of treatment. Furthermore, the RR is an easier concept to understand. [Cochrane Collaboration] A 2x2 table was constructed for each of the categories, as follows (Table 3.1).

Table 3.1: 2x2 table to calculate degree of association between category of patient safety incident and severity of harm

	Harm	*No harm*	*Total*
Category A	A	B	a + b
All categories - Category A	C	D	c + d
Total	a + c	b + d	a + b + c + d

$$OR = \frac{\text{Odds of harm in orthopaedic category A}}{\text{Odds of harm across all orthopaedic categories}}$$

$$OR = \frac{a / b}{c / d}$$

3.1.3. Results

There were 163, 595 incidents that occurred in all surgical specialties. The largest proportion of incidents reported to the NRLS was in the specialty of trauma and orthopaedics (48,095/163,595; 29.4%). Of these, 14,482/48,095 (30.1%) resulted in iatrogenic harm to the patient and 71/48,095 (0.15%) resulted in death. There were 155 NHS trusts that reported data to the database; this number includes all trusts in England and Wales. Aggregate frequencies of harm and examples of the free-text are shown in Table 3.2. The five statistically significant areas of harm include implementation of care and on-going monitoring/review (OR = 2.55, 95% CI 2.49 to 2.62), self-harming behaviour (OR = 1.60, 95% CI 1.30 to 1.96), infection control incidents (OR = 1.51, 95% CI 1.41 to 1.61), other (OR = 1.31, 95% CI 1.22 to 1.42), and treatment/procedure (OR = 1.23, 95% CI 1.19 to 1.28).

Table 3.2: Frequency of harm by category, with example incident reports

Category	No harm (percentage of all patient safety incidents; n=48,095)	All harm (percentage of all patient safety incidents; n=48,095)	Example
Implementation of care and on-going monitoring / review	1194 (2.5%)	2600 (5.4%)	*"Admitted 28 / 08 / 05 with fracture right* NOF [neck of femur fracture], *very frail. In atrial fibrillation but not confused. No input requested from medical team. Starved for op 30 / 08 / 05 and 31 / 08 / 05 . Postponed due to raised* INR [international normalised ratio] . *Starved again 01 / 09 / 05. Anaesthetist promised to take her although very high risk, theatre postponed again at 16.00."*
Self-harming behaviour	52 (0.1%)	48 (0.1%)	*'Pt checked at approx 00.00 hrs & appeared settled . Pt checked again around 01.00 hrs & found lying straight on back with upper body twisted over to right hand side face facing floor. I [SN* [Staff Nurse] *(1)] shouted the pt name & no response - turned on the light & called for help . I noticed blood on the floor & when other Staff Nurse arrived I noticed a cord around pt neck attached to unit on wall . SHO* [Senior House Officer] *(2) arrived immediately & crash team were called . Pt '; s head was being supported by SHO (2) & cord cut by myself & SN (3) . Pt put onto back (face very blue & blood around nose) . CPR* [Cardiopulmonary resuscitation] *was commenced with team present - this was unfortunately unsuccessful"*
Infection control incident	576 (1.2%)	468 (1.0%)	*"30.08.06 - Admitted with fractured NOF , unfit for surgery 31.08.06 . 30.09.06 – MRSA* [Methicillin-resistant Staphylococcus aureus] *screen completed - confirmed neg 04.09.06 . 01.09.06 - OP - 13.09 Swab taken - leakage from wound . 15.09.06 Wound dry and healed - sutures removed . 18.09.06 Confirmed MRSA from wound swab result . 19.09.06 Reviewed by Dr - nil ordered , wound healed 20.09.06 - wound discharging . 21.09.06 Urine output decreased , wound leaking blood cultures taken . 23.09.06 Blood cultures confirmed MRSA bacteraemia . 27.09.06 Pt deceased - cause of death recorded as renal 2nd to MRSA sepsis. "*
Other	603 (1.3%)	392 (0.8%)	*"On turning patient it was noted the sacrum & buttocks red small break in skin. Grade 2 pressure sore."*
Treatment, procedure	3695 (7.7%)	2091 (4.3%)	*"Patient undergoing cemented hemiarthroplasty under spinal anaesthetic. Shortly after cementing the patient deteriorated dramatically leading to a cardiac arrest from which patient failed to recover despite cardio pulmonary resuscitation. Patient certified dead at 10:55 on 01.06.09 .."*
Patient accident	12858 (26.7%)	5639 (11.7%)	*"Pt found on floor , hoisted back to bed , dressed skin tear on R lower leg , SHO reviewed , xray L hip - periprosthetic # hip - site informed.."*
Disruptive, aggressive behaviour (includes patient-to-patient)	117 (0.2%)	46 (0.1%)	*"G has been restless and trying to climb out of bed all night . DID NOT FALL . At 02:30 approx noticed that her bed sheets were covered in blood . Leg examined and sheets changed but no obvious cause for bleeding observed although the inside of the plaster soaked in blood . Dr S informed and visited . ."*

Clinical assessment (including diagnosis, scans, tests, assessments)	1053 (2.2%)	394 (0.8%)	*"Received request card from B2 requesting pelvis x-rays on a* [Patient name] *dob* [date of birth] *. This pt was brought from the ward by a porter. This pt was identified and upon further questioning it was discovered that this pt had not had any problems with her hip or any operations on her hip and was in hospital with a fractured shoulder. She did however point out that there was another pt on B2 with the surname who was awaiting hip surgery. Contacted requesting Dr who stated he had put the wrong name sticker on request card.* [Patient name] *was returned to ward and a new request card was written."*
Medical device / equipment	1231 (2.6%)	423 (0.9%)	*"Pt was sent for as her anaesthetic commenced . S / N* [Senior Nurse]*and ODA* [Operating Department Assistant] *went to check the Birmingham Resurfacing prosthesis and a 50mm head & 56mm cup x 2 were found to be missing . I had arranged that all prosthesis should be on a before 9am delivery due to the current level of activity . Pt anaesthetic was stopped whilst the prosthesis was sourced . The company was contacted and the prosthesis had been despatched on Friday - but they were unable to ascertain where it was . The hospital at X was contacted and they were able to supply us . A taxi was despatched . Pt was sent to recovery and rescheduled for when the prosthesis had arrived . On contacting supplies and the company the order was ordered on and before 9am on 31st June."*
Patient abuse (by staff / third party)	59 (0.1%)	17 (0.0%)	*"Whilst accompanying consultant in his ward round , staff member found his manner towards patient was inappropriate - saying the following : You should not have come into this hospital there nothing wrong with you . There are more patients who need your bed more than you do . Consultant then proceeded to the husband saying the same things he said to his wife and they had a heated discussion. Approached deputy sister whose in charge that time, and complaint procedure was given. Patient in Bed 2 heard what consultant had told patient and is willing to be a witness."*

Access, admission, transfer, discharge (including missing patient)	2196 (4.6%)	606 (1.3%)	*"Handover taken from A+E* [Accident and Emergency] *staff at around 1630 , Handover stated fractured Neck of femur and history of COPD* [Chronic obstructive pulmonary disease], *on home oxygen 2 litres . I contacted A+E minors at 1930 as patient still not transfered, and I was wondering if she was still coming to the ward , or if her condition had changed and she was going elsewhere . I was told she was fine, and the delay was just due to shortage of porters . Patient arrived on the ward at about 2000 escorted by staff nurse, transfered onto bed by colleagues (support workers and student nurse) as I was trying to order some bloods for another patient on the computer . The A+E nurse came to the office to ask if I had recieved a handover , I said I had recieved one at 1630 and asked had her condition changed , he said it had not . As soon as he left the ward , my student nurse came to get me to see the patient as she was concerned . The patient was in respiratory distress , she was struggling to breathe , gasping for air through her mouth , her respiratory rate was 30 , her oxygen saturations were 79% , she was tachycardic 105 and her BP* [blood pressure] *was elevated from previously . EWS* [early warning score] *was 4 . HO* [House Officer] *immediately called and changed her nasal specs to a facemask. The patient was also in severe pain and had not had any analgesia since 1830 in A+E . Sevredol prescribed and given, blood gases taken , chest x-ray taken , nebuliser given , SHO called for further advice . The patient complained of abdominal pain , and was found to be in urinary retention , she said she had not passed urine since the morning , and had talked to staff in A+E about it . Catheterised and drained 600mls straight away ."*
Medication	3617 (7.5%)	744 (1.5%)	*"Patient admitted with humeral # following fall10 / 1 / 08 . ORIF* [open reduction, internal fixation] *11 / 1 / 08 and revision surgery 18 / 1 / 08 Patient prescribed Diclofenac 50 mg tds on admission continued for next 14 days , no GI* [gastrointestinal] *ulcer prophylaxis given and patient starved for several periods of time . 24 / 1 / 08 patient had major upper GI bleed , required laparotomy for oversew bleeding DU* [Duodenal Ulcer] , *massive transfusion and ICU* [intensive care unit] *admission . No evidence that NSAID* [Nonsteroidal anti-inflammatory drugs] *prescription reviewed or GI ulcer prophylaxis considered at any stage before GI bleed despite patient being in high risk group for NSAID induced GI bleeding ."*

Consent, communication, confidentiality	1462 (3.0%)	279 (0.6%)	*"CT* [computerised tomography] *scan of pt left humerus was booked in standard manner using* EPR [electronic patient record] *system whilst she was inpatient on Cambridge ward. The request stated she had a pathalogical fracture of her left humerus. The CT took place on 25th April at 9.30am. When the films were reviewed that afternoon it was clear that infact the wrong patient had been scanned. The radiology depatment were informed of this error via. Unfortunately we are unable to find out who in fact did recieve the CT scan of her humerus as there is no way of identifying the person from the images and clearly there was no clinical indication for her to receive this scan . Asking CT to perform the scan on the correct patient so that surgery can be planned, I was informed to submit a new for on* EPR. . *"*
Infrastructure (including staffing, facilities, environment)	2370 (4.9%)	441 (0.9%0	*"Patient waited more than 48 hours for surgery. unfit 11 days. Diagnosis # NOF."*
Documentation (including electronic & paper records, identification and drug charts)	2530 (5.3%)	294 (0.6%)	*"Pt attended clinic for review post-op total knee replacement. Operation note was absent from her medical notes."*
Total	**33613 (69.9%)**	**14482 (30.1%)**	

3.1.4. Discussion

The areas of concern that I have highlighted in my study are not new to the specialty. By far the largest category of concern is that of implementation of care and on-going monitoring/review [OR = 2.55 (95% CI 2.49 to 2.62)]. One of the key areas that has been a significant burden of harm is that of fragility hip fractures; uptake of best practice guidelines released by the Department of Health has been patchy. [Healey F 2011] Some of the key components to ensure the delivery of best practice include a reduction in the delay to surgery and involvement of an orthogeriatrician in the care of patients. Different models of orthogeriatric care have been proposed with the aim of ensuring an integrated multidisciplinary team approach with evidence-based pathways. Several tools are now available to mitigate harm associated with poor care of orthopaedic patients: pre- and post-operative adjuncts such as better use of orthogeriatric services; early warning scores and trigger tools to prevent major catastrophes during pre-, intra- and post-operative phases of care; [Gardner-Thorpe J 2006] enhanced recovery protocols [Malviya A 2011] for the entire patient journey to ensure that best practice guidelines are adhered to; and intra-operative tools such as the WHO surgical checklist. [Haynes AB 2009]

This was a surprising finding and did not ring true; on further enquiry it was not corroborated by prior research. There was no way of further investigating whether this was a true finding or an anomalous finding from the NRLS. I therefore sought to map other datasets that could potentially be used to triangulate this finding. In discussion with orthopaedic colleagues, the most logical dataset is the National Joint Registry (NJR), but this only collects data on elective procedures and intra-operative outcomes directly associated with hip, knee, ankle, shoulder and elbow replacements. See Appendix 4 for correspondence with the NJR regarding the unavailability of information on suicides. Another source of potentially useful data is the Confidential Inquiries which use data from Hospital Episode Statistics (HES)'. [National Confidential Inquiry into Suicide and Homicide by

People with Mental Illness 2013] However, this only looks at patients with known mental health conditions and does not offer any insights on whether these patients were on an orthopaedic ward.

The implications of a lack of being able to triangulate my findings is that, given time and appropriate resource, an observational study should be carried out to ascertain the frequency of suicides and deliberate self-harm on orthopaedic wards.

In the interim, several recommendations have been made which place the onus on clinical services to prioritise suicide prevention and monitoring. [National Confidential Inquiry into Suicide and Homicide by People with Mental Illness 2013, National Joint Registry] The NPSA has also published a toolkit on preventing suicides. [NPSA 2009a]

Infection control incidents were also a domain of concern in my analyses [OR = 1.50 (95% CI 1.41 to 1.61)]. HCAIs are known to be the most frequent adverse event that threatens patient safety; the frequency of these infections ranges from 5.7 and 19.1 per 100 inpatients. Furthermore, HCAIs can be broken down into surgical site infections (SSIs) (29%), urinary tract infections (24%), bloodstream infections (19%), healthcare-associated pneumonia (15%) and other infections (13%). [Allegranzi B 2011] The burden of these avoidable HCAIs is large; further steps are added to the patient's journey that could include re-operation, extra nursing care and interventions, and more antibiotics. Fiscally, these factors have a significant bearing on any healthcare system. [NICE 2008] Pre-operative measures to reduce SSIs include: patient showering and hair removal; patient and staff theatre wear; movement to and from theatre; nasal decontamination which does not involve routine use of mupirocin; mechanical bowel preparation; and antibiotic prophylaxis for specific groups of patients. Peri-operative measures include: laminar flow operating rooms; body exhaust suits; hand decontamination; incise drapes, gowns and gloves; antiseptic skin preparation and diathermy; normal physiological parameters for patients (normal oxygenation, normoglycaemia and normothermia);

wound irrigation; and dressings and antiseptics before closure. Finally, in the post-operative phase, use should be made of dressings, post-operative cleaning of surgical site, antibiotic treatment for SSI and specialist wound care services. [Humphreys H 2009]

Uncertainties in orthopaedic surgery (e.g. is a cemented hip prosthesis better in a patient?) may have played a part in the errors that were classified as treatment/procedure-related problems. Surgical research has been criticised for relying on lower forms of evidence than randomised controlled trials (RCTs) to aid in clinical decision-making. [Horton R 1996] Several questions remain unanswered. The optimal treatment of hip fractures is unknown – few RCTs with small sample sizes, and outcomes with wide CIs will not help to answer this question. [Chua D 1997] Significant progress has been made to synthesise current evidence on the subject. [Parker MJ 2006] However, larger collaborative trials are needed and are currently underway to answer some key questions in orthopaedic surgery. [Bhandari M 2009]

This is the first attempt, to my knowledge, of prioritising areas of harm in the specialty of orthopaedics and trauma using a PSRS. However, this is only a start and much more needs to be done, given concerns about the utility of databases to promote safety. The NRLS held details of 158 incidents in 2003, and to date has over seven million incidents reported to it. [Pham JC 2010a] Paradoxically, despite the large number of incident reports received by the NRLS, reporting systems have been shown to detect only about 6% of adverse events found by systematic review of records. [Sari AB-A 2007] Indeed, it has been argued that national reporting systems are of great importance at identifying rare events, but of limited use in analysing trends or acting as measurements of patient safety. [Vincent C 2008] It is commendable that several solutions have been provided in the form of alerts and rapid responses (see section 1.4). However, most of these solutions seem reactive. [Lansley A 2009]

At present, the learning from national PSRSs is limited; some of the information is lost in translation. [Lankshear A 2008] Local systems of risk management opt for root cause analyses to develop local solutions to mitigate against harm to the patient. National systems rely on patient safety experts methodically trawling through patient safety incidents by severity and frequency, thereby leading to the production of quarterly reports, alerts and rapid response solutions. [Panesar SS 2009a] Such analyses are time-consuming, as the size of the PSRS increases, and may be of limited value. There is a need for applied epidemiological tools to be created to allow clusters of harmful incidents to be identified, both by hospital and specialty. Most commentators agree that the long-term and sustainable solution lies in professional engagement and local efforts. In this regard, I believe that my analyses offer a snapshot view of healthcare errors in orthopaedic surgery and will be of interest.

There are some limitations to my methods; owing to missing data, I am unable to definitely assess the effect of causative factors for errors, including those such as age and experience of doctor.

With the proliferation of incidents being reported to the NRLS, a scientific method of prioritising incidents reported to it is required; the above method is one such approach. In section 3.3, I will demonstrate how the prioritisation exercise has been used to identify four examples of errors in orthopaedic surgery and propose ways of mitigating against harm in these areas.

3.2. *Study 2:* Undertaking a content analysis approach to delineate the causes of preventable death

Patient safety incidents can yield valuable information to generate solutions and prevent future cases of avoidable harm. The aim of this study was to understand the causative factors leading to all unnecessary deaths in orthopaedics and trauma surgery reported to the NRLS over a four-year period (2005–2009), using an inductive approach to content analysis. Reports made to the NRLS are

categorised and stored in the database as free-text data. A search was undertaken to identify the cases of all-cause mortality in orthopaedic and trauma surgery, and the free-text elements were used for thematic analysis. Descriptive statistics were calculated based on the incidents reported. This included presenting the number of times categories of incidents had the same or similar response. Superordinate and subordinate categories were created. A total of 257 incident reports were analysed. Four main thematic categories emerged. These were: (1) stages of the surgical journey – 118/191 (62%) of deaths occurred in the post-operative phase; (2) causes of patient deaths – 32% were related to severe infections; (3) reported quality of medical interventions – 65% of patients experienced minimal or delayed treatment; (4) skills of healthcare professionals – 44% of deaths had a failure in non-technical skills. Most complications in orthopaedic surgery can be dealt with adequately, provided they are anticipated and that risk-reduction strategies are instituted. Surgeons take pride in the precision of operative techniques; perhaps it is time to enshrine the multimodal tools available to ensure safer patient care.

3.2.1. Introduction

Healthcare is a risky business with adequate attention to patient safety being paid only in the last decade or so. Data from 2008 revealed that approximately 152,017 incidents (15.5%) related to surgery each quarter and, of these, 32.4% (49,254 incidents) were from orthopaedic and trauma surgery. [Catchpole K 2008b] During the same period, 5,258,594 finished consultant episodes occurred in surgery and, of these, 1,144,520 were in the specialty of orthopaedics. [Hospital Episode Statistics]

Despite recent attention, patient safety is not a new or a novel concept. In fact, the process of reviewing clinical outcomes in a standardised fashion began in parallel with the rise of the modern teaching hospital. The practice was refined through the work of Ernest Amory Codman, a surgeon

at Massachusetts General Hospital in the early 20th century, who developed the 'end result system' [Mallon WJ 2000]. He detailed the clinical history and outcomes of each of his patients on a set of cards and used this information to review adverse events systematically and to categorise their precedent errors. This was the precursor to the modern day morbidity and mortality (M&M) meetings in surgery. In tandem with active steps taken to introduce these meetings as part of surgical training in the US, the Royal College of Surgeons of England demanded each hospital should hold regular M&M meetings in order to receive recognition for the training of junior surgical staff. [Royal College of Surgeons of England 1987]. The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) has focused attention on the importance of identifying deficiencies in standards of care; in addition, increasing litigation with expensive settlements provided an added stimulus to avoid problems caused by poor management or negligence. [Buck N 1987] Clearly there are lessons to be learnt by studying mortality reported to a national database of incidents.

The aim of this study was to understand the causative factors leading to potentially avoidable deaths (mortality) in orthopaedics and trauma surgery reported to the NRLS over a four-year period (2005–2009), using a mixed-methods approach. It is anticipated that the analysis of these data will generate discussion about the utility and value of reporting adverse incidents. More importantly, it will inform the development of appropriate interventions to reduce avoidable harm.

3.2.2. Methods

3.2.2.1. Study design and data collection

Data from the NRLS database were extracted, cleaned and analysed using *SAS* (Version 9) software (*SAS* Institute, *Cary* NC, USA). The sample included all incidents reported in the specialty of trauma and orthopaedics between January 2005 and December 2009. The structure of the NRLS has been described in section 1.4. The domains searched were 'acute/general hospital' and 'trauma and

orthopaedics', and the search was limited to England. Cases identified as 'deaths' were selected. Data were abstracted onto a data collection sheet designed *a priori*. A thematic analysis was appropriate as there is limited information on the causes of deaths in orthopaedics and trauma patients. This process involves categorising data through the development of a thematic framework by identifying and summarising key themes using an inductive approach.

Data from the NRLS, specifically the free-text elements, were analysed thematically by using the constant comparative method. [Pope C 2000] Cases and incident reports from the database were extracted and considered as units of analysis for the present study. Each incident report was allocated a unique identification number in order to specify which responses corresponded to the certain unit in the study, and to protect the identities and confidentiality of those involved in the cases reviewed.

A thematic framework was developed by generating thematic categories to form superordinate categories that grouped themes together. Subordinate categories were also created that broke themes down for greater granularity.

In essence, free text was read to identify common and recurrent themes. Items of data were repeatedly compared from the dataset and categories were defined in relation to each other. Subsequently, salient issues and key themes emerged. This ensured that themes, differences and relations between categories were re-examined and confirmed or modified. [Green J 1998] For the specific method in analysing the data, thematic analysis was used to determine whether there were certain concepts present in texts or written documents. [Green J 2009] The purpose of determining themes and concepts within documentation or texts is to permit the investigator to quantify and analyse the data such that inferences about the written text may be made. To conduct a thematic analysis on the text that was recorded from the responses, the responses were coded into

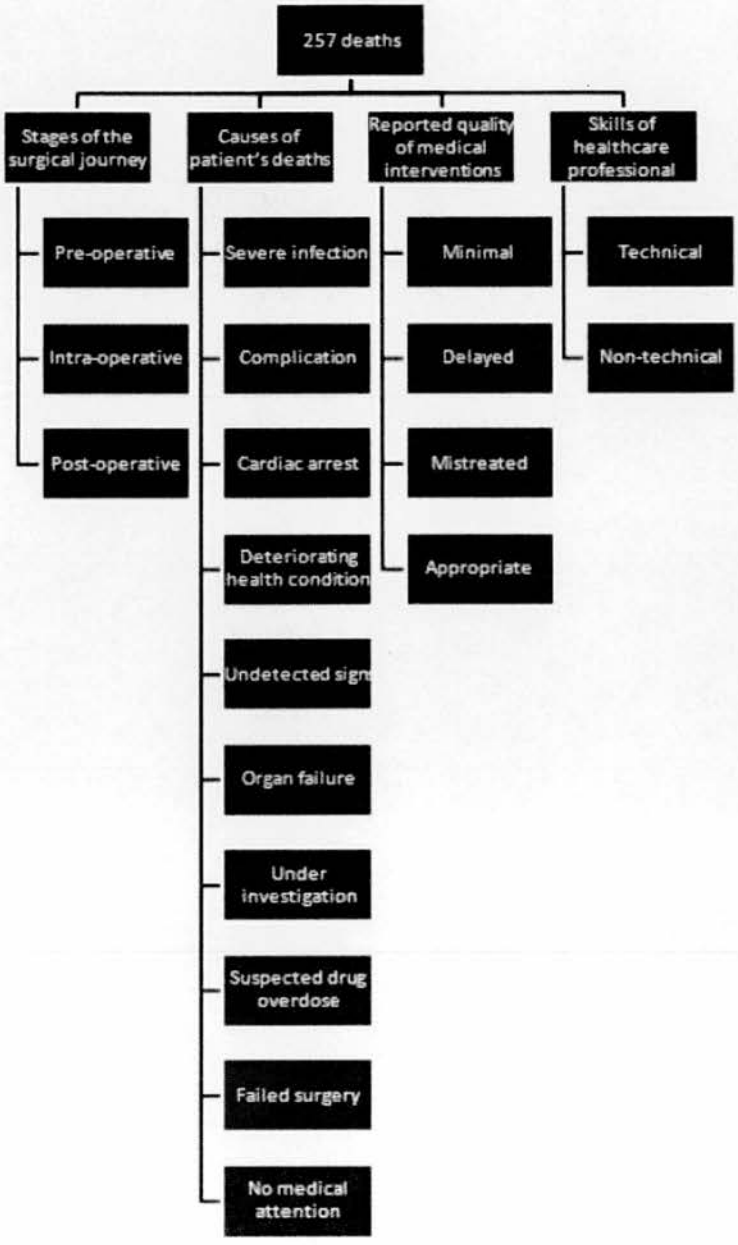
manageable categories on a variety of levels [Cushner F 2010]; this included breaking the responses down into key components, words, sentences or themes.

Indexing was achieved by coding each line of the free text according to the thematic framework. Two independent reviewers (junior doctors) undertook the coding (Dr Andrew Carson-Stevens, University of Cardiff, and myself); in the case of discrepancies, consensus was achieved by direct discussion and re-definition of categories agreed. The final coding framework applied to the reports was agreed by the two reviewers. Microsoft Excel was used to organise the themes and trends of the information generated from the incident reports.

3.2.3. Results

Two hundred and fifty seven (257) incident reports were analysed and subjected to thematic content analysis. The analysis generated four thematic (superordinate) categories: (1) stages of the surgical journey; (2) causes of patient deaths; (3) reported quality of medical interventions; (4) skills of healthcare professionals. Superordinate categories were broken down into subordinate groups, as shown in Figure 3.2. The mean inter-rater reliability (Kappa) across all categories was 0.74 (SD 0.27).

Figure 3.2: Thematic analysis of all-cause mortality



3.2.3.1. (1) The surgical journey

This referred to three distinct phases of the journey that patients underwent when undergoing an operation: pre-operative, peri-operative and post-operative stages. 191/257 (74.3%) incidents had enough information to generate thematic analysis in this section. Of these, 118 (61.7%) deaths were in the post-operative surgical period; 45 (23.5%) were during the pre-operative phase; whilst 28 reported death peri-operatively. The incidents that could not be analysed (66/257, 25.7%) ranged from brief reports where no phase could be identified as they consisted of a few words (for example *"patient fell"* or *"bleeped surgeon, no response"*), to detailed reports which could have occurred in any phase (for example *"patient deteriorated, surgical team alerted and resuscitation commenced"*).

3.2.3.2. (2) Causes of patient deaths

In the examination of the causes of death reflected in the incident reports, 193 incidents revealed 10 causes of patient death, as shown in Table 3.3.

Table 3.3: Causes of patient deaths

Categorical variable	**Number of incidents**	**Per cent of incidents**
Severe infection	62	32.12
Surgical complications	36	18.65
Cardiac arrest	34	17.62
Deteriorating health condition	22	11.40
Undetected signs	15	7.77
Organ failure	8	4.15
Under investigation	5	2.59
Suspected drug overdose	5	2.59
Failed surgery	4	2.07
No medical attention	2	1.04

There were 10 causes of accidental death identified. Severe infection was consistently indicated as the leading cause of death. The data in this group were categorised further: Clostridium difficile (C. diff; 69.8%), wound infection (12.7%), septic shock (6.3%), blood culture bacteria (2%) and 'other' infections.

3.2.3.3. (3) Quality of medical interventions

Of the 257 reviewed cases, only 126 cases reported the incident in sufficient detail to assess the quality of the medical intervention that patients received during their admission. Fifty-six per cent (56%) of these incidents were categorically classified as receiving only minimal medical intervention. On the other hand, 24/126 (19%) cases indicated that appropriate interventions were not done in a timely manner, leading to other infections and complications (further details are in Table 3.4).

3.2.3.4. (4) Skills of healthcare professionals

A failure of technical skills was identified in 32 cases. An example is given below:

> *"Patient became unresponsive with no pulse or respiratory effort. Arrest call put out. CPR* [Cardiopulmonary resuscitation] *commenced via* [ambulatory] *bag and cardiac massage. Response from arrest call was 2 staff nurses. The nurse carrying the arrest bleep informed them that she was ILS* [immediate life support] *trained but had not been updated for 5 years. The* [doctor] *appeared to be unaware of the function and working of the* [defibrillator] *machine and spent time trying to work out how to use it. It was suggested to him a number of times that he needed to secure an airway but he made no response to this. The machine then gave instructions to stand clear and press shock but no instructions were given by the* [doctor] *to move. 3 nurses had to ask the* [doctor] *to wait until everybody was clear. Switchboard* [were] *contacted to bleep the on call anaesthetist covering the ward. The anaesthetist who answered said that he did not cover* [general wards] *but he did speak to the SHO* [senior house officer] [present]. *CPR maintained during this. When the SHO returned he said that the anaesthetist would contact the Consultant anaesthetist. However no more contact was made. Further shock given by* [doctor]. *It was suggested to SHO that patient needed drugs. He stated he needed to wait as he had shocked the patient then he requested adrenaline and gave it. It was felt there was no support or anyone at the arrest with enough experience to co-ordinate the arrest. It was felt that someone who was competent in ALS* [advanced life support] *needed to ensure a co-ordinated event."*

Table 3.4: Reported quality of medical interventions

Categorical Variable	Example*	Number of Incidents to Offer this Experience	% of Incidents to Offer this Experience
Minimal	Patient condition deteriorating. Doctors intervention minimal. Doctors not answering bleep.	71	56.35
Delayed	Admitted with acute septic arthritis of failed knee replacement and collapse at home while waiting revision. Subsequently died.	24	19.05
Mistreated	Patient deteriorated over two days. Patient received possible sub-optimal care; observed not frequent enough, deterioration score not calculated correctly, lack of documentation and medical review, escalation not timely.	22	17.46
Inappropriate	A cardiac arrest call put out at 18.17, ALS procedure followed. Patient died. Examination of the medical notes and vital signs prior to this event reveal clear premonitory signs. Patient reviewed by SHO on 7/5/05 for hypotension. Gelofusin administered. It appears there is no further medical review until 9/5/05, time not stated. On the 8th at 22.00 the vital signs chart shows atrial fibrillation, rate 280. Vital signs show tachypnoea and persistent hypotension (Note seagull sign). Between 22.00 and 07.00 vital signs only done once, no time stated . No documented medical review.	9	7.14

*These reports are taken directly from the database and may be susceptible to grammatical errors

The second sub-category identified here was non-technical skills for surgeons (NOTSS). These were any incident reports that highlighted failures in "*situational awareness, communication and teamwork, leadership and decision-making*" [Yule S 2006].

3.2.4. Discussion

This is the first attempt to increase our knowledge and understanding of iatrogenic harm leading to mortality for the speciality of orthopaedics and trauma using a PSRS. However, this is only a start and much more needs to be done, given concerns about the utility of databases to promote safety.

Thematic analysis is one way to analyse qualitative information. [Taylor SJ 1984] My approach has opted for themes not explored by other groups studying patient safety in orthopaedics: stages of the surgical journey, causality of iatrogenic harm leading to mortality, quality of medical interventions and skills of the healthcare professionals. [Wong DA 2009]

I have shown that almost three-quarters of the deaths in my study occurred outside the pre-operative phase. Similar findings were reported in a recent study by Cushner and colleagues that revealed that majority of the complications seen in patients undergoing arthroplasty of the hip or knee occur during the peri-operative (e.g. bleeding) and early post-operative period (e.g. deep vein thrombosis, wound infection, pneumonia). [Cushner F 2010] Several tools are now available to mitigate harm associated with poor care of orthopaedic patients, such as: pre- and post-operative adjuncts such as better use of orthogeriatric services [National Clinical Guideline Centre]; early warning scores and trigger tools to prevent major catastrophes during pre-, intra- and post-operative phases of care [Gardner-Thorpe J 2006]; enhanced recovery protocols [Malviya A 2011] for the entire patient journey to ensure that best practice guidelines are adhered to; and intra-operative tools

such as the WHO surgical checklist. [Haynes AB 2009] Yet we know that in some settings, such as those found in England, uptake of these initiatives has been patchy. [Department of Health 2010a] A more concerted effort will have to be made by professional organisations to ensure that their members adhere to best practice guidelines to ensure safer care. The revalidation of healthcare professionals in the UK should also include domains that reflect the individual practitioner's use of patient safety tools.

In my study, C. diff was frequently noted as a causative agent for mortality. This is unsurprising as the incidence and severity of C. diff-associated diarrhoea has increased, [Wilcox MH 1996, Archibald MK 2004] in part due to antibiotic regimes that include cephalosporins, and also the demographics of the patients, who tend to be more elderly. [Al-Obaydi W 2010] Greater collaboration between orthopaedic and microbiology departments should occur to ensure that local protocols are adhered to. Furthermore, HCAIs are known to be the most frequent adverse events that threaten patient safety; as cited in the literature and within my study. The prevalence of these infections ranges from 5.7 and 19.1 per 100 inpatients. The burden of these avoidable HCAIs is large; further steps are added to the patient's journey that could include re-operation, extra nursing care and interventions, and further drugs. Fiscally, these factors have a significant bearing on any healthcare system. [NICE 2008]

In orthopaedic surgery, numerous attempts have been made to reduce SSIs in the operating theatre, including the use of peri-operative antibiotics, laminar flow operating rooms, body exhaust suits, multiple instrument trays and reduction of intra-operative operation room traffic. [Hill C 1981, Lipsett PA 2008, Der Tavitan J 2003, Mangram AJ 1999] Hand hygiene remains a key component in any infection prevention strategy. For many years, the traditional surgical scrub where the surgeon ensures that hands, nails and parts of the forearm are lathered and scrubbed has been standard

practice. However, surgeons themselves accept that their practice, both in the operating theatre and outside, has often been suboptimal; 90% compliance is not good enough. [Gawande A 2004] Some innovative solutions to the problem of SSIs include enhanced infection control initiatives [Schelenz S 2005] and multimodal quality improvement initiatives such as care bundles. [Pronovost P 2006]

My study highlights that almost half of all the deaths had elements of poor medical interventions. The highly-specialist nature of orthopaedic surgery means that surgeons are not always up-to-date or competent to deal with complex medical conditions which many patients, especially the elderly, present with. For example, it was suggested over 20 years ago that elderly patients undergoing orthopaedic surgery could benefit from input by geriatricians, owing to their comorbidities, frailty and reduction in independence. [Gilchrist WJ 1988, Kennie DC 1988, Devas MB 1974] It is only recently, however, that there has been heightened political profiling, through initiatives such as the National Hip Fracture Database (NHFD), the Royal College of Physicians' Audit of Falls and Bone Health, the Department of Health's 'Commissioning Toolkit' and NICE's hip fracture guideline. [NHFD 2009, Department of Health 2009, NICE 2009] Furthermore, hip fracture is included in the 'Best Practice Tariff', which will financially reward units which include an orthogeriatrician in leading patient care. [Department of Health 2010a] There should be no excuse for unavoidable deaths due to poor medical management which falls outside the realm of the orthopaedic surgeon's armamentarium.

One of the other key findings of this study was the large burden of a lack of non-technical skills, which account for a significant proportion of iatrogenic harm. Almost 43% of all the deaths could be attributed to a lack of situational awareness, communication, teamwork and decision-making. It has been shown that most healthcare incidents can be attributed to failures in non-technical skills rather than technical ones. [Bogner M 2004] Training in orthopaedic surgery has generally focused

on clinical knowledge and expertise, including technical skills. There have been some attempts at introducing non-technical skills training through various organisations such as the Royal Colleges. [Yule S 2006] However, greater effort is required to integrate non-technical skills into the educational activities of orthopaedic trainee doctors. Perhaps the momentum gained through the WHO surgical checklist, which aims to create well-functioning teams that improve the workings of the orthopaedic surgeon, will drive this agenda forward. Better teamwork and communication in operating theatres improves outcomes. Teamwork is definable and measurable, and can be improved through formal structured communication, such as checklists. Healthcare, and surgery in particular, is a team game, yet we have ignored the experiences of other high-risk industries, to our patients' cost. The WHO checklist and associated briefings and de-briefings are a major step forward in our approach to delivering the safe, reliable care we would want for our family, to all our patients. [NPSA 2009b]

3.2.4.1. Limitations of the study and clinical relevance

There were limitations to the coding system, both in terms of the dataset; some records had greater detail provided than others and the incompleteness of the others which could have affected the coding and there was no opportunity to verify the accuracy of the contents of the reports. A specific limitation of the coding of the incidents are that the process was undertaken by two clinical health services researchers who were also junior doctors. In the case of both doctors, we reviewed the reports of errors with a lens unique to the doctor's perspective and these remain intangible and undocumented as they rely upon previous clinical experience and knowledge. [Strauss A 1990] [Williams M 1996] [Butler T 1998] Even though we constantly questioned our own assumptions and strived to provide replicable conclusions. [Plummer K 2001]

Reflecting critically, I would have in hindsight, opted to have a more multi-disciplinary team involved in the coding of incidents. Some incidents had multiple levels of error type, causality and preventability that could be applied. An overarching-category was chosen for each incident report; secondary or tertiary levels of code were not applied as the purpose of this undertaking was to understand the causative factors leading to potentially avoidable deaths (mortality) in the orthopaedics and trauma incidents reported to the NRLS. In future, secondary and tertiary coding will be applied to ensure greater granularity of findings can be provided. Another key limitation of this study is the inability to track anonymised incident reports back to their reporting hospitals so that further information can be obtained that would enable a deeper understanding of the error reports, which would have further enhanced my analysis. Other frequently-cited issues with the free-text reports include those related to reporting and hindsight. [Catchpole K 2009]

3.2.4.2. Conclusions

Iatrogenic harm in trauma and orthopaedic surgery is an important issue and we need a multi-pronged strategy to address it. In addition, to better study the problem by building research capacity in the area, we need to act on known and proven interventions for delivering safer care; encourage better clinical leadership; promote the use of patient safety indicators as part of quality accounts for orthopaedic surgeons within hospitals; and showcase examples of best practice that use quality improvement and patient safety metrics.

3.3. *Study 3:* Using four examples as primers for ways to minimise harm

3.3.1. Introduction

Unlike the method currently deployed with the NRLS, whereby clinical reviewers identify cases of severe harm and death, and make a decision on whether to present them to the weekly response

meeting, the methods used in Study 1 (section 3.1) help to priortise, in a scientific manner, areas where efforts must be focused to better understand the causality of errors in orthopaedic surgery. The study on the 257 deaths also helped to corroborate the areas picked for further query. In reviewing the deaths, almost half were related to poor quality of medical interventions.

3.3.2. Methods

Once the top categories of patient safety incidents were identified, 100 random incidents were drawn from each category and the free text was reviewed to assess suitability for presentation to the weekly response meeting. A committee decision was made on whether to pursue the proposed topics; and national RRRs were developed for some of these. This is the first time that a scientific method was used for priority setting and it is encouraging to note that my method has led to the development of key national outputs (alerts). Different timeframes were used when searching for incidents depending upon the urgency with which national alerts had to be produced. The four examples that underwent formal scoping and development of solutions are shown in Table 3.5:

Table 3.5: Examples of development of Rapid Response Reports

Incident type	**Example**	**Study 1 priority rank**	**RRR developed (Yes/No)**
Other	*"Patient admitted for bilateral toe surgery. Tourniquet left on right toe. Re-admitted to hospital two days later complaining of no sensation in right toe. Tourniquet removed and toe black. Further surgery required."*	5	Yes
Implementation of care and on-going monitoring/review	*"Admitted 4 / 6 / 07 , likely delay getting to theatre for repair of fractured left neck of femur , no list space available for 5-6 days . ."*	1	No (NICE were reviewing their guidance on the management of hip fractures) [NICE 2011]

Treatment, procedure	*"Patient having cemented hip prosthesis inserted for fractured neck of femur. Cement inserted and prosthesis being hammered into place when patient became bradycardiac 40 / min. Unresponsive to atropine. Loss of palpable pulse with pulseless electrical activity, cardiac arrest. Cardiopulmonary resuscitation commenced and continued for 20 minutes and no response to treatment. Patient died"; "During procedure when introduction of cement the patients condition deteriorated. Patient died at 21:10"; "Patient was having an operation for a right cemented [name of prosthesis]. Patient went into asystole when cement put into hip joint".*	6	Yes
Patient accident	*"Patient admitted to [ward a] from [ward b] - on transfer to ward patient had pain in* R *hip and nursing assistant noticed* R *leg was shorter and rotated – staff nurse informed, on call doctor informed x-ray requested and shows that hip is dislocated, notes state patient fell [three days earlier]. Manipulation on ward unsuccessful so patient is now for high risk surgery."*	7	Yes

I carefully reviewed the literature on each topic and worked with internal experts at the NPSA and external specialists to formulate recommendations for the alerts.

3.3.3. Example 1: Digital tourniquets

Tourniquets are used in hand and foot surgery because of the need for a bloodless field to allow for careful dissection. They are used in a range of settings, such as operating theatres, emergency departments, community sites (for example, for minor surgery in podiatry clinics). Although rare, complications can lead to serious harm including, at worst, irreversible ischemia. [Naim S 2008]

3.3.3.1. Data mining from the NRLS

Based on work undertaken by my novel method in Study 1 (section 3.1), one type of incident that warranted further scrutiny was that involving digital tourniquets; careful trawling through the incidents between August 2005 and November 2009 revealed that healthcare staff in England and

Wales had reported 15 serious incidents in which tourniquets had been left on fingers or toes by mistake. Ten patients needed further surgery and two incidents resulted in amputation. At least six of the incidents related to surgical gloves being used as tourniquets. Fourteen litigation claims relating to tourniquets were also reported in this period. The degrees of harm are shown in Table 3.6.

Table 3.6: Classification of harm from tourniquet incidents

Classification of harm	**Number of incidents**
Amputation required	2
Further treatment required	8
Not known	5
Total	15

Table 3.7: Type of tourniquet used in incidents

Type of tourniquet used	**Number of incidents**
Surgical glove	6
Not known	9
Total	15

Table 3.8: Where tourniquet incidents occurred

Where the incident occurred	**Number of incidents**
Operating theatre	9
Emergency department	4
Community	2
Total	15

Examples of tourniquet incidents (direct quotes from the NRLS database):

"Patient had termination of tip of right ring finger. He attended plastic dressing clinic for routine follow up. When the dressing was removed his ring finger was necrotic and still had what looked like glove tourniquet in situ. Explained to patient he will require amputation" (Severe harm)

"Finger tourniquet left insitu for 14 days following minor surgery of wound debridement pulp left middle finger. Patient required amputation of finger. Initial operation performed on 05.07.06, tourniquet discovered on 18.07.06 and amputation of the left middle finger carried out on 19.07.06" (Severe harm)

"Whilst changing dressing to feet. S / N noticed? band around 2nd toe L foot. (Pt had surgery 5 / 7 ago to remove toe nails) Consultant clinic" (No harm)

"Patient had termination of tip of right ring finger. He attended plastic dressing clinic for routine follow up. When the dressing was removed, his ring finger was necrotic and still had what looked like a glove tourniquet in situ. Explained to patient he will require amputation."

Although the numbers of patients affected are relatively small, a degree of harm that requires amputation of the affected digit or further surgical treatment is very serious.

3.3.3.2. NHS Litigation Authority data

There were 14 relevant cases in the NHS Litigation Authority (NHSLA) database for the period 1 January 2004 to 23 November 2009, all of which resulted in financial settlements.

Examples of incidents reported to the NHSLA (direct quotes from the NHSLA):

"Patient admitted for bilateral toe surgery. Tourniquet left on right toe. Re-admitted to hospital two days later complaining of no sensation in right toe. Tourniquet removed and toe black. Further surgery required."

"Failure to remove tourniquet resulting in amputation of right big toe."

"Failure to remove tourniquet following removal of cyst from little finger right hand. Patient returned to minor casualty 17/4/04 - tourniquet found and removed - patient referred to hand surgeons."

3.3.3.3. Review of the literature

Digital tourniquets have been condemned because of the reported occurrence of intimal damage, vascular thrombosis, neuropraxia [Dove AF 1982] and necrosis of fingers [Saw JA 1985] leading to amputations due, in large part, to the high pressures generated directly beneath the tourniquet. [Love BR 1979] In addition, two published case reports record amputations after retained tourniquets on fingers and toes. [De Boer HL 2007, Haas F 1999]

Changes in peripheral nerves secondary to prolonged or excessive pressure beneath and distal to the site of compression have been documented in experimental animals at cuff pressures between 500 and 1000mm of Hg. [Tountas CP 1986] Although, in general, digital tourniquets are relatively safe, it has been suggested that the complication rate can be high. [Saw JA 1985, Tountas CP 1986]

Several studies have assessed pressures and pain perception in patients who have digital tourniquets used. The most definitive study compared a rolled rubber glove, commercial rubber finger tourniquet band and a urinary catheter. The authors concluded that the mean and range of pressures were highest and most variable with the catheter tourniquet, whereas the pressures of the band tourniquet came between the rubber glove fingerstall and the catheter.

Correspondingly, the visual analogue scale showed high scores with the catheter tourniquet and low scores with the rubber glove tourniquet. They went on further to suggest that rubber glove fingerstall digital tourniquets, when compared with the other two tourniquets, generate the lowest pressures with less variability and lowest pain score in a visual analogue scale, thereby reducing the potential risk of neurovascular complications. I feel that the use of the catheter tourniquet method on the finger, as proposed by Lubahn [1985], should be avoided in view of the extreme and variable pressures generated. Other studies had methodological shortcomings, including the use of indirect

pressure measuring techniques [Hixson FP 1986, Lubahn JD 1985], and small [Hixson FP 1986, Lubahn JD 1985, Saw JA 1985] and unrepresentative samples. [Saw JA 1985]

3.3.3.4. Problems identified by the NPSA

Little good quality evidence was found to support different tourniquet techniques. The use of surgical gloves as tourniquets seems to be widespread, as they are easily available and cheap, carry a low risk of infection, and are considered effective in achieving haemostasis. This practice is still recommended in manuals for emergency trainees and others. [King C 2008] But gloves are normally flesh-coloured and may inadvertently be left on. Some clinicians have advocated use of coloured gloves, [Tucker S 2002] and a widely-cited paper by Smith and colleagues describes a modified technique using a glove and an artery clip. [Smith IM 2002] However, risks still remain (as acknowledged by Smith and colleagues) with this or any other 'home-made' device, for example, the risk of neuropraxia as pressure is applied in a very narrow area. The broad safety principle is that devices should be used for their intended purpose only. [Medicine and Healthcare Products Regulatory Agency (MHRA) 2010]

3.3.3.5. Next steps

The NPSA issued an RRR on the risks of tourniquets left on fingers and toes in December 2009. [NPSA 2009b] This is shown in Appendix 5. In the absence of evidence, the NPSA and the Royal College of Surgeons consulted clinical experts to identify key actions to make practice safer:

1. Use only tourniquets with the CE marking (which indicates conformity with the European Union's safety standards), which are labelled and/or are brightly-coloured to maximise visibility. Do not use gloves as tourniquets.

2. Reconcile the number of tourniquets through swab counting procedures, and record the on/off time of tourniquets.
3. Consider including tourniquets as part of the surgical safety checklist (tourniquet removal at 'sign out' stage).
4. Once the tourniquet has been removed, check for adequate perfusion of finger or toe.
5. Ensure staff and patients know to look for later signs of tissue ischemia, necrosis and gangrene (skin discoloration or a pulseless, painful, paralysed, paraesthetic or cold digit).

Many items have been used as tourniquets, including catheters, elastic bands and surgical gloves (either whole or finger only, sometime with additions, for example, artery clips or the red string used for bundling up of gauze swabs). Some of these techniques may be safer than others, but little high-quality evidence exists. However, the wide range of practice is in itself of interest and suggests the need for evidence-based guidelines. Unfortunately, some groups believe that the surgeon decides on the type of tourniquet used and ensures that the time the finger tourniquet is applied and released is documented, and fundamentally the need for vigilance remains with the surgeon. [Barai KP 2010]

3.3.3.6. Conclusion

Early information from the manufacturers currently producing tourniquets with the CE marking shows a 140% increase in purchasing in the three months after the issue of the RRR, compared with a similar period before issue.

3.3.3.7. Effectiveness of the alert

The alert [NPSA 2009b] was released on 9 December 2009 and NHS trusts had until 9 June 2010 to implement recommendations from the document. To date, 277/389 (71%) trusts have indicated compliance; 108/389 (28%) felt they did not need to comply; 3/389 (0.8%) were still implementing

the alert; and 1/389 (0.2%) had not acknowledged the alert. Until July 2012, no cases of severe harm/death associated with the misuse of digital tourniquets have been reported. It is impossible to ascertain the role of under-reporting.

3.3.4. Example 2: Answering unanswered questions in a specialty: delay to hip surgery

Hip surgery is a usually a life-altering event which, when done well, results in a significant improvement to the patient's quality of life. For many previously fit people, hip fracture means the loss of full mobility and, for the particularly frail, a loss of their way of living. This condition must be taken seriously – the disease is complicated, results in significant morbidity and mortality, and involves the interaction of many healthcare professionals, each of whom must work particularly hard to restore the patient's pre-morbid state. The mortality of hip fracture remains significantly high, at around 20%, of which only one-third of this mortality can be attributed to the fracture. [Parker MJ 1991]

The burden of hip fracture surgery remains onerous. Just under a quarter of a million (220,000) hip fractures occur every year in the US, representing an annual cost of $9 billion to the healthcare system. [Ray NF 1997] In the UK, the care of patients with hip fracture is equally high. The average cost of a patient undergoing surgery for hip fracture was estimated as £12,163. The total cost to society has been estimated to be £726 million per annum. Most of this cost is attributable to hospital and social care. [University of York]

Significant controversies remain over the timing of hip fracture surgery. Proponents of early stabilisation believe that complications from bed rest (i.e. thromboembolism, pressure ulcers and urinary tract infections) can be reduced; however, others support a surgical delay to allow optimisation of a patient's pre-operative medical status. [Bhandari M 2004]

National guidelines do not provide any clarity either. The Scottish Intercollegiate Guidelines Network (SIGN) guidelines [SIGN 2009] stress that surgery should be performed as soon as the medical condition of the patient is stable. [Bredahl C 1992, Holt EM 1994] They found no evidence for the efficacy of early surgery (<48 hours), owing to the heterogeneity of the observational studies. [Grimes JP 2002, Siegmeth AW 2005] However, 97% of medically-fit patients went to theatre within the 24 hours target. [SIGN 2009] The Royal College of Physicians (London) concluded that there was great variability in the care offered to patients with hip fracture and an unacceptable 31% had their operations delayed beyond the 48-hour target. Indeed, they advocate the treatment of hip fractures within 24 hours. [BOA 2007] The British Orthopaedic Association (BOA), through the NHFD, recommend that all patients with a hip fracture should be operated on within 48 hours, and during normal working hours. [BOA 2007]

NCEPOD stated in 1997 that: *"There should be sufficient, fully staffed, daytime theatre and recovery facilities to ensure that no patient requiring an urgent operation waits for more than 24 hours once fit for surgery. This includes weekends".* [NCEPOD 1997] An Audit Commission report of 2001 stated that the percentage of patients having their operations within 24 hours had fallen from 50% to 35%, and those having surgery within 48 hours had fallen from 83% to 69%. [Audit Commission 2001] Data from the NHFD showed that out-of-hours operating had dropped from 14% to 4%. [NHFD 2009]

Based on work undertaken by my novel method in Study 1 (section 3.1), one type of incident that warranted further scrutiny was that involving delay to hip surgery; and all orthopaedic and trauma incidents reported to the NRLS from January 2005 to December 2009 were reviewed. Although most of the PSIs were of low harm, as shown in Table 3.9, this issue warrants an answer.

Table 3.9: Degree of harm in incidents related to delay to hip fracture surgery

Degree of harm	**Number of incidents**	**Percentage**
No harm	7,901	86
Low harm	669	7
Moderate harm	504	5
Severe harm	99	1
Death	20	0
Total	**9,193**	**100**

An example of an incident from each category of harm is given below:

Examples of PSIs related to delay to hip fracture surgery (direct quotes from the NRLS database

No harm: *"Patient waited more than 48 hours for surgery. 12 days. Diagnosis # Femur"*

Low harm: *"Pt was admitted on 02 / 05 / 07 with fracture left neck femur with surgery for the following day . Every day Pt has been starved in preparation for her operation only to be told each day that surgery has been cancelled . This has occurred four times resulting in her husband who relies heavily on her due to his poor vision and poor hearing , also his inability to cook . Pt Daughter has voiced her concerns at her , mothers reduced chances of making a full recovery due to the delay in operating . The Family at there request have spoken to NP and voiced there concerns , they plan to put in an official complaint . Leaflets given to Daughter and advice given re whom to contact . Pt has spoken with the on call Manager and Executives and plans have been made to operate between 09.00 to 12md tomorrow with the promise of an extra theatre being opened should emergency Pt take operating time . ."*

Moderate harm: *"Admitted 4 / 6 / 07 , likely delay getting to theatre for repair of fractured left neck of femur , no list space available for 5-6 days . ."*

Severe harm: *"Pt admitted via A&E on 9th March . Dr seeing patient did not see any fracture on the patient Left hip X-ray where she had pain . This is not surprising as this is an undisplaced fracture which is difficult for a junior doctor to see . Patient admitted under the elderly care team . Fracture not diagnosed until 15th March i.e . 6 day delay when X ray repeated and fracture now visible as moved . The X-ray was not reported by the radiology department until 26th March which is an unacceptable amount of time and removes the effective safety net we have in A&E exactly for such circumstances . The recomended turnaround time for reporting X - rays is 48 hours and would have resulted in a speedier outcome for the correct diagnosis to be reached if this had been the case . ."*

Death: *"Admitted 28 / 08 / 05 with fracture right NOF , very frail . In AF but not confused . Starved for op 30 / 08 / 05 and 31 / 08 / 05 . Postponed due to INR . Starved again 01 / 09 / 05 . Anaesthetist promised to take her although very high risk , theatre postponed again at 16.00 ."*

Further review of the database revealed a sophisticated level of reporting by healthcare professionals who were genuinely concerned about the duration of stay prior to the repair of the hip fracture (n = 4,521). The proportion of patients waiting for more than 48 hours is unacceptable, as shown in Figure 3.3.

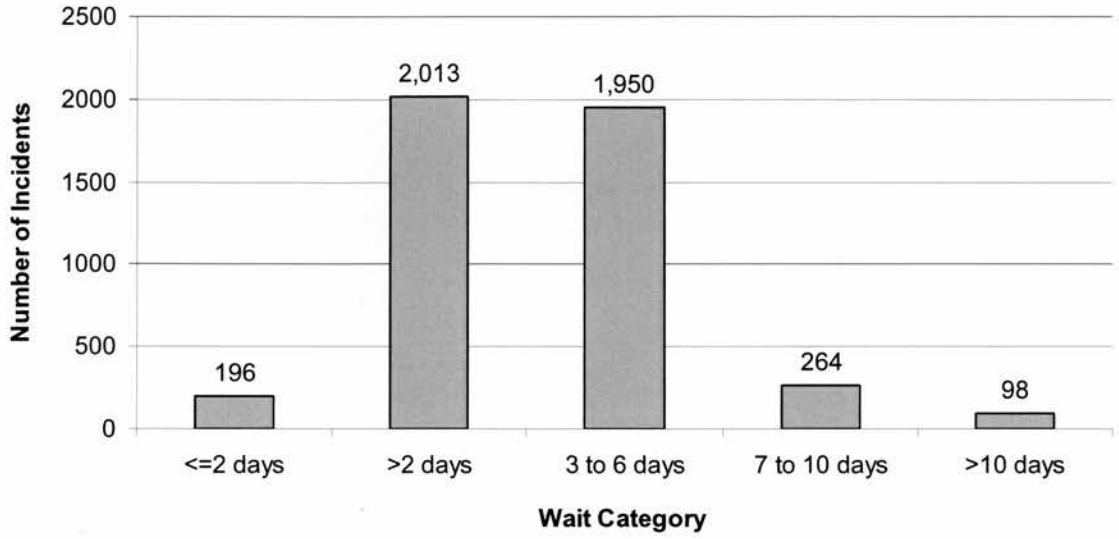


Figure 3.3: Number of incidents involving delays in treatment of fracture

The evidence for the repair of hip fractures remains controversial. Since no randomised trials exist, current evidence is based on observational data. Observational datasets are limited when baseline differences between groups arise. The largest observational study had 1,178 patients who had surgical repair of their hip fracture. Of these, 398 (33.8%) had surgery within 24 hours, and 780 (66.2%) had later surgery. Data on death and functional status at six months were available for 94% of the patients. The overall unadjusted mortality was 17.5% at six months. Early surgery was not associated with a decreased risk of death (hazard ratio [HR] 0.75, 95% CI 0.52 to 1.08) or of major post-operative complications (HR 0.55, 95% CI 0.24 to 1.1). [Orosz GM 2004] However, it is worth noting that 10 baseline characteristics differed between the two patient groups, although the authors adjusted for them in their analysis. The analysis, however, cannot exclude a clinically important reduction in mortality with early surgery (up to 48%). Although the 95% CI crosses equivalence, the current data support anywhere from a 1% to a 50% reduction in mortality with 86% confidence.

The definition of early surgery (in the first 24 hours after hospital arrival) also seems somewhat arbitrary. Despite the authors' assertion that six months of follow-up was sufficient, recovery following hip fractures may extend to one year. In a recent study involving 651 patients with hip fractures, early surgery (within 48 hours) significantly reduced the risk of death by 39% (95% CI 10 to 58) at one year. Furthermore, operating in less than 24 hours reduced the pain experienced by patients and the length of stay in the hospital ($P \leq 0.01$). [Bhandari M 2004]

A study conducted in Germany used hospital data for 2,916 hip fracture patients. It compared groups with short (≤12hrs), medium (>12 to ≤36 hrs) and long (>36 hrs) time-to-surgery and revealed only some non-significant associations with certain complications such as post-operative bleeding requiring treatment (early surgery patients) and urinary tract infections (delayed surgery patients). Both unadjusted rates of one year all-cause mortality (between 18.1% and 20.5%), and the multivariate-adjusted HRs (HR for time-to-surgery: 1.04; $P=0.55$), showed no association between mortality and time-to-surgery. [Smektala R 2008]

A small study (n=182 patients) found that delaying surgery by even six hours significantly increases the one year mortality. [Dorotka R 2003]

Another study suggests that delay to surgery was not a significant predictor of in-hospital mortality. However, a delay of more than 24 hours was a significant predictor of a minor medical complications (OR 1.53, 95% CI 1.05 to 2.22), while a delay of more than 48 hours was associated with an increased risk of a major medical complications (OR 2.21, 95% CI 1.01 to 4.34), a minor medical complication (OR 2.27, 95% CI 1.38 to 3.72) and of pressure sores (OR 2.29, 95% CI 1.19 to 4.40). It was therefore concluded by the authors that patients with a fracture of the hip should have surgery early to lessen the time to acute care hospital discharge and to minimise the risk of

complications. [Lefaivre KA 2009] Similarly, another observational study of 1,320 patients found that a time to surgery of greater than two days had a two-fold increase in 30-day mortality after adjusting for age, gender and comorbidity (OR=1.99, 95% CI 1.06 to 3.72). In a second model, also including American Society of Anesthesiologists (ASA) score, the OR decreased to 1.84 (95% CI 0.97 to 3.49). Patients with a hip fracture should have surgery within two days from admission in order to reduce 30-day mortality. [Carretta E 2010] Other studies have reported similar ORs for a delay of greater than two days: the HR of one-year mortality for postponing surgery beyond 48 hours was 1.63 (95% CI 1.11 to 2.40). [Gdalevich M 2004] In another study (n=49), patients who underwent early surgical repair (within 48 hours) had fewer post-operative complications (14.7%, as compared with 33.3% in the group undergoing surgery 48 hours after fracture). [Sircar P 2007]

All patients who have an episode of care in an NHS hospital become part of the HES database. Over a three-year period (2001 to 2004), there were 129,522 admissions for fractured neck of femur in 151 trusts, with 18,508 deaths in hospital (14.3%). Delay in operation was associated with an increased risk of death in hospital, which was reduced but persisted after adjustment for comorbidity. For all deaths in hospital, the OR for more than one day's delay, relative to one day or less, was 1.27 (95% CI 1.23 to 1.32) after adjustment for comorbidity. The proportion with more than two days' delay ranged from 1.1% to 62.4% between trusts. If death rates in patients with a maximum of one day's delay had been repeated throughout all 151 trusts in this study, there would have been an average of 581 (478 to 683) fewer total deaths per year (9.4% of the total). There was little evidence of an association between delay and emergency readmission. [Bottle A 2006]

Another potential confounding factor in the relationship between delay in hip fracture surgery and outcome is whether the surgery should be performed during working hours, which may lead to an inevitable delay, or outside working hours. A retrospective analysis of 165 patients who were

operated on outside working hours and 123 who were operated on during working hours (08.00 to 17.00) was undertaken. There was no difference in the rate of early complications (outside working hours 33% versus working hours 33%, p = 0.91) or total complications during follow-up (outside working hours 40% versus working hours 41%, p = 0.91). Both in-hospital mortality (outside working hours 12% versus working hours 11%, p = 0.97) and mortality after one year (outside working hours 29% versus working hours 27%, p = 0.67) were comparable. Adjustment for possible confounders by multivariate logistic regression analysis revealed no increased risk of complications when patients were operated on outside working hours. [Bosma E 2010]

Physicians should aim for early operative fixation of hip fractures to reduce patients' pain and length of hospital stay. Larger studies will be needed to address whether early surgery reduces mortality and the incidence of major post-operative complications.

Extracts from reported incidents – post-operative complications

"Whilst drilling left shoulder - drill bit broke unable to retrieve from patient."

"During a left total elbow replacement, while drilling down the ulna , part of one of the drills on the loan kit from biomet broke off . It was very far down the cannal of the ulna and surgeon was unable to reach the drill bit with out causing damage and affecting the elbow replacement. Therefore it was left inside the patient. The company rep was present and was asked to check the shelf life of the kit and consulted with Mr consultant before continuing the case . ."

"Patient underwent total knee replacement on 9 / 4 / 09 without notable complication . On check x-ray broken drill bit left in knee , operating surgeon and scrub nurse had not noted the broken end of the drillbit at the time of surgery . ."

"Consultant was drilling inside the upper section of the mouth to make holes in the bone for a bone craft . On giving the drill back to staff nurses it was noted that the top of the drill bit was missing , approximately 2cm long . Mouth was looked in , drapes and swabs were checked , x-ray taken , airway looked at , no drill bit found . Xray advised and to be vigilant of finding the metal . ."

3.3.5. Example 3: The story of hip cement

In 1990, 1.3 million hip fractures occurred globally. Predictions are that numbers will rise to anywhere between 7.3 and 21.3 million by 2050. [Gullberg B 1997] Mortality after a hip fracture remains substantial, being 11–23% at six months and rising to 22–29% at 12 months post-injury. [Haleem S 2008] Total hip replacement and hemiarthroplasty are the main treatment options for displaced femoral neck fractures, with broadly similar outcomes for both procedures. What is less clear, however, is whether these arthroplasties should be cemented, uncemented, or hybrid. Although to some extent an old issue, this issue has attracted renewed interest of late because of the possible risk of the potentially catastrophic bone cement implantation syndrome in those who have undergone cementing procedures. [Donaldson AJ 2009]

In the UK, the use of cement for total hip arthroplasty and subsequently hemiarthroplasty was heralded by a sentinel publication from one of the leading orthopaedic surgeons of the century, Sir John Charnley. [Gomez PF 2005] Prior to this, orthopaedic surgeons had borrowed from the dental community a form of acrylic cement suitable for surgery. Surgeons in Copenhagen and New York had used bone cement to attach plastic cups to femoral heads and secure a femoral prosthesis, respectively. [Charnley J 1960] Sir John Charnley was responsible for noting that the points of direct contact between an implant and bone requisite for a tight fit were the points where the bone would absorb and leave the implant inadequately supported. Furthermore, he proposed that cement acted as a 'grout', not as glue, so that fixation was achieved by interlocking and not by adhesion. The cement was forced into all available interstices, so the weight of the body was dispersed over a large area of bone. He believed that bold and generous use of cement improved fixation by a factor of 200. Heat generated during polymerisation was absorbed by the metal prosthesis, which acted as a heat sink. [Gomez PF 2005] It is worth noting that this leading professor of orthopaedic surgery

once stated in response to total hip arthroplasty: *"The cart has been put before the horse; the artificial joint has been made and used, and now we are trying to find out how and why it fails".* [Charnley J 1956]

It is a well-known fact that the literature in orthopaedic surgery is of variable quality. One might argue that orthopaedic surgery, like most branches of surgery, lacks RCTs and hence a greater number of meta-analyses tend to be of observational studies that are of variable quality. The number of meta-analyses increased five-fold from 1999 to 2008, but the mean quality score did not change significantly over time ($p = 0.067$). Up to 30% of meta-analyses had extensive methodological flaws. [Dijkman BG 2010] If we narrow the focus further, a recent review of the quality of the RCTs of the arthroplasty (81 hip, 80 knee and 19 combined hip/knee) literature reveals a worrying trend. This study found that the mean overall quality scores (SEM) of arthroplasty trials was low: Jadad score 2.36 (1.4), Delphi list 5.33 (1.6) and NRS score 4.30 (2.6). Multivariable analyses revealed that non-pharmacological intervention RCTs had lower odds (OR 0.28-0.39; $p = 0.008$-0.033) and those with no funding had lower odds (OR 0.28-0.50; $p = 0.014$-0.119) of being in the highest quartiles of the three overall quality scores. In contrast, multicentre RCTs had 1.8–4.7 times higher odds of being in highest tertiles of quality scores ($p = 0.017$-0.185). [Singh JA 2009]

This leads us to an issue of great importance, but one that is neglected due to its infrequent occurrence. Bone cement implantation syndrome is associated with substantial mortality and morbidity. The syndrome is characterised by hypoxia, hypotension and unexpected loss of consciousness; it can occur at any time from the time of cementation to the final deflation of the tourniquet in patients having cemented bone surgery. [Donaldson AJ 2009] Two main mechanisms have been suggested for its aetiopathogenesis. The more robust theory is that of emboli being dislodged into the pulmonary vasculature because of high intramedullary pressures and raised temperatures developing during prosthesis insertion and cementation. [Orsini EC 1987] A less

favoured but nonetheless interesting theory is that of cement monomers being formed during cementation, which in turn induce a widespread inflammatory response.

There is a paucity of evidence and hence rather predictable controversy and divergence of opinion and practice about the use of cementation. Data from national joint registries indicate that surgeons in Sweden, Denmark, the UK and Norway tend to favour cemented total hip replacements, whereas Australian and Canadian surgeons tend to favour the use of uncemented total hip replacements. For hemiarthroplasties, Swedish and Australian surgeons favour the use of cemented implants. [Panesar SS 2009b]

National patient safety incident databases have been alerted to intraoperative deaths following the use of bone cement in hip arthroplasty. My novel method in Study 1 (section 3.1), showed that treatment or procedure errors warranted priority as several cases of death likely to be contributed to the use of hip cement were noted. Careful trawling through the incidents found five cases of severe harm, which were thought to be directly attributable to the use of bone cement. Further analysis of the NRLS revealed that 96% (24/25) of the reported deaths related to a hip procedure (total hip replacement or arthroplasty) were in patients having cemented procedures, while only 4% (1/25) of deaths occurred in those receiving an uncemented prosthesis. An example of the reports is:

> *"Patient having cemented hip prosthesis inserted for fractured neck of femur. Cement inserted and prosthesis being hammered into place when patient became bradycardiac 40 / min. Unresponsive to atropine. Loss of palpable pulse with pulseless electrical activity, cardiac arrest. Cardiopulmonary resuscitation commenced and continued for 20 minutes and no response to treatment. Patient died"; "During procedure when introduction of cement the patients condition deteriorated. Patient died at 21:10"; and "Patient was having an operation for a right cemented [name of prosthesis]. Patient went into asystole when cement put into hip joint".*

Caution is urged when interpreting these results due to the frequent under-reporting of events, possible selection biases, and the inability to adjust for potential confounding factors, such as fracture severity and comorbidities. [Panesar SS 2009b]

A review of the literature in orthopaedics creates a picture of confusion. The overall death rate within 30–90 days after total hip replacement is reported to range between 0.23 and 0.45%. [Sierra RJ 2008, Sharrock NE 1995, Dearborn JT 1998, Parvizi J 2004] There has been a significant decline in this rate over the last 15 years and, in a total cohort of 30,715 patients, the death rate was 0.15% for cases having surgery in the 1990s compared with earlier decades ($p<0.0002$). [Barrett J 2005] A single surgeon series of 2,736 hips reported a death rate of 0.18% if patients with severe pre-existing disease were excluded. [Dearborn JT 1998] Sharrock studied the effect of changes in anaesthetic technique on the death rate and the in-hospital rate was reduced to 0.18% with improved techniques. [Sharrock NE 1995] The rates reported are lower than the number of expected deaths in the normal population. Another study from the US has confirmed that total hip replacement recipients survive longer than matched control in the Medicare population. [Barrett J 2005]

The latest National Joint Registry report indicates a significantly reduced mortality rate (less than half) at one year following primary total hip replacement (1.9%; 95% CI 1.8 to 2.0) than that of the general population of England and Wales, using age- and gender-adjusted standardised mortality ratios (SMR). [National Joint Registry 2007] Indeed, this SMR is less for cemented hips (0.46; 95% CI 0.42 to 0.50) than for cement-less (0.49; 95% CI 0.42 to 0.57) hips. Further, the use of cement did not significantly influence the model when analysed using multivariate analysis, and hazard ratios were similar (0.9; 95% CI 0.8 to 1.1) when cement was not used.

The 30-day mortality in a cohort of 7,774 arthroplasties was 2.4% (i.e. a 10-fold higher rate) when compared with total hip replacements. [Parvizi J 2004] The in-hospital mortality rates of 200,000 total hip replacements, 100,000 partial hip replacements and 36,000 revision hip replacements performed in the US in 2003 have been compared. [Zhan C 2007] The death rates associated with these three procedures were 0.33%, 3.04% and 0.84%, respectively. The Swedish hemi-arthroplasty register reporting approximately 12,000 joints corroborates this finding of significantly increased risk in fracture patients: the 90-day mortality following hemi-arthroplasty was over 10-fold greater (12%) compared with total arthroplasty. The authors point out that the two patient groups are entirely different. Hemi-prosthesis patients are older, generally more ill and are in need of an emergency operation with little time to stabilise their health state prior to surgery. The mortality rate was significantly higher if surgery was delayed more than 48 hours. [Department of Orthopedics 2008]

There have been many studies that have been unable to identify an increased risk of mortality with the use of cement [Parker MJ 2006, Weinrauch PC 2006, Emery RJ 1991, Khan RJ 2002a, Khan RJ 2002b, Lo WH 1994] and another has in fact shown a decrease in 30-day mortality when cement is used. [Foster AP 2005] Of note, a meta-analysis of 2,613 hemiarthroplasties found no statistical difference in the outcome of mortality experienced by the elderly hip fracture population undergoing either a cemented or uncemented procedure. [Ahn J 2008]

In a study of 25,000 hemiarthroplasty cases from the Australian Orthopaedic Association National Joint Replacement Registry, an increased mortality rate was found day one post-operatively with cement ($p = 0.05$). [Costain AD 2008] By one week, this trend reversed ($p = 0.02$). This trend reversal persisted at one month ($p = 0.03$) and one year ($p < 0.0001$) post-operatively. Cemented hips were the safer option for treatment at all time points after the day of surgery.

Conversely, one study found 23 intraoperative deaths, all in those having cemented procedures, while no intraoperative deaths occurred in more than 12,500 patients who had a non-cemented procedure. [Parvizi J 1999] Furthermore, an audit of 9,082 total hip arthroplasties using cement identified only one intraoperative death secondary to a fat embolism. [Sierra RJ 2008] Additionally, a Cochrane review concluded that in view of the limited amount of high-quality evidence available, it was not possible to definitively determine if any possible adverse effects of cement would offset any advantages from the main potential benefit of reduced revision rates. [Corkill J 1976] Interestingly, in this respect, the revision rate has been reported as being higher in the uncemented group. [National Joint Registry 2007]

Despite this uncertainty, NICE in the UK continues to recommend that cemented prosthesis should be used for total hip replacements, citing long-term viability, relative cost-benefit (cemented prostheses are cheaper), and a lack of evidence to support the idea that ease of revision in those who have had uncemented prostheses would outweigh any poorer revision rate. [NICE 2009]

The NPSA sought to offer solutions to mitigate against the harm caused by the insertion of cement. [NPSA 2009c] These solutions are in the form an RRR, which is shown in Appendix 5. This advocates adequate patient assessment, good anaesthetic technique and good surgical technique. All the recommendations are based on solid evidence-based guidelines. The risk factors associated with increased peri-operative mortality are well recognised. These include increasing age [Parvizi J 2004, Zhan C 2007]: the peri-operative mortality rate of 0.34% in 66–69 year olds increased to 3.75% if the patient was over 85 years old. [Whittle J 1993] The presence of co-morbidities including cardiovascular disease and pre-existing respiratory disease are well-documented. [Dearborn JT 1998, Parvizi J 2004, Zhan C 2007, Parvizi J 1999] Every attempt should be made to optimise the medical condition of the patients before they undergo surgery. A study has shown that hospitals with higher

volumes of surgery have superior inpatient mortality rates and a reduced length of hospital stay. [Doro C 2006]

Teams should ensure that anaesthetic and surgical techniques to reduce risk in fracture patients are implemented. Sharrock studied the effect of changes in anaesthetic care and with modified techniques reduced the risk of death from 0.36% to 0.1% after total hip replacement. [Sharrock NE 1995] Patients most at risk are those with limited cardiac reserve or with hypovolaemia as they are less able to compensate by vasoconstriction for any drop in blood pressure caused by reaming of the canal or by cement. There should be vigilant intra-operative management of the patient by the anaesthetist.

In summary, reduction of risk relies on:

1. recognition of the at-risk patient and constant monitoring of the patient throughout the operation
2. assessment of cardiac filling – there must be adequate fluid loading to increase the response to low cardiac output
3. use of vasoconstrictors/inotropes if hypotension does occur. [Dow A 2005]

Intra-operatively, every effort should be made to reduce the possibility of embolisation of fat and marrow contents whether the hip is to be cemented or inserted without cement. [Doro C 2006, Dow A 2005, Pitto RP 1998]

Thorough lavage of the medullary cavity with a pressurised system is mandatory to reduce the embolic load [Christie J 1995, Breusch S 2000] and has also been shown to improve fixation of the

femoral component. [Malchau H 2000] Lavage should be carried out before any instrumentation of the medullary cavity. [Clarius M 2005] The safest way to introduce cement is in retrograde fashion from a gun. A suction catheter placed distally above the plug must be used to reduce pressure at the cement/marrow vessel interface during cement insertion. A reduction in intramedullary pressure has been reported to lead to a three-fold reduction in the intra-operative mortality rate. [Parvizi J 1999] If the canal is adequately cleaned, and if the patient is adequately prepared and monitored during the procedure, then cement pressurisation appears to confer no disadvantage with regards to risk and improves fixation of the femoral component. [Sierra RJ 2008, National Joint Registry 2007, Department of Orthopaedics 2008]

The UK's Chief Medical Officer's Annual Report for 2007 stressed the need to find ways of reducing bone cement implantation syndrome. [Donaldson L 2008] One way of facilitating greater clarity about safety considerations would be for orthopaedic surgeons and anaesthetists to continue reporting possible safety incidents related to bone cement to the NRLS in as much detail as possible to allow meaningful interrogation of these data. In parallel, we also need greater clarity on the effectiveness of cementing compared with uncemented procedures. The logical way forward in this respect is to investigate this question in head-to-head randomised trials. Such trials, while individually almost certainly underpowered to study safety, could, if planned in a co-ordinated way, provide valuable insights into safety by facilitating meta-analysis of adverse outcomes data. In view of the frequency of the procedure and the considerable potential safety risks at stake, it is important that both clinicians and academics join forces to promote development of a robust evidence base in this neglected area.

3.3.5.1. Effectiveness of the alert

The alert [NPSA 2009c] was released on 11 March 2009 and NHS trusts had until 14 September 2009 to implement the recommendations. To date, 177/392 (45%) of trusts have indicated compliance; 212/392 (54%) felt they did not need to comply; and 3/392 (0.8%) were still implementing the alert. Until July 2012, no cases of severe harm/death owing to the use of hip cement have been reported.

3.3.6. Example 4: Inpatient falls and fractures

NRLS data from across England and Wales indicate that approximately 208,000 falls are reported in acute hospitals every year, with over 36,000 reported from mental health units and 38,000 from community hospitals. A significant number of these falls result in death, or severe or moderate injury, including around 840 fractured hips, 550 other types of fracture and 30 intracranial injuries. [NPSA 2010b] Even for the less serious falls, the human cost of falling includes distress, pain, injury, loss of confidence and loss of independence, as well as the anxiety caused to patients, relatives, carers and hospital staff.

The causes of falls are complex. Hospital patients are particularly likely to be vulnerable to falling through medical conditions including delirium, cardiac, neurological or musculoskeletal conditions, side-effects from their medication, or problems with their balance, strength or mobility. Problems such as poor eyesight or poor memory can create a greater risk of falls when someone is out of their normal environment on a hospital ward, as they are less able to spot and avoid any hazards. Continence problems can mean patients are vulnerable to falling while making urgent journeys to the toilet. In hospital settings, falls are also often an ominous 'red flag' symptom, indicating the patient's underlying medical condition may have deteriorated, and may merit urgent medical review, regardless of injury. [IOM 2001]

Prevention of falls is understandably an important patient safety challenge for most healthcare settings and a range of resources exist to help healthcare staff with this. [Patient Safety First Campaign 2009] But what happens after a fall is equally important, as detecting and treating injury from the fall as efficiently as possible will reduce the degree of harm caused to the patient. This is particularly critical for injuries such as subdural haematoma that may progress to irreversible brain damage if not detected early [NICE 2007] and fractured hip, where minimising the time elapsed between fracture and surgery is vital to reducing mortality and disability. [BOA 2007] However, the relative rarity of inpatient falls that result in serious injury – less than 1% of reported falls – can make it challenging for staff to maintain their vigilance. [NPSA 2010b]

General issues of failures in aftercare had been previously identified from NRLS data and a recommendation for NHS organisations to develop post-fall protocols was made by the NPSA in 2007 in *Slips trips and falls in hospital.* [NPSA 2007]

Very few of the incidents were related to difficult to detect injury or difficult to interpret x-rays. The majority of the delays appeared to be in basic assessment and observation, with patients either not examined by medical staff or superficially examined. Although many of the patients were confused and unlikely to have given a coherent account of their fall or their symptoms, the reports indicate they were usually expressing pain or distress. In other examples there were obvious external indications of injury found by later observers (although this may relate to bruising becoming more visible with time, or undisplaced fracture displacing later, for example). Delays in fracture detection ranged from a few hours to several days. In several cases, transfer between wards, or discharge home, was when the fracture was detected. Other issues included:

- difficulty in accessing orthopaedic advice or orthopaedic beds (delaying diagnosis or surgery)

- unsafe retrieval (for example, use of sling hoists despite suspected spinal injury or obvious fracture)
- failure to consider the greater vulnerability of anticoagulated/coagulopathic patients;
- neurological observations taken only once immediately after the fall
- patients with repeated falls where date of fracture could not be established.

While the search strategy and criteria for inclusion above were not designed to find incidents where a new illness/collapse caused the fall (for example cardiac problems or spontaneous intracranial bleed), examples of equivalent lapses in observation or medical review have also been reported to the NRLS.

It is not easy to separate the morbidity and mortality resulting from the fall injury, from that resulting from the *delay* in treating the injury. Some intracranial injury is likely to have been untreatable, even if detected in a more timely way, and some patients already had a terminal illness when they fell.

Based on work undertaken by my novel method in Study 1 (section 3.1), one type of incident that warranted prioritisation was 'patient accident'. Seventy-five incidents were reported that described apparent failures in retrieval, or detection and treatment of injury, after inpatient falls resulting in fracture or brain injury. The injuries that went undetected or where treatment was delayed were in some cases multiple, but counting the most serious injury in each case, injury types were: 11 intracranial/subdural bleeds attributed to the trauma of the fall; 45 fractured hips; two spinal fractures and 17 other fractures.

Delays in operating on a fractured hip are known to have significant impact on both mortality levels and the likelihood of the patient regaining their former level of independence. [BOA 2007] Inappropriate handling (for example, sling hoist or wheelchair use despite obvious deformity from hip fracture) can cause intense pain and may reduce the likelihood of successful surgery.

For the more 'minor' fractures (including fractures of the humerus, pubic rami or lower limbs), serious consequences of the delay in diagnosis were noted in a minority of cases in terms of loss of function or mobility. Unnecessary pain resulted in many of these cases, either through inappropriate retrieval and efforts to get the patient mobile again, or through prescribing painkillers appropriate for bruises, not fractures. Some examples of the patient safety incidents related to inpatient falls is shown in the box on the following page.

Community hospitals and mental health units can access the relevant expertise via their local emergency services. Acute hospitals can use the expertise of their emergency department and orthopaedic staff to develop post-fall protocols that conform to national guidance. Key reference documents for standards of aftercare following a fall include those produced by the British Orthopaedic Association, British Geriatrics Society and NICE. [BOA/British Geriatric Society 2007, NICE 2007]

The NICE guidance contains the following advice on frequency of neurological observations:

> *"1.7.2.1 For patients admitted for head injury observation the minimum acceptable documented neurological observations are: GCS* [Glasgow Coma Scale]*; pupil size and reactivity; limb movements; respiratory rate; heart rate; blood pressure; temperature; blood oxygen saturation"*
>
> *"1.7.3.1 Observations should be performed and recorded on a half-hourly basis until GCS equal to 15 has been achieved. The minimum frequency of observations for patients with GCS equal to 15 should be as follows, starting after the initial assessment in the emergency department: half-hourly for 2 hours; then 1-hourly for 4 hours then 2-hourly thereafter."*

"1.7.3.2 Should a patient with GCS equal to 15 deteriorate at any time after the initial 2-hour period, observations should revert to half-hourly and follow the original frequency schedule."

Examples of incidents related to inpatient falls reported to the NRLS

Neurological observations not taken or taken only once

"Patient fell in the corridor walking to the toilet ….. Neuro obs were recorded and GCS 14 extensive swelling noted to cut on left eyebrow and steristrips were applied. Also had painful arm and required analgesia. Patient was reviewed by the doctor – x-ray requested due to query fractured shoulder. Patient was responsive at 08:00. She was referred to Orthopaedics re dislocated shoulder and kept nil by mouth pending theatre. At 10:30am patient became unresponsive and was reviewed by the doctor. Attended for urgent CT which radiology informed staff that result showed a large left sided subdural haematoma. Reviewed by Neurosurgeon who stated that patient would not survive surgery…"

"Patient suffered head injury on ward previous day. Found 11.30 unconscious (GCS 3/15) bleeding from nose and aspirating blood. Fixed and dilated pupils. Significantly abnormal cardiovascular and respiratory observations. Coagulopathy on background of alcoholic liver disease. ISSUES……No neuro obs being carried out after injury."

Delay in diagnosis of fracture or dislocation

"Staff heard a bang and found pt sitting on the floor by her bed, she said she rolled out of bed. Patient got up with minimal assistance, no visible injury, complaining of pain to right ribs. Reassurance given, BP 146/70, P 74, T 36.2, refused pain relief medication. Dr bleeped, reviewed by Psych SHO. Sent to [acute hospital] [eight days post fall] admitted # right neck of femur and 7&8 right ribs, died [15 days post fall]."

"Patient admitted to [ward a] from [ward b] - on transfer to ward patient had pain in R hip and nursing assistant noticed R leg was shorter and rotated – staff nurse informed, on call doctor informed x-ray requested and shows that hip is dislocated, notes state patient fell [three days earlier]. Manipulation on ward unsuccessful so patient is now for high risk surgery."

"Standing from toilet became dizzy stated that she fell to the floor unwitnessed by staff. Sitting on floor on arrival complaining of pain in right side, rib/back pain. Observations recorded and monitor. SHO informed to review. Codeine/paracetamol prescribed. Inform family. Chest x-ray [two days later] probable rib # plural collection. Patient not to be left alone in patient toilet facilities. 2 # ribs haemothorax chest drain [five days later] transferred to ITU…"

No examination

"[Evening] *Patient found sitting on the floor opposite to toilet in the bay. Staff nurse on night duty, initially had no cause to think this gentleman had injured himself, there was no complaint of pain and they assisted him back to bed. When they later went to him he was in more discomfort and one leg appeared shorter than the other. The staff informed the next of kin who later visited the ward. The ward team and consultant were made aware first thing in the morning. They reviewed patient and requested an x-ray. On x-ray he has fractured his hip."*

Based on a random sample policy survey undertaken as evaluation of *Slips trips and falls in hospital*, the number of inpatient falls prevention policies that include advice on clinical checks after a fall has

risen from 19% in 2006 to 51% in 2009. However, very few of these post-fall protocols can be considered 'gold standard'. [NPSA 2010b] Many policies appear to have drawn post-fall instructions from a health and safety context, and omit clinical considerations (for example 'make the area safe and report the incident'). There are few protocols that also cover the common scenario of a patient falling because of new acute illness (for example heart block or stroke). Based on this survey, important clinical components of a post-fall protocol include:

- ABC (airway/breathing/circulation)
- initial checks before attempting to move the patient for signs of serious injury (for example, pain, limb deformity, loss of sensation)
- safe retrieval, including how to access equipment and expertise for patients who need immobilisation or flat-lifting, and pain relief before moving the patient if appropriate
- observations to detect any potential new acute illness that caused the fall and to detect any harm from the fall (for example, temperature, pulse, respiratory rate, blood pressure, oxygen saturations, blood glucose)
- frequency and duration of neurological observations not only for patients with visible or reported head injury, but also for patients where head injury cannot be excluded (for example an unwitnessed fall) – this may include a more intensive and prolonged schedule of observation for patients who are on anticoagulants or who are coagulopathic
- criteria that indicate which patients and circumstances need immediate, urgent or routine medical review, investigations or referral to specialist teams, including special consideration of patients who are on anticoagulants or who are coagulopathic

- providing appropriate supportive care (for example pressure relief, pain relief, fluid balance) for patients with significant injury
- explaining to the patient what is being done and why while working through the steps above
- actions to reduce the risk of further falls and fragility fractures, including identifying and acting on underlying risk factors, identifying and treating osteoporosis, and considering the need for falls prevention equipment or special observation
- non-clinical aspects of falls prevention, including making safe any environmental hazard, reporting and investigation processes, and informing relatives/keyworker. [NPSA 2011b]

In revising local post-fall protocols, organisations should take advice from their local emergency department. This is so that observations and investigations for inpatients after a fall (for example, frequency of neurological observations and thresholds for x-ray or CT scanning) reflect those which would be undertaken for patients presenting to emergency departments and conform with NICE Clinical Guideline 56. [NICE 2007] Local emergency departments will also be well placed to advise on avoiding unnecessary application of immobilisation and ensuring any period of immobilisation and subsequent management is appropriate and as short (but effective) as possible. Such advice may be based, for example, on Advanced Trauma Life Support guidelines [American College of Surgeons], National X-Radiography Utilization Study Group [Hoffman JR 1992] or Canadian cervical spine imaging rules. [Stiell IG 2001]

Concerns have previously been raised that hospitals continue to use an out-dated 14-point form of the Glasgow Coma Scale (GCS), and even hospitals using the correct 15-point scale may be reliant on local photocopying that over time creates blurred and poor quality formats. As part of revising their post-fall protocol, organisations should ensure all wards and inpatient units have access to clear

versions* and that old formats are destroyed. Where possible, formats for recording neurological observations should also contain clear guidance on how to correctly take and record the GCS (for example, advice on how to determine best motor response on the rear of the chart).† Locally-used formats should emphasise the need to seek urgent medical review if the GCS drops. [Weise MF 2003]

* Examples can be found at http://www.nice.org.uk/CG056

† Examples can be found in the falls prevention resources area of www.patientsafetyfirst.nhs.uk

Further detailed advice on hospital falls prevention, including secondary prevention following an inpatient fall, is provided in *Slips trips and falls* and the 'How to' guide to reducing harm from falls. [NPSA 2010b]

The NPSA suggested actions for the RRR on preventing falls are:

NHS organisations with inpatient beds should ensure that:

1. They have a post-fall protocol that includes:

   a) checks by nursing staff for signs or symptoms of fracture or potential for spinal injury before the patient is moved

   b) safe manual handling methods for patients with signs or symptoms of fracture or potential for spinal injury

   c) frequency and duration of neurological observations for all patients where head injury has occurred or cannot be excluded (e.g. unwitnessed falls) based on NICE Clinical Guideline 56: Head injury

   d) timescales for medical examination following a fall (including fast track assessment for patients with signs of serious injury, or high vulnerability to injury, or who have been immobilised).

2. Their post-fall protocol is easily accessible (e.g. laminated versions at nursing stations).

3. Their staff have access to clear guidance and formats for recording neurological observations using a 15-point version of the GCS and that changes in the GCS that should trigger urgent medical review are highlighted.

4. Their staff have access at all times to special equipment (e.g. hard collars, flat-lifting equipment, scoops) and colleagues with the expertise to use it, for patients with suspected fracture or potential for spinal injury.

5. Systems are in place allowing inpatients injured in a fall access to investigation and specialist treatment that is equal in speed and quality to that provided in emergency departments and conforms to NICE Clinical Guideline 56: Head Injury. [NPSA 2010b; Healey F 2011]

3.4. *Study 4:* A novel use of patient safety reporting systems: developing an Orthopaedic Error Index

The Orthopaedic Error Index (OEI) for hospitals aims to provide the first national assessment of the relative safety of provision of orthopaedic surgery. The NRLS is the largest national repository of patient safety incidents in the world. It offers a unique opportunity to develop novel approaches to enhancing patient safety, including investigating the relative safety of different healthcare providers and specialties. I extracted all orthopaedic reports from the system over one year (2009–2010). The OEI was calculated as a sum of the error propensity and severity. All relevant hospitals offering orthopaedic surgery in England were then ranked by this metric to identify possible outliers that warrant further attention. There were 155 hospitals that reported 48,971 orthopaedic-related patient safety incidents. The mean OEI was 7.09/year (SD 2.72); five hospitals were identified as outliers. Three of these units were specialist tertiary hospitals carrying out complex surgery; the remaining two outlier hospitals had unusually high OEIs: mean14.46 (SD 0.29) and 15.29 (SD 0.51), respectively. The OEI has enabled identification of hospitals that may be putting patients at disproportionate risk of orthopaedic-related iatrogenic harm and which therefore warrant further investigation. It provides the prototype of a summary index of harm to enable surveillance of unsafe care over time across institutions. This novel approach has the potential to be extended to other hospital specialties in the UK and also internationally to other health systems that have comparable national databases of patient safety incidents.

3.4.1. Introduction

Over a decade ago, the IOM published the seminal report, *To Err is Human*, [Kohn LT 1999] which revealed the previously under-recognised high burden of morbidity and mortality associated with iatrogenic harm. This was then followed by the equally influential *Crossing the Quality Chasm*, which

highlighted the need to develop and make greater use of error reporting systems to enable learning from patient safety incidents and create opportunities for system-level interventions to reduce future risks of harm. [IOM 2001] The challenge for healthcare systems globally remains the consistent delivery of safer care and the associated surveillance of safety within an organisation.

Modern day healthcare involves an array of complicated diagnostic and therapeutic decisions affected by the system within which these occur. Poorly functioning systems and teams have the potential to impact on patient safety. Inevitably, there will be unexpected variation in access, outcomes and quality of care. Whereas some variation is legitimate and indeed desirable (for example, slower surgeons should not be asked to work faster), it is the unwarranted variation that is a major cause of concern to policy-makers and regulators. [NHS Confederation] A much-favoured approach for describing this variability is the use of hospital-wide mortality rates. Proponents have argued that these tools provide useful metrics about problems with the quality of inpatient care, uncover system-wide failures, and can help patients to choose the safest hospital. [Bottle A 2010] PSRSs are unused sources of data for the surveillance of harm which enable learning from errors, so that the insights create opportunities for system-level interventions to reduce future risks of harm. Some successes have been reported, for example in identifying previously undetected risks of new drugs or procedures, but there remain doubts about the wider value of investment in developing and maintaining large-scale incident reporting systems. [Leape LL 2002]

Databases of error reports now exist in many parts of the world, including the UK and the US. [Sheikh A 1999, Panesar SS 2009a, Hickner J 2010] The UK's NRLS was launched in 2003 and has since accrued over seven million records, making it the most substantial repository of patient safety incidents in the world. Analyses of this database have revealed risks in a range of clinical areas, [Panesar SS 2009a, Cresswell KM 2008] but what has been lacking are high-level, valid summary

metrics to allow surveillance of harm across a whole healthcare system in a way that allows, for example: comparison between hospitals; monitoring of time trends; and a baseline for assessing and evaluating interventions. This is necessary because of the large volume of incident reports.

Here, I report on the development of one such summary statistic, which aims to (unlike the currently used proxy measures of harm such as hospital standardised mortality ratios [HSMRs]) provide a more direct measure of safety. [Lilford R 2010] I developed and tested this measure in the field of orthopaedic surgery. This specialty was chosen because it is associated with a relatively high level of harm. [Panesar SS 2012] For example, from 2000 to 2006, an equivalent of US$321 million was paid in adult orthopaedic surgery-related negligence settlements in the UK. [Atrey A 2010] Similar figures were reported the Physician Insurers Association of America (PIAA). [Parikh PD]

3.4.2. Methods

3.4.2.1. Developing a model for an error index

Errors will occur in complex systems such as healthcare, and their frequency will relate to the number of procedures undertaken. Such assumptions are made in other fields of risk – in road traffic accidents, for example, predicted crash frequency is a linear function of average daily traffic. [American Association of State Highway and Transportation Officials 2010]

A simple measure of error is the frequency of errors occurring in any hospital. However, since frequency is a function of the number of procedures that have been carried out, I deemed the frequency of errors per unit of procedure as a more appropriate measure after discussion with the statistician, Professor Gopalakrishnan Netuveli. This is called the *error propensity*. In order to calculate this, I extracted data on all orthopaedic reports made by all English hospitals reporting to the NRLS over a 12-month period, i.e. from 1 April, 2009 to 31 March, 2010. In parallel, I approximated the

total number of orthopaedic procedures carried out in each hospital using data from the national Hospital Episode Statistics (HES) (2009–2010) database, [Hospital Episode Statistics] which is a mandatory national database of all patient visits to NHS hospitals in England, in order to estimate the error propensity.

A second component of the OEI reflects the impact the error has on the patients, i.e. how much harm it resulted in. This I termed the *error severity*, which is based on categories of harm. Harm was defined by user self-reports; the degree of harm was classified as either: no harm, low harm (minimal harm – patient(s) required extra observation or minor treatment), moderate harm (short-term harm – patient(s) required further treatment, or procedure), severe harm (permanent or long-term harm), or death (please see Panel 1 in Chapter 3). Further details about the structure of the NRLS are provided in Sections 1.3 and 1.4. I created my summary statistic, the OEI, using principles laid out in the Standards for Statistical Models used for Public Reporting of Health Outcomes. [Krumholz HM 2006]

The OEI is the sum of the number of errors (propensity, P) and the degree of harm (severity, S). The assumption is that this should enable identification of hospitals with large numbers of errors and similarly those units with the greatest degree of harm. It is reasonable to assume that as more procedures are carried out, a larger number of errors will be reported, although I am also cognizant that there is potentially a high risk of errors in units undertaking relatively few procedures. [Birkmeyer JD 2002]

3.4.2.2. Calculating the error propensity and severity

For each hospital, *P* was calculated as:

$$P = 100\frac{n}{N},$$

where n was the number of procedures where any error had occurred and N was the total number of procedures; P had a range of 100, with 0 representing the lowest error propensity and 100 representing the largest error propensity.

The standard error of P (P_{SE}) was calculated as:

$$P_{SE} = \sqrt{\frac{P(100-P)}{N}}$$

It is also important to capture the severity of the error. Each error report in the database contains an NPSA code for severity which is ordinal in character. I developed a severity index based on proportion of each harm category weighed for its severity.

For each hospital, the Severity (S) was calculated as a weighted sum: $S = \sum w_i n_i / n$, where w_i is the weight for the ith error severity category; n_i is the number of procedures where ith error severity category occurred; and n is the number of procedures where any error occurred.

3.4.2.3. Method of determining weights

The relative frequency of each harm category was calculated using the IPW (IPW = 1/ relative frequency) and IPW relative to the no harm category.

I therefore chose a weighting system computed as 2^i where i was the ordinal number of error severity category, from 0 for no harm to 4 for death. '2' was selected as it was the smallest possible integer that can be used to show a weighting effect and should therefore produce the most conservative estimate. The error severity was also rescaled to a range of 0 to 100 as done with S.

For this purpose, the harm categories were assigned numerical values from 0 to 4 (no harm = 0, low harm = 1, moderate harm = 2, high harm = 3, and death = 4) to reflect their natural order of severity. The weight assigned to the i^{th} harm category was 2^i.

$$S = \frac{100}{16}\left(\left(\sum_{i=0}^{4} 2^i \frac{n_i}{n}\right)\right)$$

where, n_i is number of procedures where i^{th} harm category occurred and n is the number of procedures where any error occurred. The constant term 100/16, 16 or 2^4, being the maximum value possible (when all reported errors were deaths) for the variable part of the formula, was used to adjust the scale of the index so that 100 was the maximum value, representing a situation where all errors reported resulted in deaths. The minimum value would be 6.67, representing the case where all reported errors produced no harm. I intentionally avoided rescaling S, 0 to 100, to differentiate between the situation where no errors were reported and some errors were reported but they were all in the no harm category.

The standard error of S was computed as:

$$S_{SE} = \frac{100}{16}\left(\sqrt{\sum_{i=0}^{4} 2^{2i}\left(\frac{p_i - p_i^2}{n}\right)}\right)$$

An exponential approach was used as the severity of incidents in most hospitals tends to increase in such a manner; there are several-fold more 'no harm' (also sometimes known as near misses) incidents than 'low harm' incidents; furthermore, the gradation from 'death' to 'no harm' incidents in any one year, follows an inverted pyramid, similar to Heinrich's ratio in which one can see that for

every one major incident, 29 minor injuries and 300 near-misses occurred previously. [Heinrich HW 1941]

3.4.2.4. Orthopaedic Error Index, OEI

I defined the OEI, E, as the weighted sum of error propensity and error severity:

$$E = 0.5P + 0.5S$$

This index gives equal weights for propensity, which captures the overall number of errors and severity of errors, because both aspects are considered important in dealing with errors. The weights were chosen so that E has a range of 0 to 100. The standard error of E was computed as:

$$E_{SE} = \sqrt{\frac{P_{SE}^2 + S_{SE}^2}{4}}$$

To identify reporting bias, I used the relationship between number of procedures and OEI. For this purpose I first meta-regressed the OEI on number of procedures and saved the predicted values of OEI.

3.4.2.5. Analyses

I estimated P, S, and OEI and their standard errors for each hospital using STATA 11 (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP). Since propensity, severity and the OEI deviated from normality, they were first transformed: OEI using a logarithmic transformation, and severity and propensity by taking their reciprocal values. I sought to identify outliers by creating control lines at one, two and three standard deviations (SD). I plotted OEI (per 1,000 procedures) against number of procedures and superimposed lines representing the mean and +/- 2SD and 3SD of predicted OEI values. Funnel plots provided a visual representation of the

data and have been used widely in health services research to compare institutions. I defined outliers as those with an OEI outside the range of $\mu \pm 3\sigma$, where μ is the mean and σ is the SD for the whole sample. These hospitals may require closer scrutiny. [Spiegelhalter DJ 2005]

3.4.3. Strengths and limitations

3.4.3.1. Strengths

Errors can be caused by active failures, for example, mistakes and latent conditions, such as failure of system processes. [Reason J 2000] Usually primary data from small, in-depth, qualitative inquiries are used to identify factors that contributed to the errors. The main strength of this approach is that data are specific for patient safety, but a major limitation is the trade-off between the depth and breadth of the analysis. I sought to investigate the use of routinely collected patient safety incident reports to create a numerical index that could help to provide a complementary perspective by supporting the monitoring of the overall system-wide safety of healthcare provision. Other key strengths of this work included drawing on a large national dataset, comprising of over 48,000 orthopaedic reports, and utilising the full body of data reporting on patient safety incidents spanning the full spectrum of severity from no harm to death. At present, the learning from national PSRSs is limited; some of the information is lost in translation and it is unclear whether all patient-safety incidents are indeed reported. [Lankshear A 2008] The sensitivity of the NRLS at picking up errors has been questioned [Sari AB-A 2007]. Furthermore, all hospitals use the same mechanism of reporting incidents, so the effects of bias and uncertainty are limited with the OEI. Nevertheless, this should not deter exploratory work such as mine. I was also cognisant of the fact that there was likely to be a variation in reporting according to the patient safety culture within hospitals; so a hospital with a high OEI may be one that has an open culture and encourages staff to report patient safety incidents. [NPSA 2004] Of equal importance was the fact that NRLS was a voluntary

reporting system until April 2010, when mandatory reporting was introduced for serious untoward incidents. [NPSA 2010c] In Figure 3.5 I showed that large hospitals (number of orthopaedic procedures) are associated with fewer errors. This must be interpreted with caution as I was not able to adjust for patient or procedure case-mix due to the paucity and anonymity of the data. Based on work elsewhere, it has been stipulated that specialised surgical services should be provided in tertiary hospitals, although geographical or logistical impediments may occur. [Shervin N 2007] I cannot make this claim based on my findings. Some local systems of risk management in hospitals opt for root cause analyses to develop local solutions to mitigate harm to patients, but these are not shared nationally, and limited information may be provided to national reporting systems. These systems rely on patient safety experts methodically trawling through patient safety incidents by severity and frequency, thereby leading to the production of quarterly reports, alerts and rapid response solutions. [NPSA 2009d] Such analyses are time consuming and, as the number of reports rapidly increases, may in the future be unsustainable. [Lamont T 2009; Catchpole K 2008b] There is also a non-cohesive approach globally to identifying unsafe hospitals. The multitude of quality indicators that are proxy measures of unsafe care is overwhelming. The OEI is a surveillance tool that can enable direct evaluation of safer care in hospitals. It is, I believe, a novel benchmarking tool to assess patient safety across hospitals using a large patient safety reporting system.

3.4.3.2. Limitations

There are several methodological limitations to the creation of the OEI. In creating the error propensity and severity, I built on the idea that the consequences of a medical error can vary from negligible to fatal. The error propensity index treats all reported errors equally. However, there is a qualitative difference between hospitals which have the same Ep, but in one the proportion of death harm is nearly double the other. Therefore, it was necessary to create a second variable, severity.

When calculating, the IPW in the manner I chose, two important drawbacks need to be considered: first, high values were attributed to severe harm and death. Secondly, the generalisability or external validity of these findings is unknown such that another dataset with a different distribution may have yielded different weights.

My finding that greater harm categories occur less frequently than 'no harm' or 'low harm' incidents was confirmation of the famous Heinrich ratio, although this was not formally assessed. [Heinrich HW 1941] Referring to the ratio, an expert group on learning from adverse events in the NHS argued for the importance of reporting near misses:

> *"Not all unsafe systems produce bad outcomes all the time. The potential for disasters may exist, but for any number of reasons those disasters might not occur at all, or occur very rarely – what has been termed 'a dynamic non-event'. If there are no bad outcomes to monitor, safety information systems need to collect, analyse and disseminate information from incidents and near misses, as well as from regular proactive checks on the system's 'vital signs'."* [Department of Health 2000]

General limitations were those inherent to any secondary analysis of data, including the absence of specific information needed and necessities of using proxies. Ideally, I would have preferred to link HES data to corresponding NRLS incidents. At present, this is not possible, as the latter does not allow for patient identification via NHS identification numbers. HES data will also give an approximation of orthopaedic and trauma procedures due to coding inaccuracies. However, these are, I believe, largely mitigated in the present analysis by the fact that the data were collected to study error and I refer to my analyses as secondary only because the analysis approach I employed was unanticipated when the study was designed. However, the OEI has several potential limitations. Reporting of patient safety incidents is a subjective exercise and variation in the dataset is bound to

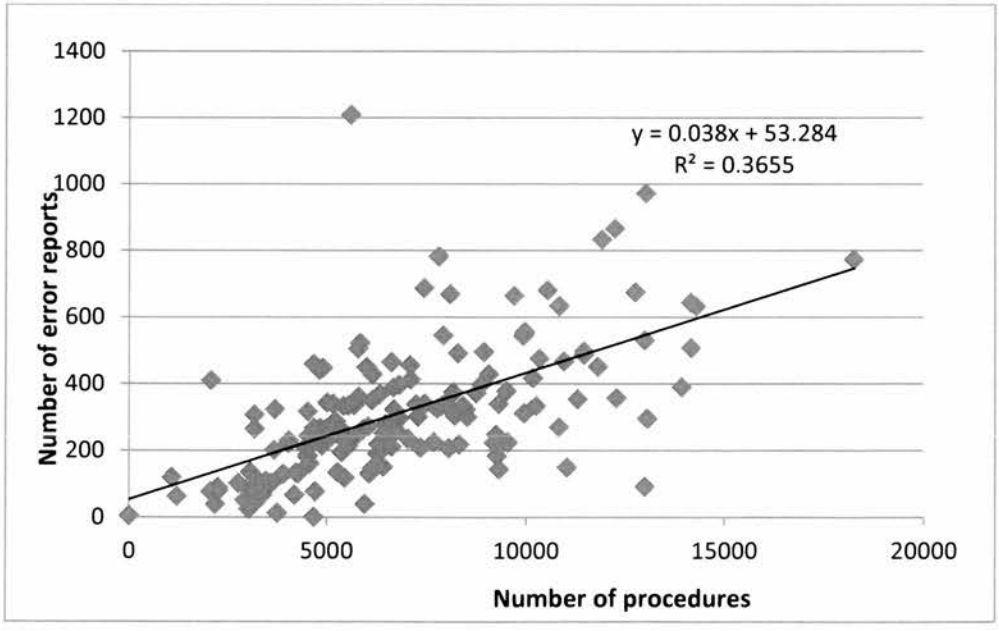
exist. Biases also exist at several levels: reporting of harmful versus non-harmful events and correct classification of categories of harm. [Heinrich HW 1941] Underlying factors for these biases, such as the level of patient safety culture within institutions, were not assessed. [Department of Health 2000] Further work on measuring the extent and likely impact of such biases is therefore now needed.

3.4.4. Results

3.4.4.1. OEI for all hospitals in England

In England, 155 NHS hospitals reported 48,971 patient safety incidents with varying degrees of harm: 34,530/48,971 (70.5%) no harm; 11,529/48,971 (23.5%) low harm; 2,632/48,971 (5.4%) moderate harm; 217/48,971 (0.4%) severe harm; and 63/48,971 (0.1%) deaths in the specialty of trauma and orthopaedic surgery during 2009–2010. The mean hospital OEI was 7.09 (SD 2.72). There was a correlation between the number of procedures and error reports of 0.40; therefore an increase of 1,000 orthopaedic procedures generated approximately 38 additional error reports (Figure 3.4).

Figure 3.4: Relationship between number of error reports and volume of procedures



3.4.4.2. Identifying outlier hospitals

Among the 155 hospitals, five lay outside the pre-specified control limits (Figure 3.5). These were hospitals which had relatively small numbers of procedures, but high OEI values. Table 3.10 identifies the key characteristics of these outliers.

Figure 3.5: The Orthopaedic Error Index for all hospitals in England

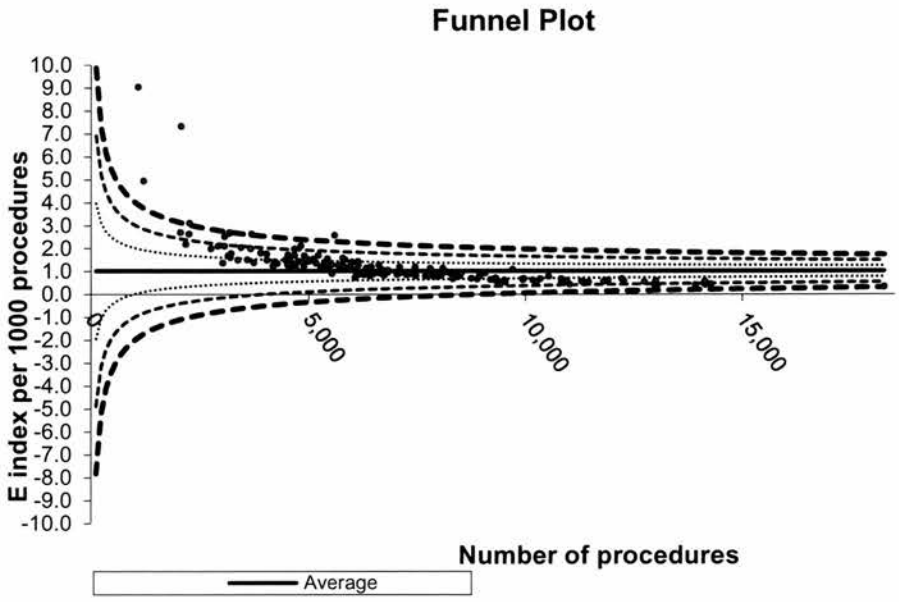


Table 3.10: Hospitals identified as outliers that warrant attention (outside 3 standard deviations from the mean Orthopaedic Error Index)

	Cluster	No. of orthopaedic procedures	No. of incidents reported	Orthopaedic Error Index (OEI)	Standard Error (SE) of OEI
1	Acute specialist hospital (including acute specialist children)	1,093	120	9.89	0.72
2	Medium acute hospital	5,601	1,209	14.46	0.28
3	Small acute hospital	2,085	410	15.29	0.51

4	Acute specialist hospital (including acute specialist children)	1,222	63	6.04	0.42
5	Acute specialist hospital (including acute specialist children)	2,277	80	7.10	0.63

3.4.5. Discussion

The OEI is the first attempt to develop automated procedures to interrogate a national database of patient safety incidents in order to identify hospitals at disproportionate risk of iatrogenic harm. Applying this tool to all hospitals providing orthopaedic care identified five outlying hospitals: three tertiary care providers and two secondary care providers. Whilst the higher rates may be expected because of case-mix considerations in the tertiary care sites, such deviations are not to be expected in the secondary care providers.

One of these two secondary care providers has subsequently been highlighted nationally as providing sub-standard care due to failures in administration, management and nursing. [Robert Francis Inquiry Report 2012]

At present, the NHS and other health systems internationally lack direct indicators of safety. Mortality is a proxy measure and cannot be used in isolation to assess the safety of a hospital. Opponents argue that the construction of HSMRs is flawed as the index is unable to discriminate between inevitable and preventable deaths, and that the huge variability in care suggested by these metrics cannot be accounted for by variable quality of care alone. [Lilford R 2010] Nevertheless, one of the hospitals that I identified as an outlier, and that has been the subject of national inquiries, was also noted to have a high HSMR; an excess of up to 1,200 deaths occurred here. [Dyer C 2011a] I

have thus shown that a PSRS, which until recently has been used as a repository collecting reports of errors, can be used to identify institutions that may pose a disproportionate risk to patient safety.

I have created a novel metric, the OEI, which is a direct marker of patient safety in individual hospitals. The thrust behind this idea has been the occurrence of several high-profile cases of hospitals such as Alder Hey, Mid Staffordshire and Stockport NHS hospitals where a catalogue of medical errors occurred that resulted in varying degrees of harm to the patient. [Delamothe T 2010] Most people would agree that in an era of large datasets, regulators and advisory bodies should have mechanisms to identify hospitals that are struggling to deliver high-quality care at an earlier stage so that corrective responses can be initiated. Despite alarming cases of unsafe care, it appears the NHS is still ill-equipped to identify high-risk hospitals through early warning systems. [Dyer C 2011b] More recently, attempts have been made in the UK to identify failing hospitals by using nationwide surveillance tools which collect data prospectively: the NHS Safety Thermometer that collects data on four domains: venous thromboembolism, urinary tract infections, pressure ulcers and falls; [NHS Safety Thermometer 2010] the National Surgical Quality Improvement Programme which collects measures of outcomes to improve surgical care; [American College of Surgeons 2012] and the Global Trigger Tool which measures adverse events. [IHI Global Tigger Tool] However, not all hospitals use these tools. Mine is the first tool that uses data from an entire national healthcare system.

3.4.5.1. Strengths and limitations

Errors can be caused by active failures, for example, mistakes and latent conditions, such as failure of system processes. [Reason J 2000] Usually primary data from small, in-depth, qualitative inquiries are used to identify factors that contributed to the errors. The main strength of this approach is that data are specific for patient safety, but a major limitation is the trade-off between the depth and

breadth of the analysis. I sought to investigate the use of routinely collected patient safety incident reports to create a numerical index that could help to provide a complementary perspective by supporting the monitoring of the overall system-wide safety of healthcare provision. Other key strengths of this work include drawing on a large national dataset, comprising of over 48 000 orthopaedic reports, and utilising the full body of data reporting on patient safety incidents spanning the full spectrum of severity from no harm to death. At present, the learning from national PSRSs is limited; some of the information is lost in translation and it is unclear whether all patient-safety incidents are indeed reported. [Lankshear A 2008] The sensitivity of the NRLS at picking up errors has been questioned in the past [Sari AB-A 2007] and the low power of the study limits generalisability of results to the entire NRLS. Furthermore, all hospitals use the same mechanism of reporting incidents, so the effects of bias and uncertainty are limited with the OEI. Nevertheless, this should not deter exploratory work such as mine. I am also cognisant of the fact that there is likely to be a variation in reporting according to the patient safety culture within hospitals; so a hospital with a high OEI may be one that has an open culture and encourages staff to report patient safety incidents. [NPSA 2004] Of equal importance is the fact that NRLS was a voluntary reporting system until April 2010, when mandatory reporting was introduced for serious untoward incidents. [NPSA 2010c] In Figure 3.5 I showed that large hospitals (number of orthopaedic procedures) are associated with fewer errors. This must be interpreted with caution as I have not been able to adjust for patient or procedure case-mix due to the paucity and anonymity of the data. Based on work elsewhere, it has been stipulated that specialised surgical services should be provided in tertiary hospitals, although geographical or logistical impediments may occur. [Shervin N 2007] I cannot make this claim based on my findings. Some local systems of risk management in hospitals opt for root cause analyses to develop local solutions to mitigate harm to patients, but these are not shared nationally, and limited information may be provided to national reporting systems. These systems

rely on patient safety experts methodically trawling through patient safety incidents by severity and frequency, thereby leading to the production of quarterly reports, alerts and rapid response solutions. [NPSA 2009d] Such analyses are time consuming and, as the number of reports rapidly increases, may in the future be unsustainable. [Lamont T 2009; Catchpole K 2008b] There is also a non-cohesive approach globally to identifying unsafe hospitals. The multitude of quality indicators that are proxy measures of unsafe care is overwhelming. The OEI is a surveillance tool that can enable direct evaluation of safer care in hospitals. It is, I believe, a novel benchmarking tool to assess patient safety across hospitals using a large patient safety reporting system.

The main limitations are those inherent to any secondary analysis of data, including the absence of specific information needed and necessities of using proxies. Ideally, I would have preferred to link HES data to corresponding NRLS incidents. At present, this is not possible, as the latter does not allow for patient identification via NHS identification numbers. HES data will also give an approximation of orthopaedic and trauma procedures due to coding inaccuracies. However, these are, I believe, largely mitigated in the present analysis by the fact that the data were collected to study error and I refer to my analyses as secondary only because the analysis approach I employed was unanticipated when the study was designed. However, the OEI has several potential limitations. Reporting of patient safety incidents is a subjective exercise and variation in the dataset is bound to exist. Biases also exist at several levels: reporting of harmful versus non-harmful events and correct classification of categories of harm. [Heinrich HW 1941] Underlying factors for these biases, such as the level of patient safety culture within institutions, were not assessed. [Department of Health 2000] Further work on measuring the extent and likely impact of such biases is therefore now needed.

3.4.5.2. Conclusions

With the proliferation of PSRSs around the world and an ever-increasing number of patient safety incidents reported to them, sophisticated analytical techniques are required to identify hospitals that need to strengthen their emphasis on patient safety. This is the first time, to my knowledge, that a surveillance mechanism for safety has been proposed using a reporting system.

4. Limitations of the dataset

Whereas the NRLS has provided what, in some cases, are the first insights into key areas of unsafe care in orthopaedic surgery and offered candidate solutions to prevent their recurrence, several limitations of this database exist and these have been grouped as follows: comprehensiveness and quality.

4.1. Comprehensiveness

The comprehensiveness of the data in the NRLS varies from organisation to organisation. The NRLS comprised data collected by over 400 different NHS Trusts, each with varying systems that collect and store data. Counts of incidents are simply incidents reported to the NPSA – they are likely to represent only a small subset of the number of incidents that actually occurred. Incident reports are often made soon after the incident occurs, but before the incident has been investigated locally. Therefore, reports to the NRLS may not contain complete information about the incident, especially findings of more detailed investigations such as root cause analysis. [Lamont T 2009; Wu AW 2008]

Some incidents recorded in local risk management systems and subsequently forwarded to the NRLS may not technically be patient safety incidents. For example, deaths from natural causes which occurred in hospital, and also deaths where patients died unexpectedly without any associated patient safety incident, are sometimes reported to local risk management systems, for local audit purposes, and hence are reported to the NRLS. The data are likely to include incidents where the impact on the patient is not clear, or where it is not clear if the incident could have been avoided. For example, suicides are often reported to local risk management systems in cases where the event could not have been prevented by health services. [Lamont T 2009]

It is also important to note that a higher number of reported incidents from a trust, specialty or location does not necessarily mean that the trust, specialty or location has a higher number of incidents; it may instead reflect greater levels of reporting. An increase in the number of incidents reported should not be taken as an indication of a worsening of patient safety, but rather an indication of increasing levels of awareness of safety issues amongst healthcare professionals.

[Robinson Wolf Z 2008, Stratton KM 2004, Mayo AM 2004] It might also indicate a worsening safety profile. However, experience in other industries has shown that as an organisation's reporting culture matures, staff become more likely to report incidents. However, even in high reporting organisations, many incidents do not get reported. [Sari AB-A 2007]

Reporting levels and rates from trusts vary greatly. Some trusts report daily, others not at all. In many cases, incidents are batched and sent in large loads. It should never be assumed that the total number of patient safety incidents is representative of totals across the NHS. The reporting culture varies between trust types. Reporting in secondary care is far greater than that in primary care. Ambulance and mental health organisations have the most varied reporting patterns. Quarterly data reports reveal the patient safety reporting tendency of trusts. [NPSA 2011a]

4.2. Quality

The reporting of degree of harm in the NRLS is intended to be the actual degree of harm suffered by the patient. There can be confusion between the potential degree of harm of an incident with actual degree of harm that occurred, for example coding near misses (where no harm resulted) as severe harm or death. The NRLS requires the degree of harm to reflect the actual and not the potential degree of harm caused by the patient safety incident. [NPSA 2004] The data in the NRLS are not checked with the reporter as the data are confidential. So there is no way to verify or clarify the contents of the incidents. Information on the identities of individual staff or patients is not held. Within the NRLS, steps are taken to maximise the quality of the data held by checking for duplicate reports and feeding back to individual trusts if there are problems with their reports.

When performing analysis on patient demographics, it is important to take into account missing data. Gender is completed for approximately 70% of patients, age in 66% and ethnicity for only 20% of patients. [Personal communication with Information Analysis Team, NPSA] It should not be assumed that the missing data are evenly distributed and levels of missing data should be stated in any output. The lack of a denominator also limits epidemiological work. [Lamont T 2009]

4.3. Epidemiological trends

The NRLS was established in 2004 and all trusts were connected by 2005. The NPSA worked with trusts to increase their reporting, and to promote a more open culture in healthcare services.

Experience in other industries has shown that as an organisation's reporting culture matures, staff become more likely to report incidents. However, even in high reporting organisations, many incidents do not get reported. [Sari AB-A 2007] Epidemiological work using the NRLS is in its infancy, although the work in this thesis should provide the momentum for others to explore this area further.

4.4. Reporting rates

Reporting levels and rates from trusts vary greatly. Some trusts report daily, others not at all. In many cases, incidents are batched and sent in large loads. It should never be assumed that the total number of patient safety incidents is representative of totals across the NHS. The reporting culture varies between trust types. Reporting in secondary care is far greater than that in primary care. Ambulance and mental health organisations have the most varied reporting patterns. Quarterly data reports reveal the patient safety reporting tendency of trusts. [NPSA 2011a]

5. Discussion

The challenges to improving patient safety in healthcare remain significant. This national database represents an important step and resource in ensuring that information about adverse events is both learned from and shared throughout the NHS. All clinicians, regardless of specialty, can contribute to these efforts by reporting patient safety incidents to the NRLS. Whilst important challenges remain in relation to encouraging fuller, franker and more comprehensive reporting, and then meaningfully analysing these data, it is, I believe, fair to conclude that very substantial progress has been made. As a clear leader in reporting systems, the successes and failures of the NRLS are likely to have major implications on reporting systems in other parts of the UK and internationally, and so it is that I suggest very much in the collective interests of patients nationally and internationally that we, irrespective as a profession, engage with, report to and make use of this resource to the best of our ability. In the next section, I will raise key questions on the NRLS; answers to these are important if we are to engage orthopaedic surgeons, and indeed the wider healthcare community, with better reporting and learning.

The aim of orthopaedic surgery is to ensure that the patient reaches the optimal condition in the shortest possible amount of time by using the safest possible techniques. Indeed the specialty has grown exponentially from rudimentary approaches of fracture reduction to sophisticated implants for fixation. These advances have been made possible through better understanding of tribology, [Walker PS 1971] which has resulted in one of the greatest contributions of orthopaedic surgery: hip replacement surgery.

Primum non nocere or 'First do no harm' is a sacrosanct term that should underpin surgical practice. Whereas this guiding principle is applied to the best of a surgeon's ability, medicine is no longer

'simple, ineffective and relatively safe' but rather 'complex, effective and potentially dangerous'. [Chantler C 1999] There are 234 million operations carried out globally each year, with almost seven million patients having major complications, and one million dying during or immediately following surgery. [Weiser TG 2008] The expansion in surgery has been made possible through extraordinary technological advances delivering considerable benefits for patients. Outcomes have improved significantly and increasingly complex surgical procedures are accepted as commonplace. The increasing complexity has made it much more difficult to deliver reliable care. The number of patients that receive everything that is expected is surprisingly low, whilst the number of those that experience some error, either of omission or commission, is surprisingly high. [Emerton M 2009] Over a six-month period in one US surgical centre, a death rate due to error of one in 270 (0.4%) was found, of which 65% (12.6% of all deaths) were deemed preventable. [Calland JF, 2002] At present, surgery has been categorised as a 'very unsafe' industry with a total rate of fatal adverse events estimated at one per 10,000. In trauma surgery, the rate of serious complications is one in 100. When these statistics are contrasted to civil aviation, railway transport and nuclear power, where the rate of death is less than one per million exposures, healthcare emerges as dangerous. [Amalberti R 2005] In addition to the cost of morbidity and mortality, there is an added financial cost. Clinical negligence claims cost £860 million in the financial year 2010/11. This is a staggering 9% increase on the previous financial year. Undoubtedly the advent and commonplace nature of 'no win no fee' legal firms has added to this encumbrance. According to the NHSLA, the highest number of clinical negligence claims came from surgical specialties. Of these, orthopaedic surgery was the worst offending specialty with 87/292 (29.8%) of all cases. [Robinson PM 2011]

This leads us to pose the question of whether the burden of errors in orthopaedic surgery is a result of the ever-increasing complexity and volume of surgical procedures, failure to embrace a safer culture, or a combination of both. Almost a decade ago, the landmark report *An Organisation with a*

Memory [Department of Health 2000] highlighted that serious failures in healthcare do occur; 10% of all hospital patients experience a medical error and half of these are preventable. It also affirmed the need to prevent these errors by improving mechanisms for reporting and learning through the creation of a national database of errors, promoting an open culture to discuss errors, developing and implementing change where errors occur, and a better understanding of the systems approach to understanding errors. This led to the birth of the NPSA which originally housed the NRLS. It is the largest database of patient safety incident reports in the world and has a repository of 900,000 errors annually. Of note, a high proportion of all surgical patient safety incidents are related to the specialty of orthopaedics and trauma (145,743/446,184; 32.6%). [Panesar SS 2012] Opponents have argued that the inherent biases of self-reporting systems limit meaningful interrogation of data. [Vincent C 2008] Proponents argue that there could be an element of under-reporting; nevertheless useful lessons can still be learned. Analysis of the database has led to a number of important insights that are helping to shape national policy – for example, the recognition of the risk of bone cement implantation syndrome associated with use of cement in hip fracture surgery, and the potential for IT-based interventions to reduce many cases of drug allergy related morbidity. [Panesar SS 2009b; Cresswell KM 2008] During the write-up of this thesis, the case of bone cement implantation syndrome due to cemented hip replacements, as outlined in section 3.3.5, has followed an almost similar course to that of metal-on-metal hip replacements. Work undertaken at the NPSA suggested that there is an increased risk with the use of cement when using hip prostheses. [NPSA 2009c] Whereas some orthopaedic surgeons accepted the risks and instituted the mitigating suggestions suggested by the NPSA alert on the subject, a significant number chose to ignore it. [Timperley AJ 2009] Indeed this, together with many other examples, falls under the poor safety culture that prevails in parts of the NHS. Recently, this has been described as 'normalisation of deviance and wilful blindness.' [Halligan A 2013] The effect of this poor practice is two-fold: the first being that a

certain degree of harm, albeit small in relative terms, is considered acceptable, and the second being that staff avert their gaze from unsafe care practices and choose not to report patient safety incidents. Don Berwick in his review into patient safety in the NHS (2013) stressed the need for constant vigilance of staff towards errors. [National Advisory Group on the Safety of Patients in England 2013] Indeed, he suggested that managers were ignoring high mortality rates, patient safety and inconvenient facts in order to meet performance management targets. Staff were blinded by the events around them and assumed that the standards being tolerated were normal. [Donnelley L 2013] This behaviour of normalising deviant behaviour is likely to have an effect on the frequency and types of incidents that are reported to the NRLS, thereby contributing to the incompleteness of the dataset.

The NRLS has consistently high-reporters and an equal number of low-reporters. [NPSA 2011a] If reporting rates vary, and the quality of reports is also heterogeneous, these pose a threat to robust and meaningful findings from the NRLS. [NPSA 2011a] The NRLS also faces varying proportions of reports from different clinical groups: nurses report more than doctors. [Panesar SS 2009a] Consequently there is no shortage of data on falls and pressure ulcers. Whilst this is important, the lack of engagement by doctors is of grave concern. [Panesar SS 2009c] Even though the work in this thesis has answered some questions and posed others, one key issue remains: there is an incomplete picture of errors portrayed by the NRLS due to under-reporting and it is unclear what effect complete reporting by all professionals and organisations will have on the results in this undertaking.

So, this begs the question, how can we improve the utility of the NRLS by the orthopaedic community? At present, there are several reporting systems. The one with significant coverage of participants (orthopaedic surgeons) is the National Joint Registry System, which is a voluntary system that collects data on joint replacements from NHS hospitals and the independent healthcare

sector. At present, it has 90% coverage, [National Joint Registry] which is far superior to the level of reporting to the NRLS. Data are collected on demographics and outcomes. The agenda is driven by the orthopaedics community. As such, an approach in the future might be to link the NRLS to the National Joint Registry to encourage reporting and learning. Another alternative might be for the National Joint Registry to start supplying data to the NRLS. Both these approaches require a more collaborative way of working between the NJR and the NRLS. Another school of thought is to have key 'Never Events' or sentinel events such as wrong site surgery reported nationally with consequent fiscal penalties and leave the reporting and learning of other types of errors, especially the near-misses, to local organisations. [Department of Health 2011a] Continuous quality improvement cycles could then be applied to eliminating or minimising these problems. [Department of Health 2013] Annual surveys might be another avenue worth exploring; the General Medical Council (GMC) now includes patient safety questions in its annual survey; [GMC 2011] the BOA could consider running one such survey to identify system and organisational failures in delivering safer care.

Another strong criticism of the NRLS, which is often cited by the wider clinical community and is common to all reporting systems, is the rather non-scientific way of analysing the database. The NRLS does not have specialists but general clinical reviewers assessing the incidents by severity of harm and using a consensus-based approach. [Lamont T 2009] A possible approach for the future would include the creation of an in-house research and development team which works with academics and clinicians to develop robust methodological approaches for analysing the database. These approaches should help to better identify the causes of errors and also allow the database to be used for surveillance. Initial attempts have been made to achieve these approaches: the Harms Susceptibility Ratio [Pham JC 2010b] and the OEI (see Section 3.4).

On a similar note, *Crossing the Quality Chasm* urges organisations who deliver care to ensure that six key aims are fulfilled; care should be safe, effective, patient-centred, timely, efficient and equitable. This is especially important in high-volume specialties, such as orthopaedic surgery. [IOM 2001] The Quality, Innovation, Productivity and Prevention (QIPP) agenda is one of the largest transformational programmes, which has stimulated a burgeoning need to embrace safety and quality. [Department of Health 2011b] Notable examples include redesigning clinical pathways for hip surgery that allow patients to receive evidence-based best practice and shorten the length of stay for such patients post-operatively. [Department of Health 2010b] Similar strides that promote local innovation in developing safer practices need to be encouraged. This behoves organisations to encourage newer ways of working in the specialty. Innovation must be encouraged so that services can be reconfigured to meet local needs and be up-scaled nationally if a clear benefit has been seen.

Further upstream of the orthopaedic patient journey lay two areas that warrant further attention. Even though procedures such as hip surgery have been described as the greatest operation of the 20th century, [Learmonth ID 2007] the variation in rate of provision of the procedure in the UK is almost 14-fold. Deprived populations have the lowest rate of arthroplasty. [NHS Right Care 2011] Can this variation, in part, be explained due to a lack of robust research? I accept that some variation might be due to clinical indications and fiscal rationing.

Historically, surgical decisions have largely been based on personal experience and recommendations from surgical authorities. In contrast to internal medicine, trials of surgical techniques and technologies have unique challenges and have therefore been slow to permeate the surgical literature. In addition, regulatory bodies have imposed less stringent controls on the validation of these technologies. As such, most surgical practice is based on lower levels of evidence. [Jones RS 2003] Current estimates suggest that less than 5% of the orthopaedic literature represent randomised

trials, although this has been steadily increasing. [Sung J 2008] However, even the quality of reporting in RCTs is highly variable. Complete reporting of allocation concealment, blinding, details of follow up and surgical expertise in trial reports has been uncommon. [Chan S 2007] Although many orthopaedic journals (i.e. *Journal of Bone and Joint Surgery, Clinical Orthopaedics and Related Research, Acta Orthopaedica, Journal of Orthopaedic Trauma* and *Orthopaedic Clinics of North America*) have adopted evidence-based approaches to reporting clinical research, there remain considerable opportunities to improve processes. Providing additional evidence-based resources and education for readers is a key first step. [Panesar SS 2010a] Whereas double-blinded RCTs would clearly be inappropriate, there is a need to explore alternative methods of building the evidence-base: expert-based RCTs, [Walter SD 2008] larger collaborative trials [Bhandari M 2009] and joint registries [Goldberg AJ 2012] are potential avenues.

The second barrier to ensuring a true patient safety culture is the lack of regulation of devices. A key example that has brought the specialty into disrepute is that of metal-on-metal hip replacements. These arrived on the market almost 15 years ago and were targeted at young, active men to serve as a joint replacement for life. Surgeons then began to use them in women too. Average seven-year failure rates were three times that of routinely-used hip implants made from other materials. [Cohen D 2012] The MHRA was alerted to the problem of mutagenicity resulting from the implants which caused poisoning by slow release of metal ions into the body. However, the regulator chose to downplay the risks by failing to publish an alert of the situation to surgeons and patients. Instead, its recommendation was to ensure that all patients signed a consent form, in which they should have been informed of potential risks with these implants. [MHRA 2007] The company that made these implants continued to ignore any suggestion of risk associated with the implant. The most recent study on the subject concluded that metal-on-metal stemmed implants give poor implant survival compared with other options and should not be implanted. [Smith AJ 2012] While it is unfair to

assume that all devices are poorly regulated, the case of metal-on-metal hip replacements alerts us to potential problems with regulation. A balance between increased regulation and innovation must be sought.

With the NHS reforms in place, there is no doubt that commissioning will be a key driving force for the provision of high-quality health services, reducing health inequalities and improving the health of the local population. Perhaps one way of ensuring high-quality care is to inter-twine hard measures of safety into the fabric of the commissioning process. Measures such as complication rates, complaints, compliments, readmission rates, outcomes, mortality and morbidity data, along with procedure specific data and patient experience questionnaires, should be up for scrutiny in the commissioning process. Quality improvement measures such as clinical dashboards, [NHS Connecting for Health 2009] specialty scorecards [Hammons D 2011] and system ratings [Leapfrog Group 2012] are all important tools that need to be disseminated wider in daily practice.

In this thesis, I sought to understand the opportunities offered by the NRLS to ascertain the frequency, types and causes of errors in orthopaedic surgery; this has been achieved and useful contributions have been made to the scientific literature in this area. I have also explored the potential of using the database to predict 'risky' hospitals and this work is currently the subject of peer-review in a leading medical journal. This will be the first time a direct measure of safety is used to benchmark hospitals against each other in the domain of safer care. Finally, I have offered a balanced discussion on the role of reporting systems for improving the care received by orthopaedic patients.

Orthopaedic surgery has the potential to be the exemplar during the zeitgeist of quality and safety. An ageing population will undoubtedly increase the musculoskeletal burden of disease.

Technological advances on their own are inadequate to deliver world-class care. In absolute terms, the number of orthopaedic patients suffering preventable adverse events is high. It is unacceptable to have almost half of all AAOS surgeons who agreed to a survey state that they had observed a medical error, of which 27 cases included wrong site surgery. [Wong DA 2009] Commissioners of care and payers, both national and private, should engage with and investigate any occurrences of 'Never Events'. This will shift the paradigm from a punitive to a blame-free culture and ensure lessons are learnt which can be disseminated within the wider orthopaedic community. Around the world, healthcare systems are identifying innovative ways of commissioning value-based services. Whereas the latest technological advance may not always suit the needs of the local population, quality and safety will be always be key in any proposed model of care. The use of a national reporting and learning system may help, in this respect.

References

Agency for Healthcare Research and Quality (AHRQ). Available online at http://www.ahrq.gov/about/stratpln.htm Last accessed on 30th June 2012.

Ahn J, Man LX, Park S, Sodl JF, Esterhai JL. Systematic review of cemented and uncemented hemiarthroplasty outcomes for femoral neck fractures. *Clin Orthop Relat Res.* 2008;466(10):2513-8

Allegranzi B, Bagheri Nejad S, Combescure C, Graafmans W, Attar H, Donaldson L, Pittet D. Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis. *Lancet* 2011;377(9761):228-41

Al-Obaydi W, Smith CD, Foguet P: Changing prophylactic antibiotic protocol for reducing Clostridium difficile-associated diarrhoeal infections. *J Orthop Surg* (Hong Kong). 2010;18(3):320-3

Amalberti R, Auroy Y, Berwick D, Barach P. Five system barriers to achieving ultrasafe health care. *Ann Intern Med.* 2005;142(9):756-64

American Association of State Highway and Transportation Officials (2010). Task Force on Development of the Highway Safety Manual. Highway Safety Manual. Washington, DC. (Fig 10-3).

American College of Surgeons National Surgical Quality Improvement Programme. Available at: http://site.acsnsqip.org/ http://www.facs.org/trauma/atls/index.html)

Arah OA, Klazinga NS: How safe is the safety paradigm? *Qual Saf Health Care.* 2004;13:226-32

Archibald LK, Banerjee SN, Jarvis WR: Secular trends in hospital-acquired Clostridium difficile disease in the United States, 1987-2001. *J Infect Dis.* 2004;189:1585-9

Atrey A, Gupte CM, Corbett SA. Review of successful litigation against English health trusts in the treatment of adults with orthopaedic pathology: clinical governance lessons learned. *J Bone Joint Surg Am.* 2010;92(18):e36.

Audit Commission. *United they stand Update.* (2001). Available at: http://www.audit-commission.gov.uk/nationalstudies/health/socialcare/pages/unitedtheystand.aspx

Australian Patient Safety Foundation (2010). Available at http://www.apsf.net.au/inc_report.php

Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *CMAJ.* 2004;170:1678-86

Barai KP, Jain R, Srinivasan MR. Does evidence confirm CE marked digital tourniquets are safer? *BMJ.* 2010. Available at http://www.bmj.com/rapid-response/2011/11/02/does-evidence-confirm-ce-marked-digital-tourniquets-are-safer

Barger LK, Ayas NT, Cade BE, Cronin JW, Rosner B, Speizer FE, et al. Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. *PLoS Med.* 2006;3(12):e487

Barrett J, Losina E, Baron J, Mahomed N, Wright J, Katz J. Survival following total hip replacement. *J Bone Joint Surg Am.* 2005;87(9):1965

Begg CB, Riedel ER, Bach PB, Kattan MW, Schrag D, Warren JL, et al. Variations in morbidity after radical prostatectomy. *N Engl J Med.* 2002;346:1138-44

Beyea SC, Hicks RW et al: Medication errors in the OR – A secondary analysis of Medmarx. *AORN J.* 2003;77:122-34

Bhandari M, Sprague S, Schemitsch EH. International Hip Fracture Research Collaborative. Resolving controversies in hip fracture care: the need for large collaborative trials in hip fractures. *J Orthop Trauma.* 2009;23(6):479-84

Bhandari M. Does early surgical repair of hip fractures improve patient outcomes? *CMAJ.* 2004;171(2):130

Birkmeyer JD, Siewers AE, Finlayson EVA, Stukel TA, Lucas FL, Batista I, et al. Hospital volume and surgical mortality in the United States. *N Engl J Med.* 2002;346:1128-37

BOA (2007). *The care of patients with fragility fracture.* 2007. Available at http://www.fractures.com/pdf/BOA-BGS-Blue-Book.pdf

BOA/British Geriatric Society (2007). *'Blue book' Guidance for the treatment of fragility fractures* (2007) BOA/BGS: London.

Bogner M. (ed) *Misadventures in Health Care.* (2004) LEA: Mahwah, NJ.

Bosma E, de Jongh MA, Verhofstad MH. Operative treatment of patients with pertrochanteric femoral fractures outside working hours is not associated with a higher incidence of complications or higher mortality. *J Bone Joint Surg Br.* 2010;92(1):110-5

Bottle A, Aylin P. Mortality associated with delay in operation after hip fracture: observational study. *BMJ.* 2006;332(7547):947-51

Bottle A, Jarman B, Aylin P. Strengths and weaknesses of hospital standardised mortality ratios. *BMJ* 2010;342:c7116. doi: 10.1136/bmj.c7116

Bredahl C, Nyholm B, Hindsholm KB, Mortensen JS, Olesen AS. Mortality after hip fracture: results of operation within 12 h of admission. *Injury.* 1992;23(2):83-6

Brennan, TA, Leape, LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *N Engl J Med.* 1991;324:370-6

Breusch S, Reitzel T, Schneider U, Volkmann M, Ewerbeck V, Lukoschek M. Cemented hip prosthesis implantation--decreasing the rate of fat embolism with pulsed pressure lavage. *Orthopade.* 2000;29(6):578

Buck N, Devlin HB and Lunn JN. The Report of a Confidential Enquiry into Perioperative Deaths. London: Nuffield Provincial Hospitals Trust and King's Fund Publishing Office. 1987

Butler T. Towards a hermeneutic method for interpretive research in information systems. Journal of Information Technology 1998;13(4):285-300.

Calland JF, Adams RB, Benjamin DK, Jr., O'Connor MJ, Chandrasekhara V, Guerlain S, Jones RS. Thirty-day postoperative death rate at an academic medical center. *Ann Surg* 2002;235-5:690-6; discussion 6-8.

Carretta E, Bochicchio V, Rucci P, Fabbri G, Laus M, Fantini MP. Hip fracture: effectiveness of early surgery to prevent 30-day mortality. *Int Orthop.* 2010

Catchpole K (2008a), Mishra, A, Handa, A, McCulloch, P. Teamwork and error in the operating room: analysis of skills and roles, *Annals of Surgery.* 2008;247(4):699-706

Catchpole K (2008b), Bell MD, Johnson S. Safety in anaesthesia: a study of 12,606 reported incidents from the UK National Reporting and Learning System. *Anaesthesia.* 2008;63(4):340-6

Catchpole K (2009), Panesar S, Russell J, Tang V, Hibbert P, Cleary K. Surgical Safety can be improved through better understanding of incidents reported to a national database. 2009. Available at http://www.nrls.npsa.nhs.uk/resources/?entryid45=63054

Chan S and Bhandari M. The quality of reporting of orthopaedic randomized trials with use of a checklist for nonpharmacological therapies. *J Bone Joint Surg Am.* 2007;89(9):1970-8.

Chantler C. The role and education of doctors in the delivery of health care. *Lancet* 1999;353-9159:1178-81.

Charnley J. Arthroplasty of the hip. Discussion. South African Orthopaedic Association *J Bone Joint Surg.* (Br) 1956;38:592

Charnley J. Anchorage of the femoral head prosthesis to the shaft of the femur. *J Bone Joint Surg.* (Br) 1960;42-B:28-30

Christie J, Robinson CM, Singer B, Ray DC. Medullary lavage reduces embolic phenomena and cardiopulmonary changes during cemented hemiarthroplasty. *J Bone Joint Surg Br.* 1995;77(3):456

Chua D, Jaglal SB, Schatzker J. An orthopedic surgeon survey on the treatment of displaced femoral neck fracture: opposing views. *Can J Surg.* 1997;40(4):271-7

Clarius M, Heisel C, Breusch SJ. Pulmonary embolism in cemented total hip arthroplasty. In: Breusch SJ, Malchau H, eds. *The Well Cemented Total Hip Arthroplasty.* Berlin, Heidelberg, New York: Springer Medizin Verlag. 320. 2005

Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. *N Engl J Med.* 2006;354(21):2205-8

Cochrane Collaboration. Measures of relative effect: the risk ratio and odds ratio, in *The Cochrane Handbook* p. 111-113

Cohen D. How safe are metal-on-metal hip implants? *BMJ* 2012;344:e1410.

Committee on Quality of Health Care in America 2011

Cooperation Council for the Arab States of the Gulf. Available online at http://www.gcc-sg.org/eng/indexa3c2.html?action=Sec-Show&ID=47 Last accessed on 30th June 2012.

CORESS. A confidential reporting system for surgery 2010. Available at http://www.coress.org.uk/

Corkill J, Lloyd E, Hoyle P, Crout D, Ling R, James M, et al. Toxicology of methyl methacrylate: the rate of disappearance of methyl methacrylate in human blood in vitro. *Clin Chim Acta.* 1976;68:141

Costain DJ, Whithouse SL, Pratt NL, Graves SE, Ryan P, Crawford RW. A review of peri-operative mortality after hemiarthroplasty using the Australian Orthopeadic Association National Joint Replacement Registry. Personal Communication, 2008

Cresswell KM, Sheikh A. Information technology-based approaches to reducing repeat drug exposure in patients with known drug allergies. *J Allergy Clin Immunol.* 2008;121:1112-7

Cushner F, Agnelli G, FitzGerald G, et al. Complications and functional outcomes after total hip arthroplasty and total knee arthroplasty: results from the Global Orthopaedic Registry (GLORY). *Am J Orthop (Belle Mead NJ).* 2010;39(9 Suppl):22-8

Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals. I. Occurrence and impact. *N Z Med J.* 2002;115:U271

De Boer HL, Houpt P. Rubber glove tourniquet: perhaps not so simple or safe? *Eur J Plastic Surg.* 2007;30:91-2

Dearborn JT, Harris WH. Postoperative mortality after total hip arthroplasty. An analysis of deaths after two thousand seven hundred and thirty-six procedures. *J Bone Joint Surg Am.* 1998;80(9):1291

Delamothe T. Repeat after me – "Mid-Staffordshire". *BMJ.* 2010;340:c188

Department of Health (2000). *An Organisation with a Memory.* London: The Stationery Office, 2000.

Department of Health (2009). Prevention Package for Older People. DoH; 2009. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103146

Department of Health (2010a). Best Practice Tariff. DoH; 2010b. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Managingyourorganisation/Financeandplanning/NHSFinancialReforms/DH_105080

Department of Health (2010b). Reducing length of stay following orthopaedic surgery: the Conquest Hospital in Hastings. http://www.dh.gov.uk/en/MediaCentre/Media/DH_112226 (date last accessed 24 May 2012).

Department of Health (2011a). *The Never Events List for 2011/12.* Available online: https://www.gov.uk/government/publications/the-never-events-list-for-2011-12

Department of Health (2011b). Quality, Innovation, Productivity and Prevention (QIPP). http://www.dh.gov.uk/en/Healthcare/Qualityandproductivity/QIPP/index.htm (date last accessed 24 May 2012).

Department of Health (2013). Berwick Review into patient safety. Available online: https://www.gov.uk/government/publications/berwick-review-into-patient-safety

Department of Orthopaedics SUH. *Swedish Arthroplasty Register Annual Report 2007.* In: Johann Karrholm GG, Cecilia Rogmark, Peter Heberts., ed. Goteborg: Sahlgrenska University Hospital. 2008

Der Tavitian J, Ong SM, Taub NA, et al. Body-exhaust suit versus occlusive clothing. A randomised, prospective trial using air and wound bacterial counts. *J Bone Joint Surg Br.* 2003;85:490

Devas MB. Geriatric orthopaedics. *Br Med J.* 1974;1(5900):190-2

Dijkman BG, Abouali JA, Kooistra BW, Conter HJ, Poolman RW, Kulkarni AV, et al. Twenty years of meta-analyses in orthopaedic surgery: has quality kept up with quantity? *J Bone Joint Surg Am.* 2010;92(1):48-57

Donabedian A. Evaluating the quality of medical care. *The Millbank Quarterly* 2005;83(4):691-729.

Donaldson AJ, Thomson HE, Harper NJ, Kenny NW. Bone cement implantation syndrome. *Br J Anaesth.* 2009;102:12-22

Donaldson L (2004). When will health care pass the orange-wire test? *Lancet.* 2004;364:1567-8

Donaldson L (2006), Fletcher MG et al: The WHO World Alliance for Patient Safety: towards the years of living less dangerously. *MJA.* 2006;184S69-S72

Donaldson L (2008). *On the state of public health: annual report of the Chief Medical Officer 2007.* July 14, 2008. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_086176

Donnelley L. NHS tsar: Mid Staffs scandal caused by the 'normalisation of deviance'. *The Telegraph.* 16 April 2013. http://www.telegraph.co.uk/health/put-patients-first/9999101/NHS-tsar-Mid-Staffs-scandal-caused-by-the-normalisation-of-deviance.html

Doro C, Dimick J, Wainess R, Upchurch G, Urquhart A. Hospital volume and inpatient mortality outcomes of total hip arthroplasty in the United States. *J Arthroplasty.* 2006;21(6 Suppl 2):10

Dorotka R, Schoechtner H, Buchinger W. The influence of immediate surgical treatment of proximal femoral fractures on mortality and quality of life. Operation within six hours of the fracture versus later than six hours. *J Bone Joint Surg Br.* 2003;85:1107-13

Dove AF, Clifford RP. Ischaemia after use of finger tourniquet. *Br Med J (Clin Res Ed).* 1982;284:1162-3

Dow A. We need a good anaesthetist for cemented THA. In: Breusch SJ, Malchau H, eds. *The Well Cemented Total Hip Arthroplasty.* Berlin, Heidelberg, New York: Sringer Medizin Verlag. 302. 2005

Dyer C (2011a). Head of Healthcare Commission excised figures on excess deaths from Mid Staffordshire report. *BMJ* 2011;342:d2900

Dyer C (2011b). Regulators are likely to miss failing trusts now, says Mid Staffordshire head. *BMJ* 2011;342:d1778

ElBardissi AW, Wiegmann DA, Henrickson S, Wadhera R, Sundt TM 3rd. Identifying methods to improve heart surgery: an operative approach and strategy for implementation on an organizational level. *Eur J Cardiothorac Surg.* 2008;34(5):1027-33

Emerton M, Panesar SS, Forrest K. Safer surgery: how a checklist can make orthopaedic surgery safer. *Orthopaedics and Trauma* 2009;23-5:377-80

Emery RJ, Broughton NS, Desai K, Bulstrode CJ, Thomas TL. Bipolar hemiarthroplasty for subcapital fracture of the femoral neck. A prospective randomised trial of cemented Thompson and uncemented Moore stems. *J Bone Joint Surg Br.* 1991;73(2):322

European Commission. Patient Safety. Available online at http://ec.europa.eu/health-eu/care_for_me/patient_safety/index_en.htm Last accessed on 30th June 2012.

Fabri PJ, Zayas-Castro JL. Human error, not communication and systems, underlies surgical complications. *Surgery.* 2008;144(4):557-63; discussion 563-5

Foster AP, Thompson NW, Wong J, Charlwood AP. Periprosthetic femoral fractures--a comparison between cemented and uncemented hemiarthroplasties. *Injury.* 2005;36(3):424

Gardner-Thorpe J, Love N, Wrightson J, Walsh S, Keeling N. The value of Modified Early Warning Score (MEWS) in surgical inpatients: a prospective observational study. *Ann R Coll Surg Engl.* 2006;88(6):571-5

Gawande A. On washing hands. *N Engl J Med.* 2004;350:1283-6

Gdalevich M, Cohen D, Yosef D, Tauber C. Morbidity and mortality after hip fracture: the impact of operative delay. *Arch Orthop Trauma Surg.* 2004;124(5):334-40

Gilchrist WJ, Newman RJ, Hamblen DL, et al. Prospective randomised study of an orthopaedic-geriatric inpatient service. *BMJ.* 1988;297:1116-8

GMC. GMC Survey – Satisfaction in training continues to increase but concerns remain. (2011) Available online: http://www.gmc-uk.org/news/23045.asp

Goldberg AJ, MacGregor A, Spencer SA. An information revolution in orthopaedics. *J Bone Joint Surg Br* 2012;94-4:454-8

Gomez PF, Morcuende JA. A historical and economic perspective on Sir John Charnley, Chas F. Thackray Limited, and the early arthoplasty industry. *Iowa Orthop J.* 2005;25:30-7

Gordon NLM, Dawson AA, Bennett B, Innes G, Eremin O, Jones PF. Outcome in colorectal adenocarcinoma: two seven-year studies of a population. *BMJ.* 1993;307(6906):707-10

Green J. Commentary: grounded theory and the constant comparative method. *BMJ.* 1998;316:1064-5

Green J. Thorogood, N. Qualitative Methods for Health Research. (2nd edition) (2009) Sage (London).

Grimes JP, Gregory PM, Noveck H, Butler MS, Carson JL. The effects of time-to-surgery on mortality and morbidity in patients following hip fracture. *Am J Med.* 2002;112(9):702-9

Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. *Osteoporos Int.* 1997;7:407-13

Haas F, Moshammer H, Schwarzl F. Iatrogenic necrosis of the large toe after tourniquet placement – clinical course and reconstruction. *Chirurg.* 1999;70:608-10

Haleem S, Lutchman L, Mayahi R, Grice JE, Parker MJ. Mortality following hip fracture: trends and geographical variations over the last 40 years. *Injury.* 2008;39:1157-63

Halligan A. The Francis report: what you permit, you promote. *J R Soc Med.* 2013 Apr;106(4):116-7

Hammons D. Central East Local Health Integration Network. Orthopedic Quality Scorecard 2011. http://www.centraleastlhin.on.ca/uploadedFiles/Home_Page/Board_of_Directors/Board_Meeting_Submenu/5_3_-_June_29_2011_CEO_Report_to_the_Board.pdf. (date last accessed 7 August 2012).

Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med.* 2009;360(5):491-9

Healey F, Darowski A, Lamont T, Panesar S, Poulton S, Treml J, Wiese M. Essential care after an inpatient fall: summary of a safety report from the National Patient Safety Agency. *BMJ.* 2011; 342:d329. doi: 10.1136/bmj.d329

Healey MA, Shackford SR, Osler TM, Rogers FB, Burns E. Complications in surgical patients. *Arch Surg.* 2002;137(5):611-8

Heinrich HW. *Industrial Accident Prevention: A Scientific Approach.* New York and London, 1941.

Hickner J, Zafar A, Kuo GM, Fagnan LJ, Forjuoh SN, Knox LM, et al. Field test results of a new ambulatory care medication error and adverse drug event reporting system--MEADERS. *Ann Fam Med.* 2010;8:517-25

Hill C, Flamant R, Mazas F, et al. Prophylactic cefazolin versus placebo in total hip replacement. Report of a multicentre double-blind randomised trial. *Lancet.* 1981;1:795

Hixson FP, Shafiroff FF, Werner FW, Palmer AK. Digital tourniquets : A pressure study with clinical relevance, *J Hand Surg.* 1986;11-A:865-7

Hoffman JR, Schriger DL, Mower W, Luo JS, Zucker M. Low-risk criteria for cervical-spine radiography in blunt trauma: a prospective study. *Ann Emerg Med.* 1992;21:1454-60

Holt EM, Evans RA, Hindley CJ, Metcalfe JW. 1000 femoral neck fractures: the effect of pre-injury mobility and surgical experience on outcome. *Injury.* 1994;25(2):91-5

Horton R. Surgical research or comic opera: Questions, but few answers. *Lancet.* 1996;347:984-5

Hospital Episode Statistics. Available at: http://www.hscic.gov.uk/hes

Humphreys H. Preventing surgical site infection. Where now? *J Hosp Infect.* 2009;73(4):316-22

Hurwitz B, Sheikh A (eds.). *Health care errors and patient safety* 2009 Oxford: Wiley Blackwell

IHI Global Trigger Tool. Available at: http://www.ihi.org/knowledge/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx

IOM. *Crossing the Quality Chasm: A New Health System for the Twenty-first Century.* (2001) Washington: National Academy Press

Jeder Fehler Zaehlt. (2010). Available at: http://www.jeder-fehler-zaehlt.de/

Jones RS, Richards K. Office of Evidence-Based Surgery charts course for improved system of care. *Bulletin of the American College of Surgeons* 2003;88-4:11-21.

Kennie DC, Reid J, Richardson IR, et al. Effectiveness of geriatric rehabilitative care after fractures of the proximal femur in elderly women: a randomised clinical trial. *BMJ* 1988;297:1083-6

Khan RJ (2002a), MacDowell A, Crossman P, Datta A, Jallali N, Arch BN, Keene GS. Cemented or uncemented hemiarthroplasty for displaced intracapsular femoral neck fractures. *Int Orthop.* 2002;26(4):229

Khan RJ (2002b), MacDowell A, Crossman P, Keene GS. Cemented or uncemented hemiarthroplasty for displaced intracapsular fractures of the hip-a systematic review. *Injury.* 2002;33(1):13

King C, Henretig FM. *Textbook of pediatric emergency medicine.* 2nd ed. Wolters Kluwer Health, 2008

Kohn LT, Corrigan JM and Donaldson MS. (eds.) *To Err is Human: Building a Safer Health System.* 1999 Washington: National Academy Press.

Krumholz HM, Brindis RG, Brush JE, Cohen DJ, Epstein AJ, Furie K, et al. Standards for statistical models used for public reporting of health outcomes: An American Heart Association scientific statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group:. *Circulation* 2006;113;456-62

Lamont T, Scarpello J. National Patient Safety Agency: combining stories with statistics to minimise harm. *BMJ.* 2009;339:b4489

Lankshear A, Lowson K, Harden J, Lowson P, Saxby RC. Making patients safer: nurses' responses to patient safety alerts. *J Adv Nurs.* 2008;63(6):567-75

Lansley A. *Memorandum by Andrew Lansley.* House of Commons 2009. Available at: http://www.publications.parliament.uk/pa/cm200809/cmselect/cmhealth/151/151we52.htm

Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med.* 1991;324(6):377-84

Leape LL. Reporting adverse events. *N Engl J Med.* 2002;347(20):1633-8

Leapfrog Group. Leapfrog Hospital Safety Score 2012. http://hospitalsafetyscore.org/about-the-score/methodology.html (date last accessed 7 August 2012).

Learmonth ID, Young C, Rorabeck C. The operation of the century: total hip replacement. *Lancet* 2007;370-9597:1508-19

Lefaivre KA, Macadam SA, Davidson DJ, Gandhi R, Chan H, Broekhuyse HM. Length of stay, mortality, morbidity and delay to surgery in hip fractures. *J Bone Joint Surg Br.* 2009;91(7):922-7

Lilford R, Pronovost P. Using hospital mortality rates to judge hospital performance: a bad idea that just won't go away. *BMJ.* 2010;340:c2016

Lingard L, Espin S, Whyte S, Regehr G, Baker GR, Reznick R, et al. Communication failures in the operating room: an observational classification of recurrent types and effects. *Qual Saf Health Care.* 2004;13(5):330-4

Lipsett PA. Do we really need laminar flow ventilation in the operating room to prevent surgical site infections? *Ann Surg.* 2008;248:701

Lo WH, Chen WM, Huang CK, Chen TH, Chiu FY, Chen CM. Bateman bipolar hemiarthroplasty for displaced intracapsular femoral neck fractures. Uncemented versus cemented. *Clin Orthop Relat Res.* 1994;302:75

Love BR. The tourniquet and its complications. In: Proceedings of the Australian orthopaedic association. J *Bone Joint Surg.* 1979;61-B:239

Lubahn JD, Koeneman J, Kosar K. The digital tourniquet: How safe is it ? *J Hand Surg.* 1985;10-A:664-6

Malchau H, Herberts P, soderman P, Oden A. *Prognosis of total hip replacements. Update and validation of results from the Swedish National Hip Arthroplasty Registry 1979-1998.* Scientific exhibit at the 67th Annual Meeting of the American Academy of Orthopaedic Surgeons, Orlando, USA, 2000. In. 2000

Mallon WJ. *Ernest Amory Codman: The End Result of a Life in Medicine.* Philadelphia, Pa: WB Saunders; 2000

Malviya A, Martin K, Harper I, Muller SD, Emmerson KP, Partington PF, Reed MR. Enhanced recovery program for hip and knee replacement reduces death rate. *Acta Orthop.* 2011;82(5):577-81

Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Committee. *Infect Control Hosp Epidemiol.* 1999;20:250

Mayo AM, Duncan D. Nurse Perceptions of Medication Errors: What We Need to Know for Patient Safety. J Nurs Care Qual. 2004;19(3):209–17

MEDMARX. *MEDMARX report may aid in error prevention.* Healthcare Benchmarks and Quality Improvement. July 2002

MHRA (2007). Minutes of the Committee on the Safety of Devices meeting, 5 July 2007. http://www.mhra.gov.uk/home/groups/dts-bs/documents/medicaldevicealert/con2023076.pdf

MHRA (2010). Medical devices alert MDA/2010/001: medical devices in general and non-medical products. 2010. http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON065771

Morrison CA, Wyatt MM, Carrick MM. Impact of the 80-hour work week on mortality and morbidity in trauma patients: an analysis of the National Trauma Data Bank. *J Surg Res.* 2009;154(1):157-62

Morse JM, Morse RM. Calculating fall rates: Methodological concerns. *QRB Qual Rev Bull.* 1988;14:369-71

Naim S, Srinivasan MS. Digital tourniquets: a comparative analysis of pressures and pain perception. *Acta Orthop Belg.* 2008;74(2):195-9

Nakajima K, Kurata Y et al: A web-based incident reporting system and multidisciplinary collaborative projects for patient safety in a Japanese Hospital. *Qual. Saf. Health Care.* 2005;14:123-129

National Advisory Group on the Safety of Patients in England (2013). A promise to learn, a commitment to act: Improving the safety of patients in England. Department of Health.

National Clinical Guideline Centre. *The Management of Hip Fracture in Adults.* London: National Clinical Guideline Centre. Available at: www.ncgc.ac.uk

National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (2013). *Annual report: England, Northern Ireland, Scotland and Wales.* Available online: http://www.bbmh.manchester.ac.uk/cmhr/centreforsuicideprevention/nci/reports/AnnualReport2013_UK.pdf

National Joint Registry (2007). *National Joint Registry fourth annual report.* 2007. Available at: http://www-new.njrcentre.org.uk/njrcentre/AbouttheNJR/Publicationsandreports/Annualreports/tabid/86/Default.aspx

National Joint Registry. *NJR Stats Online.* Available at http://www.njrcentre.org.uk/njrcentre/Healthcareproviders/Accessingthedata/StatsOnline/NJRStatsOnline/tabid/179/Default.aspx

NCEPOD. *Who Operates When?* (1997) NCEPOD ISBN0 9522069 4 3 Available at: www.nceopd.org.uk

Neale G, Woloshynowych M, Vincent C. Exploring the causes of adverse events in NHS hospital practice. *J R Soc Med.* 2001 Jul;94(7):322-30.

NHFD. *Preliminary National Report.* 2009. Available at http://www.ccad.org.uk/nhfd.nsf/Preliminary_National_Report.pdf

NHS Confederation. *Variation in healthcare – does it matter and can anything be done?* Available at: http://www.nhsconfed.org/Publications/Documents/Variation%20in%20healthcare.pdf

NHS Connecting for Health. Clinical Dashboards Toolkit 2009. http://www.connectingforhealth.nhs.uk/systemsandservices/clindash/toolkit/about. (Last accessed 7 August 2012).

NHS Litigation Authority. *Reports and Accounts 2010-2011.* London, 2011

NHS Right Care 2011. Accessed on 16th August 2012 at http://www.rightcare.nhs.uk/index.php/atlas/atlas-of-variation-2011/

NHS Safety Thermometer. (Accessed on 16 August 2012 at http://www.ic.nhs.uk/services/nhs-safety-thermometer)

NICE (2007) *Clinical guideline 56: Head injury; triage, assessment, investigation and early management of head injury in infants, children and adults*

NICE (2008) *Surgical site infection: prevention and treatment of surgical site infection.* Available at http://www.nice.org.uk/Guidance/CG74

NICE (2009). *Scope of the Hip Fracture Guideline.* http://www.nice.org.uk/guidance/index.jsp?action=folder&o=43688

NICE (2011). *The Management of Hip Fracture in Adults.* http://www.nice.org.uk/CG124

Noble DJ, Panesar SS, Pronovost PJ. A public health approach to patient safety reporting systems is urgently needed. *J Patient Saf* 2011;7(2):109-12

NPSA (2004). *Seven Steps to Patient Safety.* Available online: http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787

NPSA (2007) *Slips, trips and falls in hospitals.* Available online at http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/patient-accidents-falls/?entryid45=59821

NPSA (2008a) Reporting anaesthetic patient safety incidents. Available at http://www.npsa.nhs.uk/nrls/improvingpatientsafety/anaesthesia-and-surgery/anaesthesia-current-projects/anaesthetic-incident-reporting/

NPSA (2009a) *Preventing suicide: a toolkit for mental health services.* Available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/mental-health/?entryid45=65297

NPSA (2009b) *Reducing risks of tourniquets left on after finger and toe surgery.* Available at www.nrls.npsa.nhs.uk/tourniquets

NPSA (2009c) *Rapid Response Report. Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur.* March 11, 2009. http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/mitigating-risks-when-using-bone-cement-in-hip-surgery/

NPSA (2009d). *Patient Safety Incident Reports in the NHS: National Reporting and Learning System Data Summary. Issue 6.* NPSA. 2009

NPSA (2010a) *NHS places reporting and learning from patient safety incidents at top of its agenda – England.* NPSA: London http://www.npsa.nhs.uk/corporate/news/nhs-places-reporting-and-learning-from-patient-safety-incidents-at-top-of-its-agenda-england/

NPSA (2010b) *Slips trips and falls data update.* NPSA: London http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/patient-accidents-falls/?entryid45=74567

NPSA (2010c). Reporting patient safety incidents. http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/about-reporting-patient-safety-incidents/

NPSA (2011a). Organisation Patient Safety Incident reporting data. Available online: http://www.npsa.nhs.uk/corporate/news/npsa-releases-organisation-patient-safety-incident-reporting-data-england/

NPSA (2011b). *Rapid Response Report: Essential care after an inpatient fall.* Available online: http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=94033

NRLS. Available at http://www.nrls.npsa.nhs.uk/

Orosz GM, Magaziner J, Hannan EL, Morrison RS, Koval K, Gilbert M, McLaughlin M, Halm EA, Wang JJ, Litke A, Silberzweig SB, Siu AL. Association of timing of surgery for hip fracture and patient outcomes. *JAMA.* 2004;291(14):1738-43

Orsini EC, Byrick RJ, Mullen JB, Kay JC, Waddell JP. Cardiopulmonary function and pulmonary microemboli during arthroplasty using cemented or non-cemented components. The role of intramedullary pressure. *J Bone Joint Surg Am.* 1987;69(6):822-32

Panesar SS (2009a), Cleary K, Sheikh A. Reflections on the National Patient Safety Agency's database of medical errors. *J R Soc Med.* 2009;102(7):256-8

Panesar SS (2009b), Cleary K, Bhandari M, Sheikh A. To cement or not in hip fracture surgery? *Lancet* 2009;374:1047-49

Panesar SS (2009c), Tang V, Cleary K, Sheikh A. Asthma patient safety incidents: national perspectives need to be informed by primary care reporting. Prim Care Respir J. 2009 Mar;18(1):1-2

Panesar SS (2010a) and Sheikh A. Improving patient safety: Lessons from the world's largest national database. *Annals of Family Medicine* 2010. Available at http://www.annfammed.org/cgi/eletters/8/6/517 Invited commentary to Hickner J, Zafar A, Kuo GM, Fagnan LJ, Forjuoh SN, Knox LM, Lynch JT, Stevens BK, Pace WD, Hamlin BN, Scherer H, Hudson BL, Oppenheimer CC, Tierney WM. Field Test Results of a New Ambulatory Care Medication Error and Adverse Drug Event Reporting System--MEADERS. *Ann Fam Med.* 2010;8(6):517-525

Panesar SS (2012), Carson-Stevens A, Mann BS, Bhandari M, Madhok R. Mortality as an indicator of patient safety in orthopaedics: lessons from qualitative analysis of a database of medical errors. *BMC Musculoskelet Disord.* 2012;13(1):93

Panesar SS, Netuveli G, Carson-Stevens A, Javad S, Patel B, Parry B, Donaldson LJ and Sheikh A. The orthopaedic error index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach. *BMJ Open* 2013;3(11):e003448

Parikh PD. Key trends for Orthopedic medical liability claims. Available at: http://www.aaos.org/news/aaosnow/nov09/managing4.asp

Parker MJ (1991), Anand JK. What is the true mortality of hip fractures? *Public Health.* 1991;105(6):443-6

Parker MJ (2006), Gurusamy K. Arthroplasties (with and without bone cement) for proximal femoral fractures in adults. CochraneDatabaseSystRev 3: CD001706, 2006

Parvizi J (1999), Holiday AD, Ereth MH, Lewallen DG. The Frank Stinchfield Award: sudden death during primary hip arthroplasty. *Clin Orthop Relat Res.* 1999;369:39-48

Parvizi J (2004), Ereth MH, Lewallen DG. Thirty-day mortality following hip arthroplasty for acute fracture. *J Bone Joint Surg Am.* 2004;86-A(9):1983

Patient Safety First Campaign. *The 'How To Do' Guide for reducing harm from deterioration.* (2009). Available at http://www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/How-to-guides-2008-09-19/Deterioration%201.1_17Sept08.pdf

Patient Safety International. (2010). Available at http://www.patientsafetyint.com/aims.aspx

Pennsylvania Patient Safety Authority. (2010). Available at http://patientsafetyauthority.org/PatientSafetyAuthority/Pages/AnnualReports.aspx

Pham JC (2010a), Gianci S, Battles J, Beard P, Clarke JR, Coates H, et al. Establishing a global learning community for incident-reporting systems. *Qual Saf Health Care.* 2010;19(5):446-51

Pham JC (2010b), Colantuoni E, Dominici F, Shore A, Macrae C, Scobie S, Fletcher M, Cleary K, Goeschel CA, Pronovost PJ. The harm susceptibility model: a method to prioritise risks identified in patient safety reporting systems. *Qual Saf Health Care.* 2010;19(5):440-5

Pitto RP, Koessler M, Draenert K (1998). The John Charnley Award. Prophylaxis of fat and bone marrow embolism in cemented total hip arthroplasty. *Clin Orthop Relat Res* 355: 23.

Plummer K (2001). The moral and human face of life stories: reflexivity, power and ethics. Documents of Life – 2. London: Sage. 204-230.

Pope C, Ziebland S, Mays N. Qualitative research in health care, analyzing qualitative data. *BMJ.* 2000;320:114-6

Pronovost P (2006), Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med.* 2006;355(26):2725-32

Pronovost PJ (2009), Goeschel CA et al. Reducing health care hazards: Lessons from the Commercial Aviation Safety Team. *Health Affairs.* 2009;28(3):479-89

Rasmussen J. Skills, rules, knowledge: signals, signs and symbols and other distinctions in human performance models. IEEE Trans Syst, Man, Cybern 1983; SMC-13: 257-67

Ray NF, Chan JK, Thamer M, Melton LJ III. Medical expenditures for the treatment of osteoporotic fractures in the United States in 1995: report from the National Osteoporosis Foundation. *J Bone Miner Res.* 1997;12:24-35

Reason J (1990). *Human Error.* 1990. Cambridge: University Press

Reason J (2000). Human error: models and management. *BMJ.* 2000;320(7237):768-70

Robert Francis Inquiry Report into Mid Staffordshire NHS Trust (2012). Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113018

Robinson PM, Muir LT. Wrong-site surgery in orthopaedics. *J Bone Joint Surg [Br].* 2009;91(10):1274-80

Robinson PM, Muir LT. Surgical errors in england and wales – how common are they and are orthopaedic surgeons really the worst? *J Bone Joint Surg Br* 2011;93B-SUPP III:295.

Robinson Wolf Z, Hughes RG. Chapter 35: Error reporting and disclosure. In: Hughes RG (ed) Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008.

Royal College of Surgeons of England (1987). *Application form for hospitals seeking recognition for surgical training.*

Royal College of Surgeons of England. *Surgery and the NHS in Numbers.* 2009. Available at: http://www.rcseng.ac.uk/media/media-background-briefings-and-statistics/surgery-and-the-nhs-in-numbers#_edn3

Santell JP, Hicks RW et al: Medication errors: Experience of the United States Pharmacopeia (USP) MEDMARX reporting system. *J Clin Pharmacol.* 2003;43:760-7

Sari AB-A, Sheldon TA, Cracknell A et al., Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review, *BMJ.* 2007;334(7584):79-81

Saw JA, Demuth WW, Gillespy A. Guidelines for the use of digital tourniquets. *J Bone Joint Surg.* 1985;67-A:1086-1090

Schelenz S, Tucker D, Georgeu C, Daly S, Hill M, Roxburgh J, Franch GL: Significant reduction of endemic MRSA acquisition and infection in cardiothoracic patients by means of an enhanced targeted infection control programme. *J Hosp Infect.* 2005;60:104-10

Schioler T, Lipczak H, Pedersen BL, Mogensen TS, Bech KB, Stockmarr A, et al. Incidence of adverse events in hospitals. A retrospective study of medical records. *Ugesker Laeger.* 2001;163:5370-8

Sharrock NE, Cazan MG, Hargett MJ, Williams-Russo P, Wilson PD, Jr. Changes in mortality after total hip and knee arthroplasty over a ten-year period. *Anesth Analg.* 1995;80(2):242

Sheikh A, Hurwitz B. A national database of medical error. *J R Soc Med.* 1999;92:554-55

Shervin N, Rubash HE, Katz JN. Orthopaedic procedure volume and patient outcomes: a systematic literature review. Clin Orthop Relat Res 2007;457:35–41.

Siegmeth AW, Gurusamy K, Parker MJ. Delay to surgery prolongs hospital stay in patients with fractures of the proximal femur. *J Bone Joint Surg Br.* 2005;87(8):1123-6

Sierra RJ, Timperley JA, Gie GA. Contemporary cementing technique and mortality during and after Exeter total hip arthroplasty. *J Arthroplasty.* 2008

SIGN. *Management of hip fracture in older people.* SIGN guidelines no. 111. (2009). Available at http://www.sign.ac.uk/pdf/sign111.pdf

Singh JA, Murphy S, Bhandari M. Assessment of the methodologic quality of medical and surgical clinical trials in patients with arthroplasty. *J Rheumatol.* 2009;36(12):2642-54

Sircar P, Godkar D, Mahgerefteh S, Chambers K, Niranjan S, Cucco R. Morbidity and mortality among patients with hip fractures surgically repaired within and after 48 hours. *Am J Ther.* 2007;14(6):508-13

Smektala R, Endres HG, Dasch B, Maier C, Trampisch HJ, Bonnaire F, Pientka L. The effect of time-to-surgery on outcome in elderly patients with proximal femoral fractures. *BMC Musculoskelet Disord.* 2008;29(9):171

Smith AJ, Dieppe P, Vernon K, Porter M, Blom AW; National Joint Registry of England and Wales. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. *Lancet.* 2012;379(9822):1199-204

Smith IM, Austin OM, Knight SL. A simple and fail safe method for digital tourniquet. *J Hand Surg.* 2002;27:363-4

Spiegelhalter DJ. Funnel plots for comparing institutional performance. *Stat Med.* 2005;24(8):1185-202.

Stiell IG, Wells GA, Vandemheen KL, et al. The Canadian C-spine rule for radiography in alert and stable trauma patients. *JAMA.* 2001;286:1841-8

Stratton KM, Blegen MA, Pepper G, et al. Reporting of medication errors by pediatric nurses. J Ped Nurs. 2004;19(6):385–92

Strauss A and Corbin J. Basics of Qualitative Research. 1990. Newbury Park: Sage.

Sung J, Siegel J, Tornetta P et al. The orthopaedic trauma literature: an evaluation of statistically significant findings in orthopaedic trauma randomized trials. *BMC Musculoskelet Disord.* 2008;9:14

Suresh G, Horbar JD et al: Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pediatrics.* 2004;113(6):1609-18

Taylor SJ, Bogdan R: *Introduction to qualitative research methods: The search for meanings.* New York: John Wiley & Sons; 1984.

Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000;38:261-71

Thompson DA, Lubomski L at al: Integrating the intensive care unit safety reporting system with existing incident reporting systems. *Jt Comm J Qual Patient Safety.* 2005;31(10):585-93

Timperley AJ, Whitehouse SL. Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur. *J Bone Joint Surg Br.* 2009;91(7):851-4

Tountas CP. A disposable pneumatic tourniquet. *J Hand Surg.* 1986;11-A:600-1

Tucker S, Harris PC. The unforgettable finger tourniquet. *Injury.* 2002;33(1):76-3

University of York. *The economic cost of hip fracture in the UK. Avoiding slips, trips and broken hips.* Available at http://www.viewcare.co.uk/Publications/hipfracture.pdf

van Gestel YR, Lemmens VE, Lingsma HF, de Hingh IH, Rutten HJ, Coebergh JW. The hospital standardized mortality ratio fallacy: a narrative review. *Med Care* 2012;50(8):662-7

Vincent C (2001), Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ.* 2001;322:517e9

Vincent C (2003). Understanding and responding to adverse events. *N Engl J Med.* 2003;348(11):1051-6

Vincent C (2008), Aylin P, Franklin BD, Holmes A, Iskander S, Jacklin A, Moorthy K. Is health care getting safer? *BMJ.* 2008; 13;337:a2426.

Walker, P. S. and Gold, B. L. The tribology of all-metal artificial hip joints. *Wear.* 1971;17:285-99

Walter SD, Ismaila AS, Devereaux PJ. Statistical issues in the design and analysis of expertise-based randomized clinical trials. *Stat Med.* 2008;27-30:6583-96

Weinrauch PC, Moore WR, Shooter DR, Wilkinson MP, Bonrath EM, Dedy NJ, McMeniman TJ, Jabur MK, Whitehouse SL, Crawford RW. Early prosthetic complications after unipolar hemiarthroplasty. *ANZJ Surg.* 2006;76(6):432

Weise MF. British hospitals and different versions of the Glasgow Coma Scale: telephone survey *BMJ.* 2003;327:782-3

Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, Gawande AA. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet.* 2008;372(9633):139-44

Whittle J, Steinberg EP, Anderson GF, Herbert R, Hochberg MC. Mortality after elective total hip arthroplasty in elderly Americans. Age, gender, and indication for surgery predict survival. *Clin Orthop Relat Res.* 1993;295:119

WHO (2005) *World Alliance for Patient Safety. WHO draft guidelines on adverse event reporting and learning systems.* 2005 Geneva: World Health Organization

WHO (2008). World Alliance for Patient Safety: Forward Programme. Available at http://www.who.int/patientsafety/information_centre/reports/Alliance_Forward_Programme_2008.pdf

WHO (2009). More than words. Conceptual Framework for the International Classification for Patient Safety. Available at: http://www.who.int/patientsafety/implementation/taxonomy/icps_technical_report_en.pdf

Wilcox MH, Cunniffe JG, Trundle C, Redpath C: Financial burden of hospital-acquired Clostridium difficile infection. *J Hosp Infect.* 1996;34:23-30

Williams M, May T. Introduction to the Philosophy of Social Research. Routledge, 1996.

Wilson T, Sheikh A. Enhancing public safety in primary care. *BMJ.* 2002;324(7337):584-7

Wilson, RL, Runciman, WB, Gibberd, RW, et al. The Quality in Australian Health Care Study. *Medical Journal of Australia.* 1995;163:458-71

Wong DA, Herndon JH, Canale ST, Brooks RL, Hunt TR, Epps HR, Fountain SS, Albanese SA, Johanson NA. Medical errors in orthopaedics. Results of an AAOS member survey. *J Bone Joint Surg Am.* 2009;91(3):547-57

World Health Assembly Resolution WHA 55.18 Available online at http://www.who.int/patientsafety/about/wha_resolution/en/index.html Last accessed on 30th June 2012.

Wright MC, Phillips-Bute B, Mark JB, Stafford-Smith M, Grichnik KP, Andregg BC, Taekman JM. Time of day effects on the incidence of anesthetic adverse events. *Qual Saf Health Care.* 2006;15(4):258-63

Wu AW, Lipshutz AK, Pronovost PJ. Effectiveness and efficiency of root cause analysis in medicine. JAMA. 2008 Feb 13;299(6):685-7

Yule S, Flin R, Paterson-Brown S, Maran N and Rowley D. Development of a rating system for surgeons' non-technical skills. *Medical Education.* 2006;40:1098-1104

Zhan C, Kaczmarek R, Loyo-Berrios N, Sangl J, Bright R. Incidence and short-term outcomes of primary and revision hip replacement in the United States. *J Bone Joint Surg Am.* 2007;89(3):526

Appendix 1: Contributions to science

Selected peer-reviewed publications

- **Panesar SS,** Netuveli G, Carson-Stevens A, Javad S, Patel B, Parry B, Donaldson LJ and Sheikh A. The orthopaedic error index: development and application of a novel national indicator for assessing the relative safety of hospital care using a cross-sectional approach. *BMJ Open* 2013;3(11):e003448
- **Panesar SS,** Shaerf DA, Mann BS, Malik AK. Patient safety in orthopaedics. *Journal of Bone and Joint Surgery (British)* 2012;94(12):1595-7
- **Panesar SS,** Carson-Stevens A, Mann BS, Bhandari M, Madhok R. Mortality as an indicator of patient safety in orthopaedics: lessons from qualitative analysis of a database of medical errors. *BMC Musculoskelet Disord* 2012;13-1:93
- **Panesar SS,** Mirza SB, Madhok R. Patient safety in orthopedics: Are we doing enough? *Orthopedics* 2011;34(2):82-3
- Healey F, Darowski A, Lamont T, **Panesar S**, Poulton S, Treml J, Wiese M. Essential care after an inpatient fall: summary of a safety report from the National Patient Safety Agency. *BMJ* 2011;342:d329
- Lamont T, Watts F, Stanley J, Scarpello J, **Panesar S**. Reducing risks of tourniquets left on after finger and toe surgery: summary of a safety report from the National Patient Safety Agency. *BMJ* 2010;340:c1981
- **Panesar SS,** Cleary K, Bhandari M, Sheikh A. To cement or not in hip fracture surgery. *Lancet* 2009;374(9695):1047-9
- Noble DJ, **Panesar SS**, Pronovost PJ. A public health approach to patient safety reporting systems is urgently needed. *J Patient Saf* 2011;7(2):109-12
- **Panesar SS,** Roberts P, Scarpello J, Cleary K, Bhandari M, Sheikh A. Cementing the evidence to deliver safer patient care. Letter in response to Timperley AJ et al. *J Bone Joint Surg Br* online. Available online at http://www.bjj.boneandjoint.org.uk/content/91-B/7/851.abstract/reply

- **Panesar SS**, Patel B, Cleary K. Orthopaedics – Matching precision with safety. Letter in response to Wong et al. *J Bone Joint Surg Am* online. Available online at http://jbjs.org/article.aspx?doi=10.2106/JBJS.G.01439
- **Panesar SS**, Cleary K, Sheikh A. Reflections on the National Patient Safety Agency's database of medical errors. *J R Soc Med* 2009;102(7):256-8

Secondary publications (directly or indirectly related to the MD)

- **Panesar SS**, Noble DJ, Mirza SB, Patel B, Mann B, Emerton M, Cleary K, Sheikh A, Bhandari M. Can the surgical checklist reduce the risk of wrong site surgery in orthopaedics? Can the checklist help? Supporting evidence from analysis of a national patient safety incident reporting system. *J Orthop Sur Res* 2011;6(1):18
- Bagley CHM, **Panesar SS**, Patel B, Pickles J, Cleary K. Safer cut: revelations of surgical harm through a national database. *Br J Hosp Med* 2010;71(9):484-5
- **Panesar SS**, Fitzgerald JE, Carson-Stevens A, Emerton M. The WHO Surgical Safety Checklist - Junior doctors as agents for change. *Int J Surg* 2010;8(6):414-6
- Emerton ME, Reid J, Pickles J, **Panesar SS**, Anderson-Wallace M. WHO checklist as part of '5 steps to safer surgery' – The experience of Patient Safety First. Response to Vats A, *BMJ* 2010;340:b5433. Available online at http://www.bmj.com/rapid-response/2011/11/02/who-checklist-part-5-steps-safer-surgery-experience-patient-safety-first
- **Panesar SS**, Cleary K, Sheikh A. National Patient Safety Agency leads national implementation of measures to reduce the incidence of retained surgical materials. *Surgeon.* 2010(8):54-5
- Emerton M, **Panesar SS**, Forrest K. Safer surgery: how a checklist can make orthopaedic surgery safer. *Orthopaedics and Trauma* 2009;23(5):377-80

- **Panesar SS,** Reid J, Emerton M, Rogers H, Pickles J. Reducing error in theatre: Patient Safety First and the College join forces. *Bulletin of the Royal College of Surgeons of England* 2009;8(2):271-2
- **Panesar SS**, Cleary K, Sheikh A, Donaldson L. The WHO checklist: a global tool to prevent errors in surgery. *Patient Saf Surg* 2009;3(1):9

National Patient Safety Agency official documents

- Rapid Response Reports (RRR) (Available online at http://www.nrls.npsa.nhs.uk/resources/type/alerts/ Last accessed on 15 January 2013)
    - Essential care after an inpatient fall (13 January 2011)
    - Reducing the risks of tourniquets left on after finger and toe surgery (9 December 2009)
    - Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur (11 March 2009)
- Alerts (Available online at http://www.nrls.npsa.nhs.uk/resources/type/alerts/ Last accessed on 15 January 2013)
    - WHO Surgical Safety Checklist (26 January 2009)
- Catchpole K, **Panesar SS,** Russell J, Tang V, Hibbert P, Cleary K. *Surgical safety can be improved through better understanding of incidents reported to a national database.* 2009. Available online at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/?entryid45=63054

Abstracts presented at learned societies

- **Panesar SS,** Tang V, Cleary K, Bhandari M, Sheikh A. Cementing the evidence – can insight from a patient safety database add value? Medical Research Society Spring Meeting, London, 25 February 2010. **Poster presentation**

- **Panesar SS,** Cleary K, Bhandari M, Sheikh A. Questioning the evidence? Bone cement implantation syndrome revisited through the eyes of a national database. 2nd North British Patient Safety Research Symposium, Aberdeen, 6 November 2009. **Oral presentation**

- **Panesar SS**, Catchpole K, Russell J, Tang V, Cleary K. Surgical safety can be improved through better understanding of incidents reported to a national database. 3 International Workshop on Behavioural Science Applied to Surgery, Imperial College London, 15-16 September 2009. **Oral presentation**

Appendix 2: Permission to use the 'Swiss cheese' model (Figure 1.1)

Licensed content publisher	BMJ Publishing Group Ltd.
Licensed content publication	**British Medical Journal**
Licensed content title	Human error: models and management
Licensed content author	**James Reason**
Licensed content date	Mar 18, 2000
Volume number	**320**
Type of Use	
Circulation/distribution	**3**
Title of your thesis / dissertation	Using a national repository of error reports to obtain insights into the safety of orthopaedic surgery
Expected completion date	
Estimated size(pages)	160
BMJ VAT number	**674738491**
Permissions price	Not Available
VAT (0.0%)	**0.00 USD**
Total	Not Available

Appendix 3: Data fields in the National Reporting and Learning System

Reference Code	Item Code	Full Dataset
RP02	0	Please select
	F	Acute / general hospital
	A	Ambulance service
	D	Community and general dental service
	C	Community nursing, medical and therapy service (incl. community hospital)
	O	Community optometry / optician service
	H	Community pharmacy
	P	General practice
	G	Learning disabilities service
	M	Mental health service
RN03	0	Please select
	A	Ambulance (including call / control centre)
	00	Please select sub-category
	A0100	Call / control centre
	A0200	In vehicle / in transit
	A0400	NHS Direct
	ZA	Other
	ZA-TXT	[Free Text]
	B	Community hospital
	00	Please select sub-category
	B0100	Day care services
	B0200	General areas
	000	Please select sub-category
	B0220	Hospital buildings (inside)
	B0210	Hospital grounds (outside)
	ZB0200	Other
	ZB0200-TXT	[Free Text]
	B0300	Inpatient areas
	000	Please select sub-category
	B0310	Ward
	ZB0300	Other
	ZB0300-TXT	[Free Text]
	B0400	Outpatient department
	B0500	Support Services
	000	Please select sub-category
	B0510	Hospital transport (car)
	B0520	Laboratory
	B0530	Pharmacy
	B0540	Therapy department
	ZB0500	Other
	ZB0500-TXT	[Free Text]
	ZB	Other
	ZB-TXT	[Free Text]
	C	General / acute hospital
	00	Please select sub-category
	C0100	Accident & Emergency (A&E) / minor injury unit / medical assessment unit
	C0200	Ambulatory care & diagnostic treatment centre
	C0300	Day care services
	C0400	General areas
	000	Please select sub-category
	C0430	Hospital buildings (inside)
	C0410	Hospital grounds (outside)
	C0420	Mortuary
	ZC0400	Other
	ZC0400-TXT	[Free Text]
	C0500	Inpatient areas
	000	Please select sub-category
	C0510	Anaesthetic room
	C0520	Intensive care unit / high dependency unit
	C0530	Operating theatre
	C0540	Recovery room
	C0550	Ward
	ZC0500	Other
	ZC0500-TXT	[Free Text]
	C0600	Outpatient department
	C0700	Support services
	000	Please select sub-category
	C0710	Hospital transport (car)
	C0720	Laboratory
	C0730	Pharmacy
	C0740	Radiology
	C0750	Therapy department
	ZC0700	Other
	ZC0700-TXT	[Free Text]

Reference Code	Item Code	Full Dataset
	ZC	Other
	ZC-TXT	[Free Text]
	D	Mental health unit / facility
	00	Please select sub-category...
	D0600	Community mental health facility
	D0100	Day care services
	D0200	General areas
	000	Please select sub-category...
	D0220	Hospital buildings (inside)
	D0210	Hospital grounds (outside)
	ZD0200	Other
	ZD0200-TXT	[Free Text]
	D0300	Inpatient areas
	000	Please select sub-category...
	D0310	ECT Suite
	D0320	Intensive care unit / high dependency unit
	D0330	Secure unit
	D0340	Ward
	ZD0300	Other
	ZD0300-TXT	[Free Text]
	D0400	Outpatient department
	D0500	Support Services
	000	Please select sub-category...
	D0510	Hospital transport
	D0520	Pharmacy
	ZD0500	Other
	ZD0500-TXT	[Free Text]
	ZD	Other
	ZD-TXT	[Free Text]
	E	Primary care setting
	00	Please select sub-category...
	E0100	Ambulatory care & Diagnostic treatment centre
	E0200	Community pharmacy
	E0300	Dental surgery
	000	Please select sub-category...
	E0310	Treatment / consulting room
	E0320	Waiting room / reception
	ZE0300	Other
	ZE0300-TXT	[Free Text]
	E0400	GP Surgery
	000	Please select sub-category...
	E0410	Dispensary
	E0420	Treatment / consulting room
	E0430	Waiting room / reception
	ZE0400	Other
	ZE0400-TXT	[Free Text]
	E0500	Health centre / out-of-hours centre
	E0600	NHS Direct
	E0700	Optician / optometrist
	000	Please select sub-category...
	E0710	Dispensing area
	E0720	Treatment / consulting room
	E0730	Waiting room / reception
	ZE0700	Other
	ZE0700-TXT	[Free Text]
	E0800	Rehabilitation centre
	ZE	Other
	ZE-TXT	[Free Text]
	F	Public place (specify)
	F-TXT	[Free Text]
	G	Residence / home
	00	Please select sub-category...
	G0100	Hospice
	G0200	Intermediate care setting
	G0300	Nursing home
	G0400	Prison / remand centre
	G0500	Private house / flat etc.
	ZG	Other
	ZG-TXT	[Free Text]
	H	Social care facility

Reference Code	Item Code	Full Dataset
	00	Please select sub-category
	H0100	Day care services
	H0200	Local Authority (non-residential)
	H0300	Residential care home
	ZH	Other
	ZH-TXT	[Free Text]
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown
	Y	Not applicable
IN01		
IN01-A		
IN01-A-01	0	Year...
	X	[Years from Current – (Current Year – 10)]
IN01-A-02	0	Month...
	A	Jan (01)
	B	Feb (02)
	C	Mar (03)
	D	Apr (04)
	E	May (05)
	F	Jun (06)
	G	Jul (07)
	H	Aug (08)
	I	Sep (09)
	J	Oct (10)
	K	Nov (11)
	L	Dec (12)
IN01-A-03	0	Day...
	X	[Numbers from 01 – 31]
IN01-B	U	Date unknown
IN02		
IN02-A		
IN02-A-01	0	Hour...
	A	00 (12 AM - Midnight)
	B	01 (1 AM)
	C	02 (2 AM)
	D	03 (3 AM)
	E	04 (4 AM)
	F	05 (5 AM)
	G	06 (6 AM)
	H	07 (7 AM)
	I	08 (8 AM)
	J	09 (9 AM)
	K	10 (10 AM)
	L	11 (11 AM)
	M	12 (12 PM - Midday)
	N	13 (1 PM)
	O	14 (2 PM)
	P	15 (3 PM)
	Q	16 (4 PM)
	R	17 (5 PM)
	S	18 (6 PM)
	T	19 (7 PM)
	AA	20 (8 PM)
	AB	21 (9 PM)
	AC	22 (10 PM)
	AD	23 (11 PM)
IN02-A-02	0	Minutes...
	A	00-14
	B	15-29
	C	30-44
	D	45-59
IN02-B	0	Please select
	A	08h00 – 11h59
	B	12h00 – 15h59
	C	16h00 – 19h59
	D	20h00 – 23h59
	E	00h00 – 03h59
	F	04h00 – 07h59
IN02-C	U	Time unknown
IN04	0	Please select
	A	England
	B	Northern Ireland
	C	Scotland
	D	Wales
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown
IN05	0	Please select
	A	**Access, admission, transfer, discharge (including missing patient)**
	00	Please select sub-category
	A0100	Absconder / missing patient
	A0200	Access / admission - delay / failure in access to hospital / care
	A0300	Access / admission - unexpected readmission / reattendance
	A0400	Access / admission - unplanned admission / transfer to specialist care unit
	A0500	Ambulance / patient in road traffic accident
	A0600	Delay / difficulty in obtaining clinical assistance
	A0700	Discharge - delay / failure
	A0800	Discharge - inappropriate
	A0900	Discharge - planning failure
	A1000	Discharge - self or against medical advice
	A1100	Documentation - delay in obtaining healthcare record / card
	A1200	Documentation - missing / inadequate / illegible healthcare record / card
	A1300	Documentation - no access to
	A1400	Extended stay / episode of care
	A1500	Failure in referral process
	A1600	Failure to return from authorised leave
	A2000	Slips, trips, falls
	A1700	Transfer - delay / failure
	A1800	Transport - delay / failure
	A1900	Unsafe / inappropriate clinical environment (including clinical waste)
	ZA	Other
	ZA-TXT	[Free Text]
	B	**Clinical assessment (including diagnosis, scans, tests, assessments)**
	00	Please select sub-category
	B0100	Assessment - lack of clinical or risk assessment

Reference Code	Item Code	Full Dataset
	B0200	Cross-matching error
	B0300	Delay / difficulty in obtaining clinical assistance
	B0400	Diagnosis - delay / failure to
	B0500	Diagnosis - wrong
	B0600	Documentation - missing / inadequate / illegible healthcare record / card
	B0700	Documentation - missing / inadequate / illegible referral letter
	B0800	Documentation - no access to
	B0900	Failure to follow up missed appointment
	B1000	Patient incorrectly identified
	B1100	Scans / X-rays / specimens - inadequate / incomplete
	B1200	Scans / X-rays / specimens - mislabelled / unlabelled
	B1300	Scans / X-rays / specimens - missing
	B1400	Scans / X-rays / specimens - wrong
	B1500	Test results / reports - failure / delay to interpret or act on
	B1600	Test results / reports - failure / delay to receive
	B1900	Test results / reports - incorrect
	B1700	Test results / reports - missing
	B1800	Tests - failure / delay to undertake
	ZB	Other
	ZB-TXT	[Free Text]
	C	**Consent, communication, confidentiality**
	00	Please select sub-category
	C0100	Breach of patient confidentiality
	C0200	Communication failure - outside of immediate team
	C0300	Communication failure - with patient / parent / carer
	C0400	Communication failure - within team
	C0500	Delay / difficulty in obtaining clinical assistance
	C0600	Documentation - missing / inadequate / illegible healthcare record / card
	C0700	Documentation - no access to
	C0800	Failure to receive informed consent (includes doctrine of necessity)
	C0900	IT / telecommunications failure / overload
	C1000	Patient incorrectly identified
	ZC	Other
	ZC-TXT	[Free Text]
	D	**Disruptive, aggressive behaviour**
	00	Please select sub-category
	D0100	Physical
	D0200	Racial
	D0300	Sexual
	D0400	Verbal
	ZD	Other
	ZD-TXT	[Free Text]
	E	**Documentation (including records, identification)**
	00	Please select sub-category
	E0100	Appointment recording error
	E0200	Documentation - delay in obtaining healthcare record / card
	E0300	Documentation - healthcare record / card - mislabelled
	E0400	Documentation - missing / inadequate / illegible healthcare record / card
	E0500	Documentation - missing / inadequate / illegible referral letter
	E0600	Documentation - misfiled
	E0700	Documentation - no access to
	E0800	Patient incorrectly identified
	E0900	Scans / X-rays / specimens - missing
	E1000	Scans / X-rays / specimens - mislabelled / unlabelled
	E1100	Test request form - none / incomplete
	E1200	Test results / reports - failure / delay to receive
	E1600	Test results / reports - incorrect
	E1300	Test results / reports - mislabelled
	E1400	Test results / reports - missing
	E1500	Theatre list details incorrect
	ZE	Other
	ZE-TXT	[Free Text]
	G	**Implementation of care and ongoing monitoring / review**
	00	Please select sub-category
	G0100	Delay / difficulty in obtaining clinical assistance
	G0200	Delay / failure in recognising complication of treatment
	G0300	Delay or failure to monitor
	G0400	Documentation - delay in obtaining healthcare record / card
	G0500	Documentation - missing / inadequate / illegible healthcare record / card
	G0600	Documentation - no access to
	G0700	Extended stay / episode of care
	G0800	Failure to discontinue treatment
	G0900	Failure to follow up missed appointment
	G1000	Patient incorrectly identified
	G1100	Test results / reports - failure / delay to interpret or act on
	G1400	Test results / reports - incorrect
	G1200	Tests - failure / delay to undertake
	G1300	Transfer - delay / failure
	ZG	Other
	ZG-TXT	[Free Text]
	F	**Infection Control Incident**
	00	Please select sub-category
	F0100	Diagnosis - delay / failure to
	F0200	Diagnosis - wrong
	F0300	Failure of sterilisation or contamination of equipment
	F0400	Infection - cross / healthcare associated
	F0500	Infection - wound
	F0600	Test results / reports - failure / delay to interpret or act on
	F0700	Test results / reports - failure / delay to receive
	F1300	Test results / reports - incorrect
	F0800	Test results / reports - missing
	F0900	Tests - failure / delay to undertake
	F1000	Treatment / procedure - delay / failure
	F1100	Treatment / procedure - inappropriate
	F1200	Unsafe / inappropriate clinical environment (including clinical waste)
	ZF	Other
	ZF-TXT	[Free Text]
	H	**Infrastructure (including staffing, facilities, environment)**
	00	Please select sub-category
	H1000	Exposure to cold / heat (includes fire)
	H0100	Failure / delay in collection / delivery systems
	H0200	Inadequate check on equipment / supplies
	H0300	IT / telecommunications failure / overload
	H0400	Lack of / delayed availability of beds (general)
	H0500	Lack of / delayed availability of beds (high dependency / intensive care)
	H0600	Lack of / delayed availability of operating theatre
	H0900	Lack of suitably trained / skilled staff

Reference Code	Item Code	Full Dataset
	H0700	Unsafe / inappropriate clinical environment (including clinical waste)
	H0800	Unsafe environment (light, temperature, noise, air quality) - personal safety
	ZH	Other
	ZH-TXT	[Free Text]
	I	**Medical device / equipment**
	00	Please select sub-category
	I0100	Failure of device / equipment
	INSTR	>> Device Incident Trigger
	I0200	Lack / unavailability of device / equipment
	INSTR	>> Device Incident Trigger
	I0400	User error
	INSTR	>> Device Incident Trigger
	I0300	Wrong device / equipment used
	INSTR	>> Device Incident Trigger
	ZI	Other
	ZI-TXT	[Free Text]
	INSTR	>> Device Incident Trigger
	J	**Medication**
	INSTR	>> Medicines Incident Trigger
	K	**Patient abuse (by staff / third party)**
	00	Please select sub-category
	K0100	Physical
	K0200	Racial
	K0300	Sexual
	K0400	Verbal
	ZK	Other
	ZK-TXT	[Free Text]
	L	**Patient accident**
	00	Please select sub-category
	L0100	Ambulance / patient in road traffic accident
	L0200	Collision / contact with an object
	L0300	Contact with sharps (includes needle stick)
	L0400	Exposure to hazardous substance
	L0500	Exposure to cold / heat (includes fire)
	L0600	Inappropriate patient handling / positioning
	L0700	Slips, trips, falls
	ZL	Other
	ZL-TXT	[Free Text]
	M	**Self-harming behaviour**
	00	Please select sub-category
	M0100	Self-harm
	M0200	Suspected suicide (actual)
	M0300	Suspected suicide (attempted)
	ZM	Other
	ZM-TXT	[Free Text]
	N	**Treatment, procedure**
	00	Please select sub-category
	N0100	Delay / difficulty in obtaining clinical assistance
	N0200	Delay / failure in recognising complication of treatment
	N0300	Delay or failure to monitor
	N0400	Documentation - missing / inadequate / illegible healthcare record / card
	N0500	Documentation - no access to
	N0600	Extended stay / episode of care
	N0800	Failure to discontinue treatment
	N0900	Failure to follow up missed appointment
	N1000	Inappropriate patient handling / positioning
	N1100	Inappropriate use of control and restraint
	N0700	Infusion injury (extravasation)
	N1200	Missing needle / swab / instrument
	N1300	Patient incorrectly identified
	N1400	Retained needle / swab / instrument
	N1500	Theatre list details incorrect
	N1600	Transfer - delay / failure
	N1700	Treatment / procedure - delay / failure
	N1800	Treatment / procedure - inappropriate / wrong
	N1900	Treatment not clinically indicated
	N2000	Unplanned return to theatre
	ZN	Other
	ZN-TXT	[Free Text]
	Z	**Other**
	Z-TXT	[Free Text]
IN06		
	A	**Communication factors** (includes verbal, written and non-verbal between individuals, teams, and/or organisations)
	B	**Education and training factors** (e.g. availability of training)
	C	**Equipment and resources factors** (e.g. clear machine displays, poor working order, size, placement, ease of use)
	INSTR	>> Device Incident Trigger
	D	**Medication factors** (where one or more drugs directly contributed to the incident)
	INSTR	>> Medicines Incident Trigger
	E	**Organisation and strategic factors** (e.g. organisational structure, contractor / agency use, culture)
	F	**Patient factors** (e.g. clinical condition, social / physical / psychological factors, relationships)
	G	**Task factors** (includes work guidelines / procedures / policies, availability of decision making aids)
	H	**Team and social factors** (includes role definitions, leadership, support, and cultural factors)
	I	**Work and environment factors** (e.g. poor/excess administration, physical environment, work load and hours of work, time pressures)
	Z	**Other**
	Z-TXT	[Free Text]
	U	**Unknown**
IN07	A	[Free Text – Multi-line]
IN11	A	[Free Text – Multi-line]
IN10	A	[Free Text – Multi-line]
PD01		
PD01-A		
PD01-A-01	0	Year
	X	[Years from Current – (Current Year – 110)]
PD01-A-02	0	Month
	A	Jan (01)
	B	Feb (02)
	C	Mar (03)
	D	Apr (04)
	E	May (05)
	F	Jun (06)
	G	Jul (07)
	H	Aug (08)

Reference Code	Item Code	Full Dataset
	I	Sep (09)
	J	Oct (10)
	K	Nov (11)
	L	Dec (12)
PD01-A-03	0	Day...
	X	[Numbers from 01 – 31]
DV01	A	[Derived variable]
DV02	A	[Derived variable]
PD01-B	0	Please select age range
	M	Under 28 days
	A	1 month to 1 year
	B	2 to 4 years
	C	5 to 11 years
	D	12 to 17 years
	E	18 to 25 years
	F	26 to 35 years
	G	36 to 45 years
	H	46 to 55 years
	I	56 to 65 years
	J	66 to 75 years
	K	76 to 85 years
	L	Over 85 years
PD01-C	0	Please select...
	B	Weeks
	C	Months
PD01-D	0	Please select...
	X	[Numbers from 01 – 52]
PD01-E	U	Date unknown
PD19	A	[Free Text]
PD20	A	Yes
	B	No
	C	Don't know
PD02	0	Please select...
	A	Male
	B	Female
	C	Indeterminate
	U	Not stated / unknown
PD11	0	Please select...
	A	White
	B	Mixed
	C	Asian or Asian British
	D	Black or Black British
	Z	Other
	Z-TXT	[Free Text]
	U	Not stated / unknown
PD03	B	Learning disability(ies)
	C	Physical disability(ies)
	D	Sensory impairment(s)
	Z	Other
	Z-TXT	[Free Text]
PD04	A	A paediatrics specialty
	B	An adult specialty
PD05	0	Please select...
	A	Accident and Emergency (A&E)
	B	Anaesthetics
	00	Please select sub-category...
	B0100	Pain service
	ZB	Other
	ZB-TXT	[Free Text]
	C	Dentistry - General and Community
	00	Please select sub-category...
	C0100	Endodontics
	C0200	Oral surgery
	C0300	Orthodontics
	C0600	Paedodontics
	C0400	Periodontics
	C0500	Restorative dentistry
	ZC	Other
	ZC-TXT	[Free Text]
	D	Diagnostic services
	00	Please select sub-category...
	D0100	Blood transfusion
	D0200	Chemical pathology
	D0300	Haematology
	D0400	Histopathology
	D0500	Immunopathology
	D0600	Microbiology
	D0700	Neuropathology
	D0800	Radiology
	D0900	Virology
	ZD	Other
	ZD-TXT	[Free Text]
	E	Learning disabilities
	00	Please select sub-category...
	E0100	Community teams
	E0200	Day care
	E0300	Forensic

Reference Code	Item Code	Full Dataset
	E0400	Inpatient assessment and treatment
	E0500	Residential care
	E0600	Respite care
	E0700	Supported living
	ZE	Other
	ZE-TXT	[Free Text]
	F	Medical specialties
	00	Please select sub-category
	F0100	Audiological medicine
	F0200	Cardiology
	F0300	Care of older people
	F0400	Clinical cytogenetics and molecular genetics
	F0500	Clinical haematology
	F0600	Clinical immunology and allergy
	F0700	Clinical oncology (previously radiotherapy)
	F0800	Dental medicine
	F0900	Dermatology
	F1000	Endocrinology
	F1100	Gastroenterology
	F1200	General medicine
	F1300	Genetics
	F1400	Genito-urinary medicine
	F1500	Infectious diseases
	F1600	Medical oncology
	F1700	Medical ophthalmology
	F1800	Neonatology
	F1900	Nephrology / renal
	F2000	Neurology
	F2100	Nuclear medicine
	F2200	Palliative medicine
	F2300	Rehabilitation
	F2400	Rheumatology
	F2500	Thoracic / respiratory medicine
	ZF	Other
	ZF-TXT	[Free Text]
	G	Mental health
	00	Please select sub-category
	G0100	Adult mental health
	G0200	Child and adolescent mental health
	G0300	Drug and alcohol service
	G0400	Forensic mental health
	G0500	Mental health rehabilitation
	G0600	Older adult mental health
	ZG	Other
	ZG-TXT	[Free Text]
	H	Obstetrics and gynaecology
	00	Please select sub-category
	H0100	Community midwifery
	H0200	Fertility treatment
	H0300	Gynaecology
	H0400	Obstetrics
	ZH	Other
	ZH-TXT	[Free Text]
	I	Primary care / Community
	00	Please select sub-category
	I0100	Chiropody / podiatry
	I0200	Community medicine
	I0900	Community midwifery
	I0300	Community nursing
	I1000	Community paediatrics
	I0500	General practice - no specialism
	I1100	General practice - with specialism relevant to this patient (specify)
	I1100-TXT	[Free Text]
	I0600	Health visiting / school nursing
	I0700	Intermediate care
	I0800	Sexual health / family planning
	ZI	Other
	ZI-TXT	[Free Text]
	J	PTS (Patient Transport Service)
	K	Surgical specialties
	00	Please select sub-category

Reference Code	Item Code	Full Dataset
	K0100	Breast surgery
	K0200	Burns surgery
	K0300	Cardiac surgery
	K0400	Colorectal surgery
	K0500	Dental surgery
	K0600	ENT
	K0700	General surgery
	K0800	Maxillofacial / oral surgery
	K0900	Neurosurgery
	K1000	Ophthalmology
	K1100	Orthodontics
	K1800	Paedodontics
	K1700	Plastic surgery
	K1200	Renal surgery
	K1300	Thoracic surgery
	K1400	Trauma and orthopaedics
	K1500	Urology
	K1600	Vascular surgery
	ZK	Other
	ZK-TXT	[Free Text]
	L	Other specialties
	00	Please select sub-category...
	L0100	Nutrition and dietetics
	L0200	Occupational therapy
	L0300	Pharmacy (inpatient)
	L0400	Physiotherapy
	L0500	Speech and language therapy
	ZL	Other
	ZL-TXT	[Free Text]
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown
	Y	Not applicable
PD06	0	Please select...
	A	Standard
	B	Enhanced
	C	Non-CPA
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown
	Y	Not applicable
PD07	A	Yes
	B	No
	U	Don't know
	Y	Not applicable
PD17	A	[Free Text]
PD08	A	Inhalation
	B	Intravenous
	C	Oral
	Z	Other
	Z-TXT	[Free Text]
PD16	A	Yes
	B	No
PD09	B	**Low** (Minimal harm – patient(s) required extra observation or minor treatment)
	C	**Moderate** (Short term harm – patient(s) required further treatment, or procedure)
	D	**Severe** (Permanent or long term harm)
	E	**Death** (Caused by the Patient Safety Incident)
PD18	A	None
	B	Low
	C	Moderate
	D	Severe
	E	Death
PD12	A	Yes
	B	No
PD13	A	[Free Text – Multi-line]
PD14	A	Yes
	B	No
	C	Don't know
PD15	A	[Free Text – Multi-line]
PD10	0	Please select...
	A	Physical
	00	Please select sub-category...
	A0100	Allergic / adverse reaction
	A0200	Awareness during general anaesthetic
	A0300	Blood / fluid loss
	A0400	Collapse / loss of consciousness
	A0500	Gastrointestinal disturbances (e.g. nausea, vomiting, diarrhoea, etc.)
	A0600	Infection
	A0700	Injury to skin / tissue (pressure sore / abrasion / sharps)
	A0800	Musculoskeletal injury
	A0900	Neurological effect
	A1000	Respiratory effect (choking / aspiration)
	A1100	Unexpected deterioration
	A1200	Unintentional puncture / laceration to organ / body part
	ZA	Other physical (specify)
	ZA-TXT	[Free Text]
	B	Psychological (specify)
	B-TXT	[Free Text]

Reference Code	Item Code	Full Dataset
	C	Social (specify)
	C-TXT	[Free Text]
	J	Unknown
	Y	Not applicable
PG06	A	Yes
	B	No
PG01		
PG01-A	A	[Free Text - Positive Integer]
PG01-B	A	[Free Text - Positive Integer]
PG01-C	A	[Free Text - Positive Integer]
PG01-D	A	[Free Text - Positive Integer]
PG01-E	A	[Free Text - Positive Integer]
PG02	A	Yes
	B	No
PG03	A	[Free Text – Multi-line]
PG04	A	Yes
	B	No
	C	Don't know
PG05	A	[Free Text – Multi-line]
ST01	U	Please select
	A	Ambulance staff
	00	Please select sub-category
	A0100	Community responder
	A0200	Call centre staff
	A0400	Paramedic
	A0500	PTS operative
	A0600	Staff in training / supervision
	A0700	Technician
	ZA	Other
	ZA-TXT	[Free Text]
	B	Dental staff - general and community
	00	Please select sub-category
	B0100	Dental nurse
	B0200	Dental technician
	B0300	Dental therapist
	B0400	Dentist
	B0500	Dentist - vocational trainee
	B0600	Hygienist
	B0700	Staff in training / supervision
	ZB	Other
	ZB-TXT	[Free Text]
	C	Diagnostic and therapeutic staff
	00	Please select sub-category
	C0100	Allied health professional
	000	Please select sub-category
	C0110	Chiropodist / Podiatrist
	C0120	Dietician
	C0130	Occupational therapist
	C0140	Physiotherapist
	C0150	Radiographer
	C0160	Speech & language therapist
	C0170	Staff in training / supervision
	ZC0100	Other
	ZC0100-TXT	[Free Text]
	C0200	Scientific and technical
	ZC	Other
	ZC-TXT	[Free Text]
	D	Manager
	E	Medical staff
	00	Please select sub-category
	E0300	Consultant/ professor
	E0900	Doctor (unknown grade)
	E0500	General practitioner (GP)
	E0700	General practitioner (GP) – registrar
	E0600	General practitioner (GP) – with specialist interest
	E0100	House officer
	E1000	Medical student
	E1100	Research fellow
	E0200	Senior house officer
	E0400	Specialist registrar (includes registrar and senior registrar)
	E0800	Staff grade
	ZE	Other
	ZE-TXT	[Free Text]
	F	Nurse / midwife / health visitor
	00	Please select sub-category
	F0600	Health care assistant

Reference Code	Item Code	Full Dataset
	F0100	Health visitor
	F0200	Midwife
	F0300	Nurse
	F0400	Nursery nurse
	F0500	Staff in training / supervision
	ZF	Other
	ZF-TXT	[Free Text]
	G	Optician / optometrist
	00	Please select sub-category
	G0100	Contact lens optician
	G0200	Dispensing optician
	G0300	Ophthalmic medical practitioner
	G0600	Optical dispensing assistant
	G0400	Optometrist
	G0500	Staff in training / supervision
	ZG	Other
	ZG-TXT	[Free Text]
	H	Pharmacy staff
	00	Please select sub-category
	H0100	Chemist counter assistant
	H0200	Dispensing / pharmacy assistant
	H0300	Pharmacist
	H0400	Pharmacy technician
	H0500	Staff in training / supervision
	ZH	Other
	ZH-TXT	[Free Text]
	I	Support staff (clinical and administration)
	00	Please select sub-category
	I0100	Administration / clerical / reception staff
	I0200	Ancillary / estates
	I0300	Health care assistant
	I0400	Interpreter
	I0500	Mental health advocate
	I1000	Optical dispensing assistant
	I0600	Residential support staff
	I0900	Social worker
	I0700	Staff in training / supervision
	I0800	Volunteer
	ZI	Other
	ZI-TXT	[Free Text]
	Z	Other
	Z_TXT	[Free Text]
	U	Unknown
ST02	0	Please select
	A	Agency
	B	In-house bank / NHS Professionals
	C	Locum
	D	Permanent employee / contractor
	E	Self-employed practitioner
	F	Visiting care provider
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown
ST04	0	Please select
	A	Assisting with care delivery / procedure / treatment
	B	Directly administering to patient(s) involved in care delivery / procedure / treatment
	C	Informed of the incident
	D	Involved in the lead up to the incident around care delivery / procedure / treatment
	E	Overall responsibility for the patient(s) involved
	F	Witness to the incident
	Z	Other
	Z-TXT	[Free Text]
ST03	A	[Checkbox]
RP08	A	Yes
	B	No
DA01		
RP06	A	[Select from NHS list]

Reference Code	Item Code	Full Dataset
RP03	A	Anonymously
	B	Identifiably
RP05	A	[Free Text]
RP04	A	[Free Text]
RM01	A	[Date]
QA01	A	[Free Text]
RP09	A	[Unique user refence code]
RP10	A	[Free Text Email Address]
RP11	A	[Free Text]
RP12	A	[Free Text - Multi-Line]
RP14	A	[Free Text - Multi-Line]
RP15	A	[Free Text]
RP16	A	[Free Text - Multi-Line]
MD01	0	Please select...
	A	Prescribing
	B	Preparation of medicines in all locations / dispensing in a pharmacy
	C	Administration / supply of a medicine from a clinical area
	D	Monitoring / follow-up of medicine use
	E	Advice
	F	Supply or use of over-the-counter (OTC) medicine
	Z	Other
	Z-TXT	[Free Text]
MD02	0	Please select...
	A	Adverse drug reaction (when used as intended)
	B	Contra-indication to the use of the medicine in relation to drugs or conditions
	C	Mismatching between patient and medicine
	D	Omitted medicine / ingredient
	E	Patient allergic to treatment
	F	Wrong / omitted / passed expiry date
	G	Wrong / omitted patient information leaflet
	H	Wrong / omitted verbal patient directions
	I	Wrong / transposed / omitted medicine label
	J	Wrong / unclear dose or strength
	K	Wrong drug / medicine
	L	Wrong formulation
	M	Wrong frequency
	N	Wrong method of preparation / supply
	O	Wrong quantity
	P	Wrong route
	Q	Wrong storage
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown
MD03	0	Please select...
	A	Failure to refer for hospital follow-up
	B	Poor transfer / transcription of information between paper and/or electronic forms
	C	Poor communication between care providers (verbal or written)
	S	Use of abbreviation(s) of drug name / strength / dose / directions (e.g. MTX, 1 mg, 1 po)
	D	Handwritten prescription / chart difficult to read
	E	Omitted signature of healthcare practitioner
	F	Patient / carer failure to follow instructions
	G	Failure of compliance aid / monitored dosage system (MDS)
	H	Failure of adequate medicines security (e.g. missing CD)
	I	Substance misuse (including alcohol)
	K	Medicines with similar looking or sounding names
	L	Poor labelling and packaging from a commercial manufacturer
	T	Healthcare practitioner undertaking supplementary prescribing
	L	Variance to guidelines for sound clinical reasons
	M	Involving a medicine supplied under a Patient Group Direction (PGD)
	N	Involving an over-the-counter (OTC) medicine
	O	Failure in monitoring / assessing medicines therapy
	P	Failure of clinical assessment equipment
	INSTR	>> Device Incident Trigger
	Q	Issues associated with an infusion pump / syringe driver
	INSTR	>> Device Incident Trigger
	R	Failure to order laboratory test
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown

Reference Code	Item Code	Full Dataset
	Y	Not applicable
MD05	A	[Free Text]
MD06	A	[Free Text]
MD07	A	[Free Text]
MD07-A	A	[Free Text]
MD07-B	A	[Free Text]
MD08	A	[Free Text]
MD08-A	A	[Free Text]
MD08-B	A	[Free Text]
MD16	Q	Please select
	A	Epidural
	B	Inhalation
	C	Intramuscular
	D	Intrathecal
	E	Intravenous
	F	Intravesicular
	G	Nasal
	H	Optical
	I	Oral
	J	Per ear
	K	Per vagina
	L	Rectal
	M	Subcutaneous
	N	Sublingual
	O	Topical
	Z	Other
	Z-TXT	[Free Text]
	U	Unknown
	Y	Not applicable
MD16-A	X	[List as per MD16]
MD16-B	X	[List as per MD16]
MD09	A	[Free Text]
MD04	A	Right (intended) drug / medicine
	B	Wrong drug / medicine
MD10	A	[Free Text]
MD11	A	[Free Text]
MD12	A	Yes
	B	No
	U	Dont Know
MD13	A	Yes
	B	No
	U	Dont Know
MD14	A	Yes
	B	No
	U	Dont Know
MD15	A	[Free Text]
MD30	A	[Free Text]
MD31	A	[Free Text]
MD32	A	[Free Text]
MD33	A	[Free Text]
MD34	X	[List as per MD16]
MD35	A	[Free Text]
MD36	A	Right (intended) drug / medicine
	B	Wrong drug / medicine
MD37	A	[Free Text]
MD38	A	[Free Text]
MD39	A	Yes
	B	No
	U	Dont Know
MD40	A	Yes
	B	No
	U	Dont Know
MD41	A	Yes
	B	No
	U	Dont Know
MD42	A	[Free Text]
DE01	U	Please select
	A	Administration and giving sets
	B	Anaesthetic machines and monitors
	C	Anaesthetic and breathing masks
	D	Autoclaves
	E	Bath aids
	F	Beds and mattresses
	G	Blood pressure measurement
	H	Commodes
	I	Contact lenses and care products
	J	CT systems
	K	Dental appliances
	CF	Dental materials
	L	Dialysis equipment
	M	Diathermy equipment and accessories
	N	Dressings
	O	Endoscopes and accessories
	P	Endotracheal tubes and airways
	R	External defibrillators
	S	External pacemakers
	Q	Feeding systems - enteral
	T	Feeding tubes
	AA	Gloves
	AB	Guidewires
	AC	Hearing aids
	CC	Heart lung bypass machine
	AD	Hypodermic syringes and needles
	AE	Implants – active (general)
	AF	Implants – breast
	AG	Implants – cardiovascular
	AH	Implants – hip and knee
	AI	Implants – non-active
	AJ	Implants – pacemakers, defibrillators and leads
	AK	Implant materials
	AL	In vitro medical devices
	AM	Infant incubators
	AN	Infusion pumps, syringe drivers
	AO	Insulin syringes
	AP	Intravenous catheters and cannulae
	CD	Laryngoscopes
	AQ	Lasers and accessories
	AR	Magnetic resonance equipment and accessories
	AS	Mobile X-ray systems
	BT	Mobility devices- wheeled, seating aids and accessories
	CE	Mobility devices - non-wheeled

Reference Code	Item Code	Full Dataset
	AT	Monitors and electrodes
	BA	Ophthalmic equipment
	BB	Orthotics
	BC	Patient hoists
	BD	Patient monitoring equipment
	BE	Physiotherapy equipment
	BF	Prostheses – external limb
	BG	Radiotherapy equipment
	BH	Radionuclide equipment
	BI	Resuscitators
	BJ	Staples and staple guns
	BK	Stretchers
	BL	Surgical instruments
	BM	Surgical power tools
	BN	Sutures
	BO	Thermometers
	BP	Ultrasound equipment
	BQ	Urinary catheters
	BR	Ventilators
	BS	Walking sticks / frames
	CA	Wound drains
	CB	X-ray equipment, systems and accessories
	Z	Other
	Z-TXT	[Free Text]
DE02	A	[Free Text]
DE03	A	[Free Text]
DE04	A	[Free Text]
DE05	A	[Free Text]
DE06	A	[Free Text]
DE07	A	[Free Text]
DE08	A	[Free Text]
DE09	A	[Free Text]
DE10		
DE10-A	0	Year...
	X	[Years from (Current Year+20) – (Current Year-50)]
DE10-B	0	Month...
	A	Jan (01)
	B	Feb (02)
	C	Mar (03)
	D	Apr (04)
	E	May (05)
	F	Jun (06)
	G	Jul (07)
	H	Aug (08)
	I	Sep (09)
	J	Oct (10)
	K	Nov (11)
	L	Dec (12)
DE10-C	0	Day...
	X	[Numbers from 01 – 31]
DE10-D	A	Date unknown
DE11		
DE11-A	0	Year...
	X	[Years from Current Year – (Current Year-50)]
DE11-B	0	Month...
	A	Jan (01)
	B	Feb (02)
	C	Mar (03)
	D	Apr (04)
	E	May (05)
	F	Jun (06)
	G	Jul (07)
	H	Aug (08)
	I	Sep (09)
	J	Oct (10)
	K	Nov (11)
	L	Dec (12)
DE11-C	0	Day...
	X	[Numbers from 01 – 31]
DE11-D	A	Date unknown
DE12	A	[Free Text]

Appendix 4: Correspondence with the National Joint Registry

From: David Miller (Health SD) [David.Miller2@northgate-is.com] **on behalf of** Health Service Desk [Health_ServiceDesk@northgate-is.com]
Sent: Monday, December 02, 2013 2:20 PM
To: Panesar, Sukhmeet S
Subject: RE: data in NJR - 1928967 (DMi)

Good Afternoon

We do not record data of this nature. We do record the number of deaths within 90 days of surgery, but not the cause of death.

Kind Regards

David Miller
Service Desk Analyst
Health Service Desk

Northgate Public Services
2nd Floor, People Building 2
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4NW

From: Panesar, Sukhmeet S [mailto:sukhmeet.panesar@imperial.ac.uk]
Sent: 02 December 2013 12:55
To: enquiries@njrcentre.org.uk
Subject: data in NJR - 1928967 (DMi)

Dear Sir,

I would like to enquire whether the National Joint Registry collects any information on patients who self-harm or commit suicides whilst under the care of orthopaedic surgeons?

Many thanks.

Best wishes,

Sukhmeet

Dr. Sukhmeet S. Panesar | Honorary Clinical Research Fellow |
Department of Primary Care and Public Health | Imperial College London |
M: 07817 229 138

Appendix 5: Relevant Rapid Response Reports

NHS
National Patient Safety Agency

Rapid Response Report

NPSA/2009/RRR007

From reporting to learning — 09 December 2009

Reducing risks of tourniquets left on after finger and toe surgery

Issue

Digital tourniquets are commonly used to provide a bloodless field in hand and toe surgery. These may be used in operating theatres, emergency departments, GP surgeries and podiatry clinics. If digital tourniquets are accidentally left on, they may cause substantial harm to patients.

Evidence of harm

Following a trigger incident, the National Patient Safety Agency (NPSA) identified 15 serious incidents between August 2005 and November 2009 relating to digital tourniquets being left in place after surgery. Of these, 10 patients needed further surgical treatment and two resulted in amputation. These were reported from operating theatres (nine incidents), emergency departments (four incidents) and primary care (two incidents). Although the number of patients affected is small, the degree of harm is great. All of these cases were preventable.

At least six of the incident reports related to surgical gloves (finger or whole) being used as tourniquets. It has become common practice, well documented in the literature, to use surgical gloves as tourniquets (including techniques to reduce risks by using artery clips). However, the Medicines and Healthcare Regulatory Authority (MHRA) reminds us that the use of gloves as tourniquet in any form is beyond the manufacturer's intended purpose. As with any off-label use of medical devices, it poses possible risks to the patients and the potential for litigation against the hospital or healthcare professional.

Reducing the risk of harm

There are currently no national guidelines on the use of digital tourniquets and more research is needed.

The NPSA has based this report on the best available evidence to date. Key aspects of safer practice have been identified by clinical experts which are described in the supporting information. These include robust processes to control and reconcile the number of tourniquets used, ensuring that they are removed at the end of the procedure and using CE marked tourniquets with design features (labels and/or colour) to ensure they are clearly visible at all times.

For IMMEDIATE ACTION by all organisations where hand and foot surgery are carried out in the NHS and independent sector. Deadline for ACTION COMPLETE is 9 June 2010.

Local organisations should ensure that:

1. Guidelines include the removal of digital tourniquets as part of the swab counting procedure and specify the need to record the length of time a tourniquet is in place.
2. CE marked digital tourniquets which are labelled and/or brightly coloured should be used, in accordance with manufacturers' instructions. **Surgical gloves should not be used as tourniquets.**
3. The WHO Surgical Safety Checklist is reviewed locally to consider adding tourniquet removal at 'Sign Out' stage.
4. The NPSA clinical briefing sheet is used to raise awareness of risks using digital tourniquets and safer practice recommendations (www.nrls.npsa.nhs.uk/tourniquets).

Further information

Supporting information on this Rapid Response Report is available at www.nrls.npsa.nhs.uk/tourniquets. Further queries should be directed to Fran Watts at rrr@npsa.nhs.uk; telephone 020 7927 9890.

NPSA has informed: NHS Organisations, the independent sector, commissioners, regulators and relevant professional bodies in England and Wales.

Gateway ref: 12662

NHS
National Patient Safety Agency

Rapid Response Report

NPSA/2009/RRR001

From reporting to learning

11 March 2009

Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur

Around 60,000 planned total hip replacements and 60,000 repairs of hip fractures are carried out annually in the UK. The mortality rate following partial hip replacement after fracture treatment is ten times higher than with a planned hip replacement. Patients undergoing surgery after fracture are older, generally more ill and are in need of an emergency operation. The mortality rate is significantly higher if surgery is delayed more than 48 hours.

The most common cause of sudden intra-operative death during arthroplasty is the occurrence of venous embolisation of fat and marrow contents. This phenomenon is exacerbated by poor patient preparation, dehydration and significant co-morbidities and is associated with instrumentation of the canal and finally cement insertion. At the time of arthroplasty, embolism can occur when cement is used but has also been reported with cementless implants. The National Hip Fracture Data Base (NHFD) has recently started data collection of hemiarthroplasty use.

The National Patient Safety Agency (NPSA) is aware of 26 patient deaths and 6 cases of severe harm where bone cement was used during hip surgery between October 2003 and October 2008. Most occurred during hemiarthroplasty carried out as an emergency. The voluntary nature of reporting means that conclusions cannot be drawn from these data on the relative safety of uncemented and cemented prostheses. The Medicines and Healthcare products Regulatory Agency (MHRA) also received reports of 19 further patient deaths where cement was used during hip surgery and 6 cases of severe harm, although the cause of the incidents is unclear.

There are clinical situations where the use of cement is indicated or where the use of cement will produce a better clinical outcome. In all situations the clinician needs to make a risk benefit assessment based on the actions below to mitigate the risk no matter what implant is chosen.

For PRECAUTIONARY ACTION by clinical directors of surgery in the NHS and the independent sector. The deadline date for ACTION COMPLETE is 14 September 2009

Organisations should:

1. Report to the NPSA and MHRA every peri-operative harm or patient death for total hip replacement and hemiarthroplasty, stating use of cemented or uncemented prosthesis and share the results of local investigations with the NPSA.
2. Review local guidelines and audit current activity against best practice including submitting data to the NHFD, and reduce risks as follows:

Patient assessment:

- Identifying patients at risk (e.g. those with pre-existing cardiopulmonary dysfunction), assessing fitness for surgery and most appropriate technique

Anaesthetic technique:

- Maintain normovolemia throughout the procedure, particularly prior to cement insertion
- Maintain particular vigilance during instrumentation and fixation of the implant

Surgical technique:

- Thorough pressurised lavage of the femoral canal before broaching the canal and further instrumentation of the femur
- Consider a suction catheter to reduce the pressure in the intramedullary canal
- Introducing cement into the femur in retrograde fashion via a cement gun
- Communication with the anaesthetist regarding when cement is to be inserted

The NPSA has informed:
All NHS organisations, the independent sector, commissioners, regulators and relevant professional bodies.

Further information
Supporting information including detailed international guidance is available at www.npsa.nhs.uk/rrr or contact Dr Kevin Cleary c/o rrr@npsa.nhs.uk

NHS
National Patient Safety Agency

Rapid Response Report

NPSA/2011/RRR001

From reporting to learning — 13 January 2011

Essential care after an inpatient fall

Issue

Each year around 282,000 patient falls are reported to the NPSA from hospitals and mental health units. A significant number of these falls result in death, severe or moderate injury including around 840 fractured hips, 550 other types of fracture, and 30 intracranial injuries.

Evidence of harm

Analysis of patient safety incidents reported to the National Reporting and Learning System (in the 12 months prior to 25 March 2010) indicates that around 200 patients with fractures or intracranial injury after a fall in hospital experienced some failure of aftercare. Problems included:

- delayed diagnosis of fractures, ranging from several hours to several days after the fall;
- neurological observations not recorded at all or recorded at inadequate intervals, resulting in delayed diagnosis of intracranial bleeding;
- sling hoists used to move patients despite signs or symptoms of limb fracture or spinal injury;
- delays in access to urgent investigations or surgery.

Reducing the risk of harm

When a serious injury occurs as a result of an inpatient fall, safe manual handling and prompt assessment and treatment is critical to the patient's chances of making a full recovery. This RRR aims to ensure that local protocols and systems help staff to consistently achieve this.

For IMMEDIATE ACTION by all NHS organisations that have inpatient beds. The deadline for ACTION COMPLETE is 14 July 2011.

NHS organisations with inpatient beds should ensure that:

1. They have a post-fall protocol that includes:
   a) checks by nursing staff for signs or symptoms of fracture or potential for spinal injury before the patient is moved;
   b) safe manual handling methods for patients with signs or symptoms of fracture or potential for spinal injury*;
   c) frequency and duration of neurological observations for all patients where head injury has occurred or cannot be excluded (e.g. unwitnessed falls) based on National Institute for Health and Clinical Excellence (NICE) Clinical Guideline 56: Head Injury;
   d) timescales for medical examination following a fall (including fast track assessment for patients with signs of serious injury, or high vulnerability to injury, or who have been immobilised).
2. Their post-fall protocol is easily accessible (e.g. laminated versions at nursing stations).
3. Their staff have access to clear guidance and formats for recording neurological observations using a 15 point version of the Glasgow Coma Scale (GCS) and that changes in the GCS that should trigger urgent medical review are highlighted.
4. Their staff have access at all times to special equipment (e.g. hard collars, flat-lifting equipment, scoops)* and colleagues with the expertise to use it, for patients with suspected fracture or potential for spinal injury.
5. Systems are in place allowing inpatients injured in a fall access to investigation and specialist treatment* that is equal in speed and quality to that provided in emergency departments and conforms to NICE Clinical Guideline 56: Head Injury.

** Community hospitals and mental health units without the equipment or expertise may be able to achieve this in collaboration with emergency services.*

NHS Evidence
accredited provider
www.evidence.nhs.uk

Further information Supporting information on this Rapid Response Report is available at www.nrls.npsa.nhs.uk/alerts.
For further queries contact rrr@npsa.nhs.uk, Telephone 020 7927 9500

Gateway ref: 15328