

Generating learning from patient safety incident reports from general practice

Andrew Paul Carson-Stevens

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To William

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Abbreviations

A&E	Accident and Emergency
AIMS	Australian Incident Monitoring System
APSF	Australian Patient Safety Foundation
CRBSI(s)	Catheter-related Blood Stream Infection(s)
CCG	Clinical Commissioning Group
CQC	Care Quality Commission
COO	Chief Operating Officer
EDA	Exploratory data analysis
GMC	General Medical Council
GP(s)	General practitioner(s)
IA	Improvement advisor
ICPS	International Classification for Patient Safety
ICU	Intensive Care Unit
INR	International Normalised Ratio
INSRV	Informatics Service Team
LINNEAUS	Learning from International Networks about Errors and Understanding Safety in Primary Care (FP7 funded programme of research)
LINNAEUS	Learning in an InterNatioNal group About Errors and Understanding Safety (academic GP collaboration from early 2000s)
LMC	Local Medical Committee
LMIC(s)	Low- and middle-income countries
LRMS	Local Reporting Management System
MDG	Millennium Development Goal
MUSIQ	Model for Understanding Success in Quality
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NHS	National Health Service
NIHR	National Institute for Health Research Health Services and Delivery Research
HS&DR	
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OOH	Out of Hours
PDSA	Plan-Do-Study-Act
PISA	Primary Care Patient Safety
PPI	Patient and Public Involvement
QI	Quality improvement
RCGP	Royal College of General Practitioners
SIGN	Scottish Intercollegiate Guidelines Network
SPI	Safer Patients Initiative
UHB	University Health Board
UK	United Kingdom
USA	United States of America
WONCA	World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians
WHO	World Health Organization

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Summary

Internationally, there is an emerging interest in the inadvertent harm caused to patients by the provision of healthcare services. Since the publication of the Institute of Medicine's report, *To Err is Human*, in 1999, research and policy directives have predominantly focused on patient safety in hospital settings. More recently, the World Health Organization has highlighted 2-3% of primary care encounters result in a patient safety incident. Given around 330 million general practice consultations occur in the UK each year, unsafe primary care is a poorly understood, major threat to public health.

In 2003, a major investment was made in the National Reporting and Learning System to better understand patient safety incidents occurring in England and Wales. Over 40,000 incident reports have arisen from general practice. These have never been systematically analysed, and a key challenge to exploiting these data has been to generate learning from the largely unstructured, free-text descriptions of incidents.

My thesis describes the empirical development and application of methods to classify (structure) incident report data. This includes the development of coding frameworks specific to primary care, aligned to the WHO International Classification for Patient Safety, to describe the incident, contributory factors and incident outcomes. I have developed a mixed-methods approach which combines a structured process for coding reports and an exploratory data analysis with subsequent thematic analysis. Analyses of reports can generate hypotheses about priorities for systems improvement in primary care at a local and national level. Existing interventions or initiatives to minimise or mitigate patient safety risks can be identified through scoping reviews. Future research and quality improvement activities should deepen understanding about the risks to patients, and generate knowledge about how interventions made in practice can improve safety.

Chapter 1 – Introduction

Primary healthcare manages over 90% of healthcare encounters in the UK,(1) yet little is known about its safety. ‘Healthcare-associated harm’ is defined as “harm arising from or associated with plans or actions taken during healthcare provision, rather than an underlying disease or injury”.(2) Patient safety was recognised as a global public health concern by the World Health Assembly (Resolution 55.18) in 2002.(3) Policymakers have since deployed preventive strategies such as patient safety initiatives and patient safety incident reporting and learning systems to tackle the problem. However, these preventive efforts and related research and development have predominantly focussed on in-hospital safety. The World Health Organization’s (WHO) recent *Universal Access and Health Coverage* agendas, predicated on the provision of primary healthcare services, is now creating demand for cost-effective, community-based care models.(4) Given the relative paucity of knowledge about risk to patients receiving primary healthcare services, it is prudent and timely to identify the patient safety issues occurring in systems like the National Health Service before they are replicated in other countries.

The conceptual basis of patient safety has evolved over the past five decades. Each conceptual approach, and its related theories and frameworks, offer a means to frame safety and to understand how to make healthcare safer. In this chapter, I will describe the seminal publications, policy documents and research which shapes the modern theoretical landscape for patient safety research. I will discuss the conceptual basis of patient safety research and explore my personal perspective to these approaches.

1.1. Patient safety in healthcare

Evidence of discussions about patient safety in healthcare exists since antiquity. The teachings of Hippocrates, and the term 'iatrogenesis' (the Greek for 'originating from the physician'), is recognised as the earliest challenge to the medical profession to realise its role in healthcare-associated harm. However, in more recent times, it was the Austrian philosopher, Ivan Illich, who challenged the medical establishment in his book "*Limits to Medicine: Medical Nemesis: The Expropriation of Health*", which begins:

“The medical establishment has become a major threat to health. The disabling impact of professional control over medicine has reached the proportions of an epidemic. *Iatrogenesis*, the new name for this epidemic, comes from *iatros*, the Greek word for ‘physicians’, and *genesis*, meaning ‘origin’” (5)

Illich’s challenge was ahead of the epidemiological studies that would eventually follow to support his claims. His seminal thinking raised the fundamental questions which continue to drive the modern patient safety movement, importantly: *what is unsafe healthcare and how can it be prevented?*

1.1.1. Purpose of patient safety research

Since the turn of the millennium, patient safety has assumed an important position in public discourse, healthcare policy and scientific research. Within academia, patient safety is a subset of healthcare quality research, which itself is a subset of health services and delivery research, undertaken to generate learning to achieve safer healthcare.(6) Shojania and Panesar (7) describe five purposes of patient safety research which include to:

- evaluate progress in patient safety – the development and validation of measures to evaluate efforts to improve safety;
- translate evidence into practice – develop and evaluate interventions that increase the extent to which patients receive evidence-based practices;

- assess and improve culture – use of strategies and interventions to improve culture and communication;
- identify and mitigate hazards – use of retrospective and prospective methods to identify and mitigate hazards; and,
- evaluate the association between organisational characteristics and outcomes – determine which characteristics help or hinder achievement of patient safety practices.

1.1.2. Patient safety terms and definitions

In an effort to standardise a set of definitions of core terminology, the World Health Organization (WHO) commissioned the development of a Conceptual Framework for the International Classification for Patient Safety (ICPS). Throughout my thesis, all concepts, terms and definitions are purposefully aligned with ICPS unless otherwise stated.

The WHO defines patient safety as: “...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.”(2)

Healthcare-associated harm is the agreed term to describe the outcome of unsafe healthcare and is defined as: “harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury”.(2) Previously well-used terms with similar definitions include iatrogenesis and medical error.

Patient safety incident (or incident), defined as “events or circumstances which could have resulted, or did result, in unnecessary harm to a patient”,(2) will be used throughout the thesis. ICPS highlights the word “unnecessary” in its definition and refers to the inclusivity of *error* (omission and commission) and *violation*. It asserts errors are unintentional, whilst violations are usually

intentional, though rarely malicious. For simplicity, *incident* will also refer to *reportable circumstances*.

The outcomes from patient safety incidents can be a *near miss*, a *no harm incident*, or a *harmful incident* (also referred to as an 'adverse event').

Consistent with ICPS, I will be describing the outcomes of incidents in terms of *no harm* and *harmful* outcomes, and, when feasible, by level of harm (none, low, moderate, severe, death).

See Table 1.1. for additional definitions and examples of these key terms.

Table 1.1. International Classification for Patient Safety terms and definitions (2)

Term	Definition
Healthcare-associated harm	Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.
Patient safety incident (or incident)	Events or circumstances which could have resulted, or did result, in unnecessary harm to a patient.... The use of the word “unnecessary” in this definition recognises that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare. These are considered incidents.... Incidents arise from either unintended or intended acts. Errors are, by definition, unintentional, whereas violations are usually intentional, though rarely malicious, and may become routine and automatic in certain contexts.
Error	An error is a failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase.
Violation	A violation is a deliberate deviation from an operating procedure, standard or rule e.g. not admitting a patient with signs of an acute stroke to hospital for urgent assessment.
Reportable circumstance	A situation in which there was significant potential for harm, but no incident occurred e.g. taking a defibrillator to an emergency and discovering it did not work although it was not needed.
Near miss	A near miss is an incident which did not reach the patient e.g. wrong patient referred for CT scan but administrative staff identifying this before patient attended for scan.
No harm incident	A no harm incident is one in which an event reached a patient but no discernible harm resulted e.g. the GP prescribed penicillamine instead of phenoxymethyl penicillin V and this was dispensed by the pharmacist. The patient took two doses before notifying the GP and no harmful outcomes resulted.
Harmful incident (adverse event)	A harmful incident (adverse event) is an incident that results in harm to a patient. e.g. the GP prescribed penicillamine instead of phenoxymethyl penicillin V and the patient developed sepsis.
Incident type	An <i>incident type</i> is a category made up of incidents of a common nature, grouped because of shared agreed features and is a “parent” category under which concepts may be grouped.
Contributory factor	A <i>contributory factor</i> is a circumstance, action or influence (such as poor rostering or task allocation) that is thought to have played a part in the origin or development, or to increase the risk, of an incident. Factors may be external (i.e. not under the control of a facility or organisation), organisational (e.g. unavailability of accepted protocols), related to a staff factor (e.g. an individual cognitive or behavioural defect, poor teamwork or inadequate communication) or patient-related (e.g. non-adherence). A contributing factor may be a necessary precursor of an incident and may or may not be sufficient to cause the incident.

1.2. Ontological perspectives of patient safety research

Ontology can be thought of as concepts within a domain, and the relationships between those concepts.(8) The ontology of patient safety benefits from decades of academic insight contributed from anthropology, sociology, engineering, psychology, statistics and management. Each discipline has approached “what is safety?” with different, albeit complementary, assumptions in the sense that the overall goal is to improve outcomes. There are two mainstream conceptual approaches to patient safety; others exist although have not been validated by empirical research. I will therefore focus on describing the two approaches that have been developed and validated through empirical inquiry, which are: systems thinking and high reliability organisations.

Systems thinking is the conceptual approach behind the famed quote of the Dartmouth Professor, Paul Batalden, that “every system is perfectly designed to achieve the results it gets.” Assumptions are made about the ability to optimise the *structure* (the working conditions) and *processes* (the steps to achieve healthcare) of care delivery to minimise the risk of unsafe care *outcomes*.(9) The systems thinking approach has gained popularity within hospital safety because of its emphasis on understanding how the systems failed rather than the individual professionals involved. A similar approach may support patient safety initiatives in primary care.

High reliability theory has been another popular conceptual position that has emerged from the study of ‘high reliability organisations’ in the fields of aviation and nuclear power in the 1980s.(10) The approach encourages the development of effective communication mechanisms, autonomy amongst workers to raise concerns and act, and designing processes with multiple checks to identify failure. Given its popularity in medical specialties like anaesthesia and surgery,(10) this approach could also be beneficial in primary care.

Throughout the thesis, I will refer to ‘systems improvement’ as “the result or outcome of the culture, processes, and structures that are directed toward the

prevention of system failure and the improvement of safety and quality”.(11)
 This definition draws on the Donabedian Structure-Process-Outcome model which considers the relationship between structure, process and outcome that can be examined to evaluate the quality of healthcare delivery.(11,12) My interpretation of the original model described in Donabedian’s book,(12,13) ‘*The definition of quality and approaches to its assessments*’, was progressed by Starfield’s explanation of the dynamics between its concepts (see Figure 1.1).(13) Here, I use the Donabedian model modified by Starfield to outline my conceptual understanding of patient safety, informed by the concepts of systems thinking and high reliability theory, and consider its application in understanding safety in primary care. In doing so I will introduce further concepts and their definitions that I will use to describe my work.

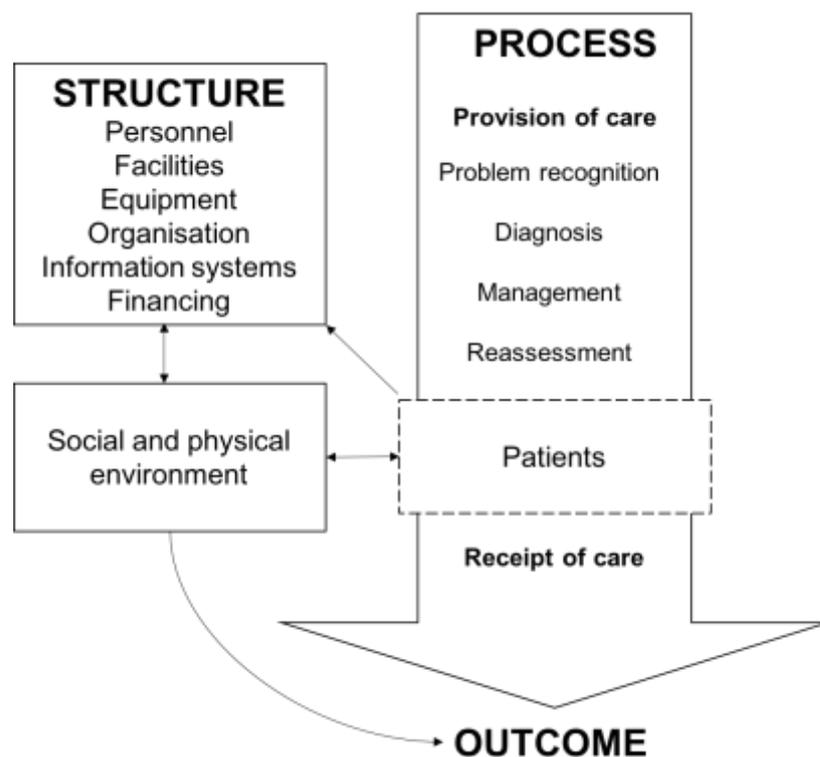


Figure 1.1. Donabedian Structure-Process-Outcome model modified by Starfield(13)

1.2.1. Donabedian's Structure-Process-Outcome model

In Donabedian's model, *structure* refers to the factors that influence the context for healthcare provision such as staffing, education and training, finance or equipment. In my thesis, structure is referred to as 'context' in the broadest sense. When it is possible to be more specific about "a circumstance, action or influence (such as poor rostering or task allocation)" that is thought to have played a part in the origin or development, or to increase the risk of an incident, the term 'contributory factor' is used.(2) *Process* considers the actions that make up healthcare delivery and can be classified as technical processes such as problem recognition, diagnosis, management and reassessment (i.e. how care is delivered) and interpersonal processes such as communication with and about the patient (i.e. the manner in which it is delivered).(4)

1.2.2. Reason's Trajectory of Accident Opportunity

To put into context how structure and process can be implicated in patient safety incidents, I will describe the 'Trajectory of Accident Opportunity' originally described by Orlandella and Reason, and later applied to healthcare by Reason. Lucian Leape brought the spotlight to Reason's work within the medical community, and it was welcomed since the Swiss cheese model helped articulate the complexity underpinning error. It also introduced the concept that healthcare professionals, in the majority, have minor roles in patient safety incidents compared with consequences arising from the overall design of systems (structures and processes).(14) Such conceptual thinking emerged from industries that took a pessimistic view of human capability to not err and which had the ability to engineer people out of their systems. Reason advocated that an individual's actions must be understood in context. This does not mean medical negligence can be justified by account of a poorly designed system.

Aveling et al.(15) have described the challenges raised by 'systems thinking' and appropriately delineate the accountability of healthcare systems and individual professionals. The authors draw upon Giddens'(16) conceptualisation of practice theory to describe the duality of structure and agency. They discuss

unsafe healthcare as an organisational phenomenon occurring as a result of everyday actions, with: i. individual agency (of professionals, staff, patients, carers, amongst others) defined as “the capacity of individuals to act independently and to make their own free choices”; and, ii. structural conditions (as described by Reason) defined as “recurrent patterned arrangements which influence or limit the choices and opportunities available” as a mutually constitutive, dynamic duality.

Reason stated an individual’s actions must be considered in the context (conditions) under which they occurred. As Aveling et al.(15) describe it: “structure creates and shapes the possibilities for agency, at the same time as agency creates and shapes structure”. In this way, they describe how Giddens introduces a notion of accountability where an individual should “explicate the reasons for them and to supply the normative grounds whereby they may be ‘justified’”.(15) In professional practice this is called the *Bolam test*, which is a judgement of whether an individual’s actions fall below the standard of a responsible body of other professionals.(17) Given the complexity of judging what is safe or unsafe, the Bolam test is an important principle for informing the design of patient safety research.

1.2.2.1. Swiss cheese model

The Swiss cheese model (Figure 1.2) uses the analogy of serial slices of Swiss cheese where each hole represents either an active failure (unsafe acts committed by humans) or latent conditions (error-provoking conditions or prior weaknesses in defences) that are transient opportunities for the steps in a process leading towards an incident.(9) Each hole in the cheese represents a ‘contributory factor’ (active failures and latent conditions) which are circumstances, actions or influences, to initiate or increase the risk of an incident that could, or might not, lead to the unwanted or unintended outcome.(2)

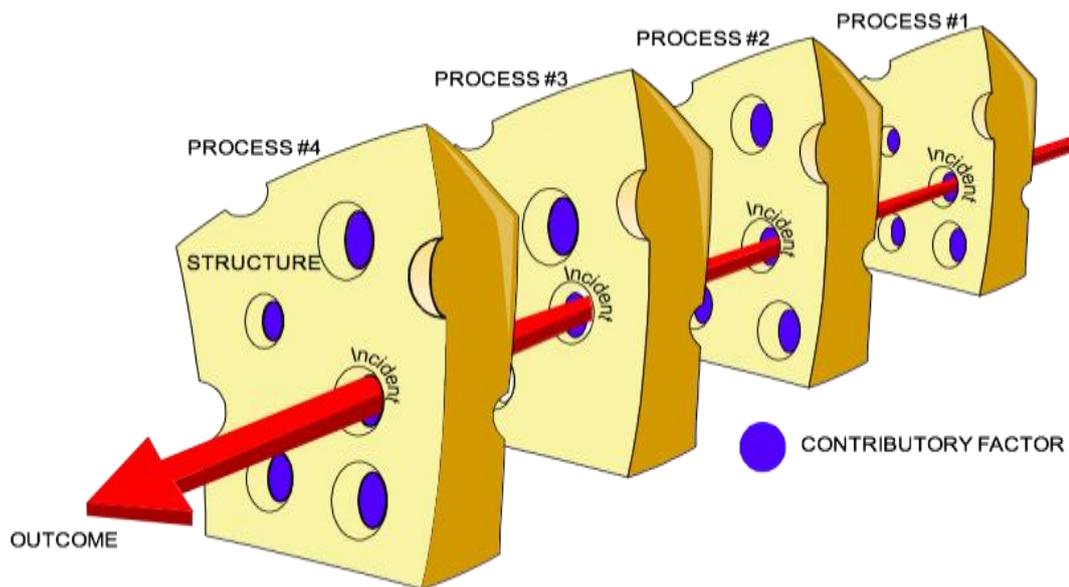


Figure 1.2. Swiss cheese model & Trajectory of Accident Opportunity annotated with WHO ICPS terms

A finite number and type of contributory factors can coexist at any one time to result in an incident. They can be diverse in nature, and thought of in terms of human factors, for example staff- or patient-related, as well as system factors such as organisational-, financial- or equipment-related issues. The ability to identify contributory factors when an incident occurs represents an opportunity to understand how healthcare systems and processes can be improved, to minimise weaknesses and strengthen defences. This study of human factors as a field of specialist inquiry is predicated on this basis and is described as: “enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture, organisation on human behaviour and abilities, and application of that knowledge in clinical settings”.(18)

It is not possible to anticipate the plethora of ways that a series of conditions could combine to culminate in a patient safety incident. An appreciation of common trajectories of incidents and contributory factors would, however, theoretically inform prioritisation efforts, and guide decision-making about what processes need to be changed to minimise the conditions, actions and influences speculated to increase risk of patient safety incidents. Such in-depth classification of incidents and contributory factors in primary care has potential

to reveal the human and system-level opportunities to improve patient safety. According to Brook et al.(19): "process data are usually more sensitive measures of quality than outcome data, because a poor outcome does not occur every time there is an error in the provision of care". Thus, understanding how and why failures in care processes (incidents) arise, in the context of the system structures that they occurred and the related contributory factors, should build a more complete picture of the challenges and opportunities for intervention. My thesis is predicated on the basis of developing and testing methods to generate such learning from incident reports.

Finally, ‘*outcome*’ describes the effects of healthcare on patients and the population. Batalden and Davidoff, in more recent years, have defined quality improvement with three outcomes, "...better patient outcomes (health), better system performance (care) and better professional development.”(20) In 2001, the Institute of Medicine in Washington, DC, USA, published *Crossing the Quality Chasm: A New Health System for the 21st Century* which defined six aims for these processes which are that healthcare is safe, timely, effective, efficient, patient-centred and equitable.(21) These aims are not mutually exclusive, and are defined as:

- safety, to avoid unintentional harm from care provided to patients;
- timeliness, reducing harmful delays;
- effectiveness, providing care, informed by best available evidence, which provides clear benefits;
- efficiency, avoiding waste;
- patient- and family-centredness, providing care that is respectful of the needs and values of patients and their families; and,
- equity, providing high-quality care regardless of a patient’s characteristics.

Observing trends in outcomes provide important signals, in terms of frequency and severity of those outcomes, for more in-depth inquiry. Incident reporting systems collect data about structure, process and outcome, although it is unclear how to formally interrogate these systems to maximise the insight yielded from such reported data. This challenge largely arises from the volume

of unstructured free-text data now captured by incident reporting systems, and how to deconstruct reports to enable learning about weaknesses in existing structures and processes to inform systems improvement.

1.2.3. Quality improvement (QI) methods

A suite of methods and tools to achieve systems improvement have emerged from the seminal works of industrial engineers and statisticians, including Walter Shewhart, W. Edwards Deming, Joseph Juran, and in more recent years the Associates for Process Improvement. Common objectives of a QI project are to minimise duplication of effort, design new ways of working, and identify the means to ensure high-quality care is delivered for every patient, every time. Such methods have informed the educational content of major patient safety campaigns in the past two decades. Quality improvement projects often involve multiple professional groups and the issues being addressed span hierarchies.

Deming's *Theory of Profound Knowledge* is a management framework which informs my conceptual understanding of how to improve systems and is based on systems theory.(22) Healthcare systems have complicated designs that over time often merge into a mesh of interconnected departments, siloed practices, and process duplication. It is often the objective of quality improvement projects to examine a system's structure and processes to seek opportunities to design or redesign new ways of working. Those leading QI show expertise which align to four major constructs described in W. Edwards Deming's Theory of Profound Knowledge (22,23):

- Variation – curiosity about variation in process and outcomes within systems, through continuous measurement and utilising statistical methods;
- Systems thinking – awareness of the system context in which change is planned and tested, and the need to monitor and mitigate unintended consequences; and, the will to execute plans in collaboration with professionals across the multidisciplinary team and hierarchical levels, while building the infrastructure to sustain successful implementation;

- Learning – a commitment to understand what changes resulted in improvement with the courage to learn from failure; and,
- Psychology – the energy to confront difficulties, including stark organisational realities of frustration, cynicism, and resistance to change.

This conceptual approach for systems improvement has been promoted by the US-based non-profit organisation, the Institute for Healthcare Improvement (IHI), since the 1990s. Their approach often involves providing local teams with direction, coaching and training to develop capacity and capability to reliably implement evidence-based strategies, data management to measure their impact on organisational outcomes, and the opportunity to learn from other hospitals' experiences.(24,25) These methods have been disseminated via national quality and safety campaigns such as the "100,000 Lives Campaign" between January 2005 and June 2006 in the United States, where hospitals agreed to implement best-practice interventions to collectively extend or save as many as 100,000 lives.(25) National programmes were later launched, supported by IHI, in Scotland (Scottish Patient Safety Programme, 2008–), Wales (1000 Lives Campaign, 2008-2010), England (Patient Safety First, 2008–) and Northern Ireland (the Health and Social Care Safety Forum in 2007). In the early years of these campaigns or initiatives, the focus was largely safety, which later extended to preventive initiatives focussed on other Institute of Medicine aims such as optimisation of chronic disease management (e.g. heart failure), patient-centred care, and equity of access. The quality improvement methods and tools, and affiliations with IHI, are the shared common threads amongst these campaigns which have been major financial investments for each country.

1.2.3.1. A programme 'theory of change'

Quality improvement (QI) projects need a programme "theory of change".(22,26) The theory of change is an articulation of conceptual thinking and programme design that should be amended with additional hypotheses throughout the course of the QI project.(27) The programme theory is comprised of an explanatory theory, an operational logic model (the Plan-Do-Study-Act plans) and draws on relevant theories of social change.(27)

The explanatory theory is an “...articulation of an overall aim, potential intervention(s) that will be tested in an attempt to achieve this aim, hypothesised cause/effect relationships linking intervention(s) to the aim and measure concepts that link to the cause/effect chains to support evaluation.” (28) Such interventions “[seek] to change individual or group behaviour, or organisational structure and performance” (29). A common tool used to graphically display the explanatory theory is called a driver diagram (described in more detail in section 1.2.3.2).

The philosophy and methods of quality improvement have been described by Langley and colleagues in the seminal textbook, ‘The Improvement Guide’.(30) ‘Logic models’ typically used in research, are used in QI projects as a structured process (called ‘Plan-Do-Study-Act’ or PDSA) for developing and learning from iterative tests of change in practice.(31) Each PDSA is thought of as a ‘PDSA cycle’ for generating learning from one test of change to inform the next test, and an opportunity to update and amend the explanatory theory. Such inductive-deductive tests of change are, as Ostom (32) cited by Davidoff et al.(33) put it, “a strategy of moving back and forth from the world of theory to the world of action”.

Finally, recognising healthcare is a complex system, the four constructs of Deming’s Theory of Profound Knowledge,(29,30,34) provide a helpful baseline to attach the more general theories used internationally to inform the approach taken to achieve improvement with teams in practice.(27) Such theories include, for example, social network and influence theory (adapting interventions to each local context), theory of communication (utilising best available evidence, tailoring key messages to different stakeholder audiences) and process re-engineering theory (the design and redesign of multidisciplinary care processes) which have been extensively described by Grol and colleagues.(35)

1.2.3.2. Action effect (driver) diagram

A QI tool called an action effect (or driver) diagram can be used to summarise the explanatory theory in terms of concepts and ideas from existing evidence

(e.g. incident reports), as well as the experience and beliefs of those within project teams. This combination is particularly pertinent for primary care improvement given the paucity of evidence that exists about improving patient safety in community settings. Langley et al. (30) originally developed the tool to enable the building of a testable hypothesis which articulates testable predictions of activities and infrastructure necessary to achieve a desired outcome. The diagram is pragmatic in nature, and outlines the changes that are proven (or believed) to be needed to accomplish an aim or outcome.

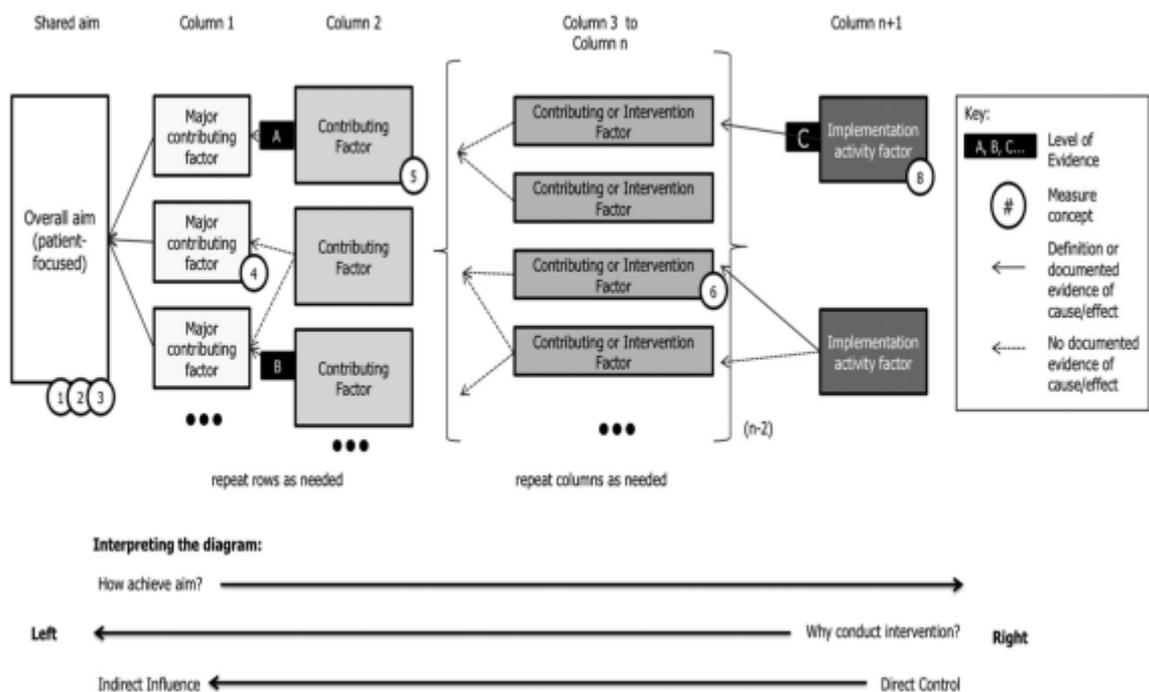


Figure 1.3. Schematic action effect diagram: guide to interpreting the components and overall structure of a typical action effect diagram. Reproduced with permission from Reed et al.(28) BMJ Quality and Safety. doi:10.1136/bmjqs-2014-003103.

In Figure 1.3, at the far left of the diagram, the aim describes the objectives of the intended QI project. Reed et al.(28) attempted to make the method for developing such diagrams more accessible. They observed how improvement teams struggled to work collaboratively to produce useful theory and perceived driver diagram construction as low value.(28) They noted the term ‘driver’ was confused with strategic influences such as financial and political motivations

rather than the actions that could be undertaken during the project. In their revised approach, primary and secondary drivers are renamed “contributing factors”. ‘Major contributing factors’ converge on the aim and summarise the high-level leverage points for change in the system infrastructure that could support achievement of an improved outcome. Connected to each major contributing factor are lower-order contributing factors which tend to be represented as actionable approaches or opportunities to make the changes that are perceived by the team to enable achievement of the desired improvement.

There is strong conceptual alignment between the WHO’s ICPS definition of contributory factor considered in the context of understanding patient safety incidents, and Reed et al’s proposed concept and term, ‘contributing factor’ represented in Figure 1.3 as a leverage point for change in the healthcare system infrastructure. Thus, in my thesis, contributory factors considered in relation to the incident type and the contexts in which they occur, are the basis of proposed issues for improvement. For example, identified contributory factors such as ‘ambiguous packaging’ and ‘adjacent storage of similar vaccines’ could be thematically combined to represent incidents related to ‘selection, retrieval and preparation of vaccines’. In the driver diagram, these issues could be represented by improvement plans to ‘reduce risk of staff mistakes’.(36)

Whilst Reed et al.(28) have identified confusion about the term ‘driver diagram’, it is the internationally accepted reference to a diagram of its nature. For the remainder of my thesis, I will refer to driver diagrams only, but highlight my conceptual alignment with how Reed et al. use the action effect diagrams in QI projects.

1.2.3.2.1. Change concepts

In Figure 1.3, straight or interrupted arrows are used to represent documented evidence of cause and effect, or absence of such evidence respectively. Nolan and colleagues advised nine major conceptual opportunities for quality improvement; these are summarised in Table 1.2, and can be used to support

ideas generation amongst teams proposing change concepts and ideas. It is common for proposed outcome measures to be included on the driver diagram.

The action effect diagram is iterated as learning about the impact of changes made in different contexts becomes apparent.(37) Comparing the diagram at the start of an improvement project and at the end, can support appreciation of how the programme theory has developed throughout the QI project. The diagram, as a visual summary of a planned or delivered improvement project, is becoming increasingly recognised as “a communication tool to engage stakeholders”.(28)

Table 1.2. Potential change concepts and examples

Nature of change concept	Example
Eliminate waste	Eliminate multiple entry.
Improve workflow	Find and remove bottlenecks; automation.
Optimise inventory	Reduce multiple brands of the same item.
Change the work environment	Conduct training; focus on core processes and purpose; share risks.
Enhance the producer / customer relationship	Listen to the end-user; optimise level of inspection.
Manage time	Reduce waiting time; optimise maintenance.
Manage variation	Develop operational definitions; develop contingency plans; exploit variation.
Design systems to avoid mistakes	Use reminders; use constraints.
Focus on the product or services	Change the order of process steps; manage uncertainty.

1.2.4. A brief history of patient safety and quality improvement

A brief history of patient safety and quality improvement initiatives is warranted given their influence in shaping the current patient safety research agenda. Specifically, the initiatives were created without formal evaluations to identify what approaches or interventions worked in different contexts.(34,38,39) Post-

hoc evaluations in more recent years have been critical of this lack of foresight, and indeed have demonstrated why this was misguided, and have brought into question the effectiveness of promoted interventions and the quality improvement methods used to implement them.(40–43)

To provide a sense of the scale of the quality improvement and safety effort in which efforts to improve primary care safety will coexist with, I will describe major international initiatives, followed by the national initiatives in the US and UK that have since been subject to evaluation. Observations from successes made in promoting patient safety as a threat to public health will be made. Lessons learnt from those evaluations that have implications for how incident reporting systems should be perceived (by policymakers, leaders, clinicians) and utilised for improvement purposes will be highlighted.

The World Health Assembly Resolution 55.18 recognised healthcare-associated harm as a public health concern in 2002.(3) This milestone for patient safety was accelerated by the publication of seminal reports which raised awareness about the scale of the problem and the lack of existing infrastructure to respond to the apparent threat.

Patient safety research dates back formally to the 1960s when clinicians reviewed the medical records of patients to identify unwarranted harm outcomes.(10,44,45) However, it was the Institute of Medicine (1999) report, *To Err is Human* which accelerated the field of patient safety forwards amongst professionals, healthcare leaders, politicians and not least the public.(46) Internationally, it was the leadership of Sir Liam Donaldson (then the Chief Medical Officer for England) that is often credited with globalising the challenge to tackle patient safety. In 2004, the WHO World Alliance for Patient Safety (later the WHO Patient Safety Programme) was launched with the fundamental purpose of facilitating development of patient safety policy and practice in member states.

To Err is Human (217) outlined several options for investment amongst policymakers to tackle patient safety. This included recommendations to:

- establish a national centre for patient safety in the United States;
- to form a mandatory and voluntary national patient safety incident reporting system;
- curate best practices and principles for beginning to achieve improved safety in practice (avoiding reliance on memory and vigilance);
- focus on user-centred design;
- move towards team-based care;
- involving patients; and,
- better information systems.

Published in 2001 by the Department of Health in England, *An Organisation with a Memory* from the Department of Health, focussed on setting out the strategic priorities for enabling the NHS to have the capacity to learn from patient safety incidents.(47) Combined, *To Err is Human* and *An Organisation with a Memory* were influential in establishing the National Patient Safety Agency in England and Wales in 2002, and its cornerstone initiative, the National Reporting and Learning System in 2003.

Since *To Err is Human*, several patient safety campaigns have emerged globally to disseminate evidence-based practices and the principles described in *To Err is Human*. The WHO has launched two international patient safety campaigns, and there are numerous examples of national campaigns.

1.2.4.1. International patient safety initiatives

The WHO launched *Clean Care is Safer Care* in 2005.(48) The initiative was designed to raise awareness of healthcare-associated infection across all income settings and focus action in five areas: blood safety; injection practices and immunisation; water, basic sanitation and waste management; clinical procedures safety; and hand hygiene. Whilst 98% of member states have since signed up to *Clean Care is Safer Care*, the campaign as a whole has not been evaluated. Interventions advocated to improve clinical procedure safety, have however, been subject to intensive evaluation and an intervention to minimise catheter-related bloodstream infections is described in more detail in section 1.2.4.2.

In 2007, the WHO World Alliance for Patient Safety launched *Safe Surgery Saves Lives* to disseminate a surgical safety checklist which comprised 19 clinical processes or tasks that should be undertaken for every patient before, during and following surgery (Figure 1.4).(49) A randomised controlled trial in eight centres in developed and developing countries demonstrated major reductions in morbidity and mortality outcomes.(50) As use of the checklist spread across the globe, mixed reviews emerged. At one extreme, the surgeons relished the complexity of their work and could see no value from introducing such basic checks into their work processes, whilst on the other extreme, the compelling evidence published in the *New England Journal of Medicine* (NEJM) enabled others to see each item on the checklist as a means of achieving reliability on important tasks for their patients. In amongst this debate, medical sociologists and patient safety researchers cautioned the risk of presenting the checklist as a piece of paper that will save lives. In their *Lancet* editorial entitled “*Reality check for checklists*”, Bosk et al.(51) emphasised the importance of understanding the contexts in which the innovation was being implemented, and said: “evidence summaries [informing each checklist item] need to be combined with an understanding of, and a strategy for, mitigating the technical and social/political and psychological (even emotional) barriers to using the evidence, and with feedback about performance.”

World Health Organization		
SURGICAL SAFETY CHECKLIST (FIRST EDITION)		
Before induction of anaesthesia	Before skin incision	Before patient leaves operating room
<p>SIGN IN</p> <p><input type="checkbox"/> PATIENT HAS CONFIRMED • IDENTITY • SITE • PROCEDURE • CONSENT</p> <p><input type="checkbox"/> SITE MARKED/NOT APPLICABLE</p> <p><input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED</p> <p><input type="checkbox"/> PULSE OXIMETER ON PATIENT AND FUNCTIONING</p> <p>DOES PATIENT HAVE A:</p> <p><input type="checkbox"/> KNOWN ALLERGY? NO YES</p> <p><input type="checkbox"/> DIFFICULT AIRWAY/ASPIRATION RISK? NO YES, AND EQUIPMENT/ASSISTANCE AVAILABLE</p> <p><input type="checkbox"/> RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)? NO YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED</p>	<p>TIME OUT</p> <p><input type="checkbox"/> CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE</p> <p><input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM • PATIENT • SITE • PROCEDURE</p> <p>ANTICIPATED CRITICAL EVENTS</p> <p><input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?</p> <p><input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?</p> <p><input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?</p> <p>HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES? <input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE</p> <p>IS ESSENTIAL IMAGING DISPLAYED? <input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE</p>	<p>SIGN OUT</p> <p>NURSE VERBALLY CONFIRMS WITH THE TEAM!</p> <p><input type="checkbox"/> THE NAME OF THE PROCEDURE RECORDED</p> <p><input type="checkbox"/> THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)</p> <p><input type="checkbox"/> HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)</p> <p><input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED</p> <p><input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT</p>

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Figure 1.4. WHO Surgical Safety Checklist (First Edition)(49)

Five years later, a study in the same journal (NEJM) concluded the checklist had no impact on morbidity or mortality outcomes in operating rooms in Ontario, Canada, despite a reported 98% uptake by hospitals.(52) In an accompanying editorial in the same issue, Lucian Leape writes:

“the story of the patient-safety movement is one of slow progress punctuated by episodes of inspiring successes that are slow to be replicated.... The key is recognizing that changing practice is not a technical problem that can be solved by ticking off boxes on a checklist but a social problem of human behavior and interaction”.(53)

1.2.4.2. National patient safety initiatives

Another seminal study was the ‘*Keystone ICU*’ project, funded by the Agency for Healthcare Research and Quality (AHRQ) in the United States, which involved 103 Intensive Care Units (ICU) in Michigan, USA, in a state-wide initiative, instituting evidence-based preventive strategies for reducing catheter-related [central line] bloodstream infections (CRBSI).(54) The project focused on changing provider behaviour through addressing safety culture, incorporating a centralised education programme for team leaders at each institution and

closely collaborating with infection control staff. The intervention almost eliminated CRBSIs in most ICUs over an 18-month follow-up period, and 1500 lives were estimated to have been saved.(54,55)

Following the success and publicity surrounding the Keystone ICU project in Michigan, '*Matching Michigan*' was a national initiative in England seeking to emulate the achievements and involved over 97% of acute NHS trusts.(55,56) The results were promising, and a 60% reduction in the number of CRBSIs was reported.(56) However, on closer analysis of data, it was difficult to determine whether the reduction in CRBSIs resulted from the Matching Michigan project or from a coinciding nationwide drive to reduce nosocomial infections, since many trusts were already implementing part of a five-point strategy employed in the Michigan intervention. There was also a decrease in other infections, which were not related to ICUs or CRBSIs.(56)

A post-hoc ethnographic observational study of ICUs in Michigan, USA, was undertaken by UK medical sociologists. They demonstrated how adopting technical solutions (i.e. a checklist with key tasks to do for every patient when inserting a central line) to a socio-technical problem may underlie the failure to emulate Michigan's achievements. Dixon-Woods et al.(43) described how the team in Michigan generated pressure for their ICUs to participate; created a sense of network amongst them; and re-framed bloodstream infections arising from central insertion as a needless, social problem; and teams were driven by learning from their data which demonstrated whether they were achieving better results for patients.

More broadly, policymakers across the world responded to *To Err is Human* and *An Organisation with a Memory* by committing to develop the infrastructure for better surveillance and by launching preventive initiatives. However, the focus was almost exclusively on hospital safety. The UK charity, The Health Foundation sponsored the *Safer Patients Initiative* (SPI) between 2004 and 2008 to develop and test organisation-wide service delivery interventions for improving hospital safety.(56–58) Twenty-eight hospitals participated over two phases. The independent summative evaluation concluded there was no

difference in improvement outcomes between hospitals that participated in SPI and a concurrent control group using a before and after design.(43,59) The evaluators wrote: “the conclusion of this study could have been different if concurrent controls had not been used.” More recently, Chen et al.(60) described the ‘rising tide phenomena’ to explain how promising service delivery interventions with contemporaneous controls can yield a null result. They argue this is because attention to the problems they intend to address is already heightened, and pressure to tackle them is mounting throughout the wider healthcare system.

1.2.4.3. Learning from implementing healthcare improvement interventions

One major criticism of patient safety initiatives has been about the lack of robust evaluation. There are no formal published evaluations of any of the major national patient safety campaigns like the 1000 Lives Campaign or Patient Safety First. I have, however, described the main findings from the focussed evaluations of Health Foundation funded programmes like SPI and Matching Michigan which highlight the overemphasis on technical interventions like checklists and other evidence-based interventions as being (unrealistic) ‘magic bullets’ for success. In the last decade, there has been an apparent disconnect between the marketing of how patient safety should be achieved and the realities of actually achieving it in practice. This needs considerable attention since the evidence is accruing that current approaches to achieving improvement in practice are not working as effectively as expected.

Healthcare is a complex socio-technical system, in which even apparently simple tasks can depend on a wide range of social (e.g. psychological, team and managerial) and technical (e.g. equipment, IT and infrastructure) factors. In a review of 34 evidence-based interventions that had been replicated in other settings, 41% were found to have a smaller effect size or were not found to be effective in the subsequent setting.(61) The Keystone ICU project and the Matching Michigan experiments demonstrate that whilst improvement initiatives can be effective, as they became more widespread, a diminishing effect on outcomes can be seen. The complexity of the intervention in Michigan was not fully understood before it was spread to ICUs across England. Whilst the

technical interventions (changes in clinical practice) were clear, the non-technical interventions (linked to leadership, teamwork and culture change), may not have been successfully replicated. In this situation, a simple but intuitively appealing summary model of the changes needed to produce improvement (i.e. a driver diagram) becomes a fixed protocol rather than the basis for teams to adapt the interventions locally.(34) This is portrayed in Figure 1.5.

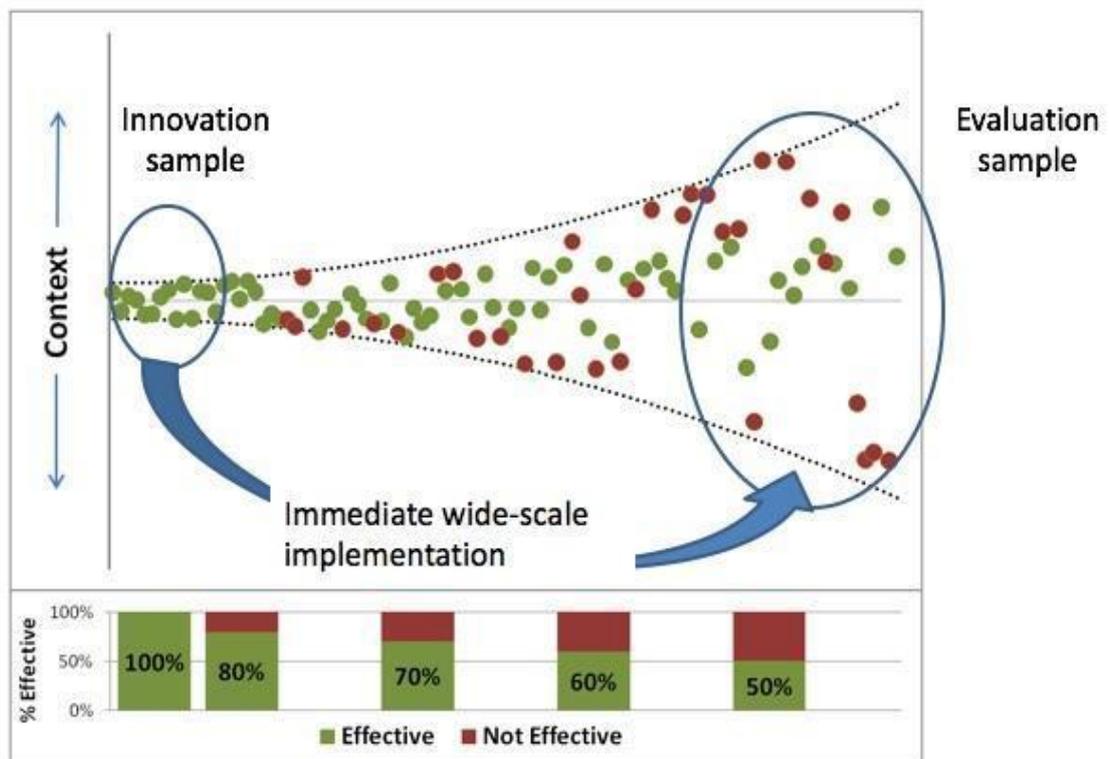


Figure 1.5. Challenges of wide-scale implementation from Parry et al.(34)

Improvement scholars, Perla and Parry,(62) frame this challenge as, “...how can [healthcare systems and leaders] design knowledgeable healthcare systems that maximise the alignment between the current best evidence (‘truth’) and the actions of healthcare providers (‘belief’)?” Drawing upon Plato’s Theaetetus, where knowledge is defined as the intersection of truth and belief, the authors describe how “knowledge cannot be claimed if something is true but not believed, or believed but not true”. Local adaptation could permit understanding about beliefs of different staff groups that would need to be considered for the intervention to be successful. Without this insight, there is a risk of rushing to

generate a summary of the changes needed to produce improvement outcomes too quickly, without truly understanding which change(s) led to improvement.(34)

1.2.5. Summary of patient safety concepts informing my thesis

I have explored the conceptual basis of patient safety research by considering the seminal polemics (Ivan Illich), policy documents and research which have informed my conceptual understanding of patient safety. In summary:

- Reason's 'Trajectory of Accident Opportunity' promotes the identification of weaknesses in systems which can be targeted for intervention.
- Systems thinking does not mean overlooking the professional accountability of individuals involved in safety incidents when warranted.
- The ability to identify contributory factors when an incident occurs, represents an opportunity to understand how structure and processes can be improved, to minimise weaknesses and strengthen defences.
- Appreciation of common trajectories of incidents and contributory factors can inform prioritisation efforts to improve patient safety.
- Concepts and related ideas for improvement must be adapted to each context in which they are implemented.
- Understanding the context in which incidents occur (and interventions are implemented) should inform the design / redesign of improvement efforts.

1.3. Why is improved patient safety in primary care needed?

Patient safety research in hospital settings has shown that healthcare-associated harm is responsible for a substantial, potentially preventable, burden of disease. Preventive safety initiatives have shown it is possible to identify patterns in patient safety incidents, which includes determining which incidents pose the greatest risk of major harm to patients and isolating those most amenable to prevention. Informed by epidemiological studies, patient safety in

hospital settings is now in an era of implementing interventions to improve safety. Similar progress is now needed for primary care.

In 2012, the WHO recognised that progress in patient safety in primary care lagged behind achievements in hospital settings. In an attempt to support the development of a more comprehensive evidence-base, the WHO convened an international group of experts to discuss, debate, and advise on directions to bridge knowledge gaps about patient safety in primary care.(63) Progress made in hospital safety was discussed in terms of approaches used to establish the epidemiology of incidents, identify priorities for intervention and methods for evaluating their impact. The group concluded that a major commitment was needed to establish the epidemiology of patient safety in primary care.(64)

Following conclusion of the Millennium Development Goals (MDG) initiative, the WHO *Universal Access and Health Coverage* agendas have promoted the development and expansion of primary care services. This has been a welcomed development with the potential to improve access to healthcare particularly in low- and middle-income countries (LMIC). Developed nations are also transitioning to predominantly primary care-based models like the UK. Unstable political and economic conditions have impeded investment and development of primary care infrastructure in many LMICs; however, such infrastructure played an important role in many achievements made by MDG programmes focussed on HIV, maternal and child health.(65) The Universal Coverage and Health Access agendas both signal a renewed interest and recognition that successful primary care services are needed to support achievement of several Sustainable Development Goals.(66)

Whilst there is no universally applicable primary care model, the challenge for each transitioning country will be to select the interventions and services that target the multiple diseases and risk factors affecting different population groups given the epidemiological, political, economic and sociocultural context in each country.(65) Improving primary care safety should benefit from the lessons learnt from attempting to improve safety in hospitals over the past two decades; however, the conceptual frameworks of patient safety need to be considered

within the context of primary care, and the epidemiology and methods of deriving and implementing interventions, may all need to be developed in their own right.(64)

1.3.1. Definitions of primary care and general practice

In my thesis, I will draw upon the 1978 Alma-Ata Declaration definition of primary care, defined as:

“...essential healthcare based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing healthcare as close as possible to where people live and work, and constitutes the first element of a continuing [healthcare] process.”(67)

The United Kingdom (UK) demonstrates that it is possible to deliver upwards of 90% of healthcare outside the hospital setting; this equates to around 330 million healthcare encounters in general practice per annum.(1) The benefits and limitations of primary care on health outcomes have previously been described.(68)

General practice consultations represent a subset of patient healthcare encounters in UK primary care. The core characteristics of general practice have been defined by the World Organization of National Colleges, Academies and Academic Associations of General Practitioners (WONCA) and are summarised in Table 1.3. These are basic characteristics of general practice. Methods developed for the purposes of the research included in this thesis

should be applicable to common contexts of care provision in different income settings, particularly due to the central positioning of general practice in healthcare systems globally. Efforts to aid their universal applicability to other primary care disciplines will be made for these to be applied in future studies.

Table 1.3. European definition of general practice defined by WONCA

The characteristics of general practice are:	
a	...is normally the point of first medical contact within the healthcare system, providing open and unlimited access to its users, dealing with all health problems regardless of the age, sex, or any other characteristic of the person concerned
b	...makes efficient use of healthcare resources through co-ordinating care, working with other professionals in the primary care setting, and by managing the interface with other specialities taking an advocacy role for the patient when needed
c	...develops a person-centred approach , orientated to the individual, his/her family, and their community
d	...has a unique consultation process, which establishes a relationship over time , through effective communication between doctor and patient
e	...is responsible for the provision of longitudinal continuity of care as determined by the needs of the patient
f	...has a specific decision making process determined by the prevalence and incidence of illness in the community
g	...manages simultaneously both acute and chronic health problems of individual patients.
h	...manages illness which presents in an undifferentiated way at an early stage in its development, which may require urgent intervention
i	...promotes health and well being both by appropriate and effective intervention.
j	...has a specific responsibility for the health of the community
k	...deals with health problems in their physical, psychological, social, cultural and existential dimensions

Models of primary care are delivered in many contexts, with variable management and financial arrangements, to provide a range of preventive health, public health and healthcare services to a diverse case-mix of patients of all ages, complexity (undifferentiated complaints, uncertain diagnoses, multiple comorbidities) and socio-cultural circumstance, by healthcare professionals (GPs, practice nurses, community pharmacists, community midwives, district nursing, dentists) that communicate through many formats. Challenges facing modern primary care could also inadvertently create greater

risks of healthcare-associated harm; for example, patients are discharged from hospital earlier than before, and receive episodic and decentralised care; GPs prescribe and monitor high-risk drugs; consultations are time-pressured; and continuity of care relies on coordination between many care providers and services.(69)

1.3.2. Epidemiology of healthcare-associated harm in primary care

A WHO-commissioned systematic review informed discussions at the WHO Safer Primary Care meeting, and concluded that 2-3% of primary care encounters result in a patient safety incident defined as “events or circumstances which could have resulted, or did result, in unnecessary harm to a patient”.(11) Of those, 1 in 25 incidents will result in a serious harm (shortening of life expectancy, permanent injury, major loss of function) or a fatal outcome.(70) From such estimates, it is unclear at which end of this range the UK belongs. Case note reviews of specific patient safety incidents like prescribing errors occurring in general practice in England suggest these occur for 1 in 8 patients.(71)

The systematic review was limited by the heterogeneity of included studies in terms of reported measurement outcomes (e.g. adverse events versus patient safety incidents) and related variations in use of terminology. Given the range of definitions used, the existing evidence-base from which to pool estimates to identify priority areas for intervention is weakened. Studies that described either the frequency or outcomes of patient safety incidents were included if they utilised a method like case note review with a reliable reported denominator. Analysis of patient safety incident reports dominate previous patient safety research activity in primary care. This also includes incident reports gathered through surveys of clinicians and through established reporting systems. Such studies have used different hierarchical taxonomies to code data. In addition, few studies have focussed on understanding the underlying contributory factors to patient safety incidents, (69,72–78) which is reflective of the wider body of patient safety literature.(79)

The systematic review reported the three most common categories of patient safety incident type were: administrative and communication incidents; diagnostic incidents; and, prescribing and medication management incidents. Diagnostic and medication incidents were most likely to result in harm, and most likely to result in severe harm.(70,80) Diagnostic incidents concerned missed or wrong diagnoses. Thirty-five studies focused explicitly on prescribing incidents, where the rate of a patient safety incident occurring was between 1 and 90 out of 100 prescriptions issued. Rates were higher in studies that focused on the elderly or those taking multiple medications.(81–84) Efforts to mitigate medication incidents are in an era of implementation and evaluation. A few more robust before-and-after studies and randomised controlled trials have found that up to half of all incidents may be preventable using interventions such as pharmacist-led medication review, computerised physician order entry and computerised decision support systems, error alert systems and education of professionals, and complex interventions combining professional education, informatics and financial incentives.(85–95)

A systematic review by Makeham et al.(96) of interventions to minimise the risk of non-medication safety incidents identified nine studies (summarised in Table 1.4). Safety culture, patient compliance, and incident report frequency were commonly stated outcome measures.

Table 1.4. Features of primary care patient safety intervention studies including outcome measures from Makeham et al.(96)

Paper	Design	Intervention description	Key findings	Outcome measures
Arora et al. 2015 (97)	Randomised controlled trial	Intervention to improve safety in transitions of care	SMS reminders improved attendance at follow-up appointments	Patient compliance with follow-up appointment attendances
El-Kareh et al. 2009 (98)	Longitudinal survey	Computerised clinical decision support systems	Clinicians reported increasingly positive perceptions over the year	Safety culture/climate measurement using a physician perceived quality measures - questionnaire
Garment et al. 2012 (99)	Randomised controlled trial	Intervention to improve safety in transitions of care	Transition of care intervention improved the odds of completion of patient care tasks	Patient compliance with follow-up appointment attendances Physician assessment of performance based on compliance with assigned tasks
Gurwitz et al. 2014 (100)	Randomised controlled trial	Intervention to improve safety in transitions of care	An electronic health record with enhanced information for primary care clinicians had no significant effect on measures	Patient compliance with follow-up appointment attendances Re-hospitalisation rates
Hoffmann et al. 2014 (101)	Randomised controlled trial	Educational intervention to improve patient safety practices	The Frankfurt Patient Safety Matrix increased numbers of reported safety incidents and led to better quality reports There was no significant effect on safety culture or climate	Incident reporting numbers Safety culture/climate measurement using a validated survey tool
Marsteller et al. 2010 (102)	Quasi-experimental	Educational intervention to improve patient safety practices	The educational intervention resulted in a significant positive increase in safety measures	Safety culture/climate measurement using a practice based tool with 21 safety measures
Singh et al. 2009 (103)	Quasi-experimental	Educational intervention to improve patient safety	Junior doctors' skills improved following their exposure to the curriculum	Physician assessment of performance based on student performance in an

		practices		Objective Structured Clinical Examination (OSCE)
Verbakel et al. 2015 (104)	Cluster randomised trial	Improvement of incident reporting systems	Practices which participated in a safety culture questionnaire and workshop increased their incident reporting	Incident reporting numbers
Zwart et al. 2011 (105)	Quasi-experimental	Improvement of incident reporting systems	Implementation of a local incident reporting procedure improves system uptake	Incident reporting numbers

Current global estimates suggest healthcare-associated harm results in 23 million disability-adjusted life years.(80) Research about patient safety in primary care do not inform those estimates despite providing the majority of healthcare encounters in most healthcare systems. The global scale of healthcare-associated harm, once inclusive of outcomes arising from patient safety incidents in primary care, is still to be realised, although could highlight gross underestimates of the scale of the problem. The frequency and burden of avoidable significant harm is the subject of a separate Department of Health funded research study, the Avoidable Harm Study, being undertaken between the University of Nottingham, Cardiff University and others (April 2015 to December 2017).

1.3.3. Primary care patient safety research and development priorities

A three-round modified Delphi consensus study was undertaken at the WHO Safer Primary Care meeting to seek agreement on which safety incidents merit most attention, the contexts and disciplines that should be involved in different economic settings, and what empirical evidence was needed to follow the trajectory of success seen in hospital medicine.(63)

General practice and community pharmacy were considered the main care settings to focus future research and development to advance patient safety in

primary care across all income categories. This should also extend to care home and nursing home settings in high income settings. Patient safety incidents requiring further study across all economic settings included communication between healthcare professionals and with patients, teamwork within the healthcare team, laboratory and diagnostic imaging investigations, issues relating to data management, transitions between different care settings, and chart/patient record completeness. Interventional, regulatory, and methodological issues for further development were agreed on by over 80% of participants after round 3, including:

- education and training;
- data collection methods;
- developing policy to promote patient safety;
- raising the public profile of patient safety;
- greater clarity on definitions of patient safety incidents in primary care;
- facilitating learning from patient safety incidents;
- regulations to ensure that systems to improve patient safety are put into practice; and,
- improved taxonomies and better ways of classifying errors in primary care.(63)

1.4. Incident reporting systems

Building on the experiences from other high-risk industries seeking to improve safety for their workers, a consistently high priority in many healthcare systems around the world have created patient safety incident reporting systems. Such systems permit healthcare professionals, patients/carers and others to detail their safety concerns and these reports can be systematically interrogated to derive learning. Patient safety incident reporting systems have been developed in several high-income countries, with the UK now having by far the largest such system in the world. Incident reports permit a retrospective 'window' on the healthcare system, providing a means of looking to the future, by identifying weaknesses of the system that are still present and could lead to further incidents involving patients.(10)

1.4.1. Types of incident reporting systems

National systems which receive reports from healthcare organisations are well described in Denmark,(106–108) Norway,(109) and England and Wales.(110–126) Regional systems exist for state-level learning in Australia (e.g. Victoria and New South Wales) or province-level learning in Canada (e.g. British Columbia Patient Safety and Learning System) and the United States (e.g. Pennsylvania State Reporting System), as well as at the provider level (e.g. The Veterans Health Administration).

Theme-based systems also exist; for example: medication-related incidents like the MedMARx® system run by the Institute for Safe Medication Practice in the United States which has been extensively characterised;(117,127–146) the UK Bowel Screening programme which focuses on reports of harm associated with screening;(147–149) and, The University of Texas Hospital Close Call Reporting System which was established to collect reports about potentially serious events that did not lead to harm.(150,151) Case studies from individual hospitals are also commonly reported and published in peer-reviewed journals.(152–156)

The purpose of these systems is to enable learning from incidents across local, organisational and national levels to inform improvements in patient safety. The intended learning feedback mechanisms are summarised by Benn et al.(157) in Figure 1.6 NHS staff have been encouraged to report patient safety incidents which were defined as “any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS care”.(158) In England and Wales, each hospital and healthcare facility has a reporting system that collects paper or electronic incident forms. These are first reviewed and analysed at a local level and then sent in batch returns by the organisation's risk manager to the National Reporting and Learning System (NRLS).

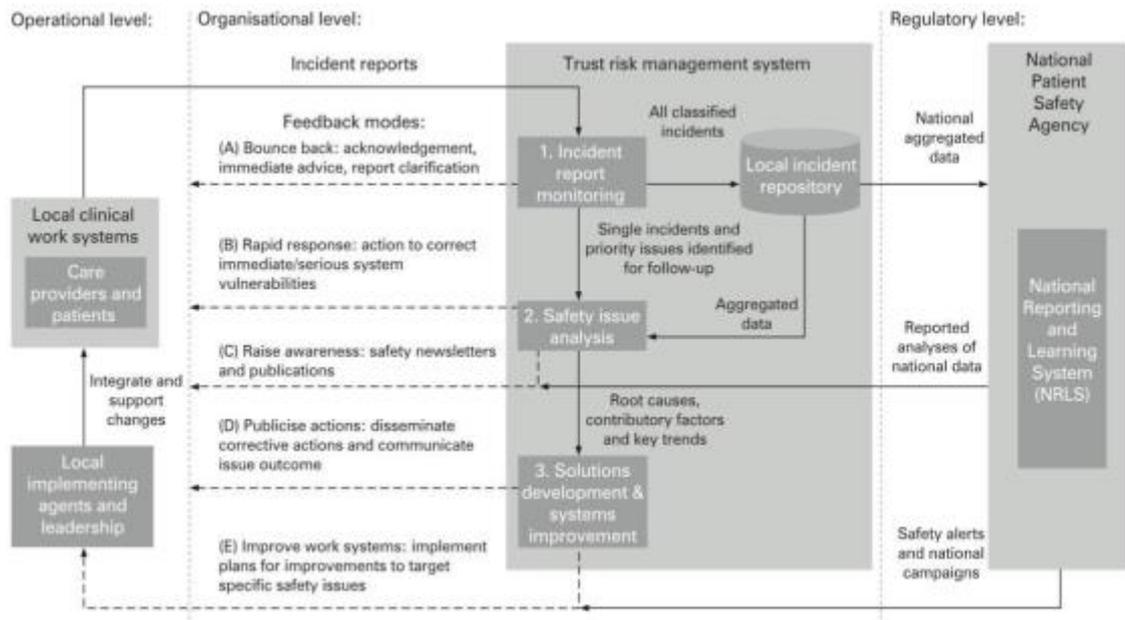


Figure 1.6. Framework for Safety Action and Information Feedback from Incident Reporting developed by Benn et al.(157)

1.4.2. Evaluation of the National Reporting and Learning System

A Special Health Authority called the National Patient Safety Agency (NPSA) was launched in 2002, with a responsibility of running the NRLS for England and Wales. The NPSA developed several categories of guidance designed to assist the NHS to learn from patient safety incidents (see Table 1.5 for an overview of outputs). These included patient safety alerts, patient safety notices, and quarterly data summaries. Evaluations of the outputs typically focussed on the uptake of guidance rather than the efficacy of the educational output as an intervention.(159,160) Several themed reports focussed on the improvement of safety in secondary care settings, and were published by special arrangement with the British Medical Journal, including: prescribing and monitoring lithium therapy;(161) reliable administration of insulin;(162) early detection of complications in surgical care;(163) and, essential care after an inpatient fall.(164) The NPSA also collaborated with Royal Colleges and permitted health services researchers to explore the data; for example in anaesthesia, system deficiencies relating to practical procedures, communication of information to patients, verbal and written communication practices, and continuity of care issues were identified as areas for

improvement.(165,166) Such analyses also led to the development of an anaesthesia-specific incident report data collection form.(167)

Table 1.5. Overview of NPSA outputs (168)

NPSA Output	Description
Patient safety alerts	Published regularly and containing information on patient safety requiring urgent action.
Patient safety notices	Published regularly and containing information requiring longer term, system-wide changes.
Themed reports	Occasionally published in-depth reports into specialist subjects.
Cause for concern letters	Sent to trusts to follow up reports of patient deaths causing concern (Sept 2007 onwards) and for all incidents resulting in severe harm were subjected to the same process (April 2008 onwards). Letter highlighted where urgent local action was needed and required acknowledgement from board level in the reporting trust.
Quarterly data summaries	High-level aggregate of reports by describing their patterns and trends.
Detailed feedback reports, issued to individual trusts from 2007	Aggregated report covering incident reporting and comparison data over the preceding six months.

The NRLS currently contains over 14 million reports and continues to receive approximately 100,000 reports per month from healthcare organisations in England and Wales.(169) 98% (13.75 million) of incident reports in the NRLS have been received from hospitals. Approximately 230 000 reports from primary care (<0.5% of total reports), and 47,000 reports from general practice, have been received by the NRLS in over a decade. The under-representation of general practice within the NRLS is possibly a reflection of the national emphasis placed on patient safety in hospital settings. This is a paradox given at least one million healthcare encounters occur each day in community care settings. Despite this, primary care outputs from NRLS have included patient safety alerts on:

- ambulatory syringe drivers;
- prescribing, dispensing and administering of insulin;
- vaccine storage;

- lithium therapy;
- preventing harm to children with parents with mental health needs; and,
- methotrexate compliance.(170)

1.4.3. Effectiveness of patient safety incident reporting systems

Stavropoulou et al.(171) reviewed 35 case studies extracted from published academic papers describing patient safety incident reporting systems in healthcare settings worldwide to determine their effectiveness on improvement of settings, structures, and outcomes. The authors concluded there is little evidence that incident reporting systems improve outcomes or enable cultural changes.(171) The authors might have reached this conclusion because case studies are seldom described and reported in the published literature. Also, patient safety incident reporting systems are complex interventions to improve safety and must function in complex healthcare systems. Such judgements of effectiveness risk oversimplifying the diverse range of contexts in which reporting and learning systems exist, as well as the diverse contexts in which learning arising from the system should be applied to inform practice improvement. This is highlighted in an assessment of the impact made by medication safety outputs issued by the NRLS; whilst organisations deemed the different outputs as essential for raising awareness and improving patients safety,(160,172) over half of the organisations studied were unable to communicate effectively and reliably with their junior doctors that were largely undertaking the prescribing.(173)

Studies that have examined the sensitivity of patient safety incident reporting systems reveal they can be poor detectors of incidents occurring in organisations.(174–177) In England, Sari et al.(174) reported only 1 in 20 patient safety incidents are reported to a formal incident reporting system. Studies in Australia and the United States have corroborated this finding.(175,177) Such studies highlight that the inherent bias of patient safety incident reporting systems must be carefully considered when analysing incident data.

Patient safety incident reporting systems often detect a small percentage of serious incidents compared with other patient safety data sources like complaints data. Staff often report issues with low harm outcomes that do not trigger more intensive investigation, although these reports do at least represent concerns felt by staff about the ability to deliver safe patient care. In addition, the frequency of reports reflects reporting patterns and cannot be used to monitor improvements in an organisation. Different methods used in a single system provide the broadest perspective for understanding the nature of risk to patients,(178) and can support the formulation of risk reduction strategies for systems improvement, with each method having distinct advantages:

- patient safety incident reporting systems can yield rich descriptions and context about incidents to inform practice improvements, and provide clinicians with a feedback mechanism;(179)
- clinical record review enables estimates of incident prevalence; and,
- malpractice database reviews can provide greater detail on incidents with serious clinical outcomes.(178)

Studies comparing learning from the aforementioned methods indicate there is little overlap in their results.(180) The methods yield different insights by virtue of their nature. For example, incident reporting systems require professionals to report an incident, and this requires their awareness that a patient safety incident has occurred. Alternatively, clinical records do not provide the same depth and contextual information about contributory factors that incident reports do because they will often contain descriptions of care as delivered although it may not be possible to identify errors of commission or omission unless explicitly described.(181)

1.4.4. National-level patient safety agenda setting

The *Francis Inquiry* report, published in 2013, found little evidence that primary care organisations have the capacity, down to the level of individual practices, to learn from safety incidents.(168) The need to develop infrastructure and clinical governance for patient safety in primary care is not new. The *Safety*

First report, published in 2006, considered NHS organisation arrangements to place patient safety at the heart of the healthcare agenda. The report recommended Primary Care Trusts (the current equivalent in England being Clinical Commissioning Groups which are clinically led statutory NHS bodies) be made accountable for ensuring all providers had effective reporting systems and were implementing technical solutions.(182) The low frequency of reports from general practice since 2005, described previously, suggest this recommendation made minimal impact.

Despite important demonstrable value derived from secondary care incident reports whilst the NPSA was functioning, there has been a hiatus in the development of methods for making full use of the majority of incident reports that are not routinely analysed. Current incident reporting systems are undervalued and underutilised, garnering little respect from the health information and research communities.(183) Their role in systems improvement, in terms of informing the design of quality improvement projects or initiatives, has not yet been realised.

The NRLS in England and Wales is the largest patient safety incident reporting system in the world. Unstructured data in the system exist as free-text narratives about incidents and need to be classified in order for any meaning to be derived. The WHO International Classification for Patient Safety (ICPS) was an international commitment to standardise the terms used to describe patient safety for comparison between contexts (this will be described in detail in chapters 2 and 3). Efforts to apply this classification system to primary care are needed, as well as a description of the process for coding data to learn from trajectory of error and related human factors and system conditions. Learning generated from characterisation of incidents in general practice in England and Wales should be transferable to common contexts of care provision in different income settings, and be used to stimulate discussion and thinking about strategies for improvement.

1.5. Learning from patient safety incident reports

The relationship between learning, knowledge creation and organisational performance has been described in detail.(184–187) Patient safety is predicated on the ability to learn from healthcare-associated harm with a view to re-engineer systems. Establishing the National Patient Safety Agency, and the National Reporting and Learning System (NRLS), presented an opportunity for the National Health Services in England and Wales to embrace an era of ‘organisational learning’. Systems scientist, Peter Senge, coined the concept of the ‘learning organisation’ which has been defined as “an organisation that exhibits adaptability, learns from mistakes, explores situations for development, and optimises the contribution of its personnel”.(188,189) Learning organisations require the support of infrastructure for a range of activities and processes to create what is often described in healthcare organisations as a ‘culture of learning’.(190,191)

Martin et al.(192) make an important distinction between data, knowledge and intelligence; they say: “data represent the raw material of knowing, but need to be identified, selected, processed, interpreted, and made the basis of action”. Data can be objective, quantitative information (‘hard data’), for example about outcomes, or more subjective, qualitative information that can contain rich contextual information from the first-hand perspective of patients, families and carers, or staff (‘soft data’). Both types of data can guide patient safety improvements:

- hard data can provide signals for further interrogation (frequency or prevalence of incidents); and,
- soft data can provide opportunities to gain an understanding about what happened and why it occurred, and be used to pinpoint specific actions or circumstances that increase the likelihood of healthcare-associated harm in different contexts.

Drawing on Dretske’s (1981) definition of knowledge, Martin et al.(192) describe the ability to generate actionable learning from soft (qualitative) data as ‘soft intelligence’. This includes the processes and behaviours to seek and identify

soft data, as well as “the knowledge-producing activities of collation, synthesis, interpretation and application of insights”. Incident reports contain hard data in the form of categorical information (e.g. location of incident, type of incident, patient age group) and soft data in free-text descriptions of what happened, the reporter’s perceptions of why and how the incident occurred and the plans to prevent future recurrence.

1.5.1. Challenges to generating learning from incident reports

In 2005, The (UK) National Audit Office’s report, *A Safer Place for Patients: Learning to improve patient safety (Safer Place for Patients)*, raised concerns about the outputs generated from the NRLS. A later report published in 2006 by the Chief Medical Officer of England’s office, called *Safety First: A report for patients, clinicians and healthcare managers (the Safety First report)* observed insufficient use of nationally collected incident reports to generate learning for systems improvement. It concluded:

“despite the high volume of incident reports collected by the NPSA to date, there are too few examples where these have resulted in actionable learning for local NHS organisations. The National Reporting and Learning System (NRLS) is not yet delivering high-quality, routinely available information on patterns, trends and underlying causes of harm to patients.”

A public inquiry in England led by Robert Francis QC was undertaken to review the failings in care that resulted in 1200 excess deaths at Mid Staffordshire NHS Foundation Trust between 2004-2009. The inquiry reviewed the role of the NPSA, and the NRLS, in supporting the identification of patient safety issues. The report concluded the NRLS played no part in uncovering the lack of safety at Mid Staffordshire. This does not seem a surprising conclusion considering the circumstances in which the NRLS operated. Whilst reporting systems had been identified as an important mechanism for learning from unsafe healthcare, they were borrowed from safety critical industries like aviation. Whilst aviation industry leaders might expect around 400 reports per year, the NRLS in

England and Wales receives over one million reports each year.(193) The NRLS had limited capacity (administrative and clinical expertise) and could only review incidents reported with severe harm or death outcomes.(168)

1.5.2. Opportunities to learn from incident reports

Following the Francis Inquiry, the Berwick report, *A promise to learn - a commitment to act: improving the safety of patients in England* (2013),(194) highlighted that “organisational learning is key to improving patients’ safety”. This recommendation echoes previous recommendations made in *An Organisation with a Memory* (2001) and suggests the NHS had been slow to realise how to generate and act on learning from healthcare-associated harm.(47) The report highlighted ‘incident reports’ and ‘incident reporting levels’ should be used within a suite of indicators to assess safety improvement and variation. Berwick stresses the need for healthcare organisations to have functional reporting systems:

“Organisations should demonstrate that they have in place fully functional reporting systems for serious incidents, that staff know how to use them, that the systems are used, and that appropriate action is taken in response to incidents, including provision of appropriate support to the affected patients and their carers.” (194)

There also remains a strong advocacy for national patient safety incident reporting systems at an international policy level, and as recently as March 2016, the WHO convened healthcare system leaders from low- and middle-income countries to support and advance discussions towards the development of national reporting and learning systems.

Despite this strong position on the opportunities from patient safety incident reporting systems, there is a consistent message about missed opportunities that incident report data are not being more effectively utilised to inform systems improvement, or as Macrae puts it: “we collect too much and do too little” (193). Major investments have been made internationally to establish the infrastructure

for patient safety incident reporting systems. There is still uncertainty about how such systems can inform improvement in outcomes. Research and development is needed to better understand how to optimise them in healthcare.

1.5.3. Classifications systems

Since 1988, the Australian Patient Safety Foundation (APSF), led by William Runciman, has worked to understand how to “deconstruct” the information in patient safety incident reports to facilitate subsequent analysis and learning.(195) Classification systems (sometimes referred to as taxonomies) have been developed which are “an arrangement of concepts into classes and their subdivisions, linked...to express the semantic relationships between them.”(11,196) APSF developed a classification system to support the identification and retrieval of relevant information about an incident, and outlined a process for collecting and classifying incident reports. This approach underpinned the basis for the WHO-commissioned International Classification for Patient Safety (ICPS) which is described in more detail in chapter 2.(2,197) ICPS contains concepts (and preferred terms) used to deconstruct patient safety incidents and is intended to aid transition from data to knowledge and intelligence that can inform systems improvement.(11)

Reports from general practice collected by the NRLS have never previously been systematically classified in England and Wales. There has, however, been a considerable volume of academic papers detailing the analysis of patient safety incident reports, including from general practice in other countries.(70,198) Learning from patient safety incidents hinges on the ability to generate learning from incident reports.(157,199) Given the expectations raised by WHO for incident reporting analysis in the publication of ICPS in 2009, a review of existing classifications and methods used to analyse patient safety incident reports is needed.

1.6. Aims and objectives of PhD

The aims of the PhD are to:

- Develop and apply methods to generate learning from patient safety incidents occurring in general practice; and,
- Explore how incident reports can be analysed to inform healthcare systems improvement.

The objectives of the PhD are to:

1. Review existing methods used to analyse the content of general practice patient safety incident reports.
2. Empirically develop classification frameworks aligned to the WHO International Classification for Patient Safety to structure coding and sensemaking of incident report content.
3. Test the classification frameworks on a sample of safety incident reports from general practice reported to a national database, to:
 - a. Describe the frequency of different types of incidents, contributory factors and healthcare-associated harm outcomes and explore which characteristics are associated with different levels of harm;
 - b. Map relationships between reported contributory factors and other variables to propose contributory themes occurring in similar groups of incidents; and,
 - c. Propose areas with the greatest need and opportunity for future intervention strategies to improve patient safety in general practice.
4. Determine the process for using incident report analyses to inform the design of improvement projects at a) national- and b) local-levels.
5. Propose areas for future research and development to improve the ability to generate learning from patient safety incidents.

1.6.1. Conceptual justification of methodology to address aims and objectives

The philosophical paradigm of my research, or put simply the “set of common beliefs and assumptions amongst scientists about how problems should be understood and addressed” (200,201) is strongly influenced by two main issues:

1. Identifying priorities in big data – incident reporting system contain large volumes of data and a process for reliable data reduction is needed for prioritisation; and,
2. Unstructured, jargon-laden data – interpretation of free text requires clinical knowledge to ‘sense make’ what is meant and generate understanding about context.

1.6.1.1. Quantitative and qualitative belief systems

Quantitative and qualitative knowledge can be conceptualised as belonging to two distinct, and opposing ‘belief systems’.(202) As Scott (202) puts it: “Quantitative knowledge is intrinsically bound to a realist ontology and objectivist epistemology. Qualitative knowledge is intrinsically bound to a relativist ontology and a constructivist epistemology.”

An objectivist approach to analysis of incident reports means the researcher would code only what is explicitly stated. This is appealing given how incident reporting systems function in healthcare organisations. For example, healthcare administrative teams are often involved in the coding of reports received by the local system, or the reporter themselves are required to select high-level codes that represent the type of patient safety incident. Further, the identification of priorities requires a reliable and auditable process. Minimising variation in coding practices prior to the identification of priorities would support the reliability of agenda setting methods to reflect what gets reported by healthcare professionals and staff. From a research perspective, the objectivist approach is appealing because the application of codes can be considered in terms of inter-rater reliability.

At the other end of the spectrum, a constructivist approach to analysis of incident reports means the clinical researcher would make sense of what is stated, based on their knowledge and understanding of a phenomena in the clinical setting and ability to interpret jargon-laden text. This could enable a deeper understanding about the contexts in which clusters of similar incidents had occurred. Given the resource intensive nature of the qualitative methods affiliated with this approach, a focus on identified priorities (clusters of similar reports) can be made.

1.6.1.2. Combined belief systems – a mixed methods research paradigm

Mixed methods research combines knowledge from both belief systems and can be called the 'pragmatic paradigm'.(29,203) Conceptual concerns with mixed methods research arises from arguments about 'epistemological incompatibility' from opposing belief systems. However, those in favour of a mixed methods research paradigm stress how the nature and purpose of policy research should benefit from co-existing belief systems, and their related methods.(29,202–204)

Examples of mixed methods research demonstrate how quantitative data can inform sampling options for further in-depth qualitative inquiry,(205) and advocate how combinations of approaches can facilitate richer data and develop the analysis.(204) The *pragmatic* paradigm has a deconstructive epistemology, which means, knowledge about reality is constantly negotiated, debated and interpreted in light of its usefulness in new, unpredictable situations (200). As described in section 2.1.1, Martin et al.(192) describe 'soft intelligence' as a process of selecting data, making sense of the message and realising the learning. Others have described a similar process called 'sensemaking', defined as "the active process of assigning meaning to ambiguous data".(206)

1.6.1.3. Personal beliefs and process of inquiry

Mixed-methods research is focussed on practical, operational issues and is predicated on the ability to optimise learning from the breadth and depth of understanding and corroboration possible from combined qualitative and

quantitative methods.(203) Morgan,(203) citing John Dewey, points to the importance of joining beliefs and actions in a process of inquiry that underlies a search for knowledge (Figure 1.7).

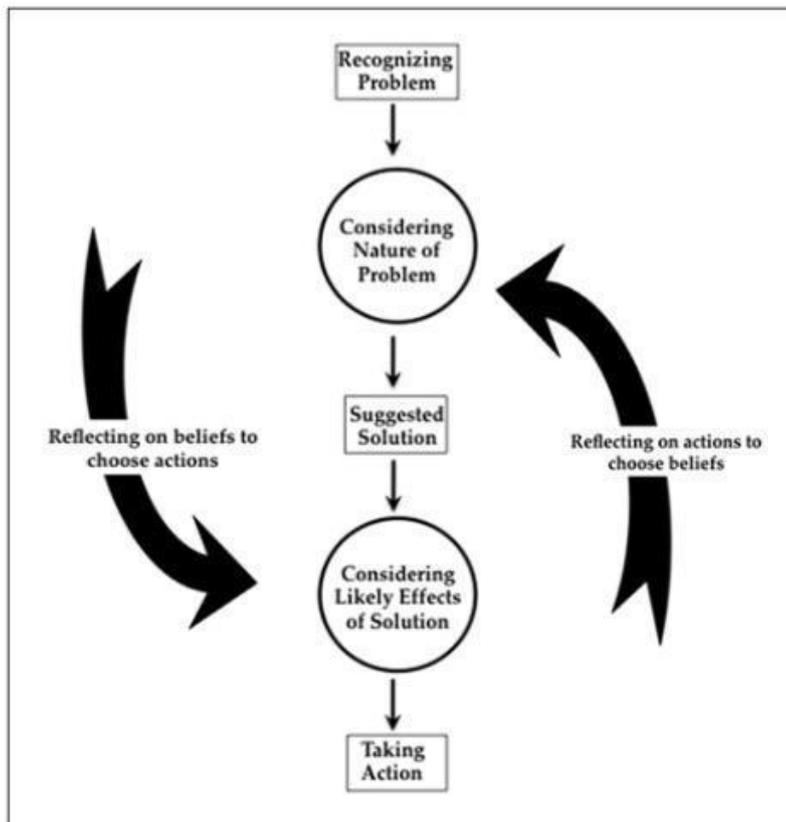


Figure 1.7. Dewey's systematic approach to inquiry

I described in section 1.2.4.3 how improvement scholars, Perla and Parry, have explored the concept of knowledge in the context of implementing new innovations in healthcare. They said: "...how can [healthcare systems and leaders] design knowledgeable healthcare systems that maximise the alignment between the current best evidence ('truth') and the actions of healthcare providers ('belief')?". They described how improvement science methods, a newly developing branch of mixed methods research, can support identification of beliefs about what aided an innovation to work or fail in a system. In a similar vein, I have designed my research with the belief that incident reporting systems can offer an opportunity to understand the beliefs of healthcare professionals in primary care about how and why an incident occurred, in order to raise hypotheses about how the system can be designed or redesigned to

improve its structures and processes. A deconstructive epistemology will support my in-depth inductive exploratory processes (objectives 2-3).

Dewey's systematic approach to inquiry (Figure 1.7) is based on five steps, which promote an explicit mechanism for linking my beliefs and actions (and learning) occurring throughout my PhD study.(203) The approach has aided my inductive development of classification frameworks and methods related to generate learning from incident reports. This includes efforts to promote personal and team-based reflexivity to achieve objectives 2-4. Objective 4b was designed to permit a deductive reflection on a case study of how the methods generated from concurrent research to achieve objectives 1-4a could be applied in a local context.

Chapter 2 – Scoping review of methods to analyse patient safety incidents

In this chapter, I will describe a scoping review of existing methods used to analyse the content of general practice patient safety incident reports (objective 1).

Scoping reviews are undertaken with the purpose of mapping a body of literature, and generating a descriptive overview, on a particular subject.(207,208) Alternatively, other literature review methods like systematic reviews or meta-analysis provide a synthesis of the best available evidence from studies assessed for risk of bias.(209) My scoping review,(207,210) was undertaken by following a framework developed by Levac et al.(210) which drew on systematic review principles for structured searches and review of the included literature. Scoping reviews are recommended to map broad topics, especially where the body of evidence is still emerging.(207,210,211)

2.1. Levac et al. approach to scoping reviews

The approach proposed by Levac et al.(210) includes the following stages:

- identifying the research question – to clearly articulate the review question(s) and consider the purpose and intended outcomes of the review;
- identifying relevant documentation – to use the identified research question(s) and purpose to inform decision-making about types of documentation to be eligible for inclusion;
- study selection – to adopt an iterative process throughout the study which involves searching the literature, refining the search strategy and reviewing potential documents for inclusion in the review; a commitment to regular meetings between reviewers at agreed intervals to discuss challenges and uncertainties about included documents;

- charting the data – the study team should collectively develop the data-charting form; charting should be an iterative process and independent data extraction is recommended;
- collating, summarising and reporting the results – three distinct phases of work including generating a descriptive numerical summary analysis and a qualitative thematic analysis; producing the ‘outcome’ relevant to the overall purpose or review question(s); and, consideration of the meaning of the findings for future research, practice and policy; and,
- consultation – clearly articulate the type of stakeholders to consult and how their feedback will be collated and used to inform the overall scoping review outcome.

2.1.1. Review questions

The purpose of my review was to compare approaches used to analyse patient safety incident reports in healthcare, particularly those developed for use in primary care.

The review questions were:

- What patient safety classification systems have been used in healthcare?
- What methods have been used to analyse patient safety incident report data? and,
- What classification systems and methods have been used to analyse patient safety incident reports from general practice?

2.1.2. Identifying relevant documentation

A search strategy of key terms was developed from a range of topic areas pertinent to incident reporting. Synonyms, alternate spellings, abbreviations and historical terms were incorporated into the search strategy (Appendix 1). This search strategy was peer-reviewed by subject matter experts (Peter Hibbert and Meredith Makeham) and designed to facilitate maximum recall of relevant studies. Keywords were mapped to database search terms and subject headings. In addition, the key terms were searched as text word terms for all

databases. Boolean operators were used to combine search terms and maximise precision. Given the diverse involvement of academics from many disciplines in patient safety, searches of 14 electronic peer-reviewed and grey literature databases were chosen to include literature from biomedical science, health and social care disciplines, psychology, social science, economics, amongst others. The decision to undertake a review of such an extensive list of databases was informed by my earlier experience of the coverage each database permits whilst undertaking a systematic review of the primary care patient safety literature.(70)

The following databases were searched: ABI/Inform, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane Library, EconLit, EMBASE, MEDLINE, PsycINFO, Social Sciences Abstracts, University of York Health Technology Assessment Database, Grey Literature Report, Papers First, ProQuest Dissertations & Thesis, University of Laval KUUC Knowledge Utilisation Database, and WorldCat. Searches were undertaken by me, with the support of three medical students (Phillippa Rees, Hope Ward and Amy Butlin). In addition, members of the research team compiled a list of websites relevant to patient safety (Appendix 2). These websites were systematically hand searched using key terms. All references were exported to endnote and duplicates removed.

2.1.3. Study selection

Titles and abstracts of search outputs were scanned for relevance (Rees, Ward, Butlin). The full text articles of potentially relevant abstracts were retrieved. Two reviewers independently screened retrieved articles from the published literature (Butlin, Rees) and two reviewers (Ward, Rees) screened content retrieved from grey literature sources, for inclusion using pre-specified criteria with 3rd reviewer arbitration (Carson-Stevens) where needed. The inclusion and exclusion criteria were derived from the review questions (Table 2.1).

Table 2.1. Inclusion and exclusion criteria used for article selection

Inclusion	Exclusion
Articles that describe an analysis of patient safety incident reports and include a description of methods.	Non-English articles or abstracts.
Published and unpublished English articles (or non-English articles with English abstracts) of all evidence types.	Descriptions of efforts to improve incident reporting systems.
	Studies investigating the reliability of incident reporting systems detecting incidents.
	Descriptions of incident reporting systems from non-healthcare organisations.

2.1.4. Charting the data

A customised data extraction form was developed in Microsoft Excel 2013 software to collect the following variables: study title, authors, journal, country, year of publication, clinical specialty, study design, conceptual approach, patient safety classification system and method(s) of analysis.

2.1.5. Collating, summarising and reporting the results

Frequencies of each variable (described in section 2.1.4) were calculated and the relationships between variables were explored by cross-tabulation through the use of a data summarising tool called a pivot table.

2.1.6 Consultation

The final list of included studies and a summary of the results, including a discussion of the key findings in relation to existing literature, practice implications and policy was reviewed by subject matter experts that developed the WHO ICPS project (Hibbert) and had previously developed a classification for general practice (Makeham). Their feedback was sought via comments on the manuscript and subsequent discussions on the telephone about those comments.

2.2. Results

A total of 346 potentially relevant articles was assessed, from which 252 articles were included (Figure 2.1). See Appendix 3 for a table of included studies, and Appendix 4 for a list of excluded studies.

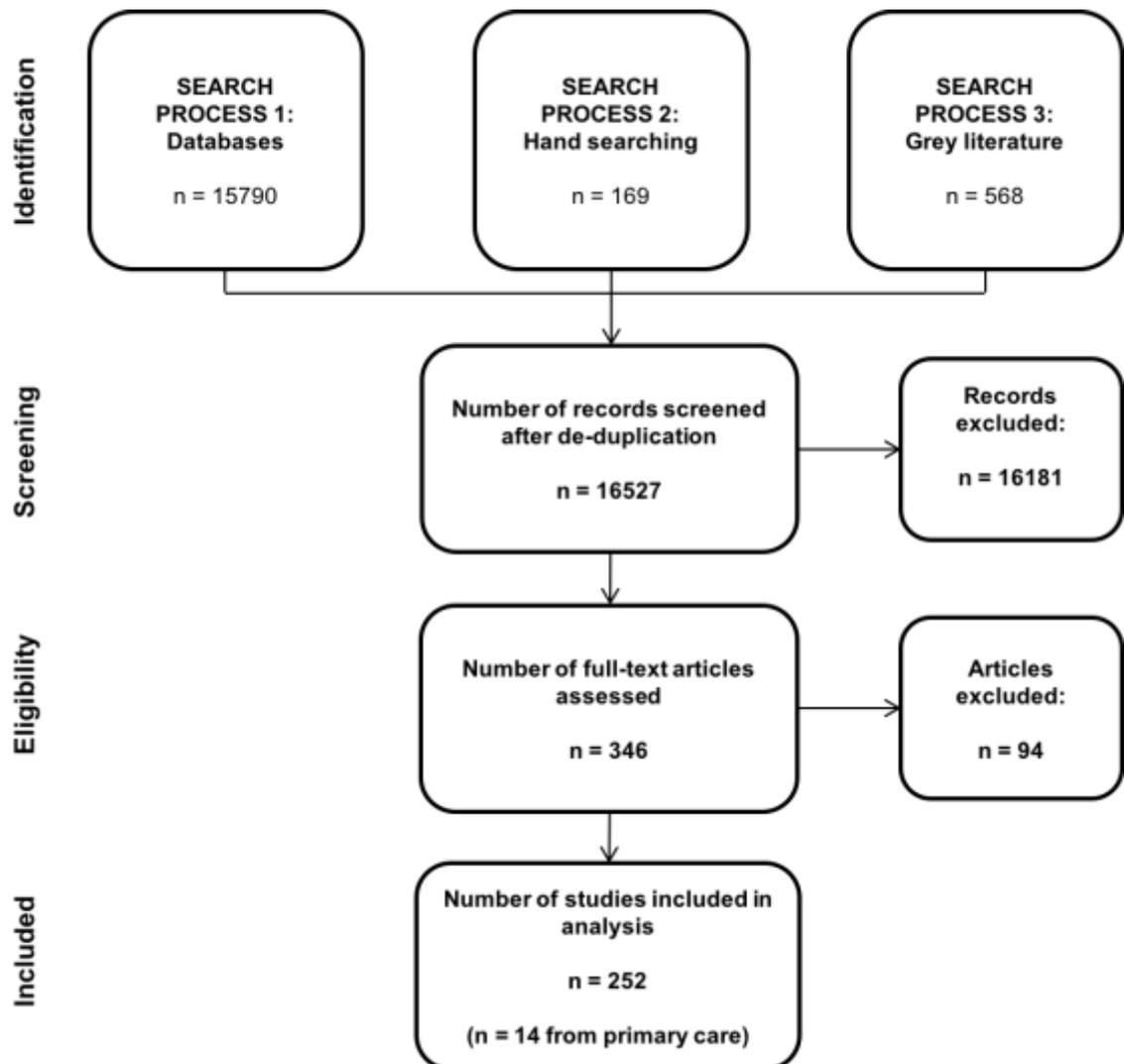


Figure 2.1. PRISMA diagram of the review process

Of included studies, 87% (n=218) were published since the Institute of Medicine's seminal publication *To Err is Human* in 1999, and 45% (n=113) were published since the publication of ICPS in 2009. The majority of analyses were undertaken in North America (30%, n=76), United Kingdom (22%, n=56) and Australasia (19%, n=48). Over half (n=25) of the 48 publications from

Australasia pre-dated *To Err is Human* and reflects the early developmental work undertaken by the APSF (Figure 2.2). A minority of studies (6%, n=14) analysed incidents from primary care.

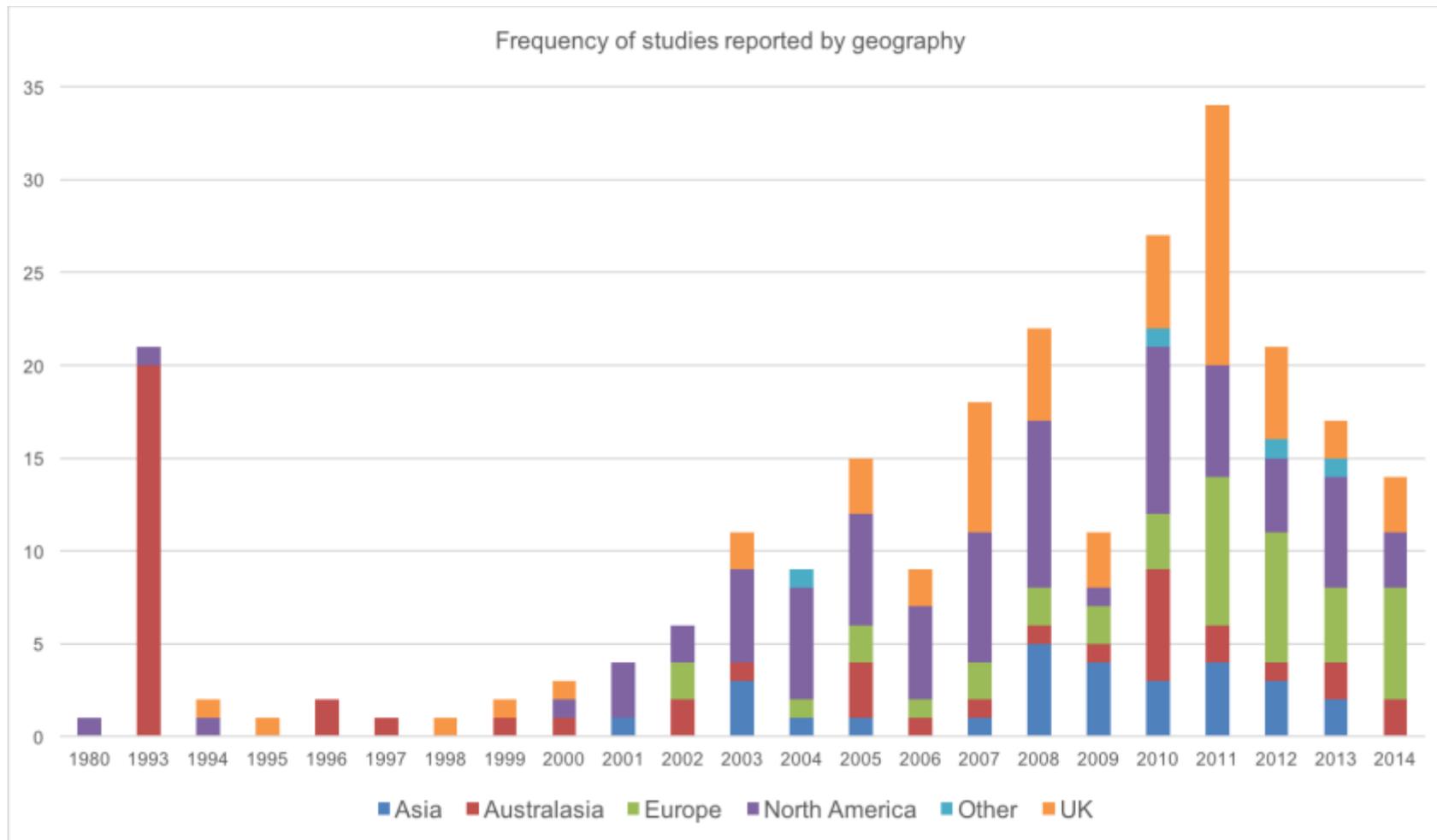


Figure 2.2. Clustered bar chart of the frequency of studies of incident report data by geography between 1980 and 2014

The most frequently stated types of study design were ‘cross-sectional’ (n=184), ‘descriptive’ (n=31) and ‘mixed methods’ (n=18) (Table 2.2).

Table 2.2. Reported study designs involving incident report data

Study design	Frequency
Case-control study	1
Case study	5
Cohort study	5
Cross-sectional - prospective	61
Cross-sectional – retrospective	117
Cross-sectional – retrospective and prospective	4
Descriptive study	31
Evaluation	3
Implementation study	1
Mixed methods	18
Quasi-experimental	5
RCT	1
Total	252

2.2.1. Classification approach to analyse incident reports

Twenty distinct patient safety incident classification systems were identified.

2.2.1.1. Novel classifications

The majority of papers described a ‘novel’ approach to analysis (n=90, 36%). This included a description of how they structured their analysis as well as adoption of existing coding frameworks (e.g. Harvard Malpractice Study error types, the UK Royal College of Anaesthetists incident categories, Veterans Administration Severity Assessment codes) which may or may not have been originally intended for incident report analysis. Authors commonly gave titles to their classification approaches; for example, the ‘Medical Event Reporting

System for Transfusion Medicine',(212) and the 'International Taxonomy for Errors in General Practice'.(213)

2.2.1.2. Commonly used classifications

Novel classifications that have been independently used by others outside of the initiating research institution, health organisation or research collaboration are included in Figure 2.3, and include: the Australian Incident Monitoring System (AIMS) inclusive of its earlier form as the Generic Occurrence Classification for Incidents and Accidents in the Healthcare System (n=31, 12%); The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) in the United States (n=29, 12%); the National Reporting and Learning System (NRLS) in England and Wales (n=15, 6%); the Eindhoven Classification Model for System Failure (n=6, 2%), the International Classification for Patient Safety (ICPS) (n=5, 2%), and the International Taxonomy of Medical Errors in Primary Care (LINNAEUS) (n=5, 2%).

2.2.1.3. Classification not explicitly stated

When a description of the process to develop and organise the codes was absent, or a citation to previous frameworks or descriptions was absent, this was coded as 'not explicit' (n=71, 28%).

Frequency of classification approaches described to analyse patient safety incident reports

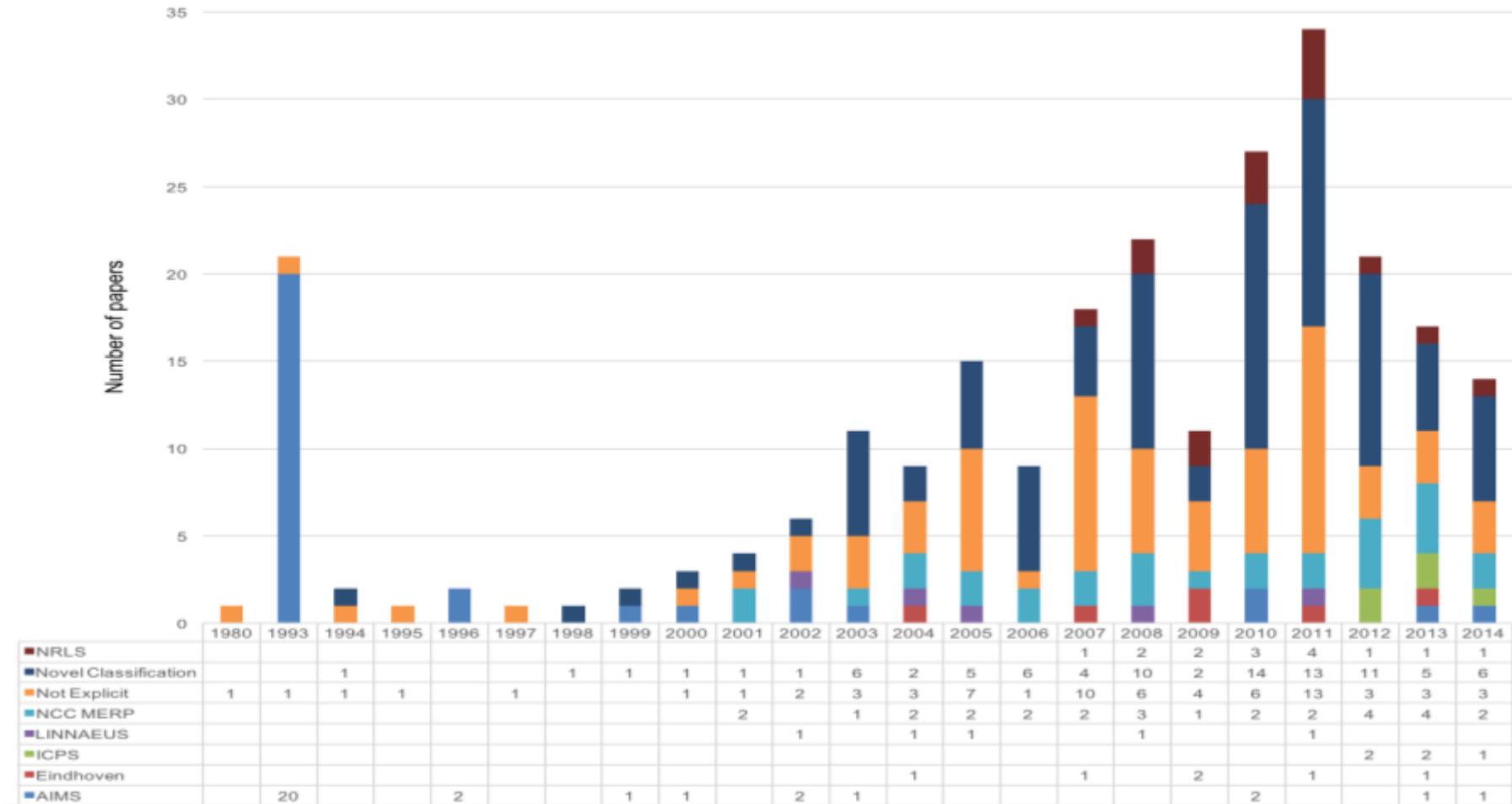


Figure 2.3. Clustered bar chart of classification systems described in papers published between 1980 and 2014

2.2.1.4. Additional stated conceptual approaches for analysis

The following conceptual approaches were stated to inform the analysis in 15 papers only, including:

- Reason's Trajectory of Error or 'Swiss cheese' model, n=7;(214–222)
- Vincent's 'London Protocol' n=3;(223–225)
- non-specific descriptions of 'system factors', n=3;(221,226,227)
- Macrae's Theory of Risk Resilience, n=1;(228)
- International Loss Control Institute's Loss Causation Model, n=1;(224)
- and,
- Rasmussen's Skill-Rules-Knowledge based behaviour model, n=1.(222)

2.2.2. Methods used to analyse incident reports

The methods used to analyse incident reports are displayed in Table 2.3. The majority of studies used quantitative methods to describe proportions and examine relationships between coded data. Statistical tests and modelling methods have been undertaken where the investigators are seeking to determine: whether a staff group from a particular care setting reports more incidents; whether some incidents are reported more commonly than others; or a comparison of incidents received by different databases. Of the 18 studies with a mixed methods study design, all combined descriptive statistics with at least one qualitative method.

Table 2.3. Reported methods used to analyse incident reports

Method	Frequency
Quantitative	
Descriptive statistics (means, medians, proportions)	216
Chi-squared test	60
Logistic regression	32
Odds ratios	25
t-test and ANOVA	15
Fisher's exact test	14
Mann–Whitney U test	8
Other (Kolmogorov-Smirnov test, Bayesian hierarchical modelling, cross-tabulation, impact ratios, rate ratios, relative ratios, relative risk, odds of harm, Rao-Scott modified Chi-squared, Wilcoxon rank sum tests, proportional similarity index, Cochran-Mantel Haenszel, Kruskal-Wallis, Kendall's Tau-b, Pearson's Correlation Coefficient, Spearman's correlation, Poisson distribution, Z-test of equality between proportions, disproportionality analysis, cluster analysis)	51
Qualitative	
Comparative analysis	18
Descriptive case study analysis	15
Root cause analysis (229)	15
Causal analysis	15
Thematic analysis	11
Content analysis	10
Case reports	15
PRISMA (Prevent and Recovery Information System for Monitoring and Analysis)(230)	5
Other (cascade analysis, data mining, mapping, trend analysis, critical incident analysis)	9

2.2.3. Primary care studies of incident reports

Fourteen included papers described incident reports from primary care settings, including: general practice, n=8; community pharmacy, n=2; ambulatory care

settings, n=1; out-of-hours general practice, n=1; community nursing =1; and generally primary care, n=1. The characteristics of the studies are displayed in Table 2.4. The International Taxonomy of Medical Errors in Primary Care is the most commonly utilised classification approach. Only the earliest reported study by Britt et al.(72) from 1997 has an explicitly stated conceptual basis.

Table 2.4. Characteristics of studies analysing incident reports from primary care

Reference	Setting	Conceptual model	Classification system	Methods
Britt H et al.(72)	General practice	Human error theory	Not explicitly stated	Critical incident analysis and descriptive statistics
Hadziabdic et al.(231)	Community nursing	Not specified	Novel classification - no name specified	Content analysis
Hickner et al.(232)	Ambulatory care	Not specified	Novel classification - Medication Error and Adverse Drug Event Reporting System	Descriptive statistics
Kosiek et al.(233)	General practice	Not specified	Novel classification - Learning from International Networks about Errors and Understanding Safety in Primary Care	Not applicable
Knudsen et al.(234,235)	Community pharmacy	Not specified	Novel classification - no name specified	Descriptive statistics
Makeham et al.(213)	General practice	Not specified	Novel classification - International Taxonomy for Errors in General Practice	Descriptive statistics
O'Beirne et al.(236)	General practice	Not specified	WHO International Classification for Patient Safety	Cascade analysis, descriptive statistics, logistic regression

Rosser W et al.(237)	General practice	Not specified	International Taxonomy of Medical Errors in Primary Care (LINNAEUS)	Descriptive statistics
Shaw et al.(238)	Primary care trust (from a multicentre study including acute care trusts, mental health and ambulance trusts)	Not specified	Not explicitly stated	Descriptive statistics
Woolf SH et al.(76)	General practice	Not specified	International Taxonomy of Medical Errors in Primary Care (LINNAEUS)	Cascade analysis and descriptive statistics
Zwart DL et al.(105,239, 240)	General practice	Not specified	International Taxonomy of Medical Errors in Primary Care (LINNAEUS) Eindhoven	PRISMA, descriptive statistics and Fisher's exact test

2.3. Discussion

2.3.1. Main findings

Internationally, there is considerable variation for classifying and analysing patient safety incident reports. The majority of studies use a novel classification approach (n=90, 36%) which limits comparison between studies in the interests of maximising learning from different care settings. Since the ICPS was launched in 2009,(2) of the 113 studies published between 2010 and 2014, only five (4%) explicitly used, or was aligned to, ICPS. However, development of frameworks aligned to ICPS was evident in studies from researchers based in Europe, Australasia, UK and North America. Few studies (n=15, 6% of total included studies) had an explicitly stated conceptual basis to the research.

A diverse range of methods was identified; descriptive statistics were most commonly used to summarise incidents, and statistical tests (e.g. Chi-squared test) and modelling (e.g. logistic regression) was used to explore relationships

between variables, whilst qualitative options sought to identify relationships between similar incidents (e.g. thematic analysis, descriptive case study analysis) and understand causation (e.g. cascade analysis, root cause analysis).

The 14 articles from primary care demonstrated variation in analytical approaches similar to the wider body of literature. One study described developing an incident reporting form aligned with the ICPS, and the International Taxonomy of Medical Errors in Primary Care (LINNAEUS) classification was used in five papers.

2.3.2. Strengths and limitations

I undertook a systematic scoping review following published guidelines to summarise a broad literature base.(210,241,242) The aim of a scoping review approach is to present an overview of identified existing evidence, rather than appraisal of the best available evidence.(211,242) A range of search terms were developed to reflect the diverse, unstandardised terminology used in patient safety, to maximise recall. The list of terms, and final list of included studies, was reviewed by subject matter experts that led the WHO ICPS project (Hibbert) and developed a classification for general practice (Makeham).

In the absence of methodological standardisation such as a quality criteria checklist, I followed all six stages (the sixth, optional, stage involving expert consultation and review of results) of the Levac et al. guidelines.(210) I also undertook a quality assessment using AMSTAR (A MeaSurement Tool to Assess systematic Reviews) criteria for systematic reviews. The scoping review achieved a score of 9 / 11 which reflects rigorous and transparent methods to identify and analyse relevant literature.(243) Of note, two points were not awarded according to the AMSTAR criteria because methodological quality assessment and risk of bias assessment of included studies is not a component of scoping reviews.(243,244)

2.3.3. Relationships with existing literature

Since *To Err is Human*, there has been a proliferation in classification systems which all offer an understanding of patient safety. Within primary care, the International Taxonomy of Medical Errors in Primary Care was developed in 2002 by the LINNAEUS collaboration (which is an acronym of 'Learning in an InterNatioNal group About Errors and Understanding Safety').(245) The taxonomy was initially derived from the qualitative analysis of opinions expressed by participating primary care professionals involved in the collaboration. It is organised by the following classes: type of error, action taken, consequences, severity of harm, contributing factors, and prevention strategies.(245) Makeham et al.(213) later developed the International Taxonomy for Errors in General Practice by testing an earlier taxonomy developed in the United States,(246) by applying it to incident reports from general practice in five countries including Australia, Canada, United Kingdom, New Zealand, and the Netherlands.(213,247) In this system, incidents are coded as either process errors, or knowledge and skills errors, within a five-level coding system.

The WHO launched ICPS in 2009, which was the culmination of a five-year programme of activity to propose an international conceptual framework informed by existing classification systems, and to achieve international consensus on the key concepts and preferred terms needed to deconstruct a patient safety incident.(2) The purpose of ICPS was to avoid the need to create any further classification systems for deconstructing and understanding patient safety. Whilst ICPS does not provide a complete classification with explicit coding frameworks, it provides those seeking to understand patient safety with a method of organising patient safety data.(11) Given twenty individual classifications were identified by the scoping review, it would be prudent for future efforts to develop ICPS classes (and coding frameworks) applied to a discipline or specialty rather than create new classification systems.

Coinciding with the launch of ICPS, European Union Framework 7 programme funding was awarded to researchers from seven countries to undertake the

LINNEAUS project (“Learning from International Networks about Errors and Understanding Safety in Primary Care”). One of the work packages was to develop a classification system for European primary care. The investigators undertook a systematic review to identify salient features in existing classification systems. They proposed and tested a novel classification for primary care using hypothetical vignettes and subsequent critical appraisal by a modified Delphi with international experts.(248) The resulting *Patient Safety Incident Classification for Primary Care* is available on the LINNEAUS project website (<http://www.linneaus-pc.eu/>). One study included in the scoping review used this classification for medication safety incidents by testing it on ten patient safety incident reports.(233) The LINNEAUS project’s study findings have only emerged from 2014 onwards.(233,248–250) Earlier patient safety classifications, including LINNEAUS, demonstrate variation in concepts and preferred terms used to describe patient safety incidents. O’Beirne et al.(236) have used several ICPS classes to structure their incident report form, although the paper does not explicitly describe the development of coding frameworks aligned with ICPS.

2.3.4. Implications for my research

ICPS was launched to harmonise patient safety nomenclature.(11) The development of a new classification system for patient safety is not needed; however, the classes within ICPS do require development for application, in the form of coding frameworks, to incident reports. Future work must involve empirically developing coding frameworks explicitly aligned to ICPS classes to understand patient safety in primary care. Existing coding frameworks, that align with ICPS concepts, could be used to inform *a priori* content for iteration by reviewing the content of incident reports and applying codes. The NRLS contains over 270,000 primary care reports and could be used to develop these coding frameworks. Such efforts to develop controlled vocabularies to deconstruct patient safety incident report data should be aligned with the internationally agreed concepts, preferred terms and definitions.

2.4. Conclusion

Coding frameworks, aligned with ICPS classes, do not exist for primary care and need to be developed. A volume of patient safety incident reports from general practice in England and Wales would serve as substrate for the empirical development and testing of these classes. In subsequent chapters, I will describe the methods to develop the coding frameworks require to generate learning from patient safety incident reports from general practice. This is particularly relevant given: i. the paucity of explicit description of the conceptual basis of the majority of previous analyses of incident report data; and, ii. description about methodological (i.e. classification and coding framework) development.

Chapter 3 – Characterisation of patient safety incident reports from general practice

In this chapter, I will present an analysis of patient safety incident reports from England and Wales. This analysis permitted the empirical development of several WHO International Classification for Patient Safety classes to code and make sense of incident report content (objective 2). The coding frameworks for each class were applied to characterise incident reports as part of a mixed methods study of patient safety incidents reported to general practice from England and Wales (objective 3a-c), in order to:

- Describe the frequency of different types of incidents, contributory factors and healthcare-associated harm outcomes and explore which characteristics are associated with different levels of harm;
- Map relationships between reported contributory factors and other variables to propose contributory themes occurring in similar groups of incidents; and,
- Propose areas with the greatest need and opportunity for future intervention strategies to improve patient safety in general practice.

The outline of this chapter is summarised in Table 3.1.

Table 3.1. Overview of chapter

Section	Description
3.1	The methods developed and applied to generate learning from patient safety incident reports from general practice.
3.2	Description of the characteristics of all included incident reports and will discuss the reports that have been excluded from the analysis in the interests of highlighting how the incident reporting system is misused or the purpose of the system is misinterpreted.
3.3	In-depth exploration of each of five categories of safety incident described in general practice.
3.4	Analysis of all reports describing serious harms and deaths, and describe inherent themes relating to the underlying reported preventable causes of such incidents.
3.5	Summary of findings.

3.1. Method to design and implement a classification framework

3.1.1. Funding of a NIHR HS&DR study

The National Institute for Health Research HS&DR funded a research study to characterise patient safety incident reports from general practice (HS&DR 12/64/118). I was the co-PI with Professor Adrian Edwards (lead PhD supervisor) and Professor Tony Avery was a co-applicant (2nd supervisor). A copy of the original study protocol is included in Appendix 5.

3.1.2. Objectives of NIHR HS&DR study

The original objectives of the study were to:

- Empirically develop classification frameworks aligned to the WHO International Classification for Patient Safety to structure coding and sense making of incident report content (PhD objective 2).
- Test the classification frameworks on a sample of safety incident reports from general practice reported to a national database (PhD objective 3), to:
 - Describe the frequency of different types of incidents, contributory factors and healthcare-associated harm outcomes and explore which characteristics are associated with different levels of harm;
 - Map relationships between reported contributory factors and other variables to propose contributory themes occurring in similar groups of incidents; and,
 - Propose areas with the greatest need and opportunity for future intervention strategies to improve patient safety in general practice.

Amendments to the objectives were proposed by a professional advisory group and will be described in section 3.1.6.3.

3.1.3. Study design

The HS&DR study was a cross-sectional mixed methods analysis of patient safety incidents occurring in general practice reported to the National Reporting and Learning System (NRLS) in England and Wales.(251,252) In this chapter, I

will describe the NRLS and the content of reports it receives. I will also describe the study population and my related data sampling strategy.

3.1.3.1. Overview of the National Reporting and Learning System

In 2001, an arm's-length body of the Department of Health in England (and part-funded by the Welsh Government) was formed called the *National Patient Safety Agency* (NPSA). The centrepiece of the NPSA strategy was to create the *National Reporting and Learning System* (NRLS) which integrated information from local systems in healthcare organisations in England and Wales. Since 2004, NHS staff have been encouraged to report patient safety incidents which were defined as "any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS care".(253) Each hospital and healthcare facility has a reporting system that collects paper or electronically submitted incident forms. These are first reviewed and analysed at a local level and then sent in batch returns by the organisation's risk manager to the NRLS. A small number have been made by staff and patients directly to the NRLS through an online submission process. The NPSA was abolished in 2010 by the UK government although the governance and functions of the NRLS have since moved to other Department of Health funded bodies and currently reside within NHS Improvement.

Healthcare professionals have a duty to report incidents to their organisations' incident management system.(254) These are anonymised and uploaded to the NRLS. Reporting incidents that resulted in severe harm or death of a patient became mandatory in June 2010; however, before this all reporting was voluntary, and remains so for incidents resulting in no, low or moderate harm. How data are entered into the NRLS is variable. For example in England, some Clinical Commissioning Groups (CCGs) have a Local Reporting Management System (LRMS) which serves as the conduit to the NRLS for all mandatory reports. Organisations without a LRMS notify all severe harms and deaths directly to the CQC which then forwards reports to the NRLS. The CQC does, however, advise general practices to also report all incidents to the NRLS.(255)

3.1.3.2. Content of incident reports

The NPSA advised the following inclusion criteria for reporting:

- Incidents that you have been involved in;
- Incidents that you may have witnessed;
- Incidents that caused no harm or minimal harm;
- Incidents with a more serious outcome;
- Prevented patient safety incidents (known as 'near misses').(256)

An incident report contains structured categorical information about the location of the incident, patient age and the reporter's perception of the level of harm experienced by the patient (see Table 3.2). The report also contains unstructured free-text descriptions of the incident, potential contributory factors and planned actions to prevent reoccurrence. The free-text description, in which the reporter is asked to describe what happened and why they think it happened, offers a rich body of qualitative data for identification of areas for improvement.(183,257) These descriptions provide insight into the harms occurring or detected by reporters in general practice (which can include healthcare professionals, administrative staff, patients or carers) from their perspective.

Table 3.2. Data variables in the NRLS (example report)

Category	Code name	Description	Example
RP01	Unique ID	Numerical	1456789
RP02	Care setting	Structured	Community
RP05	Local reference ID	Numerical	3657
RP07	Trust organisation code	Numerical	0344
PD01	Patient age	Numerical	84
PD05	Specialty	Structured	General practice
PD09	Clinical outcome	Structured	No harm
IN01	Date of incident	Date	01.03.2015
IN05	Incident category	Structured	Administration
IN06	Contributing factors	Unstructured	Education and training of all staff on this overlooked; transparency of administrative processes needed; staff sickness.
IN07	Free-text description of incident	Unstructured	GP dictated urgent referral letter to dermatologist. Secretary off sick for 4 weeks. Temp staff were not aware of folder where urgent referrals were dictated. Delay of 4 weeks. Patient's lesion since diagnosed by biopsy as benign.
IN10	Reoccurrence prevention	Unstructured	A standardised operating procedure for accessing dictations for administrative team available. Identified as a practice the administrative processes that could lead to potential patient harm if routine processes not adhered. Each staff member contributed to this.

3.1.3.3. Study setting

Incident reports were included from 571 different locations, such as Health Boards (formerly Local Health Boards) in Wales and Clinical Commissioning Groups (formerly Primary Care Trusts) in England.

3.1.3.4. Study population

Around 90% of patient encounters in the NHS occur via primary care services including, but not limited to, general practice, community pharmacy, district

nursing, community midwifery, and health visiting. Primary care is delivered across a multitude of care settings by a diverse health and social care staff. A recent WHO-commissioned Delphi consensus study recognised general practice as a priority context in which to understand and advance patient safety in primary care. General practice makes a major contribution to primary care delivery (up to 1 million encounters per day in the UK) and characterising incidents and identifying priorities would be an important first step towards improving patient safety in primary care.(1,63) Incident reports received by the NRLS between April 2005 and September 2013 from general practice were considered as the complete data set (n = 42,729 reports).

3.1.3.5. Study sample

From previous analyses of NRLS reports led by the team, (198) I had estimated each clinician could code between 20-30 reports per hour. Thus, it was not feasible, nor pragmatic, to code all 42,729 reports during the study timeframe. The study was therefore designed and costed to enable coding of approximately 13,500 reports.

Multiple sampling options were considered, with each having potential opportunities and drawbacks.(258) For example, whilst an analysis of the most recent reports (e.g. from 2012 onwards) would have resulted in the identification of the most recent safety incidents, reports describing lower levels of harm outcomes would have dominated the sample by virtue of their current proportions. However, omitting learning from no harm and low harm reports would mean overlooking the learning from the majority of incidents experienced by healthcare professionals and their patients.

Given the inductive and exploratory nature of the study, the study management group comprised of my collaborators (see Appendix 6) agreed by consensus that it was a major priority to characterise all incidents resulting in severe harm or death (n=1119), and to achieve a balanced representative observation of 12,500 non-fatal reports which included no harm, low harm and moderate harm outcomes. To ensure that non-fatal reports in the sample were more current, a weighting was applied to the random sample so that recent reports (from 2012

onwards) were given a higher priority for inclusion than reports from previous years (2005–11). Since the ratio of no harm, low harm, and moderate harm reports was approximately 9:2:1, increasing proportions from no harm (n=30,979), low harm (n=7433) and moderate harm (n=3485) were selected with approximately 15%, 30% and 60% in each stratum using a simple random sample without replacement. This stratified sampling approach meant that the probability of drawing a report from group 2 (reporting period 2010-11) was twice the probability of drawing a report from group 1 (least recent, April 2005–9, and increasing proportions of level of harm, from no harm to moderate harm), and four times more likely in group 3 (most recent, 2012 – September 2013, and increasing proportions of level of harm, from no harm to moderate harm) than in group 1. This approach resulted in a data set with 12,500 reports. The frequencies for each combination can be seen in Table 3.3.

Table 3.3. Sampling strategy for no harm, low harm and moderate harm reports

Reporting period	Group	Group size (n)	Level of harm			Total
			None	Low	Moderate	
April 2005–9	1	17,238	2162	846	631	3639
2010–11	2	12,588	2237	894	770	3901
2012–September 2013	3	10,413	2292	1721	947	4960
TOTAL			6691	3461	2348	12,500

3.1.4. Classification of incident reports

Given the volume of unstructured data that each incident report can contain, it has been the trend internationally to deconstruct (“classify”) reports into their constituent parts to identify where and how to intervene in terms of better prevention and mitigation strategies.(259)

The free text descriptions included in reports vary considerably in terms of style, length and completeness. Analysis of free text has largely been organised and managed using classification systems which comprise a taxonomy of classes (“a group or set of like things”) to support identification of relationships between them.(105,239,260–266) Multiple patient safety classifications have been

developed, including those specifically for general practice.(2,195,260,267–272) As identified in chapter 2, most classifications pre-date the WHO-commissioned development of *The Conceptual Framework for the International Classification for Patient Safety* (ICPS).(2) ICPS was developed to support learning from patient safety incidents, and permit comparison across care settings and between countries. ICPS contains 10 high-level classes. Figure 3.1 overviews the semantic relationships between classes, and the intended flow of information to empirically inform “actions taken to reduce risk”.

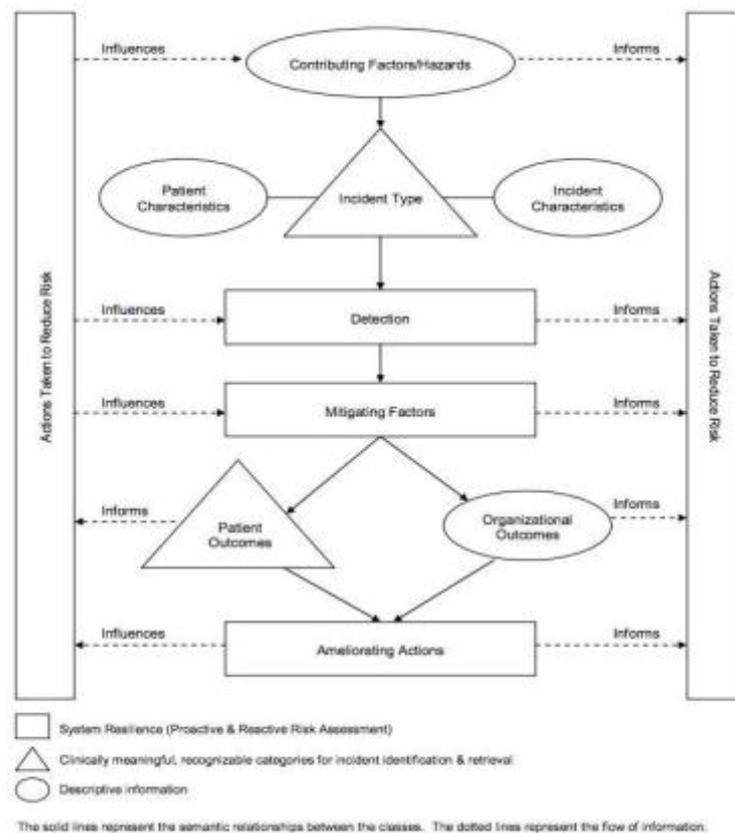


Figure 3.1. World Health Organization International Classification for Patient Safety

3.1.4.1. Judgements about classification

In most studies describing an analysis of incident report data, the content of reports is usually deconstructed into the following classes, which align with ICPS: incident types(72,262,273–279) contributory factors;(72,263,273,274,277,280) and, harm outcomes.(72,263,273,274,277–284) However, given the conceptual influence of Reason’s work on my

research, I intended to code (deconstruct) the narrative in incident reports at a granular level in order to preserve meaning on reconstruction. This required two major decisions:

1. To empirically develop a detailed classification system for application to general practice reports; and,
2. Code the data in a structured way in order for the relationships between codes to be understood and a thread of narrative to be preserved as much as possible on reconstruction.

Previous classifications identified by the scoping review described in chapter 2, particularly Makeham's International Taxonomy for Errors in General Practice and Runciman's Australian Incident Management System, (195,247) provided considerable guidance about the detail required in the coding frameworks. (195,260,267–272,285) However, whilst existing classification systems specific to general practice or primary care offered high-level codes, they would not permit the detailed coding necessary to describe potentially complex incident trajectories. Whilst the Australian Incident Management System offered the granularity of codes sought for my study, it had been developed for hospital safety with a big emphasis on application in anaesthetics. Thus, for the purposes of my study, I concluded the empirical development of three new coding frameworks was needed for general practice, to include: incident type (which includes contributory incidents), contributory factors, and patient and organisational outcomes. Further, these coding frameworks should be aligned to WHO ICPS and contain codes that can be used in conjunction with rules to preserve understanding about the sequence of events and contributory factors that culminate in, and contribute to, the incident in the context of general practice. The existing WHO ICPS coding framework for 'level of harm' was deemed suitable, and agreed by my collaborators and professional advisory group, for use in the study. (11,195,285,286)

3.1.4.2. Example of a classified incident report

This is an example of free-text from the NRLS:

“Child had been placed with adoptive parents and adopted mum had been advised by a social worker to attend family practice to complete primary vaccinations. Mum attended surgery with parental held record, no other family practice or child health medical records available. Only two immunisations had been recorded in the red book, remaining immunisations given with consent. Later informed by social services that child has already completed her primary immunisations.” [report edited]

The free-text report about the looked after child who received the wrong number of vaccine doses has been coded in Figure 3.2. Salient features of the narrative have been represented by codes belonging to each class (incident characteristics, contributory factor, outcome, level of harm). As demonstrated in Figure 3.2., unstructured free-text data can be deconstructed into codes (e.g. ‘Looked after child’) which can be later reconstructed and still retain the original report’s narrative.

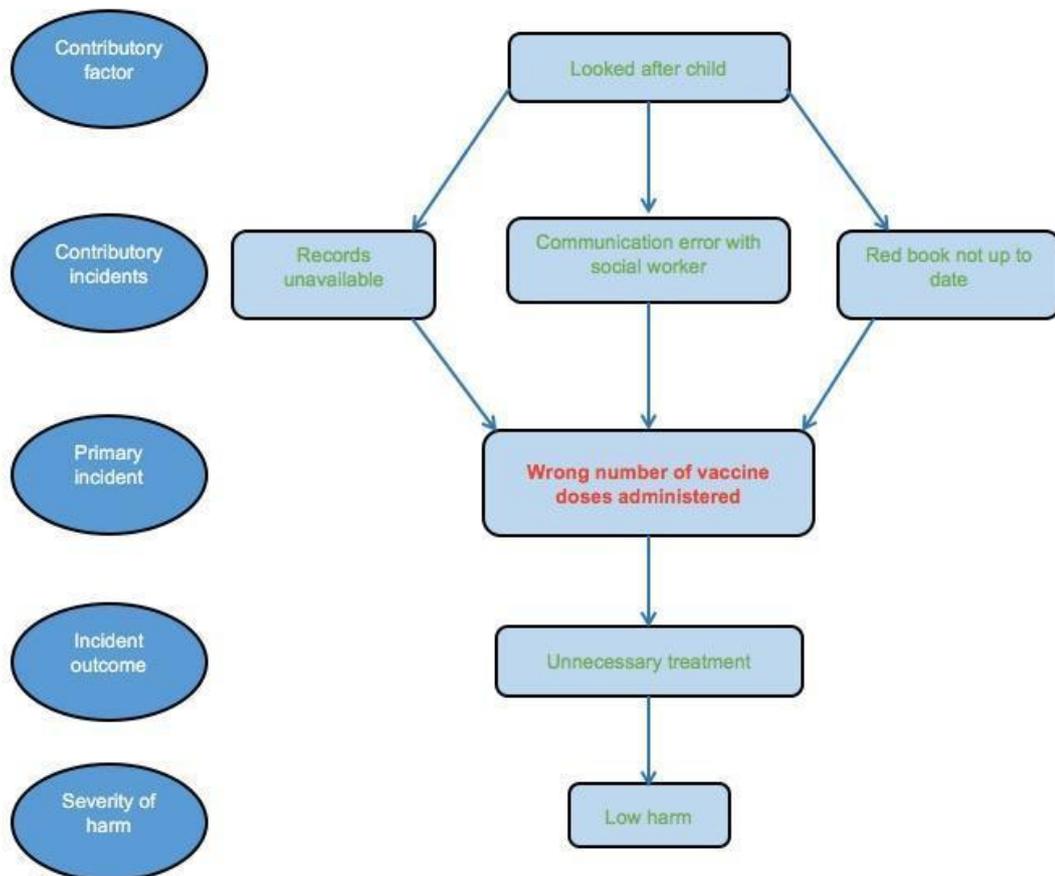


Figure 3.2. Overview of classes and codes

Codes are selected systematically to reflect the chronology (trajectory) of the incident (see Figure 3.3), and adhere to multiple rules about the nature of each class (see Table 3.4). Primary incidents included those proximal (chronologically) to the patient outcome, whereas contributory incidents included those that contributed to the occurrence of another incident. Multiple codes for incident type, contributory factor, and incident outcome were applied to each report where necessary. This permitted modeling of the steps preceding and leading to primary incidents, e.g., contributory incidents and factors, which, in turn, resulted in patient outcomes (Figure 3.3).

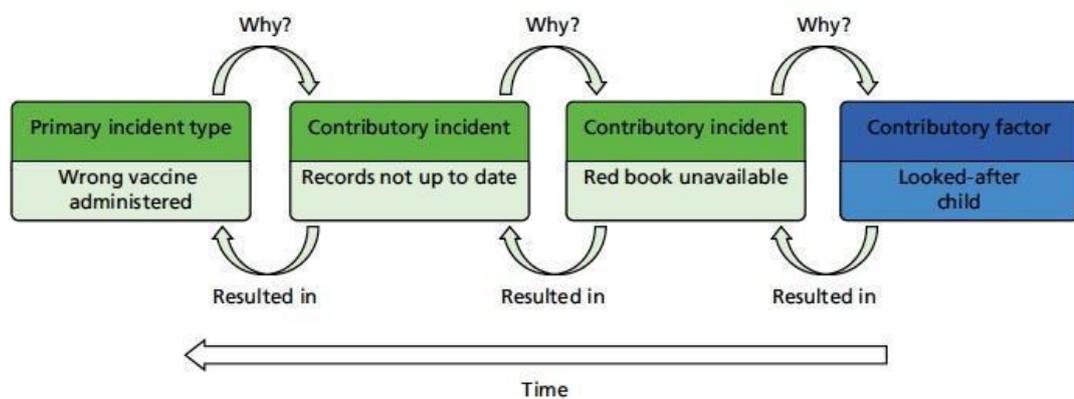


Figure 3.3. Example of codes from the classification system using the Recursive Model of Incident Analysis (287)

Table 3.4 Rules of the Recursive Model of Incident Analysis (288)

Rule	Example
1. An incident has a set of contributing factors	The wrong vaccine was administered (incident) because the child's 'Red Book' was not available (CF) and the computer records were not up to date (CF)
2. An incident can be a contributing factor to another incident	Records not up to date (incident and CF), the wrong vaccine was administered (incident)
3. Some contributing factors cannot be incidents in their own right	A mistake (CF, not an incident) led to the wrong prescribed medication dose (incident)
4. An incident has a set of outcomes	Wrong vaccine administered (incident) requiring the correct vaccine to be administered (outcome)
5. An incident can be an outcome of another incident	Records not up to date (incident) leading to the wrong number of vaccine doses (incident and outcome)
6. Some outcomes cannot be incidents in their own right	Admission to hospital (outcome) after wrong prescribed medication (incident)
7. An outcome of an incident could be a contributing factor to another incident	Communication error between HCPs (incident) led to records not being up to date (incident and outcome) which led to a vaccine-related error (incident)
8. An incident type can be designated the 'principal incident type' (i.e. the incident proximal to the descriptive patient outcome)	Communication error (incident) led to inaccurate records (incident) and results in the incorrect vaccine administration (principal incident type)
9. The outcome of a principal incident type cannot be an incident	Admission to hospital (outcome) after failure to access relevant HCP (principal incident type)

CF, contributory factor.

Information about systems resilience, such as detection and mitigation factors, are not explicit free-text categories of information in the NRLS. Such information relating to resilience would be identified and included in my analysis by memos generated during coding (stage 1 of analytical process) and thematic analysis (stage 3).

3.1.4.3. Coding management system

To ensure the classification system could be utilised in healthcare organisations, and to enable future implementation in low- and middle-income countries, I decided not to use existing coding and qualitative data analysis software in favour of a database that utilised open source software. In addition, in the interests of data security and given the distributed and international nature of the project (members of the research team in the UK, the USA and Australia), I commissioned a bespoke solution to support the iteration of frameworks and provide secure access to numerous concurrent reviewers regardless of geographical location. The system comprised a back-end

database system and a web-based portal. The back-end database was built on Microsoft SQL Server 2014 (Microsoft Corporation, Redmond, WA, USA) by Huw Evans (an academic F2 doctor with informatics expertise), with custom SQL algorithms to provide, for example, live concordance checks of reviewers' double-coding. The web front end was also produced by Evans using a customised version of Portofino 4.1.1 (Many Designs, Genoa, Italy), an open-source web framework written in JavaScript (Netscape Communications Corporation, Mountain View, CA, USA).

3.1.5. Reviewer training

A multidisciplinary team of clinicians was recruited as report reviewers. These included a research nurse with a special interest in human factors and patient safety (Anita Deakin), two general practitioners (Huw Williams and Alison Cooper), and two academic foundation year two doctors (Huw Evans and Emma Shiels).

Preparatory online modules on patient safety provided by the Institute for Healthcare Improvement Open School were completed by all reviewers. Next, a human factors expert and co-author of the WHO ICPS, Peter Hibbert, delivered training on incident analysis, classification, root cause analysis and human factors in healthcare and supported reviewers via weekly calls to undergo simulation with a practice data set. During the training period, to focus reviewers on the relevant content of interest, they were asked to identify in each incident the content which corresponded to each question outlined in Figure 3.4. I developed these questions by undertaking a pilot content analysis of 500 randomly sampled incidents with a medical student (Hope Ward). The initial frameworks used as the basis of the coding frameworks in the main study were developed during this pilot work which is accepted standard practice for qualitative research.(289)

- Who**
- 1.1. Who is reporting the incident?
 - 1.2. Which member(s) of staff were involved?
 - 1.3. Were people in the situation aware that there was a problem?
- What**
- 2.1. What happened, or what was the problem?
 - 2.2. What was the outcome for the patient in this incident?
 - 2.3. Was there a risk inherent in the clinical situation (e.g. medication adverse event)?
 - 2.4. Is this an isolated incident or is it wider problem?
- Where/when**
- 3.1. In which area of health care did something go wrong?
- Why**
- 4.1. Is there an identifiable cause to the problem?
 - 4.2. Could this harm have been predicted?
- Preventing reoccurrence**
- 5.1. How could the harm have been prevented?
 - 5.2. Has anything been learned from the situation?
 - 5.3. Have measures been put in place to prevent reoccurrence?

Figure 3.4. Criteria for orientation to incident report content

The reviewers' interpretations were informed by tacit knowledge, clinical expertise and the human factors training received to guide sensemaking, defined as "the active process of assigning meaning to ambiguous data", in order to identify the learning that can be used to inform improvements in clinical care.(290,291) Once greater than 70% agreement (kappa statistic) between reviewers and an experienced coder (Huw Williams) was achieved, the reviewers were eligible to code the study data.

To achieve reflexive processes that permitted iterative developments of my methods, I established effective communication with my team that worked under my close supervision via weekly group meetings. In addition, I sought feedback about methods from collaborators including a patient and public involvement (PPI) representative meeting with Antony Chuter on a monthly basis, and a professional advisory group meeting at least every six months (members listed in Appendix 7) over a 24-month period.

3.1.6. Description of analytical methods

The overarching analytical plan for my study corresponded, in qualitative research approach terms, to a Framework Analysis.(292) This approach was designed by the National Center for Social Research specifically for generating policy and practice-orientated findings. However, given the scale of the study in terms of the volume of free-text data for analysis, the opportunity to generate a coding frameworks that could be used by other research groups and healthcare organisations, the number of clinical reviewers, and an effort to promote transparency throughout the analytical process, modifications to the processes of conventional Framework Analysis processes were needed.

The five steps of Framework Analysis described by Ritchie and Spencer (292) are: 1. familiarisation; 2. identifying a thematic framework; 3. indexing; 4. charting; and 5. mapping and interpretation. The aim of the analysis is to order data to facilitate interpretation. On review of these steps, processes inherent in each step were considered and alignment with the three overall stages of my analysis plan: steps 1–3 as ‘stage 1: familiarisation and data coding’; step 4 as ‘stage 2: generation of data summaries, using exploratory data analysis (EDA) methods’;(293) and step 5 as ‘stage 3: interpretation of themes and learning’.

3.1.6.1. Modifications of Ritchie and Spencer’s Framework Analysis

The major modifications to the steps described by Ritchie and Spencer were made in order to strengthen the overall analytical process in the interests of producing coding frameworks aligned with the WHO ICPS as an output from steps 1–3 (stage 1); and, a structured, analytical plan for transparency, and to permit the generation of an audit trail of analysis by quantifying the data and using descriptive statistics in step 4 (stage 2).

In stage 1, I aligned my methods with Ritchie and Spencer’s approach to first code the data with sequential interpretation (stages 2 and 3); therefore, report reviewers were instructed to code data objectively based on the explicit content described in reports. This was an important decision because it also permitted

use of the Recursive Model of Incident Analysis rules for structuring the data.(288)

In stage 2, the methods of cross-tabulation used during EDA aligned with the matrices advocated by Ritchie and Spencer (292) for aiding the identification of themes and explanations (stage 3). This approach also supported maintaining the context of the data, and cross-tabulations were linked back to the original reports. Cross-tabulations supported a question-focussed approach which is also promoted in Ritchie and Spencer's (292) approach.

Given the objectives of my study, and conceptual influence by Reason's work, the focus of this stage of analysis was to identify and explain the contributory themes present amongst clusters of similar reports. An interpretive and explanatory analysis followed in stage 3 which was supported by the infrastructure generated by preceding stages. For example, the Recursive Model of Incident Analysis structured the application of codes, and enabled sequential interpretation of their relationships. My method for stage 3 was aligned with best practices of thematic analysis advised by Ritchie and Spencer and other scholars.(200,292,294,295) My personal preferences for developing a thematic framework, given my qualitative research methods preparation from MPhil study (2008-9), meant I had encouraged the writing of reflexive memos and hunches by the team throughout stages 1 and 2, and this supported me and a colleague (Huw Williams) to link together themes, identify patterns and evidence such links.

In summary, the three stages of analysis were:

- stage 1: familiarisation and data coding, which involved reading the free text of the report and applying codes to describe incident type, potential contributory factors and level and type of harm.
- stage 2: generation of data summaries, using EDA methods.
- stage 3: interpretation of themes and learning; seeking to understand the most commonly identified patient safety incidents, contributory incidents and reported contributory factors, and the contexts within which they occurred.

Each stage will now be considered in more detail.

3.1.6.2. Stage 1: data familiarisation and coding

Reviewers orientated themselves to content by reading the incident report. The reviewer was required to objectively choose the codes, with no inferences made, that represented the content described in each report from four classes: incident type, contributory factors and type and degree of harm (see Figure 3.5 for a summary of the data coding process). Collectively the four classes were referred to as the “Primary Care Patient Safety (PISA) coding frameworks” or the PISA framework. The nine rules for applying the Australian Patient Safety Foundation ‘Recursive Model of Incident Analysis’ (see Table 3.4) were used to guide chronological ordering of coded data (Figure 3.3).

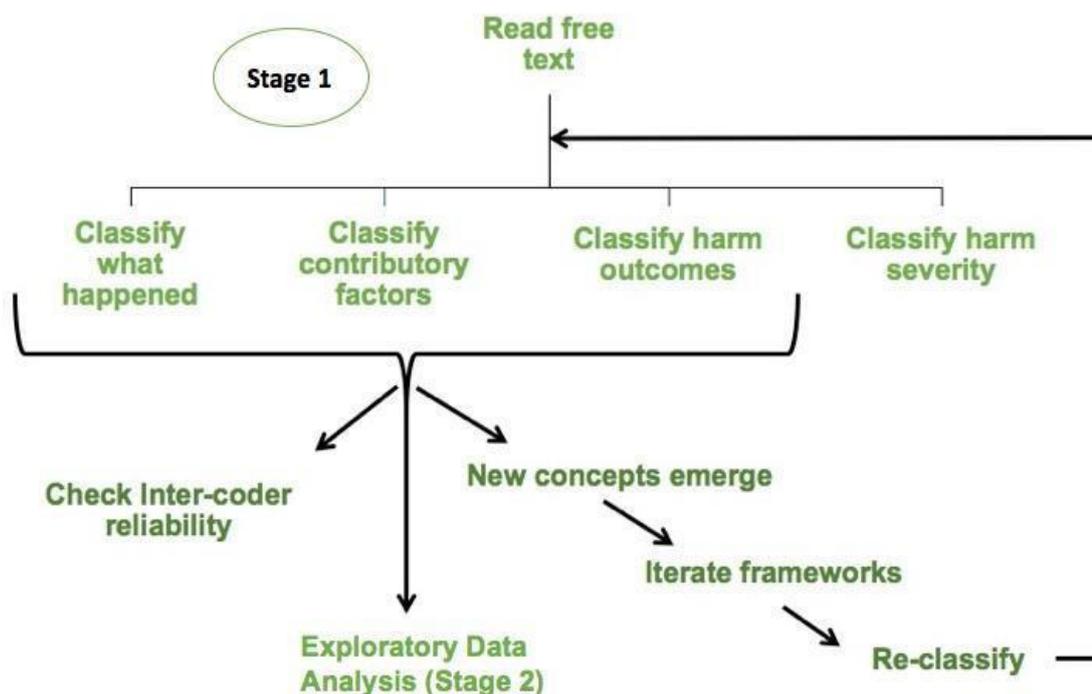


Figure 3.5. Process summary of stage 1 - data coding

Coding such a large amount of data required effective teamwork amongst simultaneous coders in order to utilise the tacit knowledge and experience of multiple coders.(295) To ensure validity and reliability of coding throughout the study, regular intercoder reliability checks were undertaken on a 20% random

sample of each reviewer's coding quota for every 250 reports coded.(296) Kappa statistics were calculated for each principal incident type, defined as the incident that occurred just before the harm or potential harm. A kappa of > 0.7 was sought and is consistent with previous studies of a similar nature.(268) The reviewers met to discuss discordant reports and where discrepancies could not be resolved by discussion between reviewers, I provided third-person arbitration as the senior investigator.(296)

Learning from discussions about discordance was shared at weekly coding meetings and informed the inductive iteration of codes and their definitions throughout the study process. The study team comprised professionals from medicine, nursing, physiotherapy and mixed-methods researchers, and also benefited from the participation of a pharmacist (my PhD student, Khalid Muhammad, at the University of Nottingham) and dentist (my PhD student, Dr Eduardo Ensaldo-Currasco, at the University of Edinburgh) present via teleconference. A human factors expert (Peter Hibbert) attended weekly meetings and advised the team on classification development and analysis of complex incident reports. These meetings were also used to discuss intercoder agreement and attempted to resolve any issues that related to the understanding and application of specific codes, as well as for wider discussion among a multidisciplinary team. Ideally, a code book (a collection of coding classes) should be 'all inclusive' with codes with definitions that are 'mutually exclusive'.(297) When an existing code was not available to describe the incident characteristics, at the weekly coding meetings, the study team discussed whether a new code was needed or the definition of an existing code should be amended to be more inclusive. Cimino described twelve desiderata for the design of a controlled healthcare vocabulary in "desiderata for the 21st Century" (see Table 3.5.). These rules guided the development of each class.

Table 3.5. Desiderata for the design of a controlled healthcare vocabulary.

Modified from Cimino (298)

Desiderata	Definition
Concept orientation	The unit of symbolic processing is the concept and each concept in the vocabulary should have a single, coherent meaning.
Concept permanence	A concept's meaning cannot change and it cannot be deleted from the vocabulary.
Meaningless concept identifier	Concepts typically have unique identifiers (codes) and these should be non-hierarchical (see code-dependance) to allow for later relocation and for multiple classification.
Polyhierarchy	Entities from the vocabulary should be placed in more than one hierarchy location if appropriate.
Formal definitions	Semantic definitions of concepts, for example, <i>Streptococcal tonsillitis=Infection of tonsil caused by streptococcus.</i>
No residual categories	Traditional classifications have rubrics that include <i>NOS, NEC, Unspecified, Other</i> whose meaning may change over time as new concepts are added to the vocabulary. These are not appropriate for recording data in an electronic health record.
Multiple granularities	Different users require different levels of expressivity. A general (family) practitioner might use <i>myocardial infarction</i> whilst a surgeon may record <i>acute anteroseptal myocardial infarction.</i>
Multiple consistent views	Although there may be multiple views of the hierarchy required to support different functional requirements and levels of detail, these must be consistent.
Representing context	There is a crucial relationship between concepts within the vocabulary and the context in which they are used. Cimino defines 3 types of knowledge: Definitional - how concepts define one another Assertional - how concepts combine Contextual - how concepts are used

Graceful evolution	Vocabularies must be designed to allow for evolution and change, to incorporate new advances in healthcare and to correct errors.
Recognise redundancy	Where the same information can be expressed in different ways, a mechanism for recognising equivalence is required.

Hypotheses emerged from each step of analysis and were noted by reviewers during coding and analysis via electronic memos that were also discussed at weekly coding meetings. I chaired proceedings at meetings. As advocated by Macqueen (2008), one member of the team (Huw Evans) was the “codebook editor” responsible for the update of the codebook.(295) For example, as codes were assigned (e.g. ‘wrong dose administered’ and ‘wrong drug administered’) and the codebook was developed, the study team observed how cases clustered around particular codes or sets of related codes emerged, such as ‘administration errors’.(299) Implications of changes to the code book were considered on a case-by-case basis; given the structured nature of the coding process, it was possible to isolate reports that would be impacted by new codes or changes to the definition of existing codes (see Figure 3.5). Examples of the coding frameworks are included in Appendix 8.

Examples of the data collection form used to code data from each incident report are shown in Figures 3.6 and 3.7.

In07 description of what happened:	Child with breathlessness sent from A&E department into busy GP Out-Of-Hours waiting area . When seen in primary care child's condition had worsened as had not been put through as urgent and there was a delay in diagnosis
In10 actions preventing reoccurrence:	NA
In11 apparent causes:	NA
Age at time of incident:	3
Pd01 b patient age range:	2 to 4 years
Pd09 degree of harm severity display:	Moderate
Dv01 patient age at time of incident:	Y3
Period:	NA
Incident 1:	<input type="text" value="8.2."/>
Incident 2:	8.2 Between Healthcare Professionals Errors in communication between healthcare professionals
Incident 3:	8.2.1 Failure to Convey Seriousness/Urgency of Patient
Incident 4:	Condition D Failure to communicate or emphasise the need for immediate or fast care

Figure 3.6. Example of selecting incident type from PISA coding frameworks

Rp01 unique incident id:	341906
In07 description of what happened:	Dispensing error - prescription for Erythromycin 250mg dispensed chlorpromazine 50mg tablets 16 year old patient took wrong medicine for 3 days and suffered serious side effects including catatonic seizures
In10 actions preventing reoccurrence:	Pharmacist Action - Different brand of chlorpromazine to be kept in pharmacy PCT action - contacted manufacturer to request re - assessment of packaging Manufacturer action - re - assessment is already underway
In11 apparent causes:	Similarity of packaging led to error in tablet selection
Incident 1:	6.3.1 Wrong medication Incorrect medication dispensed
Incident 2:	
Incident 3:	
Incident 4:	
Incident 5:	
Contrib 1:	2.3.1.2. Similar medication names / appearances confused
Contrib 2:	
Contrib 3:	
Contrib 4:	
Outcome 1:	1. Patient clinical harmPathophysiological/disease-related Pain
Outcome 2:	1.1.16 Seizure
Outcome 3:	

Figure 3.7. Example of codes used to describe an incident in the PISA database

3.1.6.3. Stage 2: generation of descriptive summaries

The originally proposed methods for generating descriptive summaries was:

“Differences in proportions of demographics such as incident type, the incident location, and patient characteristics with the severity of harm event will be assessed by Chi-squared and Fisher’s exact tests, with differences in means calculated by t-test. Subsequent logistic regression modeling will evaluate the relationships between incident type, incident

location, and patient characteristics, to harm outcomes in the data (objective 3). Logistics odds ratios will be calculated to determine the odds of an event occurring; for example the odds of an event occurring in the out-of-hours clinic compared with all other settings. To rank the incident locations according to the degree of reported harm, we will calculate Harm Susceptibility Ratios, (Pham et al. 2010; Martinez et al. 2011) which are the odds of reported harm for each incident location compared with the average odds of reported harm across all other incident locations.”

I convened a professional advisory group (Appendix 7), comprised of health services researchers with quantitative and qualitative methods, policy and PPI expertise, to review and advise on methodological development. The group, together with my study collaborators, considered the aims and objectives of the study, and proposed a substantial amendment to the proposed methods following a pilot analysis of paediatrics reports, presented to the advisory group in July 2014.

The advisory group highlighted the multiple caveats needed to be expressed upfront before calculating and interpreting odds ratios, including: justification about the reference incident type in the absence of robust epidemiological data; and, what the odds ratios meant given the nature of incident reports and their intrinsic biases (under-reporting, selective-reporting, incomplete reporting, and incident non-detection).

The following points were raised during discussion:

- The strength of incident reporting lies in identifying clusters of like phenomena, and analysing them in detail with respect to contributory factors and context.
- Large discrepancies between ethnographic studies, medical record review and incidents reported are well recognised. Thus, incident reporting cannot be used to reflect the frequency of patient safety incident in practice because of under-reporting, selective-reporting, incomplete-reporting and incident non-detection, not least a minimal

primary care patient safety literature base to fill in the gaps generated by those uncertainties for the purposes of multivariate modelling.

- The frequency of the characteristics described in reports, given the intrinsic biases of the data, do not constitute the basis for robust indices about harm.

The advisory group agreed by consensus that most methods (Chi-squared, Fisher's exact test, t-test, logistic regression and Harm Susceptibility Ratios) were of limited value for informing efforts to raise practical, pragmatic recommendations about the key change concepts to improve safety for children.

The advisory group proposed a modification to the study design by recommending an amendment to the following research objective: "...determine which characteristics are associated with different levels of harm." The advisory group did not think that the word *determine* was an appropriate term to use given the unknown denominator for these data and the inherent reporting biases of identifying and reporting incidents. The proposed amendment was to change this to "...explore which characteristics are associated with different levels of harm."

The professional advisory group underscored the purpose of this stage of the analysis should be to identify the reports containing descriptions of the most frequent incidents and most severe levels of harm. They advised an EDA approach, as championed by Tukey (1977), could be used to inform decision-making about which reports should undergo further thematic analysis.(293) Common tools associated with EDA include cross-tabulation, frequency tables and Pareto charts, and can be used to support the identification of clusters of similar reports.(300) Further, in the interests of developing methods that could be emulated by healthcare organisations, especially by teams without formal training in statistical modelling, the advisory group championed using simple descriptive statistical methods to offer a logical and transparent process that others should be able to adopt with minimal training.

The recommendation and change in method was supported by the NIHR's appointed scientific advisors.

3.1.6.3.1. Exploratory data analysis (EDA)

EDA is an approach to analyse and summarise data in terms of their main characteristics, often with visual methods.(293) It can be used to explore what data can reveal beyond formal modeling or hypothesis testing. John Tukey was a strong advocate for EDA to encourage researchers to formulate hypotheses that could lead to new data gathering or experimentation.(293) For the purpose of my analysis, the objectives of EDA were to describe and summarise data to inform hypotheses about the most frequently reported incidents and their causes; and, identify patient safety issues that would benefit from further research and development. The nature of the inquiry was inductive and was guided by clinical expertise.

Descriptive statistics were used to explore relationships between variables. The exploration was a systematic inquiry comprised of frequency tables and cross-tabulations of variables that the study team had identified as essential processes for first, determining the most frequent and most severe incidents; and second, the nature of those incidents by virtue of their relationship with other variables. Given the conceptual influence of Reason's Trajectory of Error in this study, such relationships can indicate potential causal chains of incidents occurring in sequence and clusters of contributory factors which could all be potential targets for improvement.

EDA methods were used to produce, for example, frequency tables, cross-tabulations and bar charts, ready for interpretation and refinement through expert clinical guidance.(293) As the purpose of the study was to generate learning to support healthcare professionals to improve the safety of care delivery, I recognised (with supporting consensus agreement from the professional advisory group) that it was essential for the outcomes of the EDA to be both accessible and provide a logical account of how priority issues for possible intervention were identified. Frequency tables enabled identification of the most common and most harmful reported incident types. Cross-tabulations

between data variables (e.g. age group, incident type, contributory factor and incident outcomes), and between incident codes and contributory factor codes, helped to identify priorities (e.g. high frequency of vaccine errors in children aged 1–5 years old).

Table 3.6 outlines the sequence of cross-tabulations undertaken based on a *priori* knowledge of the WHO ICPS and the major conceptual relationships between variables, and what they meant in terms of using such insights about those relationships to inform improvement strategy. Where there was a strong apparent relationship between variables (e.g. prescribing error and administration error), further sub-characterisation was undertaken by exploring the relationships with other variables (e.g. age, contributory factors). This exploratory process is similar to the constant comparative approach used within grounded theory-based approaches.(301) In this way, ideas about associations between variables are being generated and tested through further cross-tabulations. This systematic process permitted the researcher to remain close to the data and identify clusters of similar reports for more in-depth exploration by thematic analysis.

Table 3.6. Structure of cross-tabulation queries

1st variable	2nd variable	Purpose
Incident type	Age Location	Identification of reporting patterns for particular patient groups or from a specific healthcare organisation;
	Contributory factor	Identification of reported incidents with the most contributory factors described, and which contributory factors (in terms of frequency) were described for each incident;
	Contributory incidents	Incident type with: identification of reported trajectory of incidents;
	Outcomes	Identification of reported incidents with different levels of patient harm outcome, and organisational outcomes;

3.1.6.4. Stage 3: identification and interpretation of themes

The application of codes in stage 1 was, in qualitative terms, a form of structural coding which applies “a content-based or conceptual phrase” to data. Such phrases were derived whilst adhering to the desiderata for the design of a controlled healthcare vocabulary. To maximise insight from the analysis, a second “cycle” of coding was required to deepen the analysis and interpretation gained in stage 1 (coding and description of characteristics of incidents) and stage 2 (identifying patterns in the data) to identify and prioritise the most important patient safety problems.(251) The purpose of this stage of the analysis was to develop a coherent synthesis of the data by identifying the themes and concepts apparent from the first cycle of coding. This additional interpretive and explanatory analysis enabled identification and description of additional recurring themes (or in improvement terms, change concepts for improvement), not captured by the quantitative data (stage 2) or earlier *a priori* themes, that could be targeted to mitigate future safety risks.

EDA (stage 2) enabled collation of relevant codes and to explore the relationships between the most common and most harmful reported safety incidents and contributory factors and outcomes. Re-examination of these incidents in clusters (theoretically generated samples) of similar incidents provided an opportunity to identify contextual issues within each subset of data (e.g. all reports describing moderate harms or worse following issues relating to access of clinical services for urgent assessment). The subsets of reports were independently re-read by me and Huw Williams. We sought to identify any relevant clinical contextual issues that might not have been explicit in the report that could help explain the relationships identified from the EDA in more detail.

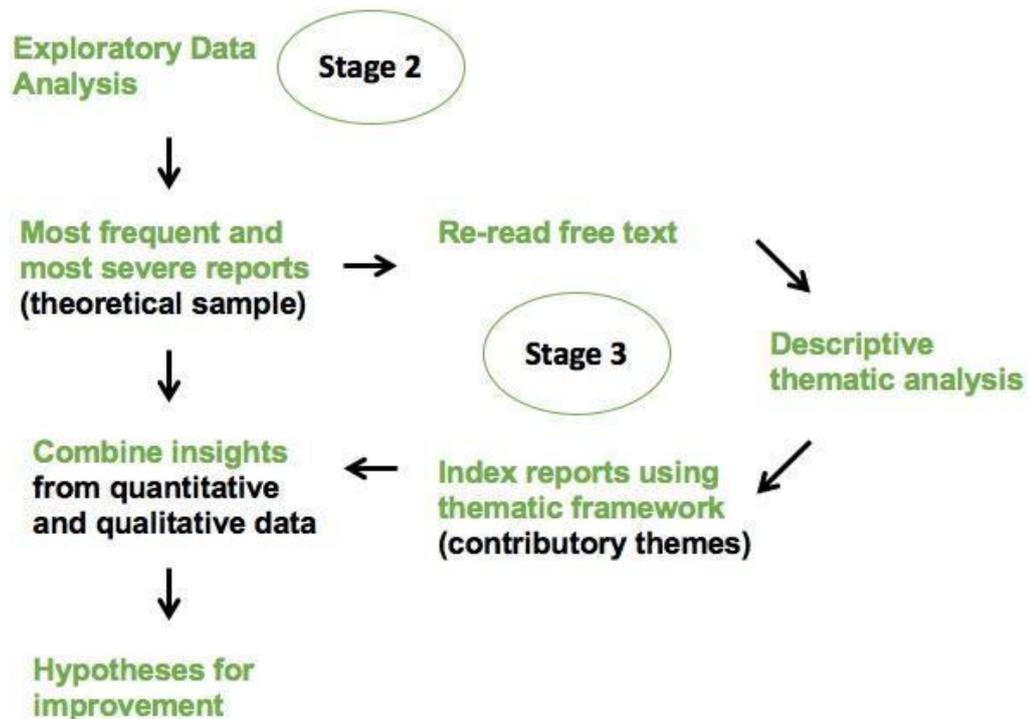


Figure 3.8. Process summary of stage 3 – interpretive and explanatory analysis

During stage 3, interpretation of report content and the identification of stand-alone and cross-cutting themes about reported causes and opportunities to prevent recurrence within the data were encouraged (see Figure 3.8). Saldana (2015) describes a theme as: “an outcome of coding, categorisation, and analytic reflection”. The outcome from stage 2 was to identify which codes belonged to which categories. Whilst this is largely defined by the parent-child relationships in coding frameworks, opportunities to form new categories exists by grouping similarly coded data based on their shared common characteristics.

The purpose of the analysis was to identify priority issues for improvement, which in itself requires a “theory of change”. The methodological processes used in my study are not utilising a grounded theory approach. Whilst at a cursory level the outputs seem intuitively similar, where the outcome of a grounded theory approach is the development of a social theory, the analytical stages to achieve this are less suited to a team approach.(302) Grounded theory approaches require a more intensive initial ‘open coding’ which is often a line-by-line analysis of the primary data which is not feasible given the volume

of reports for my study.(302) However, I deemed the 'reflexivity' encouraged for this approach to be beneficial for this study. In anthropological terms, reflexivity is the "...researcher's awareness of an analytic focus on his or her relationship to the field of study".(302,303) To maximise insights about what constituted explicit or implicit judgements made by clinicians coding the incident report data, I recognised weekly team meetings and analytical memos would add value and were woven into my modified form of Framework Analysis to aid reflexivity throughout the project.

Framework Analysis promotes a process to allow themes to emerge from the data throughout the project.(251) Categories were formed by grouping codes with similar characteristics. My analytical goals, with Williams, were to reduce the most frequent codes into categories (e.g. communication with and about patients). These were largely informed, although not entirely, by existing parent-child relationships in the classes belonging to the coding frameworks. Next, I sought to identify 'manifest themes' which were explicit descriptions of the key relationships between incidents and contributory factors in each sub-category e.g. barriers to accessing clinical services (theme) and message handling and telephone calls (sub-theme). Whilst re-reviewing reports belonging to each manifest theme, "integrative themes" (what I call 'contributory themes' in the context of patient safety) emerged that wove the manifest themes together (e.g. lack of IT infrastructure resulting in poor administrative processes). Final manifest and integrative themes, and their supporting data including clinical vignettes, were discussed by the study team and recommendations for further research and improvement were agreed. See Figure 3.9 for an example of the relationship between codes, categories and themes.

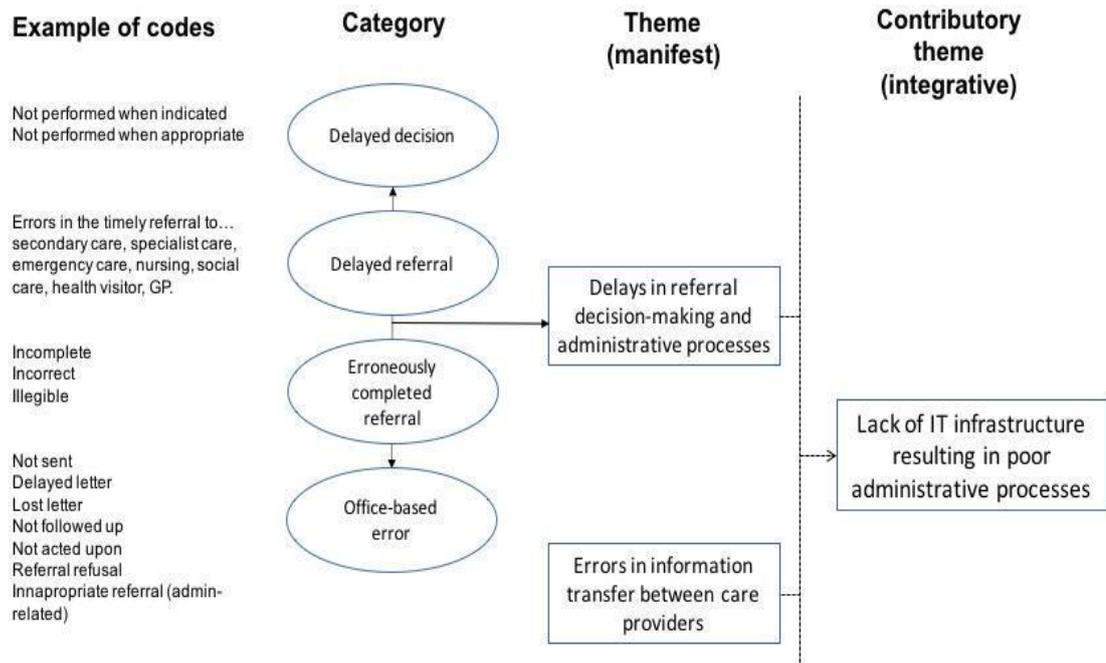


Figure 3.9. An example of the relationship between codes, categories, manifest and integrative themes

3.1.7. Ethics and data governance

The Aneurin Bevan University Health Board Research Risk Review Committee waived ethics approval given the anonymised nature of the data (research and development reference number SA/410/13; see Appendix 9). No incidents were identified from the information within reports that raised serious professionalism or ongoing patient safety issues.

3.1.7.1. Ethical considerations

Recent public discourse concerning the security of health and care information has raised issues concerning how the public make choices about how their data are used, including in research.(304) My application for access to NRLS data was deemed by NHS England to fully adhere to Caldicott principles. A Data Sharing Agreement was signed between Cardiff University and NHS England.

Additional data about NHS patients were not collected following review of incident reports. Incident report data had been anonymised by NHS England and there was no method to contact the original reporter; therefore, it was not

possible to obtain consent from patients. There was no method of re-identifying patients or healthcare organisations without contacting NHS Improvement.

Should information within a report raise professionalism or ongoing patient safety concerns, I had agreed to inform the relevant leads at English NHS commissioning groups or NHS Wales Boards to appropriately deal with those concerns.

Whilst reports had been anonymised according to NHS England's information governance policies, an additional level of scrutiny was developed by the research team in order to minimise identifiability. For the purposes of choosing vignette examples, if an extract contains any of the following details, the suggested changes or omissions stated in ***bold italics*** were made:

- Patient/relative should be made
 - Name/nickname/initials ***change to [patient] (number 1, 2... if necessary)***
 - Date of birth (***remove***)
 - Address (***remove***)
 - Age (***change to age range or remove depending on relevance to incident e.g. 23-year-old male to [male in his twenties]***)
 - Hospital number/ NHS number/ any identifying number (remove)
- Staff
 - Name/nickname/initials ***change to e.g. [doctor, nurse, staff member] (number 1,2... if necessary)***
 - An unusual or unique job title (e.g. Chief Nursing Officer) (***use judgement to anonymise effectively***)
- Location
 - Name of hospital/ site/ ward name/unit name ***change to a generic term such as [hospital, ward name, GP surgery, haematology unit]***
 - An unusual title of a site or unit e.g. paediatric oncology unit. (***use judgement to anonymise whilst retaining meaning if relevant***)

- o Name of geographic location (e.g. postcode, street name, town or city) (**remove**)
- Dates relating to the incident (**remove if irrelevant to report or improve anonymity if it is relevant e.g. 7/12/14 change to [December of that year] or [three months later]**)

If the extract contained any of the following clinical details, considerations were made about whether the nature of the incident or disease could be identifiable by virtue of its rare occurrence:

- Rare diagnosis / rare treatment or rare presentation e.g. common diagnosis but rare in that age group;
- Rare incident or sequence of incidents or rare outcome; or,
- Indication of surrounding media attention.

3.1.7.2. Data security

The Data Sharing Agreement stipulated the security measures needed throughout the lifecycle of the information, in particular, during storage, transmission and destruction in line with ISO 27001 (specifies the requirements of information security management systems) and the HMG Security Policy Framework (high-level policies on security for the Government and its suppliers).

The SQL database was stored on a designated patient safety research computing cluster located in the Division of Population Medicine at Cardiff University built in conjunction with the Informatics Services team (INSRV) at Cardiff University. The cluster has full NHS Information Governance Toolkit assurance for secondary use of data (IG Toolkit ID: 8WG65-PISA-CAG-0182). A full information security framework risk assessment was completed on the housing of the incident report data and was submitted to INSRV. All work was completed within the Division of Population Medicine on the Patient Safety Research Cluster. The data security requirements were scrutinised by INSRV at Cardiff University. The patient safety cluster was subject to monthly penetration testing by the INSRV Security Team to ensure compliance with all policies. Data

were backed up every 15 minutes to local storage and overnight to encrypted tapes which were stored in a fireproof safe in the INSRV data centre.

3.2. Overview of results

A total of 13,699 reports from general practice was coded. Five high-level incident-type categories summarise the majority of safety incidents described within the reports, and in descending order of frequency are:

1. communication with and about patients;
2. medication and vaccine provision;
3. errors in investigative processes;
4. treatment and equipment provision; and,
5. timely diagnosis and assessment.

Of the 9031 reports included in the analysis, the severity of harm could be determined in 5755 cases. This was unclear for the remainder (n = 3276 incidents). Table 3.7 shows the number of incidents for each category of harm severity and also gives an example of an incident with different levels of severity of harm.

Table 3.7. Examples, description and number of reports by severity of harm

Severity of harm	Description	Example	Reports, n (%)
Unclear	It is unclear from the free-text description what level of harm has occurred	Patient given medication to which they had a documented allergy, but no mention of an allergic reaction	3276 (36.3)
None	Patient outcome is not symptomatic or no symptoms detected and no treatment is required	Patient given medication to which they had a documented allergy, but did not develop an allergic reaction	1210 (13.4)
Low	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g. extra observation, investigation, review or minor treatment) is required	Patient given medication to which they had a documented allergy and developed a minor rash which did not require any additional treatment	3549 (39.3)
Moderate	Patient outcome is symptomatic, requiring intervention (e.g. additional operative procedure or additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function	Patient given medication to which they had a documented allergy and required hospital admission for further treatment and observation	631 (7.0)
Severe	Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function	Patient given medication to which they had a documented allergy and subsequently had an anaphylactic reaction requiring intubation and admission to intensive care	122 (1.4)
Death	On balance of probabilities, death was caused or brought forward in the short term by the incident	Patient given medication to which they had a documented allergy and subsequently had an anaphylactic reaction from which they died	243 (2.7)

Just over half of the included reports (50.3%, n = 4545) described harm to one or more patients.

3.2.1. Severity of harm by incident category

Table 3.8 reports the number and proportion of incidents in each category and the proportions resulting in no harm, harm or serious harm (all incidents resulting in moderate harm, severe harm or death).

Table 3.8. Number of incidents in each category by the severity of harm

Incident category	Harm, n (%)	No harm, n (%)	Serious harm or death, n (%)	Harm not specified, n (%)	Total, n (%)
Communication with and about patients	82 (46)	463 (17)	172 (6)	1061 (38)	2805 (21)
Medications and vaccines	1280 (52)	425 (17)	238 (10)	779 (31)	2484 (18)
Investigative processes	536 (40)	84 (6)	38 (3)	719 (54)	1339 (10)
Treatment and equipment provision	515 (68)	64 (9)	116 (15)	175 (23)	754 (6)
Diagnosis and assessment	575 (79)	33 (5)	366 (50)	120 (17)	728 (5)
No harm from primary care (excluded reports)					4668 (34)
Other ^a					921 (7)
TOTAL					13,699 (100)

^a Not broken down by level of harm.

Incidents related to communication with and about patients were the most frequently reported safety issues (n = 2805, 21%), followed by incidents related to medications and vaccines (n = 2484, 18%) and investigative processes (n = 1339, 10%). Incidents relating to timely diagnosis and assessment (n = 728, 5%) and treatment and equipment provision (n = 754, 6%) were less frequently reported. However, diagnosis and assessment-related incidents were most likely to describe harm occurring to the patient; whilst 79% of incidents in this category resulted in a harmful outcome, two out of three of all harmful outcomes were serious harms or deaths (n = 366, 50%). This was followed by incidents relating to treatment and care equipment (68%, n = 515), and then medications and vaccines (52%, n = 1280). Although communication with and about the patient was the most frequently reported incident category, 46% (n = 1282) of these incidents resulted in harm and 6% (n = 172) resulted in serious harm or death.

3.2.2. Reporting locations

Although 462 separate locations provided at least one report, over half of the reports originated from only 30 locations (n = 7071, 52%). Sixty-seven locations reported only one incident. Figure 3.10 demonstrates the variation in reporting across locations. This implies that some organisations do not report general

practice safety incidents to the NRLS or do not have a mechanism for receiving incident reports from general practice. The top reporting location (shown in black) reported 920 incidents, of which 26% (n = 243) resulted in harm and 4% (n = 40) in serious harm. Other locations are similar to the organisation in blue where, of the 368 incidents reported, over half (60%, n = 219) resulted in harm. Where they do report, different thresholds for receiving reports (i.e. only serious harms or deaths), as well as different mechanisms or thresholds for uploading incident reports to the NRLS, could explain the variation identified.

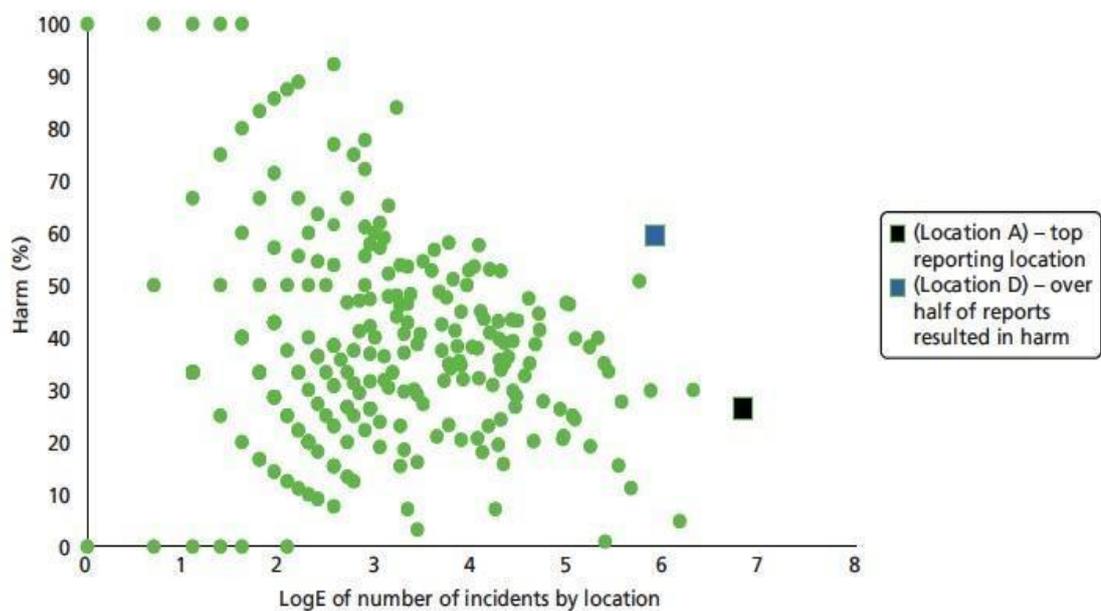


Figure 3.10. Scatter plot of the percentage of harmful incidents by the frequency of reports per location

3.2.3. Reported age of patients

The age of the patient was described in 6472 (47% of total) incident reports. Figure 3.11 demonstrates the frequency of reports by age group. The age group accounting for the highest proportion of incident reports was 76–85 years (n = 1403, 22%), and 53% (n = 3417) of all reports involved a patient aged > 65 years while 9% (n = 576) involved patients aged < 4 years. The frequency of incident reports by age group shows peaks at both extremes of age (children and elderly patients), consistent with the expected number of contacts with general practice in these age groups. This pattern was apparent across all the

incident categories (see section 3.4). In 2574 cases, both the level of harm and patient age were reported.

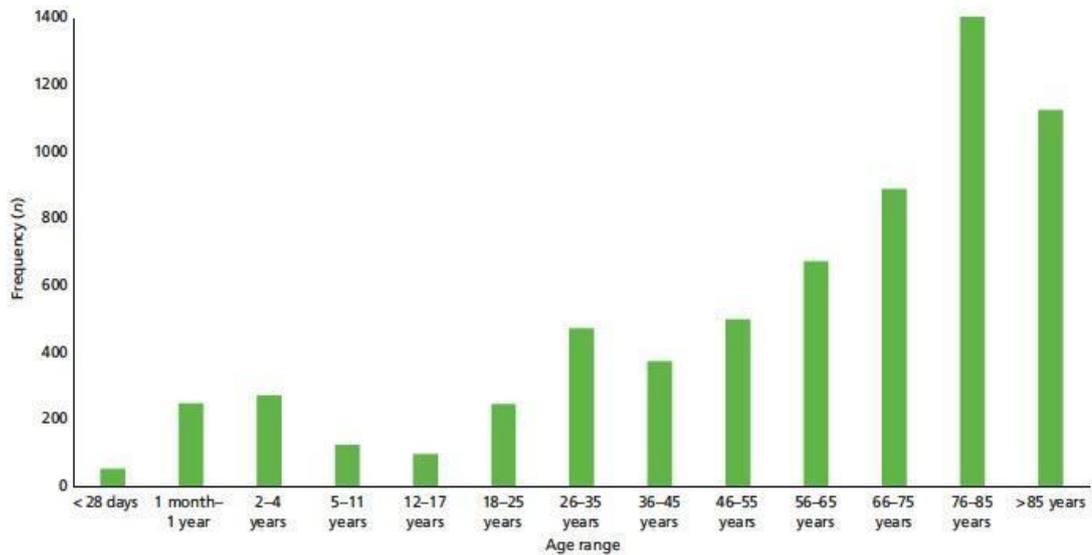


Figure 3.11. Frequency of reports by age group

Figure 3.12 demonstrates the clustered frequencies of each level of harm outcome per age group. Figure 5.3 also shows that those aged > 65 years feature most within incident reports describing serious harms (moderate harm or worse). The age group with the highest proportion of reports that resulted in serious harm was the 66–75 years age group (24%).

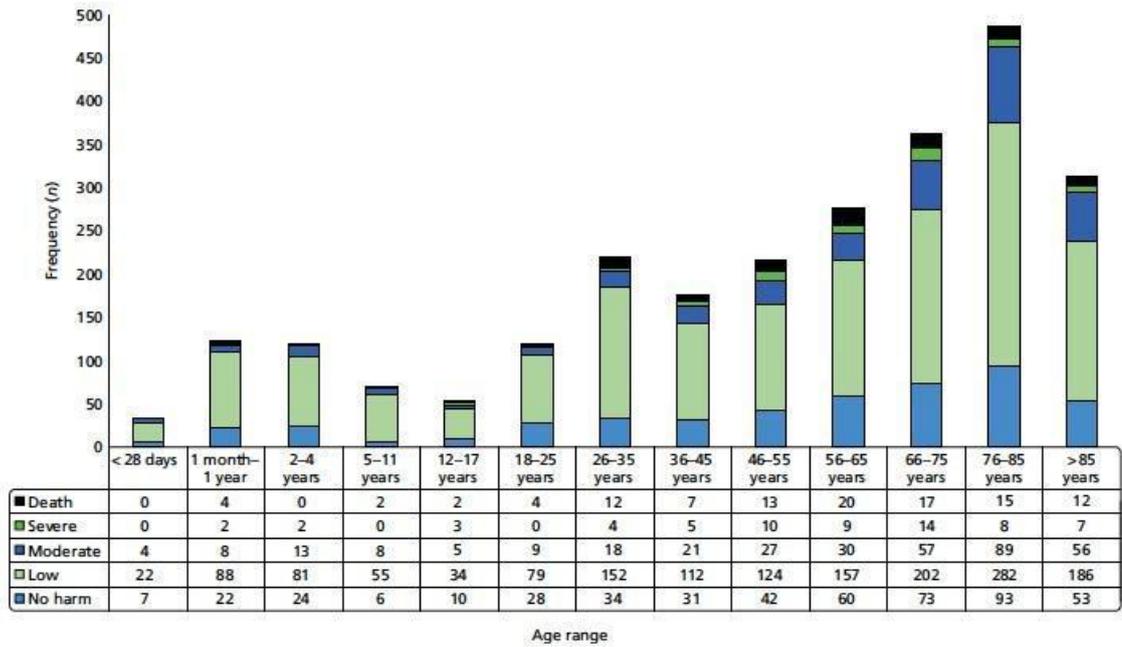


Figure 3.12. Frequency of level of harm by age group

3.2.4. Reported contributory factors

In total, 4862 contributory factors, defined as issues that did not directly cause, but contributed to, the occurrence of an incident, were identified. Only around one-third of incident reports described reasons why the incident occurred, which significantly inhibits learning to improve future practice. Staff-related factors (n = 1792) were most frequently identified, followed by service- (n = 1505) and patient-related factors (n = 1383). A breakdown of those contributory factors classes is included in Table 3.9.

Table 3.9. Summary of contributory factors

Contributory factors	Contributory factor subtheme	Examples of frequently described contributory factors	Total (n)	
Patient-related factors (N = 1383)	Patient characteristics (n = 1051)	Patient pathophysiology	127	
		Patient is a child	89	
		Patient frailty	83	
		Rare disease or rare presentation	69	
	Language or patient decision-making (n = 258)	Patient behaviour	117	
		Non-compliance with instructions from HCPs	82	
		Patient speaks a language other than English	21	
	Geography (n = 74)	Patient new to area	51	
		Access difficulties	12	
Staff-related factors (N = 1792)	Staff decision-making (n = 806)	Failure to follow protocol	460	
		Inadequate skill set or knowledge	266	
		Wrong professional carries out task	44	
	Mistake (n = 986)	Not otherwise specified	552	
		Misread/did not read	96	
		Distraction/oversight	25	
Equipment-related factors (N = 182)	Design and usability (n = 142)	Poor equipment design	110	
		Inadequate medication storage or packaging	32	
Service-related factors (N = 1505)	Inadequate protocols (n = 520)	Investigation-related protocols	155	
		Medication-related protocols	87	
		Referral-related protocols	82	
	Continuity of care (n = 412)	Out-of-hours services	98	
		Transfer of information between secondary and primary care	86	
		Continuity of care within primary care	59	
	Working conditions (n = 420)	Inadequate provision of health-care staff	Inadequate provision of health-care staff	261
			Busy/overloaded by work	126
	Education and training (n = 95)	Knowledge of others' roles	Knowledge of others' roles	53
Service availability (n = 58)	Long wait for service	Long wait for service	37	
		Service unavailable	21	

Although staff mistakes, defined as a deficiency or failure in judgement or inferential processes (omissions and commissions), were described in 986 reports, additional information that could yield any insight into ways to improve future practice was minimal. However, reports describing failures in staff decision-making processes (n = 806) included failure to follow protocols (n = 460) such as for international normalised ratio (INR) monitoring or an

inadequate skill set or knowledge (n = 266), for example relating to patients at risk of acute deterioration.

Unavailability or inadequate protocols (n = 520), pressures from low staffing levels (n = 420) and operational interruptions to ensure continuity of care (n = 412) were the most common service-related contributory factors (see Table 3.9 for further details). Lack of familiarity of different staff member roles was also described in 53 reports.

Patient-related factors included the physical and physiological characteristics of children and elderly people, as well as behaviour-related issues such as compliance. Several patient groups were discussed in terms of their potentially vulnerable status, particularly those with pre-existing pathophysiology or disability (n = 127), children (n = 89) and the frail elderly (n = 83). Non-compliance with instructions from healthcare professionals (n = 82) was described in a small number of incidents.

3.2.5. Excluded reports

Around one in five reports (n = 3147, 23%) contained insufficient detail or did not describe a patient safety incident. Of note, although pressure ulcers can represent the outcome of poor care, most reports relating to pressure ulcers contained little descriptive or contextual information or had not occurred in the community setting (e.g. incident report simply stated 'pressure ulcer, grade 3') and were therefore also excluded from the analysis. Table 3.10 shows a summary of excluded reports.

Table 3.10. Summary of excluded reports

Reason for exclusion	Frequency
<i>Inappropriate use of system</i>	
Irrelevant – did not describe a patient safety incident	784
Insufficient detail – report did not contain sufficient detail about what happened	810
Incident not related to health care, for example a fall in the GP surgery car park or patient has self-harmed despite appropriate intervention from GP	762
Defensive reporting – reporting system being used by professionals to defend their involvement in events other than a safety incident	97
Reporting death – a patient death with no apparent health-care-related cause was reported	233
Act of violence by patient – violence from a patient to HCPs	105
Complaint/coroner investigation – detail about a complaint and the need for, or outcome of, a coroner investigation	118
<i>Outcomes from secondary care or unclear</i>	
Pressure ulcer – grade of pressure ulcer stated but no description of how it occurred within community	1703
Health-care-associated infection – a hospital-acquired infection	56
TOTAL	4668

3.2.6. National Reporting and Learning System data limitations

One of the study objectives was to describe characteristics of the patient and incident such as gender, ethnicity, geography, time of day, and level of patient harm. Rather than amend my objectives as a result of various limitations, I have included them in order to highlight opportunities to improve the quality of data uploaded to the NRLS.

- Gender is inconsistently provided as a structured variable to the NRLS and present in < 40% of reports.
- Ethnicity is not captured via a structured coding framework.
- Time of day is an inconsistent and unstructured variable that can be identified by free-text analysis; a decision was therefore made to highlight where it is important as a contextual issue.

Finally, it was not possible to identify reports written by patients.

3.3. Patient safety incidents in general practice

Five categories of safety incidents described in reports were received from general practice and the inherent themes relating to the underlying reported causes. Cohen's kappa statistic of inter-rater (coding) reliability for primary incidents was high, $k = 0.71$ (95% CI 0.67–0.76; $p < 0.01$).

The five categories of incident type, in descending order of frequency, are:

1. communication with and about patients;
2. medication and vaccine provision;
3. errors in investigative processes;
4. treatment and equipment provision; and,
5. timely diagnosis and assessment.

3.3.1. Communication with and about patients

Over one-fifth ($n = 2805$) of the reports described problems relating to communication with and about patients. Five themes were evident from synthesis of the reported descriptions of events and contributory factors:

- barriers to accessing clinical services;
- errors in information transfer between care providers;
- up-to-date patient records;
- delays in referral decision-making and administrative processes; and,
- miscommunication with patients and between professionals.

Barriers to accessing clinical services ($n = 636$) and delays in referral ($n = 746$) were the most frequent incidents and also contained descriptions of the most harm outcomes.

Table 3.11 provides an overview of themes and subthemes associated with levels of harm for communication-related safety incidents.

Table 3.11. Themes and subthemes of communication-related incidents

Incident theme	Harm, n (%)				Total (%)
	Yes	No	Serious	Not specified	
Barriers to accessing clinical services	412 (65)	85 (13)	60 (9)	139 (22)	636 (100)
Message handling and telephone calls	24	9	3	16	49
Arranging appointments	88	37	3	42	167
Accessing a clinician	300	39	54	81	420
Errors in information transfer between care providers	235 (31)	135 (18)	22 (3)	386 (51)	756 (100)
Communication not acted on	17	8	4	6	31
General transfer of information between care providers	19	13	2	39	71
Information errors between secondary and primary care	177	104	15	340	621
Information errors within primary care	22	10	1	1	33
Availability and accuracy of patient records	56 (13)	95 (22)	2 (<1)	276 (65)	427 (100)
Availability of medical records	26	29	0	188	243
Accuracy of medical records	27	63	2	77	167
Other documentation	3	3	0	11	17
Delayed referrals	466 (62)	90 (12)	70 (9)	190 (25)	746 (100)
Delayed decision	213	29	34	64	306
Delayed referral	87	15	12	20	122
Erroneously completed referrals	27	20	2	25	72
Office-based errors	139	26	22	81	246
Miscommunication	113 (47)	58 (24)	18 (8)	69 (29)	240 (100)
With patients	78	36	11	38	152
Between HCPs	35	22	7	31	88
TOTAL	1282 (48)	463 (17)	172 (6)	1060 (38)	2805

3.3.1.1. Barriers accessing clinical services

Problems accessing clinical services were identified in 636 reports, and 65% of those described a harm outcome. Reported incidents related to difficulties in arranging appointments with GPs, nationally planned assessment services (e.g. ‘new-baby check’ or cervical smears), or for message handling by, or telephone calls with, receptionists and delays in presentation or timely advice as a result of involvement of NHS Direct.

Barriers to accessing acute care services had the highest proportions of serious harm (n = 60). Patients experienced difficulties or delays in accessing home visits or telephone call assessments with a triage nurse or GP, or in securing a primary care appointment. In addition, reports described patients not receiving

visits from community-based healthcare professionals, such as health visitors, because of a lack of information transfer from secondary care. For example:

Notification of birth details not faxed through to surgery. Health visitor only aware on day 14 when discharge summary faxed through to surgery. Discharge summary telephone number of client incorrect. Midwife made aware by client but still no communication with Health visitor so no birth visit scheduled.

3.3.1.2. Errors in information transfer between care providers

Incidents arising from ineffective or inadequate transfer of clinical information from one provider to another were identified in 756 reports. Over one-quarter of these incidents led to harm (n = 235, 31%), and few incidents led to serious harm (n = 22). The majority of incidents occurred at the interface between primary and secondary care (n = 621).

Reports described patients receiving letters intended for the GP from the hospital consultant, for example:

Copies of neurology results not sent with letter concerning serious diagnosis – instead, sent to direct to patient. No details in letter as to further treatment or follow-up. Information and copy results eventually obtained from secretary to consultant.

Some discharge and clinic letters were delayed, incorrect or incomplete, or indeed never sent, sometimes after long and complex inpatient stays leading to GPs and nurses struggling to make sense of management plans. Often the error was identified before the patient experienced any harm, for example:

Discharge summary had bisoprolol 10 mg daily and atenolol 50 mg daily (both beta-blockers). Medication should have been bisacodyl tablets 10 mg and atenolol 50 mg. Patient went to see the doctor 4 days later, blood pressure was low: 96/76.

These incidents caused distress to patients and carers, and healthcare professionals spent a lot of time mitigating possible harmful clinical outcomes by following up on actions made by the hospital team. Once errors occur, the consequences for the patient can escalate quickly, as in the following example:

Discharge summary for patient received from ward on [Date]. Seven new medications on the discharge summary with no indication why they were started. Contacted the ward and spoke to consultant. He checked the notes and rang back the following day. He confirmed that the patient should not be taking the medications and they were not prescribed in hospital. A new discharge summary was agreed to be issued. We tried to contact the patient but he had been readmitted. Senior house officer on the admitting ward confirmed the patient has been receiving the seven medications since readmission. The patient is still in hospital.

3.3.1.3. Availability and accuracy of patient records

Reports describing unavailable or inaccurate patient records (n = 427, 15%) resulted in multiple communication incidents. Around 10% of reports involved patients aged < 1 year, which perhaps reflects the complexity of medical records for this age group, which include parent-held records (the Red Book), GP surgery records and public health vaccine records. Inaccurate or unclear medical records were often caused by filing errors (n = 58). For example:

Patient presented with stepmother for preschool booster. Written consent from father was brought but parental held record was not available. Nurse explained she was giving REPEVAX and MMR [measles, mumps and rubella]. The following day stepmother called expressing concern that MMR had already been given in 2004. Incomplete documentation of initial dose of MMR booster.

Other reports described cases of patient notes being unavailable and thus delaying or hampering child protection meetings or case conferences, and others reported that notes were unavailable because of IT connection problems,

highlighting IT system failure consequences:

A loss of IT connection due to a loose connection at a surgery resulted in two surgery sessions without access to computer appointment or patient notes.

3.3.1.4. Delays in referral

Delayed referrals account for 41% of the described serious harm outcomes for all communication-related incidents. Referrals were most commonly delayed by clinician decision-making (n = 306), or a clinician forgetting to send referral letters or awaiting further information before doing so (n = 122). For example:

Dr failed to send 2-week-rule cancer referral for patient. The training implication has been addressed with the doctor in the practice.

Erroneously completed referrals, either from primary to secondary care services or from secondary to primary care, were described in 72 reports. Reports described practitioners' confusion about the correct referral method to select from several available (especially out of hours or at weekends and public holidays). Ineffective protocols were identified as the most common contributory factor described in these reports (n = 49). Across the reports, it was apparent that staff found it difficult to identify the appropriate referral protocol or form or the correct fax number to use when sending referral letters:

Attended surgery [Date] with symptoms, which warranted a 2-week cancer referral (upper GI [gastrointestinal] cancer). Secretary not at surgery Friday afternoon so form faxed by reception staff to fax number on form. Secretary checking referrals [1 month later] and noted no acknowledgement. Realised wrong fax number on form. The number of the fax on the cancer referral form is now for a fax machine in the Orthopaedic dept. Presumably they received the first fax but it wasn't passed on or taken further.

As a result of these communication failures, patients did not receive medication (such as warfarin or insulin), dressings were not changed and surgical wounds or pressure ulcers were left untended for days. Failures to reinstate care packages also left vulnerable patients without basic care that led to a worsening of their condition and readmission.

3.3.1.5. Miscommunication with patients and between professionals

Miscommunication incidents could be divided into failures of communication between professionals and patients (n = 152) and failures of communication between healthcare professionals (n = 88). Around half of these incidents were harmful (n = 113, 47%), and of these incidents one in six led to serious harm. For example, a patient was given erroneous advice about insulin that could have resulted in a fatal outcome:

Patient sought advice from OOH [out of hours] about his insulin – his insulin pens had accidentally been frozen and he was due to go away on holiday and needed to take meds with him. He was advised to leave pens out for 1.5 hours and they would be OK.

Reports described doctors, nurses or reception staff giving patients incorrect advice with regards to taking medication, where to attend for medical attention or how to access other services. This led to patients being seen in an inappropriate setting, taking medication in incorrect doses or at an incorrect frequency, or being unclear as to when they should seek attention in the event of deterioration. Others described a lack of clear communication over the telephone or face to face between professionals with regard to how seriously unwell a patient was and how urgently they needed to be assessed, leading to an inappropriate delay in their assessment.

3.3.2. Medication and vaccine provision

Almost one-fifth of reports (n = 2484) described medication- and vaccine-related incidents. Five themes were evident from synthesis of the reported descriptions of incidents and contributory factors:

- safer medication provision;
- reliable therapeutic drug-level monitoring processes;
- avoidable adverse drug events;
- immunisation-related errors for children, elderly and the immunocompromised; and,
- clinician decision-making about treatments.

Table 3.12 provides an overview of themes and subthemes associated with described levels of harm for medication- and vaccine-related incidents. ‘Serious harm’ is an aggregation of all reports with a moderate, severe and death outcome. The themes are also summarised by level of harm severity in a stacked bar chart in Figure 3.13.

Table 3.12. Themes and subthemes of medication- and vaccine-related incidents

Theme	Harm, n (%)				Total (%)
	Yes	No	Serious	Not specified	
Safer medication provision	559 (38)	327 (22)	84 (6)	543 (40)	1429 (100)
Prescribing	293	181	45	289	763
Dispensing	143	94	24	172	409
Administering	123	52	15	82	257
Therapeutic drug monitoring	79 (65)	9 (8)	22 (18)	32 (27)	120 (100)
Avoidable adverse drug reaction	130 (94)	2 (1)	63 (45)	7 (5)	139 (100)
Immunisation-related errors	321 (69)	32 (7)	12 (3)	111 (24)	464 (100)
Prescribing	9	4	1	3	16
Dispensing	4	4	0	5	13
Administering	267	20	1	99	386
Other	41	4	10	4	49
Clinician decision-making	70 (58)	18 (15)	26 (21)	33 (27)	121 (100)
Other	121 (57)	37 (18)	31 (15)	53 (25)	211 (100)
TOTAL	1280(52)	425 (17)	238 (10)	779(31)	2484

Prescribing incidents were most frequently described (n = 763, 31% of all medication- and vaccine-related incidents), followed by dispensing incidents (n = 409, 16%) and immunisation-related errors (n = 464, 19%). Avoidable adverse drug events were less common (n = 139), although they were the reports with the highest proportion of serious harm (n = 63, 45%). Warfarin (n = 59) and opiates (n = 21) were the drugs most often described in reports;

inadequate monitoring or hospital admissions because of avoidable complications were described as contributory factors. Opiate-related incidents were often related to drug-seeking behaviour, unintentional drug overdoses or failure to treat symptoms in palliative care patients in a timely manner. Other drugs described in reports are summarised in Figure 3.14.

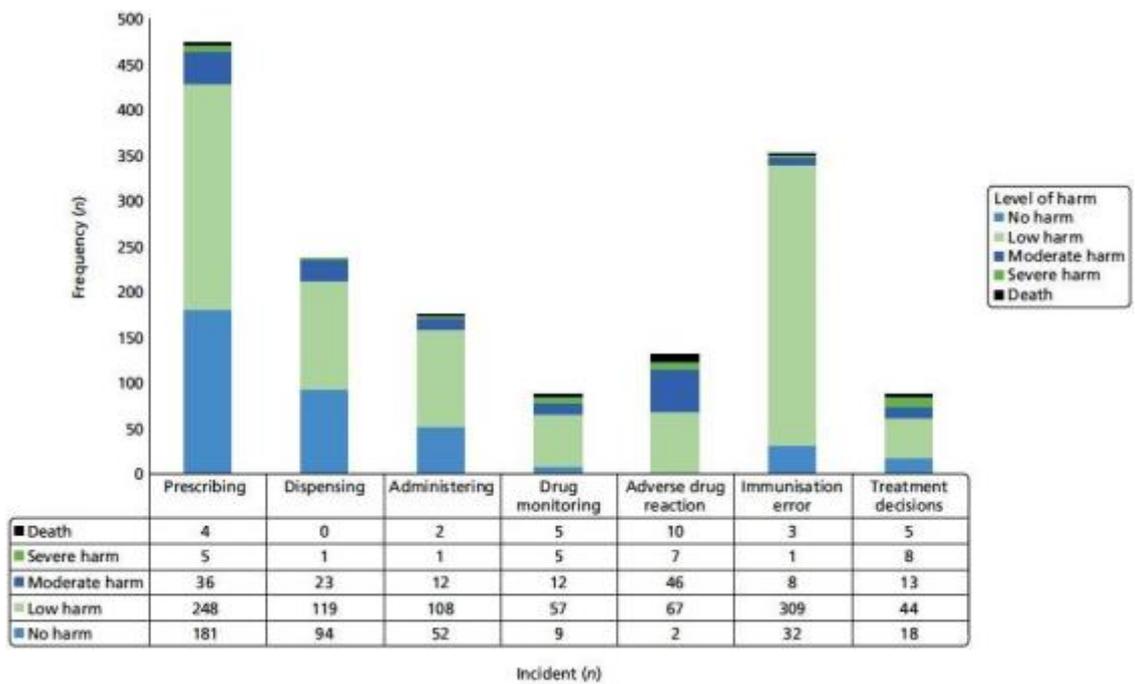


Figure 3.13. Stacked bar chart of medication- and vaccine-related incidents by level of harm

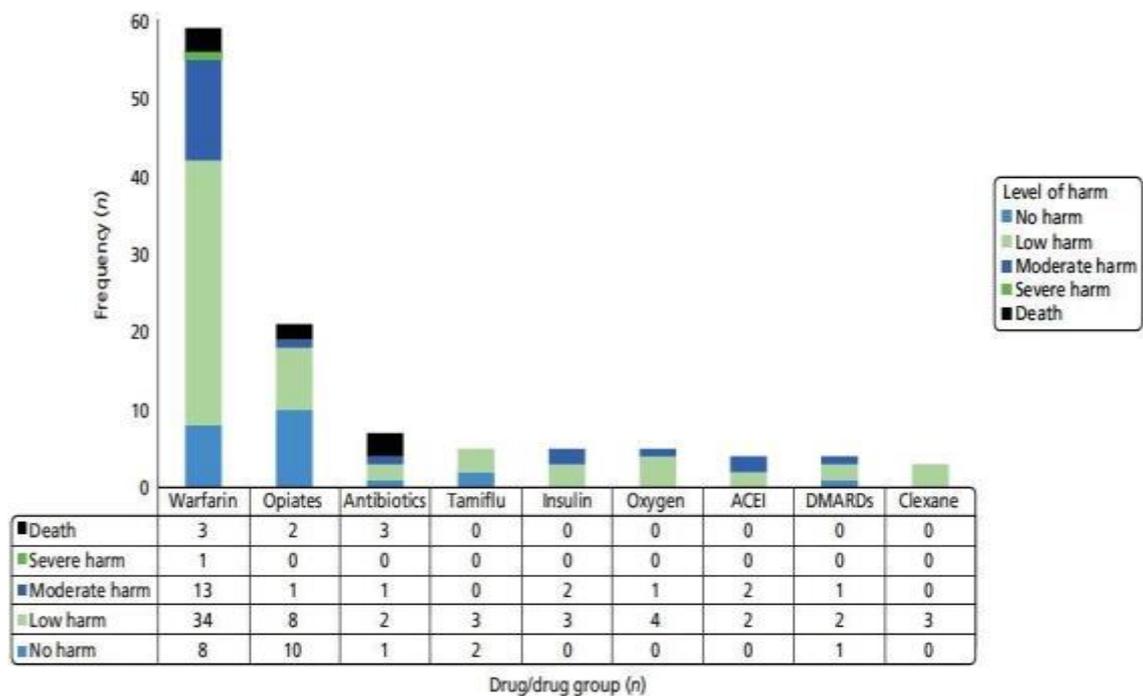


Figure 3.14. Stacked bar chart of drugs/drug groups by level of harm. ACEI, angiotensin-converting enzyme inhibitor; DMARD, disease-modifying anti-rheumatic drug.

3.3.2.1. Safer medication provision: prescribing

Prescribing errors were the most frequent (n = 763, 31%) of all medication- and vaccine-related incidents; they included prescribing the wrong dose (n = 226) or even the wrong medication (n = 151). Illegible prescriptions, wrong formulations and prescription of wrong routes of administration were also reported.

The most frequent events preceding a prescribing-related incident were errors of administration (n = 99, 43% of such reports), documentation (n = 36, 16%) or communication (n = 39, 17%). Errors in transfer of information from secondary to primary care were described in 90 reports; this was often because of a delay in receiving the information or incomplete/inaccurate information.

Staff mistakes were the most frequently described contributory factor and were linked to other contributing factors such as IT failures (n = 17, 4%), disruptions to continuity of care (n = 51, 11%) and non-adherence to protocols for repeat prescribing (n = 26, 5%). Being a child made up 7% (n = 34) of described

patient-related contributory factors, and was also associated with non-continuity of care and staff failure to follow protocols.

3.3.2.2. Safer medication provision: dispensing

Dispensing errors were described in 409 reports (15% of all medication- and vaccine-related incidents). The wrong drug was described in 114 reports (29% of dispensing-related reports), and seven reports described serious harm outcomes. The wrong dose of medication dispensed was the next most frequent incident type (n = 91, 22%), and nine of those incidents resulted in serious harm outcomes.

Descriptions of staff mistakes featured often (n = 84), and 32 reports identified confusion between similar medication names, such as trazodone and tramadol; amisulpride and amitriptyline; and pregabalin and Pregaday® (Wülfig Pharma GmbH, Gronau, Germany). For example:

53-year old man dispensed trazodone 50 mg instead of tramadol 50 mg, sticker said tramadol on the trazodone box. Patient saw GP 5 days later complaining of dry mouth, blurred vision and feeling 'spaced out'.

3.3.2.3. Safer medication provision: administering

Errors in the administering of drugs or vaccines (including oxygen) were described in 257 reports (9% of all medication- and vaccine-related incidents). Failure to administer medication at the correct time was the most frequently described error (n = 53, 21%), with five reports describing serious harm outcomes, including one patient death. For example:

The nurse in a nursing home left the enoxaparin injection on the bedside table in preparation to inject the patient but the patient administered it orally because she thought it was analgesia.

Administration of the wrong dose of medication was the next most frequent type of incident (n = 62, 24% of administration-related incidents) with seven of those reports describing serious harm outcomes and one resulting in death. Cases of

administration of the wrong medication (n = 44, 17%) or at the wrong time (n = 41, 16%) were also reported.

Prior incidents that led to an administering incident included a prescribing error (n = 21), inability to access a healthcare professional (n = 10) and poor communication between healthcare professionals and patients (n = 13). Reported contributory factors included staff mistakes (n = 60), including distraction (n = 9) or misreading labels (n = 12) and similar medication names (n = 7); and staff failure to follow protocol (n = 11); inadequate skill set/knowledge (n = 6); and patient behaviour factors (n = 9), including non-compliance.

3.3.2.4. Reliable therapeutic drug-level monitoring

Incidents related to therapeutic drug-level monitoring were described in 120 reports (only 4% of all medication- and vaccine-related incidents); 22 reports described serious harm and included five patient deaths. Identified sub-themes identified included monitoring not commenced (n = 24) and doses not adjusted following monitoring (n = 12); warfarin was the most frequently involved drug (n = 17) and resulted in two patient deaths.

Prior incidents that led to drug monitoring-related incidents included inadequate transfer of information from secondary to primary care (n = 11), referrals not made when appropriate (n = 5) and miscommunication between the healthcare professional and the patient (n = 6). In contrast to other medication incidents, staff mistakes rarely contributed to therapeutic drug-level monitoring incidents, being cited in only two such reports. Staff failing to follow protocol was described in 12 reports, for example failure to request a repeat INR for a patient when a new treatment was commenced. Inadequate organisational protocols contributed to 13 incidents, of which six related to protocols about transferring patients between secondary and primary care. Patient factors were also reported (n = 19), 10 of which resulted from patient non-compliance. Several reports made reference to patients on warfarin who were non-compliant with monitoring. Some reports described the ethical issues doctors faced, knowing that withdrawal of treatment would also put the patient at risk of life-threatening events such as pulmonary embolism or stroke.

3.3.2.5. Avoidable adverse drug events

Avoidable adverse drug events were described in 139 reports (6% of all medication- and vaccine-related incidents), and 63 of those (45%) resulted in serious harm outcomes, with 10 reports recording patient death. For example:

*Patient was given a script by a community matron for Oramorph[®,
Boehringer Ingelheim Limited, Bracknell, UK] 2.5 ml 4–6 hourly as
required but the label on the bottle said take 2.5 5ml spoons, result in a
total of 12.5 ml. This is five times the prescribed amount on the script.
The patient had three doses over 12 hours and passed away at 6.00
a.m.*

Twenty-six reports described patient-related contributory factors, such as pre-existing pathophysiology and frailty; seven reports involved patients with known allergies and 22 related to patients on drugs that necessitated patient monitoring (not mutually exclusive). Warfarin was the most frequently described medication, and 16 reports described a serious outcome resulting in hospital admission, for example epistaxis, vaginal bleeding, haemoptysis or cerebrovascular accident.

3.3.2.6. Immunisation-related errors for children, the elderly and the immunocompromised

Immunisation-related incidents were described in 464 reports (19% of all medication- and vaccine-related incidents). The majority concerned vaccine administration (n = 386, 83%) and resulted in low harm, although three deaths were reported, and two incidents related to the pneumococcal vaccine not being administered at the appropriate time. Incidents in which either the wrong vaccine was administered (n = 138, 30%) or the wrong number of doses was administered (n = 122, 26%) were also recorded. Incidents relating to administration of the wrong number of doses often involved children and occurred because the medical documentation was inaccurate and not checked, resulting in the child receiving an additional, unnecessary, vaccine that could potentially cause an adverse event.

Immunisation administration errors involving medical records (n = 49) included discrepancies in GP records or personal records (Red Book) and/or other child-health records. Frequent contributory factors were staff mistakes (n = 105), for example staff unaware of the new immunisation programme, staff confusing vaccinations with similar names or staff not checking the medical records, resulting in administration of a vaccine that was not indicated.

3.3.2.7. Clinician decision-making about treatments

Issues underpinned by clinician decision-making about treatments in acute and chronic situations were described in 121 reports (4% of the total medication- and vaccine-related incidents), with 24 reports recording serious harm outcomes including four patient deaths. Specifically, these reports described no treatment given (n = 37), insufficient treatment given (n = 19) and the wrong treatment given (n = 16). See examples in Box 1.

Box 1. Examples of clinician decision-making errors about treatments

Example 1

A patient with central chest pain radiating to her jaw saw the GP (after ECG), who wrote a letter querying a MI and sent the patient home to pack a bag and wait for the ambulance. He noted in the letter that the patient lived alone and had no help. When the ambulance arrived, the patient was packing a bag in her bedroom still suffering chest pain. She had received no medications and was thrombolysed in her bedroom. She was then transferred to a CCU.

Example 2

A patient with poorly controlled asthma visited a GP who did not change treatment or provide any steroids, resulting in respiratory arrest and resuscitation.

Example 3

A GP arranged for CTPA of an outpatient basis. The patient received no treatment while awaiting a CTPA, contrary to definitive guidelines for outpatient management.

CCU, critical care unit; CTPA, computed tomography pulmonary angiography; ECG, electrocardiography; MI, myocardial infarction.

A range of incidents preceded clinician decision-making errors, including inaccurate medical records (n = 6), poor discharge planning (n = 3), and delays in responding to results (n = 3). These low numbers perhaps reflect the fact that

reasons for errors in clinical decision-making are multifactorial. Lack of continuity of care was the most frequently cited contributory factor (n = 18), and was attributed to issues with out-of-hours care (n = 5), lack of communication between secondary and primary care (n = 2) and locum staff (n = 3). Within reports, poor communication between healthcare professionals that contributed to the GP not seeing the 'whole patient' was a frequent cross-cutting theme.

3.3.3. Errors in investigative processes

A total of 1339 reports described incidents related to clinical investigations. Four themes (Table 3.13) were evident from synthesis of the reported descriptions and contributory factors:

1. ordering incorrect investigations to inform differential diagnosis;
2. practical and administrative barriers for collection and transfer of specimens;
3. administrative failures leading to delays, wrong results or failure to receive results; and,
4. misinformed clinical decision-making and incorrectly interpreted investigative results.

Table 3.13 provides an overview of each theme and the harm outcomes described in reports. There were few reports of serious harm (n = 38, 3% of investigative process-related incidents). Practical and administrative barriers to the collection and transfer of specimens were described in 866 reports (66%); of these, mislabelling clinical samples accounted for the majority of incidents (n = 486, 56%).

Table 3.13. Themes and subthemes of investigative process-related incidents

Theme	Frequency, n (%)				
	Harm	No harm	Serious harm	Not specified	Total
Ordering incorrect investigations to inform differential diagnosis	66 (61)	10 (9)	7 (6)	32 (30)	108 (100)
Wrong diagnostic imaging test ordered or not ordered	15	6	3	10	31
Wrong investigation ordered or not ordered	51	4	4	22	77
Practical and administrative barriers for collection and transfer of specimens	279 (32)	44 (5)	8 (1)	543 (56)	866 (100)
Mislabelled request form	4	2	0	25	31
Mislabelled sample	123	26	2	337	486
Errors in the process of obtaining or processing a laboratory specimen	121	12	3	140	273
Errors in the process of obtaining or processing of a diagnostic image	11	3	1	17	31
Errors in the process of obtaining or processing of other diagnostic investigation	5	0	0	1	6
Lost specimens	5	0	1	7	12
Other	10	1	1	16	27
Administrative failures leading to delays, wrong results or failure to receive results	109 (45)	22 (9)	9 (4)	109 (45)	240 (100)
Error in the process of physician receiving accurate laboratory test results including errors of delay	77	19	6	77	173
Error in the process of physician receiving accurate diagnostic imaging test results including errors of delay	27	1	3	23	51
Error in the process of physician receiving accurate other test results including errors of delay	5	2	0	9	16
Misinformed clinical decision-making and incorrectly interpreted results	82 (66)	8 (6)	14 (11)	35 (28)	125 (100)
Response to a laboratory result	63	6	10	25	94
Response to a routine laboratory result	3	0	2	4	7
Response to imaging result	7	1	2	4	12
Response to drug level	3	1	0	2	6
Response to other investigations	6	0	0	0	6
TOTAL	536 (40)	84 (6)	38 (3)	719 (54)	1339

3.3.3.1. Ordering correct investigations to inform the differential diagnosis

Diagnoses were often delayed or missed because of mistakes in the investigative process. The wrong laboratory test was ordered, or not ordered at all, when it would have been appropriate, in 77 reports. In 51 cases, this led to harmful outcomes. For example:

A patient attended with abdominal pain and was advised they had irritable bowel syndrome but investigations recently have revealed late

stage ovarian cancer with spread to the lymph nodes. If an ultrasound scan had been done earlier this could have been detected sooner.

Reports also described situations in which, if clinicians had organised further investigations or put in place a safety net for the patient to return, serious diagnoses could have been detected sooner. For example:

*Patient presented with frank haematuria from which a renal carcinoma was identified. It was noted that patient had presented last year with another incident of haematuria urinalysis * 2 positive for blood microscopy negative not investigated further.*

Delays in undertaking investigations, largely because of waiting lists, carry a risk of delayed treatment for preventable illness and worsening of the condition. It was apparent, however, that if the patient did not demand to be seen or undergo an investigation, then such delays would not be identified. For example:

2-week-rule referral made by GP for suspected pancreatic cancer due to jaundice and deranged bloods. Seen in clinic and urgent scan was requested [by hospital team]. Patient re-attended surgery several times and scan date was chased. GP chased scan report as now 5 weeks post referral and still no [date]. Eventual diagnosis made of pancreatic cancer.

3.3.3.2. Practical and administrative barriers for labelling and transfer of specimens

Errors in administration (i.e. form filling, labelling, completing the form), although common (n = 796, 59%), largely resulted in low harms, such as the need for retesting. Transport errors were also reported; the issue of 'sample deterioration' was highlighted and concern was raised about result accuracy and impact on correct interpretation when needless delays in transfer had occurred.

3.3.3.3. Administrative failures leading to delays, incorrect results or failure to

receive results

Issues with the administrative (electronic and paper-based) processes enabling the timely receipt of test results were described in 240 reports. These issues were varied and included not receiving the results, delays in receiving the results and receiving inaccurate results. Communication issues between professionals and inconsistent message-handling procedures within GP surgeries were also implicated. Failures in practice processes to review results that did not occur on the same day as investigation, or those being processed out of hours and noted as urgent, was a recurring issue. For example:

...lab phoned through a result early afternoon giving a high potassium level, they said it needed to be reported to a GP asap but with no other indication of urgency. GP on call was already out on visits and could not be contacted by phone, there were no other GPs in the building. Unfortunately the patient died whilst packing his bag to go to hospital.

Most test results are sent electronically to practices. Earlier reports from the sample described paper copies being sent as a safety net. However, although the GP might read an electronic report, over-reliance on the software for planning next steps for management in the clinical record system does highlight the need for parallel (possibly manual) processes when the findings are potentially so serious. For example:

The patient presented with cough, bloody sputum . . . known smoker and heavy drinker. A chest X-ray was ordered and patient given [a]moxil 500 mg x 21. [software] mailbox showed that the GP had read the X-ray report but there was no direction shown, it was left unedited, no action taken, The X-ray was not 'sent to anyone' it appears to have dropped from the active mailbox into a 'bucket' awaiting action. (WORSE [sic] than this the GP did not know about the 'bucket')...The chest X-ray showed an early lung tumour which was not picked up until the patient presented 1 year later. His condition is now advanced and probably terminal. The GP had 10 minutes training on [software] with 4 GPs around one computer.

3.3.3.4. Misinformed clinical decision-making and incorrectly interpreted investigation results

Errors in the review and interpretation of test results were cited in 125 reports (10% of all investigative process errors), of which 82 described harm outcomes. For example:

Elderly male patient...attended surgery with recent but not current chest pain. Given ECG [electrocardiography], which was misread. Patient advised to return home but should have been sent to hospital urgently. Patient died at home from heart attack within 24–48hrs...Evidence the machine may have given GP undue confidence in his diagnosis, as it gave a reading of normal sinus rhythm.

Unreliable or non-existent processes underpinned failures to review patients' notes before the end of the general practice day or re-routing results to the wrong doctor for review.

3.3.4. Treatment and care equipment

Incidents involving treatment and care equipment provided for community care were described in 754 reports (6% of total reports). Three themes were evident from synthesis of the reported descriptions of events and contributory factors:

1. decisions about methods of administering treatments;
2. complications of therapeutic procedures; and,
3. functioning and availability of care equipment.

Table 3.14 provides an overview of themes and subthemes related to treatment and care equipment and associated levels of harm.

Table 3.14. Themes and subthemes of treatment- and care equipment-related incidents

Theme	Harm, n (%)				
	Yes	No	Serious	Not specified	Total (%)
Decisions about methods of administering treatments	95 (76)	8 (6)	32 (26)	22 (18)	125 (100)
No treatment	14	1	3	4	19
Insufficient treatment	62	6	20	16	84
Incorrect treatment	17	1	7	2	20
Other	2	0	2	0	2
Complications of treatment procedures	230 (79)	21 (7)	57 (20)	40 (14)	291 (100)
Ordering treatment	1	0	0	0	1
Implementation	48	13	9	18	79
Complication	135	2	38	15	152
Timeliness	39	4	9	6	49
Choosing correct procedure	5	2	0	1	8
Wrong site/side	1	0	0	0	1
Other	1	0	1	0	1
Functioning and availability of care equipment	190 (56)	35 (10)	27 (8)	113 (33)	338 (100)
Lack of functioning therapeutic equipment	72	7	13	18	97
Insufficient supply of care adjunct	5	6	0	12	23
Failure of equipment	104	21	11	71	196
Stolen	0	0	2	5	5
Other	9	1	1	7	17
TOTAL	515 (68)	64 (8)	116 (15)	175 (23)	754

Harm was identified in the majority of reports (n = 515, 68%). Serious harm was caused by 15% of these incidents (n = 116). The unavailability of functioning care equipment (n = 338), such as beds to prevent pressure sores or catheter replacements, was the most common incident, followed by problems carrying out treatments in the community (n = 291).

Patient characteristics such as age, frailty or pregnancy were described (n = 55, 21%). Other contributory factors included patients not following advice or having sufficient knowledge for safe self-care (n = 48, 18%), or making mistakes such as misreading information (n = 27, 10%).

3.3.4.1. Decisions about methods of administering treatments

An error in the clinical decision of what, if any, treatment to give a patient was identified in 125 reports, with 95 (76%) describing a harm outcome. These decisions were subdivided into three sub-themes.

1. No treatment was given (n = 19, 15%). Treatments not administered varied but included insulin, dressings and emergency contraception. In 15 cases, another incident was involved, for example a pregnant patient was not treated for herpes infection and another patient's pressure ulcer was not treated because the equipment that was ordered was not in stock and an alternative in the interim was not sought. Only three (16%) of these reports resulted in serious harm.
2. Insufficient treatment or monitoring was undertaken (n = 84, 68%). Pressure ulcers developed or deteriorated in 33 reports, often because of the lack of equipment, patients choosing not to use suggested treatment or poor care. Other reports described GPs calling an ambulance for sick patients, but not monitoring them or starting basic treatment while waiting for the ambulance. Twenty incidents in this category (24%) led to serious harm.
3. Incorrect treatment (n = 20, 16%) following clinical assessment. This was a diverse group, with reports describing the wrong type of dressing used on leg ulcers, insertion of contraindicated intrauterine contraceptive coils and cauterising a cancerous 'wart'.

3.3.4.2. Complications of treatment procedures

Complications arising during procedures were described in 291 (39%) reports. Minor infections following minor surgery and needle-stick injuries were described. More serious outcomes highlight the major risks associated even with commonplace procedures performed in general practice, which included uterine perforation following coil insertion, a fragment of a needle remaining in the shoulder joint after injection and an abscess forming at an injection site. These incidents were generally considered a complication of a procedure rather than being attributed to poor technique; thus, only 29 reports (10%) had an identifiable contributory factor, of which 10 were related to the patient's

pathophysiology, and only three were considered to be due to a healthcare professional's lack of skills.

Incidents in which a procedure was not carried out correctly were described in 79 reports, resulting in poor infection control, needle-stick injuries, dressings adherent to wounds, new leg wounds from incorrect bandaging or urinary retention. Contributory factors included failure to follow protocol (n = 9), inadequate skill set (n = 8) and staff mistakes (n = 8).

The other common group of incidents was related to timeliness of treatment (n = 49, 17%). Many of these involved the care of catheters, but incidents related to the emergency care of patients and wound care were also reported. For example:

*Patient called *** as catheter had fallen out during the night. *** called district nurse and left a message at 03:40 giving details of the problem and asking if they could attend in the morning to re-catheterise. Patient was wearing a pad. It was a Sunday and worker alone got a message just after 08:00 and was unable to attend immediately.*

In 40 of the 49 reports, the incident occurred because the district nurses did not receive a referral on discharge. Of those, nine reports (18%) described serious harm outcomes.

3.3.4.3. Functioning and availability of care equipment

Errors around the provision and operation of equipment involved in patient care were described in 338 (45%) reports. Failure of equipment was common (n = 196, 58%), and the most frequently reported types of incident involved malfunctioning of pressure-relieving equipment, fridges going above the recommended temperature range and power cuts compromising IT systems' functioning.

Issues directly related to access to care equipment such as dressings, insulin needles or catheters were identified in 97 reports. For example, some patients

were sent home from hospital without the necessary equipment and in other cases pharmacies incorrectly dispensed a short-term rather than a long-term catheter. In 28 reports, poor discharge planning preceded problems with care equipment provision. Insufficient supply of care equipment was reported 23 times, and was generally related to not having the right equipment in the surgery or central stores. Items included electrocardiography paper, blood bottles, dressing packs and continence pads.

3.3.5. Timely diagnosis and assessment

Seven hundred and twenty-eight reports (5% of total reports) described issues with diagnosis and assessment of patients; three themes were evident from synthesis of the reported descriptions of events and contributory factors:

1. timely triage and assessment of patients;
2. patient assessment for safe discharge; and,
3. missed or wrong diagnosis.

The majority of reports described harm, and three in five of those incidents resulted in serious harm outcomes (n = 366, 64%). Table 3.15 provides a summary of incident themes and subthemes.

Table 3.15. Themes and subthemes of diagnosis- and assessment-related incidents

Theme	Harm, n (%)				Total (%)
	Yes	No	Serious	Not specified	
Missed or delayed diagnosis	297 (86)	8 (2)	217 (63)	40 (11)	345 (100)
Missed/delayed diagnosis	285	7	207	39	331
Wrong diagnosis	12	1	10	1	14
Timely triage and assessment of patients	189 (78)	12 (5)	118 (49)	41 (17)	242 (100)
Triage process	39	6	28	11	56
Identifying acute conditions	30	1	23	1	32
Identifying risk of deterioration	3	0	2	0	3
Delayed assessment for care	27	1	3	0	28
Identifying vulnerable patients	9	1	4	9	19
Refusal to do home visit	9	0	4	2	11
Examination of patient	7	1	4	2	10
History taking	0	1	0	3	4
Identifying mental health issues	29	0	29	1	30
Other	36	1	21	12	49
Discharge risk assessment	89 (63)	13 (9)	31 (22)	39 (28)	141 (100)
TOTAL	575 (79)	33 (5)	366 (50)	120 (16)	728

Four in 10 reports had identifiable contributory factors (n = 292, 40%). Reports largely described four key contributory issues: lack of continuity of care (n = 56, 19%); staff decision-making processes, mainly related to a failure to follow protocols or insufficient knowledge (n = 52, 18%); patient characteristics such as age, frailty or not having English as a first language (n = 51, 17%); and disease characteristics such as rare conditions or a rare presentation of a condition (n = 48, 16%).

3.3.5.1. Timely triage and assessment of patients

Timely triage and assessment issues were described in 242 reports; they included failures to recognise acutely unwell patients (n = 32) and those at risk of deterioration (n = 29), patients who were vulnerable to abuse or being abused (n = 19), and those at risk of harm from mental health problems (n = 30). For example:

Call received regarding a child who had died, the mother reported that she had sought assessment and advice from NHS Direct. The call was

prioritised as a P2 and placed in the First Advice Queue. It was picked up by X 24 minutes later. The child was assessed using the 'Breathing problems toddler Age 1–4 years Algorithm' and a disposition of self care was recorded. Boards have reviewed the call and concerns raised regarding the quality of assessment and appropriateness of the disposition.

Problems with triage processes were described in relation to healthcare professionals in 13 reports and non-healthcare professional workers in eight reports. In another example involving telephone triage, the severity of the patient's condition was not ascertained:

Patient telephoned NHS Direct following aches in her shoulders and experiencing excess wind. After clinical assessment they advised the patient she was probably suffering from trapped wind and received information relating to indigestion. Following the call to NHS Direct the patient symptoms worsened and her husband telephoned 999 for an ambulance. Whilst the patient's husband was on the telephone, the patient collapsed, lost consciousness and subsequently died. The post mortem report stated that the cause of death was ischaemic heart disease and coronary artery atheroma.

A failure to recognise signs of abuse was preceded by poor information transfer from secondary to primary care in 22 reports, and by a failure to refer for nursing care on discharge from hospital in nine reports. Contributory factors included lack of continuity of care with out-of-hours services (n = 14), and 10 reports queried whether or not the healthcare professional cited in the report had sufficient professional knowledge. Serious harm outcomes were described in 86 reports (61%).

3.3.5.2. Patient assessment for safe discharge

Issues with risk assessment for discharge were described in 141 reports. Analysis of linked incidents showed that this resulted in multiple problems following discharge, including poor information transfer to primary care (n = 51), failure to refer patients for emergency care when indicated (n = 9), failure to refer patients for nursing care at home (n = 8), prescribing errors (n = 7) and problems with the provision of care equipment (n = 28). Such issues described in reports are reflected in the following example:

Message received from GP [Date] – patient was discharged from . . . ward [day before] late pm – no referral sent to child district nurse. Urinary catheter (long term) in situ. No advice given to family re: changing bags/care of catheter and no bags supplied on discharge. No information whether DN [district nurse] can change catheter.

The next example describes the discharge of twin babies with a complex in-hospital history:

The health visitor carried out a primary birth visit following the twins' discharge from the SCBU (Special Care Baby Unit). There was no discharge letter with information for the service or medications required. No discharge plan. No resuscitation training given to the parent. The mother stated that she was told it would be given prior to discharge, but that it was not received. Twins discharged on oxygen therapy. No apnoea monitor. No risk assessment surrounding the twins' care. No official referral to the paediatric community nurse and no involvement pre-discharge. The paediatric community nurse was not informed of the discharge. The twins had been cared for over the past seven weeks in the SCBU (Special Care Baby Unit). No liaison had been made with the community staff.

Most patients affected (75%) were aged \geq 66 years, possibly reflecting the complex needs of the elderly on discharge. Not all reports highlighted so many

opportunities to improve clinical care as the previous example. Only 21% of reports (n = 30) documented a contributory factor, of which the majority (n = 17) discussed the complexity of the patient in terms of comorbidities. This may be because the reports were written in primary care and, therefore, the report writer was not involved in planning the discharge.

3.3.5.3. Missed or delayed diagnosis

Problems with diagnosis were identified in 345 reports, with 86% (n = 297) describing a harm outcome. A total of 331 reports described a missed or delayed diagnosis. The conditions that were missed were wide-ranging and included fractures, tuberculosis, diabetes mellitus, infection, pregnancy and myocardial infarction. These cases illustrate the difficulty of clinical decision-making in complex patients with undifferentiated presentations, for example, delineating between known side effects from a prescribed drug and a possible red flag for a more serious diagnosis:

The patient was an 85-year-old man with dementia and Parkinson disease who had symptoms of diarrhoea and was taking Aricept[®], Pfizer Inc., New York, NY, USA]. The diarrhoea was attributed to being a side effect of his Aricept and the doctor failed to diagnose his progressed colon carcinoma.

A missed or delayed cancer diagnosis was described in 128 reports. Diagnostic problems were preceded by insufficient assessment in seven reports, by insufficient examination in eight reports and by failure to recognise acute conditions in seven reports, which suggests that missed or delayed diagnoses are underpinned by lack of clinical skills. This is also suggested by the 16 reports in which the knowledge or skill of the healthcare professional was described as a contributory factor. For example, a lack of prior knowledge of the patient's history would make it more difficult to interpret test results and determine if they were normal, as was evident in the following example:

Patient had undergone radical prostatectomy for cancer. Had follow up PSA [prostate-specific antigen] levels – which should be undetectable. Any detectable PSA level, even in ‘normal’ range, is abnormal. Previous detectable level passed as normal result. The patient noticed this.

In 31 cases, the rare presentation of a condition was a contributory factor, and in 18 reports, the continuity of care between primary healthcare professionals was discussed. The latter contributory factor was associated with high rates of harmful outcomes, as 72% (n = 207) of cases led to serious harm. Fewer reports (n = 14) described a wrong diagnosis. These reports related to a wide variety of conditions, some of which were more serious than others. Wrong diagnoses were largely, although not exclusively, due to failures of professional competence, such as failing to examine a patient fully; however, some were attributed to unusual clinical presentations (un-differentiating signs or symptoms) and these cases accounted for a high proportion of serious harm incidents (n = 10, 71%).

3.4. Serious harms and death in general practice

Of the total 13,699 incident reports, 996 incidents resulted in moderate or severe harm to, or death of, a patient. Moderate and severe harms, using the WHO ICPS definitions, were permanent loss of function, conditions necessitating hospital admission or disability. I called these *serious harms*.

An overview of level of harm outcome by incident category is provided in Table 3.16.

Table 3.16. Summary of incident reports describing serious harm or death

Incident category (N, % of total)	Incident type	Serious harm or death, n
Diagnosis and assessment (N = 366, 37%)	Diagnosis	217
	Assessment	149
Medication and vaccine provision (N = 238, 24%)	Adverse event	63
	Prescribing	45
	Clinical decision-making	26
	Dispensing	24
	Monitoring	22
	Administration	15
	Immunisation-related	12
Provision of treatment and care equipment (N = 116, 12%)	Treatment	89
	Equipment	27
Communication with and about patients (N = 172, 21%)	Referrals	70
	Accessing clinical services	60
	Information transfer	22
	Miscommunication	18
	Inaccurate knowledge about patients	2
Investigative processes (N = 38, 4%)		
Others (N = 66, 7%)	Transporting patients	20

3.4.1. Contributory themes

Fewer than half of the 996 reports (n = 431, 43%) contained descriptions of contributory factors. Combined with insights generated by thematic analysis, the four main contributory themes underpinning serious harm- and death-related incidents were:

1. communication errors in the referral and discharge of patients;
2. physician decision-making;
3. delays in cancer diagnosis associated with unfamiliar symptom presentation and/or inadequate administration; and,
4. delayed management or mismanagement following failures to recognise signs of clinical (medical, surgical and mental health) deterioration.

Table 3.17 highlights the number of serious harms and death outcomes by each theme.

Table 3.17. Summary of incident reports describing serious harm or death outcomes by contributory theme

Theme	Harm (n)			
	Moderate	Severe	Death	Total
Communication errors in the referral and discharge of patients complicated by failures in IT systems	72	11	17	100
Referral not performed when indicated	27	8	12	47
Premature and poor discharge planning	27	2	2	31
Information transfer between care providers	18	1	3	22
Physician decision-making	64	18	14	96
Prescribing	40	5	5	50
Treatment decisions	12	8	4	24
Monitoring	12	5	5	22
Delayed cancer diagnosis associated with unfamiliar symptom presentation and/or inadequate assessment	30	42	21	93
Delayed management or mismanagement following failures to recognise signs of clinical (medical, surgical and mental health) deterioration	26	5	30	61
Errors in the process of triaging patients	14	1	13	28
Identifying acute clinical conditions	6	2	15	23
Diagnosis of emergency condition delayed	6	2	2	10
TOTAL	192	76	82	350

3.4.2. Factors contributing to incidents

In this section, I provide a summary of the contributory factors identified in all serious harm and death reports. Patient-related factors were the most frequently reported (n = 215) contributors to incidents resulting in serious harm and death. These included patient characteristics, such as patient pathophysiology (n = 51) or frailty (n = 21). For example, one patient without a care package following discharge from hospital, and with poor eyesight, self-administered the wrong dose of insulin. Rare presentations, such as for an atypical cancer presentation, or a rare disease such as bladder cancer in a young child, may have made diagnosis more challenging in 43 incidents.

Service-related contributory factors were also frequently described (n = 190). The out-of-hours primary care services (n = 48) were often implicated; for example, some incidents were attributed to the failure of healthcare

professionals to share information. In one case, the out-of-hours service failed to pass on urgent blood test results to the patient's GP and thereby delayed further assessment.

Forty-one incidents were attributed to inadequate protocols; for example, regarding the handling of referrals by mental health teams resulted in some cases in delays in assessment, and led to deterioration in the patient's mental health or death by suicide. Working conditions, such as staff being too busy to spend sufficient time assessing a patient, were described in 17 reports. Staff-related factors were described in 108 reports and included failure to follow protocols (n = 38), such as those for warfarin dosing, and staff members having an inadequate skill set or knowledge to assess acutely unwell patients, resulting in missed emergency diagnoses (n = 36).

3.4.3. Examination of contributory themes

In this section, I describe each contributory theme by considering the role of identified contributory factors, and, when relevant, the contributory incidents leading up to the incident, and other contextual issues identified by thematic analysis.

3.4.3.1. Communication errors in the referral and discharge of patients

Errors in the processes involved in transferring patient information compromised the continuity of care (contributory factor) between primary and secondary care. The most frequently reported error, mentioned in 47 reports, was the failure of referral (contributory incident) to take place as intended. These resulted in delays in management (incident) for 18 patients and in the death (harm outcome) of 10 patients. For example:

Discharge home with pressure sore on sacrum and x 2 heels from [community hospital]. Unable to mobilise and/or eat and drink – district nurse was not informed.

Errors relating to referrals not being made were sometimes preceded by a contributory incident, including poor discharge planning, for example failure to refer to community practitioners such as district nurses for wound reviews (n=10), missed diagnoses (n=7) or failure to transfer patient information (n=5), such as failure to send patients' discharge summaries to their GP.

Premature or incomplete discharge planning (incident) was described in a further 31 reports. In 27 cases, this resulted in the patient being readmitted to hospital (outcome) and two patients died (outcome). One report described a frail elderly (contributory factor) gentleman who could not cope without additional support at home following discharge and, as a result of self-neglect (contributory factor), developed cellulitis from leg wounds (outcome). He was eventually readmitted to hospital but later died (outcome). Of the 21 incidents in which patient age was reported, nearly three-quarters (n=15) of patients were aged ≥ 66 years (contributory factor).

A further 22 incidents involved errors in the transfer of patient information between different healthcare settings (incident), with 10 resulting in the patient's admission to hospital (outcome). These included incomplete discharge summaries (n=5), failure to send discharge summaries (n=5) and delay in sending discharge summaries (n=4). In four cases, the patient's GP failed to action recommendations included in the discharge summary. For example:

Patient attended GP appointment with a new resident GP. Enquired about the referral to urology department at acute hospital that should have been made by the long-term locum GP 3 months previous. On investigation, it was found unsent in the records.

Few contributory factors were reported in relation to incidents involving poor communication between healthcare providers. Poor continuity of care between healthcare providers was only explicitly reported as a potential contributory factor in five cases.

3.4.3.2. Clinician decision-making

In total, 96 incidents were about physician decision-making as follows: 24 reports described errors in treatment decisions, 50 reports described errors in decisions about prescribing medications and 22 recorded errors made in monitoring dose-dependent medications. For example:

Patient discharged from [hospital] on [date]; no warfarin dose or INR results sent to GP. INR checked and information added to INRstar (or did not enter dose was changed in hospital). Patient given 2 mg daily (subsequently found dose in hospital was 0.5 mg). Patient suffered GI [gastrointestinal] bleed and died on [date].

Over half (n=56, 58%) of the reports were preceded by another incident (contributory incident). How physicians interact with paper-based and/or computer-based systems was the apparent underlying issue in a number of these incidents. These contributory incidents include errors in the transfer of patient information between healthcare settings (n=17), and errors in the process of recording and accessing patient documentation in a further seven reports. Missed opportunities to seek important information from patients that could inform decision making was described in eight reports. For example, one report detailed a district nurse missing the opportunity to check the immunisation status of a patient; the patient did not receive the required pneumococcal vaccine and subsequently developed pneumococcal sepsis. In another example, the GP failed to act on discharge advice:

Practice notified that patient was being discharged following 10-day admission for treatment of iatrogenic hypercalcaemia caused by a high dose of alfacalcidol. GP did not change dose of alfacalcidol as stated in letter.

At least one contributory factor was identified in over half (n=54, 56%) of GP-related medication errors. Twelve reports described how patient behaviour or actions contributed to the development of incidents, for example non-compliance with instructions from the patient's GP in some cases resulted in adverse drug events and recurrence of the patient's illness. A further 15 incidents were due, at least in part, to staff members failing to follow protocols or having an inadequate skill set or knowledge. For example, one GP prescribed 10 times the recommended dose of trimethoprim for an 8-week-old baby. Service-related factors included poor continuity of care between different healthcare professionals (n=8); for example, one patient received the wrong doses of insulin as a result of the lack of communication between the discharging medical team and the district nurses.

Four incidents arose, at least in part, because the patient received care from an out-of-hours service. For example, one patient was prescribed a large quantity of amitriptyline by an out-of-hours GP despite a history of overdose, and was found dead 2 days later. This highlights the lack of background clinical information available to out-of-hours service doctors (contributory incident) when making clinical decisions. Of particular note, 17 incidents followed an error in the process of monitoring medications, of which 14 involved staff failing to follow protocol or having an inadequate skill set or knowledge (contributory factors). This included one case in which a patient's INR was not monitored despite the patient being prescribed anti-tuberculosis medications known to interact with warfarin. The patient subsequently developed a pontine cerebrovascular event and was found to have an INR of 10.

3.4.3.3. Delays in cancer diagnosis associated with unfamiliar symptom presentation and/or inadequate administration

Missed or delayed cancer diagnosis accounted for 9% (n = 93) of reports describing serious patient harm or death (outcomes). In 25 cases, these were preceded by a contributory incident involving investigative processes, such as an error in reporting of diagnostic imaging results. For example, an elderly patient (contributory factor) with an identified lung opacification on a chest

radiograph was given a routine rather than an urgent referral (contributory incident). By the time adenocarcinoma was diagnosed, the cancer had metastasised and the patient developed carcinomatosis (outcome). Another 59 reports recorded a delay in the assessment or management of a cancer diagnosis, and 18 of those described the death of a patient. For example:

Patient attended surgery with symptoms of irritable bowel syndrome. Given prescription, over next few months came back for telephone advice. Told had colitis and given further medication. Patient was not given a PR [per rectal] examination at any visit. Referred to endoscopy 7 months later and found to have bowel tumour. Patient undergoing chemotherapy at the time of report.

In over half of incidents resulting in a delayed cancer diagnosis, the patient's age was recorded (n=24, 62%), and missed cancer diagnoses were reported for a broad range of age groups. Symptoms of a rare presentation was the most common contributory factor for a delayed cancer diagnosis. Other contributory factors included non-disclosure of symptoms (n=9) and visiting different healthcare professionals for the same symptoms (n = 6). For example:

Patient's mother contacted the Patient Advice and Liaison Service, stating that her adult daughter died. For 6 months prior to her daughter's death, the GP had been treating her for migraine, anxiety, depression and panic attacks. In addition, she had been losing her eyesight but the GP had insisted that she see an optician who had referred her back to the GP, stating that something else was amiss. The patient had been told that the GP was in touch with the optician. After the patient died, two brain tumours were discovered.

3.4.3.4. Failures to recognise signs of clinical deterioration

Missed or delayed diagnosis of an acute clinical condition (n = 61) frequently resulted from errors during telephone triage (n = 28), of which seven involved out-of-hours services (contributory factor). For example:

Call passed from NHS Direct to out-of-hours service with a 'less urgent' priority. 10-week-old baby with central cyanosis, increased respiratory rate, and 'noisy' breathing.

Acute clinical conditions were missed (outcome) in 23 reports, and a further 10 reports described the delayed diagnosis of an emergency condition (incident), such as bowel perforation, which resulted in a delayed hospital admission (outcome) and the death of a patient (outcome). Another example includes:

2-month-old baby taken to A&E [accident and emergency] as Sudden Unexpected Death of Infancy having died at home. Baby had been seen by GP on previous evening with temperature of 38 Celsius; diagnosed with possible chest infection and prescribed amoxicillin. NICE guidance states that fever ≥ 38 Celsius in child less than 3 months is a red flag and a child should be admitted to hospital. Preliminary results from post-mortem suggest that infection is likely cause of death.

Involvement of out-of-hours services (contributory factor) was described in 10 of these incidents. For example:

Patient seen on home visit. Advised had been seen with symptoms strongly suggestive of an acute stroke at home by out-of-hours service at approximately 2015 hours yesterday evening and told to contact her GP the next morning. Policy is that patient suspected of suffering an acute stroke should be admitted as a 999 to hospital for appropriate diagnosis and treatment.

In eight cases, a chain of incidents occurred; for example, the healthcare professional did not appreciate the severity of illness (contributory incident), leading to delays in escalating concerns and co-ordinating urgent transport to

hospital (contributory incident), leading to a missed or delayed diagnosis of an acute condition (incident). Of the 36 reports that described emergency transport delays (contributory incident), 10 stated that the delay was preceded by failures in triaging patients (nurses in OOH call centres and on call GPs triaging home visits) or in the direct physical assessment of acutely unwell patients (contributory incidents). In addition, four incidents were preceded by inadequate verbal communication between healthcare professionals (contributory incident).

Errors in the process of identifying patients at risk of deterioration because of mental health problems (contributory factor) were largely fatal, with 27 out of 29 incidents in this sample resulting in the death of a patient. The majority of these involved the patient taking an overdose of medication (incident). Patient actions, such as not attending a planned review with their GP (contributory factor), contributed to these incidents in five cases.

3.5. Summary of findings

In this chapter, I have demonstrated the diverse range of patient safety incidents reported from general practice in England and Wales.

In section 3.1, I have described the development of coding frameworks and their processes for application to patient safety incident reports in general practice.

In section 3.2, I have highlighted how incident reporting systems in general practice are currently being used. A structured approach, guided by definitions, for reviewing the content of incident reports can support the identification of reports describing actual patient safety incidents. One in every three reports (n = 4668, 34% of total reports) was excluded from this study since they contained insufficient detail or did not describe a patient safety incident. Of included reports, two-thirds of incident reports did not explicitly describe reasons about why the incident occurred. This raises important issues about the current knowledge and understanding of the purpose of incident reporting systems.

In section 3.3, I have explored the relationships between similar categories of incidents, their contributory factors and outcomes, to pinpoint apparent opportunities for improvement (discussed in chapter 7 – Discussion). I examined the relationship between incidents and their contributory factors as a means of explaining why incidents might have occurred.

In section 3.4, I have demonstrated how incidents with similar outcomes such as serious harms and death can permit understanding deeper underlying contributory themes which are not necessarily apparent when considered in isolation. This analysis pinpointed several processes for quality improvement and research activity needed at a practice and organisational level, including: referral and discharge processes; how physician decision making is impacted by administrative and information technology systems; cancer recognition and diagnosis; and, recognising signs of clinical (medical, surgical and mental health) deterioration.

In chapter 4, I will explore how this method can be applied to a volume of reports identified by virtue of patient characteristics (e.g. vulnerable children), and how aligned recommendations for improvement can be generated with existing evidence or initiatives mapped to those and gaps for further work identified.

Chapter 4 – A programme theory and identified interventions to improve safety for vulnerable children

In this chapter, I will address objective 4a which is to determine the process for using incident report analyses to inform the design of improvement projects at a national level. I will demonstrate how the methods developed for my thesis (and described in section 3.1) can be applied to a focussed analysis of national-level reports involving vulnerable children to yield a programme theory which articulates potential improvement priorities, and how a structured scoping review of published and grey literature can identify existing interventions for improvement relevant to each priority. I have detailed the rationale and method for utilising incident reports to generate programme theory in section 1.2.3.1. In this chapter, I illustrate how to generate a programme theory for an exemplar scenario of incident reports describing patient safety incidents involving vulnerable children.

The outline of this chapter is summarised in Table 4.1.

Table 4.1. Overview of chapter

Section	Description
4.1	Methods used to identify a sample of incident reports for national-level analysis and the scoping review processes to identify existing interventions in the published or grey literature.
4.2	Description of the characteristics and themes present in incident reports about vulnerable children. A first-draft programme theory to improve care for vulnerable children is proposed.
4.3	Findings from a scoping review of interventions to improve care safety for vulnerable children are described.
4.4	An updated programme theory with mapped interventions is proposed.
4.5	Summary of findings.

4.1. Methods for a national-level analysis of incident reports

In section 3.1, I previously outlined the processes that were developed and refined to make sense of, and prioritise, learning present in unstructured incident report data. Through a mix of quantitative and qualitative methods, apparent priorities for improvement emerged from discussion and interpretation of 'what happened', 'why did it occur' and related 'outcomes'. I used the same methods to characterise incident reports about vulnerable children as previously described in section 3.1.

In this section, I will describe my methods for moving from a homogenous group of incident reports (e.g. patient safety incidents involving vulnerable children) to a plan (a programme theory) for quality improvement. I will outline the systematic search undertaken to identify incident reports for inclusion in the national-level analysis (section 4.1.1). My analysis will be summarised as a driver diagram which is an explanatory narrative of the theory for improvement (described in section 1.2.3.2).(29,305) Finally, I will describe the scoping review processes used for identifying existing interventions ('improvement ideas') to map against each identified change concept (section 4.1.2.).

4.1.1. Identifying patient safety incident reports about vulnerable children

To identify incident reports about vulnerable children, an operational definition was needed to structure the scope of the key terms that would be used to identify patient safety incident reports about this patient population. On review of the literature, it was apparent there was variation in existing definitions. A scoping review was previously undertaken to determine the key domains and related keywords described in the published and grey literature (including current policy directives and non-governmental organisations).(27) All existing definitions of vulnerability were abstracted into a Microsoft Excel Spreadsheet (see Appendix 10 for the range of definitions identified for 'vulnerable child').(27)

All included definitions were agreed between me and a BSc medical student (Adhnan Omar) who abstracted the definitions. A comparative analysis

undertaken by me and Omar highlighted common themes about what was meant by vulnerability (see Figure 4.1).

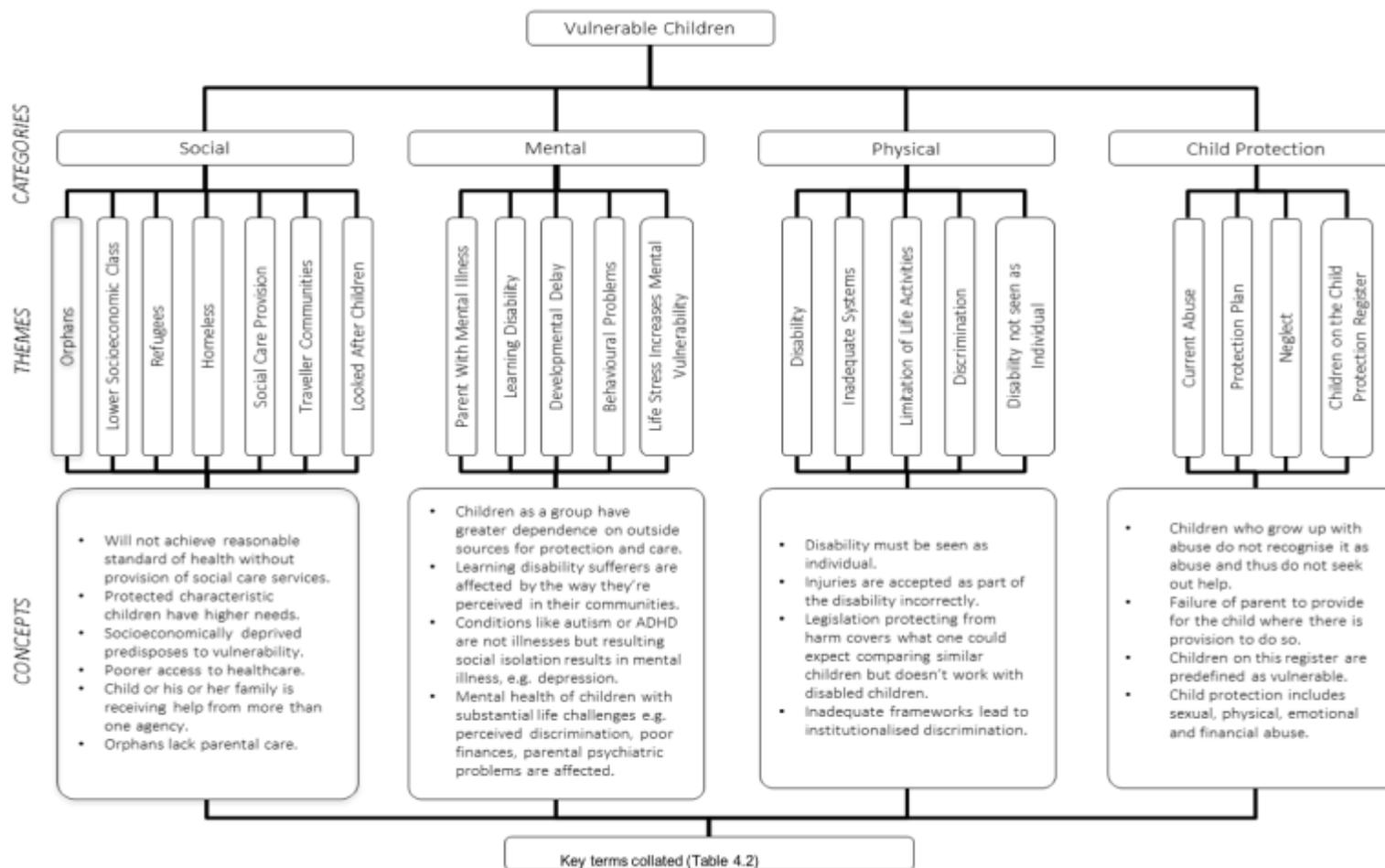


Figure 4.1. Outcome from comparative analysis of vulnerability definitions

Concepts and themes were synthesised in discussion with a multi-disciplinary team including academic pediatricians (Sabine Maguire and Alison Kemp, Cardiff University), to inform the following definition:

‘All children can be argued as vulnerable but circumstantially vulnerable children are defined as anyone under the age of 18, who are more susceptible to welfare loss above the socially accepted norm if faced with adversity, without provision of additional support services. Children were categorised as socially, psychologically or physically vulnerable; or vulnerable due to child protection risks, (See Figure 4.1 for definitions of categories of vulnerability) these categories are not mutually exclusive.’
(23)

A list of key terms was derived to search the free text of incident reports in the NRLS database (c. 270,000 primary care reports) (see Table 4.2).

Table 4.2. Key terms for searching NRLS dataset

Category	Key Terms
Social	Children In Care, Social Care, Foster Care, Social Services, Public Housing, Council Housing, Social Housing, Public Authority, Agency, Social Worker, District Nurse, Low Income, Poverty, Traveller, Refugee, Minority, Looked After Children, Social Support, Homeless, Ethnic Minority, Deprived, Marginalised, Caregiver, Young, Orphan, Social Isolation, Adopted.
Mental	Refugee, Mental Health, Depression, Anxiety, Stress, Dependant, Culture, Migration, Immigration, Discrimination, Racism, Language, Low Income, Lower Socioeconomic Class, Poverty, Poor, Parental Mental Illness, Parental Psychiatric Illness, Learning Disability, Impairment, Intellectual Disability, Learning Difficulties, Mental Retardation, Dyslexia, Dyspraxia, Epilepsy, Autism, ADHD, Young Carer, Uncertain, Social Isolation, Distress, Anxiety, Mental Handicap, Abuse, Adverse Life Event, Self-harm, Self-Harm, Substance, Developmental Delay.
Physical	Disabled, Injury, Injuries, Wheelchair, Aids, Crutch, Abuse, Impairment, Physiotherapy, Physical Handicap, Communication, Education, Isolation, Mobility, Discrimination, Needs Assessment, Occupational Therapy, Housing, Stress.
Child Protection	Abuse, Maltreatment, Harm, Child Protection, Injury, Stress, Neglect, Development, Self-Protection, Abandonment, Mistreatment, Desertion, Disregard, Protection Plan, Agency, Response, Child Protection Register, Violence, Conflict, Homelessness, Vagrancy, Exploitation, Learning Disability, Significant Harm, Sexual/ Emotional/ Physical Abuse, Violent, Protection Order, Case Order, Safeguard, Shaken.

4.1.2. Identifying existing interventions

Mapping interventions onto a driver diagram starts to operationalise the identified improvement concepts.(27) Undertaking a systematic review for each improvement concept would make the process of planning a QI project very resource intensive. A form of literature review was sought to address broad questions, be inclusive of published and grey literature, and enable processing of potentially large volumes of literature.

Scoping reviews can be used to synthesise large volumes of literature rapidly, usually to identify existing research and policy gaps for perceived priority areas for intervention.(241) The advantages and disadvantages of scoping reviews are considered in Table 4.3.(207,211,306)

Table 4.3. Advantages and disadvantages of scoping reviews

Advantages	Disadvantages
<ul style="list-style-type: none">· Rapid collection of data· Identification of parameters and gaps in the literature· Thematic analysis of qualitative data· Inform policy makers as to whether or not a full systematic review is required· Attempt to be systematic, transparent and replicable, sharing some characteristics of the systematic review	<ul style="list-style-type: none">· Potential for bias between different individuals who are conducting the scoping study· Quality of data are not assessed which has important implications for the use of the reviews in conclusions whereby the existence of studies rather than their quality forms the basis for drawing conclusions

Scoping reviews were first developed by Arksey and O'Malley, (207) and numerous authors have suggested amendments to this process to advance the method.(241) See Appendix 11 for a comparison of scoping review methods. I have adhered to the amended framework proposed by Levac et al.(210) that includes additional systematic review principles, and includes:

- identifying the research question;
- identifying relevant documentation;
- study selection;
- charting the data; and,
- collating, summarising and reporting the results.

I will describe each of the scoping review stages in sections 4.1.2.1 – 4.1.2.5.

4.1.2.1. Identifying the research question

A scoping review question is typically broad and should consider the target population (e.g. vulnerable children), concept of interest (e.g. interventions and initiatives to improve an aspect of care quality) and outcomes of interest (e.g. safety). Given the acknowledged paucity of patient safety research in primary care, a scoping review approach could support rapid identification of existing efforts to improve the concept of interest. The research question was: what existing interventions have been used to improve the safety of care delivered to vulnerable children in primary care?

Key terms and Medical Sub-Headings (MeSH) were developed to reflect the operational definition of each variable. For example, the definition for vulnerable children has been defined as “anyone under the age of 18, with needs or circumstances requiring additional support, who are susceptible to inadequate care without the means to cope independently. These circumstances put these children at greater risk of negative events or welfare loss above a socially accepted norm”.

Four overarching mechanisms have been identified by which care can be insufficient for vulnerable children. These categories were not mutually exclusive, and included:

- Physical health: due to disabilities or long-term conditions,
- Psychological health: with mental illness or learning disabilities or have increased risk of mental susceptibility through life-stress or living with parents with mental illness,

- Social circumstances: where children's' health or development is likely to be significantly impaired without social care provision or their lower socioeconomic class or housing/family situation or their migration status or,
- Child protection proceedings: including previous or current trauma, abuse, neglect, current abuse or those already on the child protection register.(307)

4.1.2.2. Identifying relevant documentation

Key terms and MeSH terms were developed and tested in the Medline Ovid database, before being adapted for other databases (see Appendix 12 for search strategy). Synonyms, alternative spellings, and abbreviations were included. Boolean operators combined search terms to balance sensitivity and maximise precision. Eight databases were searched for published literature: PsychINFO, HMIC (Health Management Information Consortium), EMBASE, Medline Ovid, Medline in process and other non-indexed citations, WHO Library Database (WHOLIS), Google Scholar and the System for Information on Grey Literature in Europe (SIGLE). The final three databases were established grey literature search engines. Searches were limited to articles published from 2000 to coincide with the introduction of the Millennium Development Goals agenda for child health.(308) The most recent search was undertaken in March 2016. All references were exported to Endnote version X7 (Thomson Reuters).

4.1.2.3. Study selection

Two independent reviewers (Adhnan Omar and Philippa Rees) reviewed titles, abstracts or full text articles of relevant papers being assessed for inclusion. Reviewers discussed the review process to discuss challenges and uncertainties related to selection. If required, the search strategy was refined accordingly. Where disagreement occurred, I was the third-person arbitrator to determine final inclusion or exclusion.

All study designs were included if they described or proposed improvement initiatives. For inclusion, the research: involved children under 18 years old;

occurred in primary care settings (initially) and later expanded to inclusion of secondary care settings; and described initiatives that mitigate safety issues arising in children with vulnerabilities. I met with the Reviewers (Omar and Rees) at the beginning, midpoint and final stages of the abstract review process to discuss any challenges and uncertainties about selection. The initial inclusion criteria included interventions or initiatives in primary care only. However, reports made by primary care professionals commonly described inter-sector issues; therefore, it was decided to include studies describing efforts to improve system processes for vulnerable children in secondary healthcare settings also. Further, studies or initiatives from all income settings were included given the international agenda set by the Sustainable Development Goals to minimise health and social care inequalities for children.⁽⁶⁶⁾ This iterative process throughout data selection is promoted by Levac et al.⁽²¹⁰⁾ Non-English studies, abstracts, letters and editorials were excluded as well as studies exclusively assessing patient safety incidents without proposing improvement ideas.

4.1.2.4. Charting the data

Included studies were extracted by a reviewer (Adhnan Omar) to a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA). The main variables for data extraction were agreed with a second reviewer (Philippa Rees) after independent review of five articles (see Appendix 13 for an overview of variables). The discussion centred on keeping the extraction approach consistent with the objectives of the study.

4.1.2.5. Collating, summarising and reporting the results

Tables were used to describe interventions and the type of vulnerability addressed. A narrative synthesis was undertaken to summarise descriptions of the interventions and their reported outcomes. The literature was organised thematically according to manifest and integrative themes identified by analysis of incident reports.

The purpose of the scoping review was to identify interventions that have explicit descriptions of the intervention in terms of the change concepts and related ideas that were developed and tested in practice. Thus, assessment of

the quality of the studies was not undertaken since it was beyond the scope of the review. However, the strength of actions specified for each intervention can be assessed in terms of human factors principles where the “most effective actions accommodate or control for the limitations of human behavior and how people interact with systems, tools, tasks and the environment through the use of design and standardisation”.(229)

I assessed the strength of the interventions with a general practitioner with human factors training (Huw Williams) using the Action Hierarchy developed by the United States (US) Veterans Affairs National Center for Patient Safety Strength Intervention Classification (see Table 4.4).(229) The tool was modelled on the US National Institute for Occupational Safety and Health Administration’s Hierarchy of Controls which had supported effective and sustained safety improvement in other industries.

Table 4.4. Strength of intervention assessment tool (229)

Strength	Definition	Example
Strong	The best at removing the dependence on the human to “get it right” (they are physical and permanent, rather than procedural and temporary).	<ul style="list-style-type: none"> ● implemented new devices or redesigned processes with usability testing ● standardisation of equipment ● forcing functions
Intermediate	Reduce the reliance on the human to get it right, but do not fully control for human error.	<ul style="list-style-type: none"> ● increased staffing or decreasing workload ● implementation of checklists or cognitive aids ● standardised communication tools ● enhanced documentation ● software enhancements
Weak	Support/clarify the process, but rely solely on the human.	<ul style="list-style-type: none"> ● new protocol or standard operating procedure ● training and education ● introducing warning or hazard labels ● double checking

Lessons from those industries suggests choosing at least one strong or intermediate strength action, or weaker actions as temporary measures until stronger actions can be committed. In healthcare, weaker interventions such as new training and policy establish expectations, used in isolation are unlikely to

achieve sustained patient safety improvements. Morse and Pollack (309) also consider the effort required by strength of intervention (see Figure 4.2).

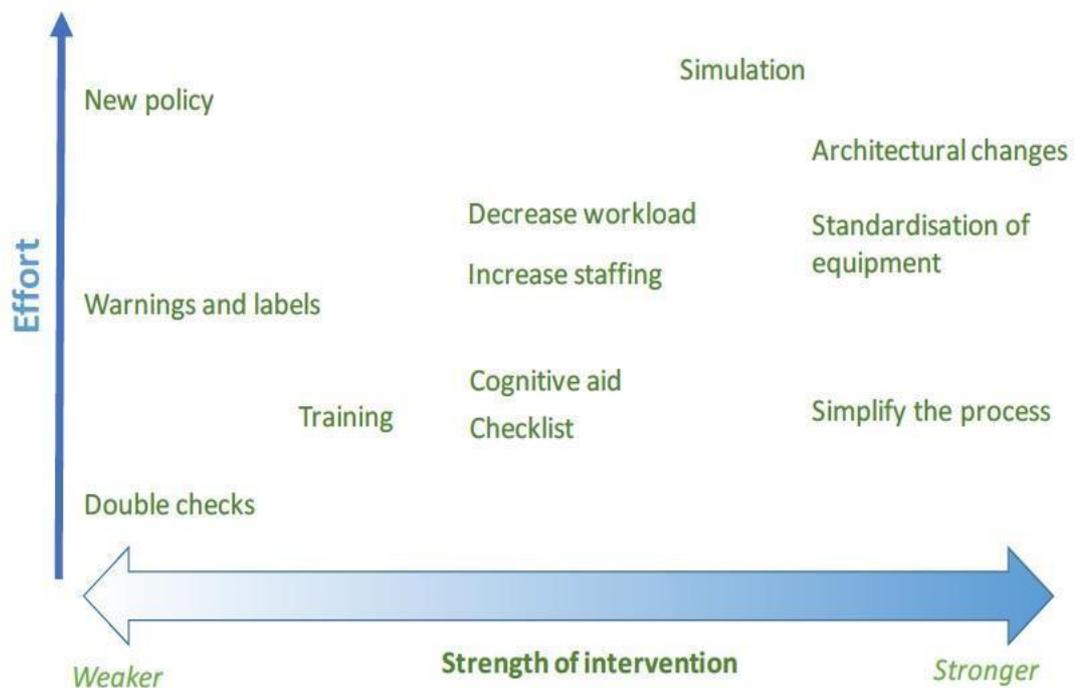


Figure 4.2. Nature of intervention effort and the strength of intervention developed from Morse and Pollack (309)

For transparency, Levac et al.(210) advise a descriptive numerical summary analysis and a thematic analysis for synthesising results. A programme theory from analysis of incident reports has been used to empirically inform the design of the scoping study; thus, in my study this was the thematic framework for update / amendment following the scoping review. Next, they advocate the production of an output that refers to the overall purpose or research question.(210) In my study, the output is an updated programme theory articulated as a driver diagram. Interventions which contain change concepts relevant to each integrative theme were mapped on to the driver diagram.

4.2. Draft programme theory to improve care safety for vulnerable children informed by incident report analysis

In my searches of the NRLS database, I identified 2,015 reports, of which 1,183 reports were included for analysis. Table 4.5 provides an overview of frequent staff group reporters, age of children, levels of harm, and range of vulnerabilities described in the reports. Table 4.6 illustrates the frequency of incident types occurring in this sample, grouped into three integrative themes by virtue of their definition and meaning. Reports described harm outcomes (n=311, 27%) for vulnerable children ranging from low severity to death. The remaining reports did not describe incidents that resulted in harm (n=402, 34%) or lacked sufficient detail for assessment of harm severity (n=470, 40%). The most frequently described incidents involved:

- Deficiencies in healthcare planning (n=187, 16%);
- Unsatisfactory referrals (n=154, 20%);
- Investigation and diagnosis errors (n=128, 11%); and,
- Errors in safeguarding proceedings (n=75, 10%).

Table 4.5. Overview of included incident reports

INCLUDED REPORTS		
<i>Most frequent reporters</i>	n	%
Health visitors	278	23
Nursing staff	198	17
Community teams	183	16
Child and Adolescent Mental Health Services	47	4
<i>Age of children in incidents</i>	n	%
<2 years old	341	30
2 – 10 years old	443	39
>10 years old	348	31
<i>Level of harm</i>	n	%
No harm	402	34
Low harm	222	19
Moderate harm	76	6
Severe harm	12	2
Death	1	-
Insufficient detail	470	40
<i>Vulnerability</i>	n	%
Physical	124	11
Psychological	189	16
Social	353	30
Child protection	517	44
EXCLUDED REPORTS	n	%
Not describing safety incident in primary care	256	31
Contained insufficient information	239	29
Appropriate breaches in confidentiality'	214	26
Defensive reporting	70	8
Not vulnerable children	35	4
Pressure ulcers	18	2

Table 4.6. Overview of harm outcomes for each patient safety incident type

Integrative themes	Type of patient safety incident	Harm	No Harm	Moderate / Severe	Not Specified	Total, n
Recognising needs to implement intervention	Care planning: inadequate health or social care intervention received	27 (2%)	114 (10%)	9 (<1%)	37 (3%)	187 (16%)
	Safeguarding: delayed or absent detection of a child in need	29 (2%)	57 (5%)	20 (2%)	56 (5%)	162 (14%)
	Investigation and diagnosis: errors in standard investigative and diagnostic processes	35 (3%)	22 (2%)	13 (1%)	58 (5%)	128 (11%)
	Treatment and medication: issues in the medical treatment of patients	32 (3%)	13 (1%)	18 (2%)	23 (2%)	86 (7%)
	Access to healthcare: reaching the required healthcare setting	5 (<1%)	32 (3%)	6 (<1%)	6 (<1%)	49 (4%)
	Equipment: provision of essential equipment (e.g. tracheostomy, insulin needles, dressings)	8 (<1%)	13 (1%)	0	9 (<1%)	30 (3%)
Referrals between health and social care services	Referral: referral of patients from one service to another	38 (3%)	61 (5%)	13 (1%)	57 (5%)	169 (14%)
	Breaches of confidentiality: where patient information is taken or shared without consent	9 (<1%)	4 (<1%)	1 (<1%)	35 (3%)	49 (4%)
Information transfer to enable continuity of care	Documentation: errors in medical records or documentation	6 (<1%)	33 (3%)	1 (<1%)	71 (6%)	111 (9%)
	Transfer of information: errors in information sharing not done face to face	8 (<1%)	24 (2%)	2 (<1%)	61 (2%)	95 (8%)
	Administration: management of patient healthcare appointments	4 (<1%)	19 (2%)	1 (<1%)	24 (2%)	48 (4%)
	Communication: errors during face to face interactions	15 (1%)	7 (<1%)	5 (<1%)	14 (1%)	41 (3%)
Other	Professionalism: inappropriate conduct of healthcare professionals	6 (<1%)	3 (<1%)	0	19 (2%)	28 (2%)
	Total	222 (19%)	402 (34%)	89 (8%)	470 (40%)	1183 (100%)

4.2.1. Interpretation of integrative themes

All reports for each of the top four incident types, and *all harm reports (low harm, moderate harm, severe harm and death)* from the other incident types, were re-examined as per stage 3 of the mixed methods analytical process described in section 3.1.6.4 in chapter 3.

Three integrative themes emerged:

- **‘recognising needs to implement intervention’** included incidents where clinical decision making was affected by a diagnosis-related incident, deficiency in care planning or the initiation or delivery of treatments (medication) and equipment when needed;
- **‘referrals between health and social care services’** included incidents where referral documentation contained inadequate detail, was incomplete or lost, or decisions about referrals were delayed; and,
- **‘information transfer to enable continuity of care’** included incidents where lack of essential information about a child had not been efficiently exchanged within and between health and social care providers.

The integrative themes represent major core functions of a system capable of providing safe health and social care to children. Where relevant, themes that existed between them were also described.

In the following sections, I will highlight how the Recursive Model of Incident Analysis has been applied to incident reports, I will annotate the described content with the following terms in brackets: incident, a contributory factor, contributory incident or outcome.

4.2.1.1. Recognising needs to implement intervention

Children frequently suffered harm because of poorly planned interventions for physical care, particularly children with complex physical health problems, or children with child protection needs (n=459, 39% of total reports). These children predominantly had vulnerabilities (contributory factors) relating to social

issues (n=176, 38% of the planning and implementation incidents) and child protection issues (n=167, 36%). An inadequate assessment of essential health needs was the most common incident (n=114, 25%), and such children went without important care resources like tracheostomy care or wheelchairs (n=30, 7%)(see example 1). This also meant newly 'at risk' children were not identified (contributory incident) and did not receive the protection needed (incident) in hindsight (n=63, 14%) (see examples 1, 2).

Example 1. This patient has been waiting for 12 months to be seen in the enuresis clinic since referral. There has been another referral from another agency since the first referral. This child has been waiting for 12 months. The patient's mother has informed me that enuresis problem is really affecting him as it is worsening his behaviour problems and he is currently [receiving care from] the Community Learning Disability Nurse. I have now apologised to mum for the long wait and have now managed to discharge a patient who is now dry and I have now given him an appointment for the [date].

Example 2. Discharged patient home following acute hemiparesis. Patient discharged without access to a wheelchair or appliances to improve mobility. Patient requires high level of rehabilitation that cannot be fully met by the community team.

Many children had outdated child protection plans (n=127, 28%). As a result, vulnerable children were in harmful or violent environments with unmet health and social needs (contributory factors). Staff factors underpinned many of these incidents. Secondly, healthcare professionals and social workers faced difficulties in attending multi-disciplinary case conferences to review children's protection circumstances (n=39, 8%) (see example 3). Consequently, local authorities had outdated safeguarding or care packages in place for children, and inconsistencies arose in the identification and action of child protection concerns (contributory incidents). These were exacerbated by organisational factors which included strict shift constraints, workload and multiple commitments (n=67, 15%).

Example 3. Information received from Senior Nurse in safeguarding team that she attended an initial safeguarding conference on [date] which raised concerns of missed opportunities from health regarding the welfare and protection of a child. It was deemed the child was suffering chronic neglect and the senior nurse was concerned that this child had not had all possible opportunities explored. Procedures had not been adhered to regarding failed visits and significant events, and subsequent seeking of supervision, which led to a delay in neglect being recognised and acted upon.

4.2.1.2. Referrals between health and social care services

Reports described failures in referral processes from social services to health visiting services (n=86, 18%), or protection services to community professionals (n=62, 13%) (see example 4). Inadequacies in communications about a child's intended health and social care provision, safeguarding issues, or follow up plans were frequently described incidents (n=465, 39% of total reports). Many of the contributory factors concern children's social vulnerabilities (n=148, 32% of these information transfer reports). Seventy of those children in institutional care experienced harm (n=70, 15%).

Example 4. Request for records received from [police] as part of investigation into serious assault on a child. On reviewing the CAS record to fulfil the police request, concerns were raised that no child protection referral had been made for this call at the time it was taken and following the nurse assessment. The child was subsequently taken to hospital and found to have a number of non-accidental injuries.

Failures in decision-making whilst referring children to the necessary social or healthcare service resulted in delayed, incomplete or lost referrals (n=66, 14%). The lack of clarity during referrals was a frequently described contributory incident that resulted in delayed child protection intervention and unmet health

and social care needs outcomes (n=49, 11%) (see example 5).

Example 5. Step-father called about his step-daughter who had returned from a weekend at her father's with vaginal pain, soreness and smelly frothy discharge. Her behaviour had altered over the past month crying a lot and having nightmares. Step-father concerned that she has been sexually abused. Call assessed by nurse and sent through to the GP [out of hours] service but did not do clinical summary for GP highlighting the concerns. No referral made to social services.

In addition, follow-ups were sometimes insufficient for the children's physical health needs (n=28, 6%) (see examples 6, 7).

Example 6. Referral by midwives regarding cannabis use by a mother during pregnancy was received but not acted upon by health visitors. Baby went on to develop and die from a neuroblastoma which is recognised as being linked to recreational drug use in pregnancy. There is no record of baby being seen by health visitors after new birth visit; however she was seen several times at the GP surgery for developmental check at six-to-eight weeks and for primary immunisations. This omission was picked up during child protection supervision when records were reviewed following the baby's death.

Example 7. While in a multi-agency meeting I identified that the child being discussed had been lost to follow up in paediatrics. Last seen in my clinic with four month follow up recorded on system and letter. Went into system but no further appointments have been made. Has developmental issues but also growth issues that may need endocrine referral which potentially will have been delayed by this.

Recurrent outcomes for these children were variable levels of harm in terms of deterioration in their social circumstances or medical conditions due to delays in accessing the required care (contributory incident) (see example 8 and 9).

Example 8. Following discharge from hospital visit for bruising, on [date]. Child was not noted as 'at risk'. The child's health deteriorated and required subsequent re-hospitalisation. Later checks identified the mother's current partner has history of abusing children – no safeguarding measures had been undertaken in discharge planning.

Example 9: Informed on [date] by the children's community nursing team that [patient] had been discharged home from [hospital] with a nasogastric tube in situ. We had not been informed by the hospital dieticians or the ward, therefore we did not know what feed and equipment she required and had not registered her with [name of professional] for delivery of equipment for feeding via her nasogastric tube. Attempted to visit patient but could not gain access. On second visit, we discovered mum spoke no English and dad speaks very little. They had run out of syringes for feeding but were using syringes given to them by the community nurses. Both parents were very anxious about the situation.

4.2.1.3. Information transfer to enable continuity of care

Healthcare professionals often did not have the necessary information available about the child to deliver the required care (n=259, 22% of total reports). The nature of these children's health needs meant they were often involved with multiple providers from social care, health visiting and/or child protection services (contributory factors) (n=106, 41% of care continuity reports).

Reports described difficulties in the organisation and coordination of simultaneous health and social care interactions (contributory incident) (n=97, 37%) (see example 10). Access to services was challenging for patients for whom English was not a first language (contributory factor) (n=76, 29%), owing to difficulty with interpreter services. As a result, repeated visits were often required before appropriate health and / or social care was initiated (n=53, 20%). Patients who had changed residential address several times (n=67, 26%), which is common for children in foster care, also faced difficulties. Such

children faced challenges being registered with required services (contributory factor) and having documentation available (contributory incident) which summarised their needs (n=45, 17%) (see example 11).

Example 10: Due to mother's previous history it was decided the baby would be removed at birth for protection. From conference on xx/xx/xxxx there has been no communication from Social Services regarding the mother and unborn child. Birth notification arrived from Child Health Dept and we have statutory obligation to visit. We are unaware of baby's whereabouts. Hospital contacted - stated baby has gone to [location] - no address available despite original planned interventions.

Example 11. Baby was brought to see GP by mother with several problems – conjunctivitis, wheezy chest and burn-like mark. Entry was made in clinical notes detailing 'burn-like' lesion with cause unknown. No further action was taken. Another member of staff saw the entry and realised the child had recently been taken off the child protection register and the mother had already had four previous children taken from her.

4.2.2. A draft programme theory

A summary of the integrative and manifest themes that have emerged from analysis of the incident reports is outlined in a driver diagram (Figure 4.3). Such themes represent key issues for improvement identified from incident reports.

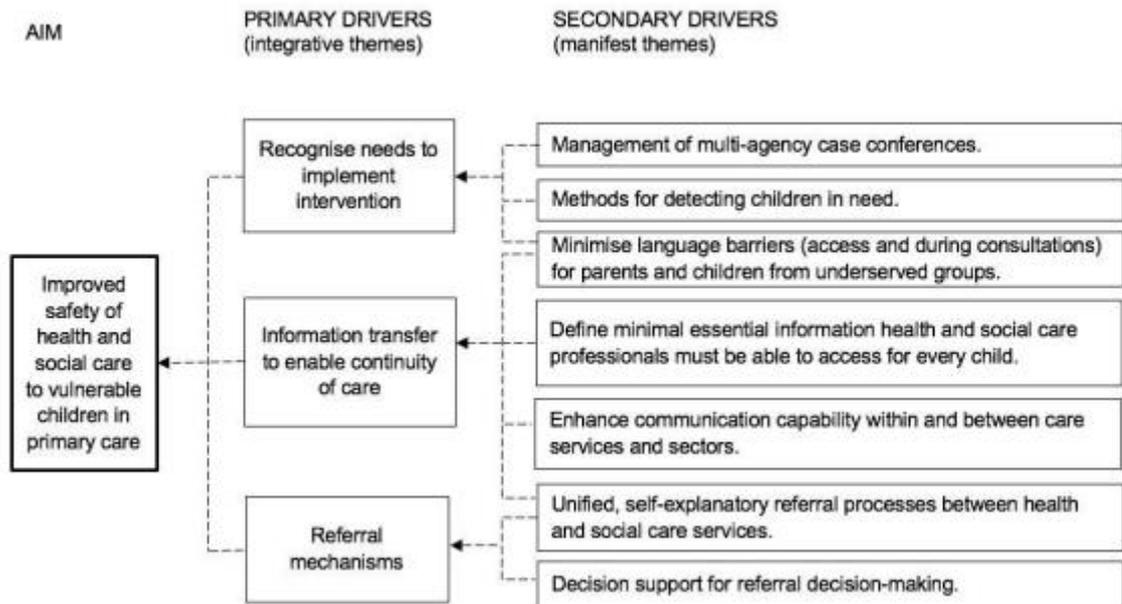


Figure 4.3. A programme theory arising from analysis of incident reports about vulnerable children

4.3. Findings from a scoping review to identify Interventions to improve care safety for vulnerable children

In this section, I will describe the key findings from the scoping review of existing interventions or initiatives (collectively referred to as interventions here forth) in the published or grey literature.

4.3.1. PRISMA Diagram

A total of 384 potentially relevant article abstracts was retrieved from searches, from which 17 were included (Figure 4.4).

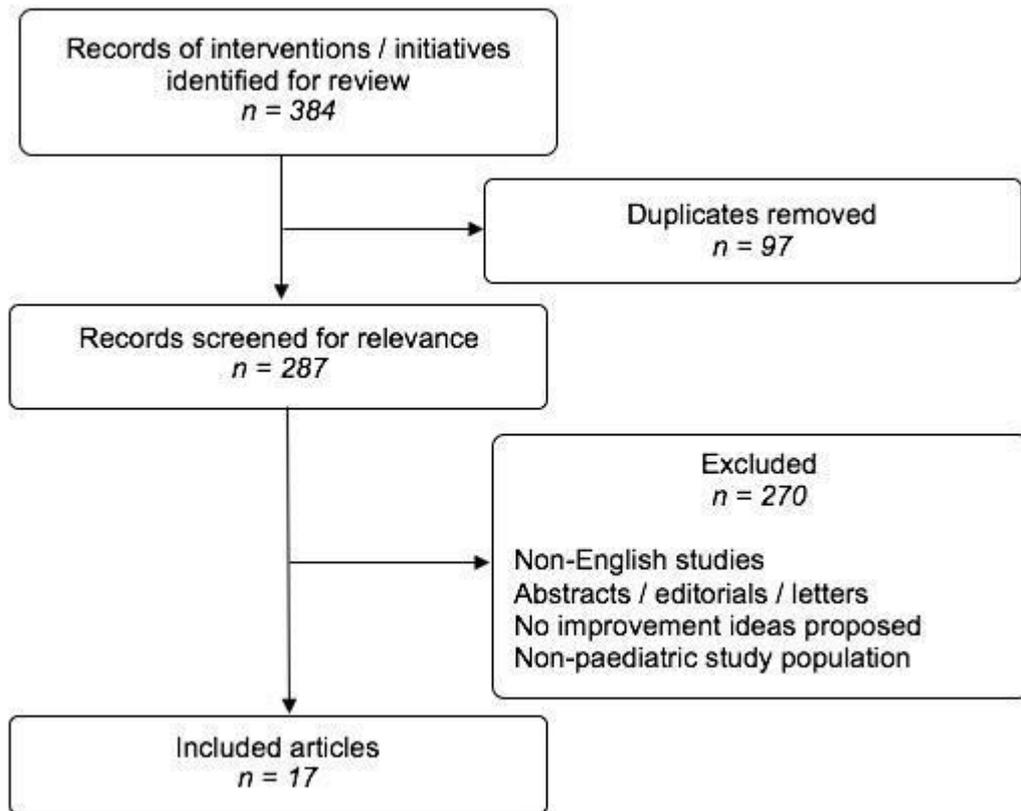


Figure 4.4. Flow diagram of included studies

Articles originated from six countries, most commonly describing interventions in healthcare systems in upper income countries, such as the United States (n=12) and the United Kingdom (n=4). Studies were explicitly reported from primary (n=12) and secondary (n=2) care settings. Studies are summarised in terms of study design, strength of action for each intervention, and the vulnerability focus of each intervention are summarised in Table 4.7. The strength of the intervention is also considered 'strong', 'intermediate' or 'weak' as per the US Veterans Affairs National Center for Patient Safety Strength Intervention Classification.(310)

Table 4.7. Overview of interventions

Study design <i>Type of study</i> <i>Author, year of publication</i>	Description	Strength of action	Vulnerability*			
			P	M	S	C P
Interventional						
<i>Randomised controlled trial</i>						
<i>Tait R et al. 2004</i>	A 'support worker' to facilitate attendance for substance misuse treatment following an alcohol- or other drug-related presentation.	S		X	X	
<i>Quasi-experimental (matched comparison)</i>						
<i>Gadomski A et al. 2015</i>	Identify mental health issues amongst adolescents prior to GP consultation.	I		X		
<i>Nordentoft M et al. 2005</i>	Suicide prevention centre run by psychologists and social workers.	S		X	X	
<i>Quasi-experimental (pre- and post-)</i>						
<i>Hendrickson S, 2005</i>	Novel programme in family homes to minimise home safety-related injuries.	S			X	
<i>Miller A and Barlup Toombs K, 2014</i>	Educational intervention to improve identification of signs of maltreatment / sexual abuse.	W				X
Observational						
<i>Cross-sectional</i>						
<i>Brenner E and Freundlich M, 2006</i>	Enhanced documentation to report incidents to an incident reporting system for social workers.	I			X	X
<i>Ringeisen H et al. 2009</i>	Outreach and engagement programme targeting vulnerable racial and ethnic groups with mental healthcare issues.	S		X	X	
<i>Rinke M et al. 2010</i>	Recommendations from a characterisation of medication incidents involving children prescribed antidepressants.	W	X	X		
<i>Cohort</i>						
<i>Zeanah C. et al, 2001</i>	Multi-agency, intensive assessment of children placed in foster care for abuse or neglect, and their caregivers, to inform management plans.	S			X	X

Qualitative						
<i>Focus groups</i>						
<i>Rooke J, 2015</i>	Proposed design for educational programmes to support social workers to avoid burnout and practice safely.	W				X
<i>Case study</i>						
<i>Hingley-Jones H and Allain A, 2008</i>	Multi-agency collaborative working to enhance communication between team and improve care continuity for disabled children.	S	X			
<i>Home Office, 2014</i>	Multi-agency safeguarding hubs to promote collaborative working for enhanced communication to achieve safer practices.	S			X	X
Mixed methods						
<i>Quality improvement report</i>						
<i>Hunter J, 2015</i>	Standardising of nurse-led telephone triage communication protocols embedded into an electronic health record tool.	I				X
<i>Woodman J et al. 2012</i>	Enhanced documentation of child protection concerns in GP medical records.	I				X
Literature review						
<i>Non-systematic</i>						
<i>Chin M et al. 2009</i>	Management and leadership recommendations for quality improvement culture.	N/A	X		X	
<i>Keane C and Chapman R, 2008</i>	Options to improve detection of child protection concerns in EDs.	N/A				X
<i>Schilling S et al. 2012</i>	Options to screen for interpartner violence amongst families attending the ED.	N/A				X

Key: P = physical; M = mental health; S = social; CP = child protection; ED = emergency department; GP = general practice; N/A = not applicable. S = Strong; I = Intermediate; W= Weak. * = more than one vulnerability addressed by an intervention / initiative if explicitly stated.

4.3.2. Descriptive summary of identified interventions

I will now describe each of the included studies grouped by the integrative theme to which they predominantly correspond. Where the manifest theme represents a concept which could belong to either integrative theme, this overlap is represented in the driver diagram (Figure 4.3). An additional integrative theme was apparent across the identified sources in terms of 'leadership for quality and safety' (see Figure 4.5 later) which describes an organisation's agenda for learning from patient safety incident reports and performance data, (311,312) and effective leadership and management of multi-agency teams.(313)

4.3.2.1. Recognise needs to implement intervention

Three bodies of literature were identified, including interventions for detection of parental inter-partner violence, detection of mental health problems in adolescents; and detection of child protection issues. Six studies (or reports) were identified that described interventions to mitigate potential harms arising from absent or inadequate health and social care intervention. For clarity, any substantive studies referenced by those studies are described here.

4.3.2.1.1. Detection of parental inter-partner violence

A review by Schilling et al.(314) describes processes for detection of inter-partner violence of parents (IPV) presenting with their children in the emergency department setting. The review outlines a strong rationale that children exposed to IPV are at significant risk for child maltreatment and short- and long-term medical, behavioural, and mental health problems. Studies cited in the review outline the conceptual basis and content of options for introducing an IPV screening tool into an Emergency Department (ED) or GP surgery, and includes:

- A discussion of the prevalence of the link between IPV and child maltreatment;(315)
- What interventional options exist to screen for IPV,(316) including the most frequently cited three question tool available;(317)

- A synthesis of socio-cultural barriers to IPV screening and ideas for overcoming those;(314) and,
- Lessons learnt from implementation in practice;(314,318) for example, computer-based screening options are preferable to face-to-face screening and can successfully identify children at increased risk and promote vigilance amongst staff.(318)

4.3.2.1.2. Detection of mental health problems in adolescents

Gadomski et al.(319) report a quasi-experimental study of a tablet-based mental health screening tool, called “The DartScreen”, which was developed and tested to improve mental health discussions between adolescents and GPs.(319) The tool covered sensitive topics such as depression, reproductive health and weight. Patients should complete the screening tool before their consultation, and their responses are made available to the doctor to review prior to their consultation. The study demonstrates a pre-visit screening tool that incorporated mental health screening can enable adolescents to discuss psychosocial issues more openly.

4.3.2.1.3. Detection of child protection issues

A range of interventions were identified to support: the detection of child protection issues to initiate safeguarding processes and documentation in EDs,(320–324) and via telephone triage processes;(325) improved detections of physical signs of child abuse on clinical examination;(326) and assessment of the child and caregivers to formulate management plans.(327,328)

Two studies demonstrate improved detection and subsequent management of child protection incidents by educating healthcare professionals. Keane and Chapman’s literature review of the role of ED nurses detecting child abuse explores options,(320) including:

- an educational training and reminder flowchart that was developed for a quality improvement project to improve knowledge and skills for abuse identification and enhanced documentation for suspected cases amongst ED healthcare professionals; (321,322)

- an approach for reviewing documentation of suspected child abuse in preschool children with fractures in ED departments;(323) and,
- an example of legislative interventions, including mandatory reporting of suspected sexual abuse, to tackle child abuse problems in rural communities in Australia.(324)

A pre-post feasibility study of a brief educational intervention developed for physicians in Malawi to increase knowledge in assessing for evidence of child sexual abuse was described by Miller and Barlup Toombs.(326) The intervention was comprised of two one-hour lectures distinguishing between signs of trauma, pathology and sexual contact. The authors describe a statistically significant improvement in self-reported comfort for performing examinations and identifying signs of sexual abuse amongst the 11 (out of 21 potentially eligible) physicians in the pre-post evaluation surveys.

Hunter described a quality improvement project which aimed to improve telephone triaging of suspected child maltreatment cases.(325) The project was informed by surveys of nurses in primary and secondary care clinics, and measured the impact of introducing a script for guiding telephone calls about maltreatment. Improved confidence in the triaging process, including an increased ability to identify risk factors for maltreatment, and an increase in knowledge about appropriate protocols was reported. The benefits of using simulation to prepare nurses was discussed.

A cohort study described by Zeanah et al.(27) evaluated a complex intervention designed to provide assessments and intervention to children younger than 48 months of age who were placed in foster care for abuse or neglect, and to their birth and foster families. The authors report more children were freed for adoption and fewer children were returned to their birth parents. The relative risk reduction for future maltreatment was lower for children in the intervention group. A comprehensive description, including its conceptual basis, has been described by the authors in an earlier publication.(328) The intervention was comprised of:

- intensive assessment (observation, interviews, self-report surveys) of the child and their caregivers to define the child's important caregiver relationships (birth parents, foster carers, and child care provider) and identify which interventions could be needed to return the child safely to their parents;
- streamlining the number of contacts by staff from the same services for better assessment and provision of care; and,
- a multidisciplinary case conference informs a feedback session for parents and a report to the juvenile court to detail findings and recommendations.

4.3.2.2. Referral mechanisms

4.3.2.2.1. Multi-agency unified work processes

A Home Office report (329) includes a case study describing multi-agency information sharing models called Multi-Agency Safeguarding Hubs (MASH) across England. Evaluation of MASH showed a larger proportion of cases being 'escalated' to a more serious rating and a smaller proportion being de-escalated to a less serious rating. MASH identified more risks than single agencies. Multi-agency refers to collaborative working between children's social care, the police, healthcare professionals, education, probation, housing and the youth offending service. The report outlines multiple concepts to promote enhanced functioning of a hub, including co-location of agencies; development and use of a shared risk assessment tool; independent management and leadership between services and teams; integrated information technology systems; strategic buy-in from agencies and safeguarding boards; professional development schemes to promote rotation of staff; and, aid interprofessional working.(329)

A case study of integrated services for disabled children at two English local authorities by Hingley-Jones and Allain (330) corroborates the benefits of co-locating agencies to promote communication and effective information transfer between professionals. The authors advise investment in the development of clear processes and boundaries between services.(330)

4.3.2.3. Interventions addressing the care continuum for vulnerable children

Three interventional studies were identified that focussed on improving the continuity of care for vulnerable children. These studies focused on minimising the risk of children from underserved, 'at-risk' or lower socioeconomic backgrounds going without health and social care.(331–333) Further, a quality improvement project has been undertaken to enhance documentation of child protection concerns in general practice medical records to support communication and continuity of care between professionals.(334) Finally, a cross-sectional study was identified and demonstrated the utility of nationally collected data (when available) for determining priority groups for targeted improvement efforts.(335)

4.3.2.3.1. Medical record alerts and flagging systems

Woodman et al.(20) described a quality improvement project to improve the recording of child maltreatment concerns in general practice. The authors developed an approach for 'red flagging' children with child protection needs as a 'child is cause for concern' in their medical records. They advised an optional template is available for staff to include additional contextual information. This approach was designed for simplicity and feasibility for implementation in UK general practice.

4.3.2.3.2. Targeting improvement at priority groups

Ringeisen et al.(335) demonstrate that data like the United States National Survey of Child and Adolescent Well-Being data can be used to determine the frequency and burden of unmet care needs in ethnic or racial minority groups. Such analyses can support prioritisation of resources for the development and sustainability of targeted outreach and engagement programmes.(335)

The review identified two interventional studies. A randomised controlled trial by Tait et al.(331) demonstrated the effectiveness of assigning a support worker (a member of staff employed to look after the physical and mental wellbeing of children or vulnerable adults in care) to minimise potential barriers to treatment. The support worker provided reminders and offered transport to healthcare

appointments. At four-month follow-up, this intervention facilitated adolescent attendance at healthcare consultations to receive treatment and overall significantly reduced hazardous drug use behaviours.(331) Nordentoft et al.(30) assessed by a matched comparison study the efficacy of a suicide prevention centre for young people by offering a two-week social and psychological treatment programme following principles of cognitive behavioural therapy. At one year, a significant reduction in attempted suicide was reported in the intervention group, and improvements in measures of depression, hopelessness, self-esteem and alcohol abuse.

In-home injuries are a major source of health disparities in many neglected populations. Hendrickson (2005) developed a home safety intervention targeted at underserved Spanish-speaking populations with limited English language proficiency. The intervention offered a bespoke behaviour change counselling to minimise in-home safety risks and hazards, and the parents were given a brochure on injury prevention. The evaluation demonstrated high retention rates of safety improvements made in the home and improved self-efficacy for home safety behaviours.(333)

4.3.2.4. Leadership for quality and safety

Two reports were identified that discuss options for improving leadership for improved quality of care and safety for vulnerable children. Brenner and Freundlich (311) described the merits of a critical incident reporting system for learning from safety events involving children in foster care. The authors proposed a reporting tool for social workers to report predefined priority incidents with some requiring more urgent follow-up and action than others. The authors proposed a template for follow-up reporting that included what changes were planned and who was responsible for this process change. The tool includes a series of help screens to assist completion. A survey of users concluded the tool saved time, was easy to use, and helped to manage incident reports. Chin et al.(313) makes key recommendations about the ways in which healthcare organisations can introduce a quality improvement culture driven by performance data.

4.4. Updated programme theory with mapped literature

The programme theory (Figure 4.3), informed by analysis of incident reports, has been updated following the scoping review (Figure 4.5). The purpose of the scoping review was to identify the concepts used to improve the safety of care delivered to vulnerable children. Each intervention contained one or several change concepts and these were mapped against relevant, and sometimes multiple, manifest themes (secondary drivers). Such change concepts describe ways to minimise circumstances, actions or influences that initiate or increase the risk of an incident.

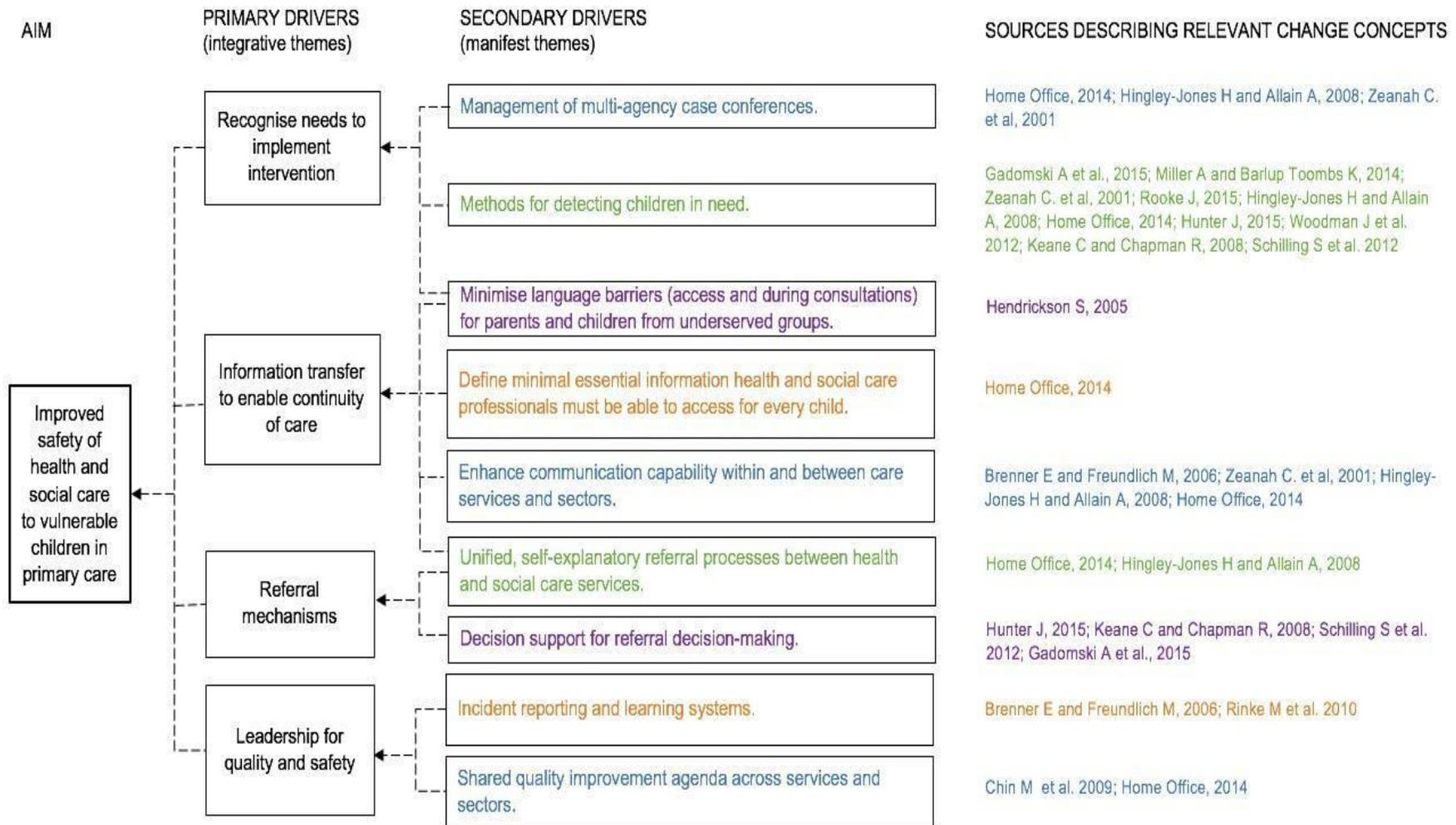


Figure 4.5. Updated programme theory with mapped relevant literature

Given the heterogeneity of contexts from which the described change concepts had been tested, summative judgements of their effectiveness are not considered although the study design is included for reference in Table 4.7. I have made a judgement about the strength of their proposed action in human factors terms (described in Table 4.4) in Table 4.7. For example, 'methods for detecting children in need' includes a range of concepts with weak, intermediate and strong actions. Alternatively, concepts informing 'management of multi-agency conferences' all demonstrate strong human factor actions. Strong interventions often require significant investment in staffing, finances, and redesign of processes. They require the team or organisation to commit to develop and test many changes before arriving at an infrastructure to enable sustainability of the changes that achieve improvement. Mapping the concepts to secondary drivers is intended to support ideas generating (for each concept) and not a means of prioritising which secondary driver should be tackled in an organisation first. Such priority setting should emerge from discussions within a QI project team and with stakeholders. This concept is demonstrated in more detail in chapter 5.

4.5. Summary of findings

In this chapter, I sought to outline a process for using incident report analyses to inform the design of improvement projects at a national level (objective 4a). I have demonstrated how a focussed analysis of incident reports using mixed methods processes, including the PISA coding frameworks (objective 2), can be used to generate a programme theory for improvement. Scoping review methods have been used to identify existing interventions that comprise change concepts that could support the mitigation of issues and redesign of processes for improved patient safety. In the next chapter, I will demonstrate how the mixed methods approach can be applied to another exemplar topic area (i.e. anticoagulation) in a local context.

Chapter 5 – Case study of a local incident reporting system

In the previous chapter, I illustrated the process for using incident report analyses to inform the design of QI projects using national level data (objective 4a). To address objective 4b, I will now present a case study that explores this process at a local level. Thus, I sought to understand how a reporting system can be used to generate learning for quality improvement in a healthcare organisation. The case study seeks to offer insights for strategies to guide development of similar systems in other organisations by exploring how a quality improvement team in an organisation can apply the PISA coding frameworks to generate and apply learning from incident reports in the context of anticoagulation. The Health Board was selected because it had developed an incident reporting system for GPs which is novel given the limited promotion of an incident reporting culture amongst primary care professionals.(96,183)

I will discuss how the methods and approach that I had developed were applied in the context of anticoagulation. The outline of this chapter is summarised in Table 5.1.

Table 5.1. Overview of chapter

Section	Description
5.1	As per the case study approach,(336) a description of why this case study is important given the emerging international interest in incident reporting systems.
5.2	Description of the case study method, including data sources and the conceptual basis of the analysis.
5.3	Description of the case including background information about the development of the reporting system and an outline of timeline of events for context, and identification of important challenges facing the management and leadership arising from learning derived from the reporting system.
5.4	Analysis of case study findings in relation to Senge's five disciplines of learning. (337)
5.5	Summary of findings.

5.1. Why this is an important case study

Major investments have been made internationally to establish incident reporting systems as leading mechanisms for patient safety learning in healthcare organisations.(338) There have been few evaluations of the effectiveness of incident reporting systems or their outputs at either a local or national level in healthcare, and there is little evidence to demonstrate how they can be effectively used to improve patient safety outcomes.(339) It is well recognised that incident reporting systems are limited by under-reporting, selective reporting, and incomplete reporting.(198) They are unable to inform estimates of the frequency and burden of incidents, and when compared to other methods of examining patient safety in organisations they often reveal different issues.(340) In terms of how organisations learn from incident reports, Waring (2009) cautions against transforming knowledge into de-contextualised 'narrow narratives' which is “de-authored and re-constructed to reflect managerial assumptions about learning”.(341)

In chapter 1, I described how patient safety incident reporting systems can be considered complex interventions to improve safety. There is mounting evidence that evaluations are not always well aligned with the intent and maturity of the intervention, and this can sometimes lead to a finding of no effect with what has been termed Rossi's Iron Law of Evaluation, defined as:

“The expected value of any net impact assessment of any social program is zero. This means that our best a priori estimate of a net impact assessment of a program is that it will have no effect. It also means that the average of net impact assessments of a large set of social programs will crawl asymptotically toward zero.”(342)

Summative judgements about the effectiveness of complex interventions risk oversimplifying the diverse range of contexts in which they function. However, a recent systematic review of 43 studies identified evidence that incident reporting systems can improve safety outcomes, although all authors acknowledged the difficulty in demonstrating a causal relationship since they are often embedded

within a wider programme of safety initiatives. There was some evidence of changes to clinical processes and insubstantial evidence of any cultural change or changes in mindset.(339) None of the studies included in the systematic review described incident reporting systems for primary care or general practice. The guiding question of my case study will be to explore how, and under what conditions, can an incident reporting system for general practice initiate learning to improve patient safety.(34)

5.2. Case study method

In this section, I will describe the methods used to undertake a case study of a quality improvement project to improve incident reporting from GPs at Cardiff and Vale University Health Board. It will explore how the Clinical Governance team in the organisation used the methods and principles from my research to analyse their locally-held patient safety incident report data, identify improvement priorities for a QI project in the organisation, and use QI tools to visualise their data and establish buy-in to make changes from stakeholders across the organisation and its general practices.

5.2.1. Funding of improvement project

The opportunity to serve as a 'quality improvement coach' at Cardiff and Vale University Health Board was funded by the (former) Translation, Innovation, Methodology and Engagement Institute at the School of Medicine, Cardiff University. My tuition fees were paid to enrol in a one-year Improvement Advisor Professional Development (IA) programme at the Institute for Healthcare Improvement in Cambridge, Massachusetts, USA. Throughout the IA programme, I was responsible for coaching a member of staff and their team to undertake a QI project at the Health Board.

The Cardiff University organisational sponsor was Professor Keith Harding, Dean of Clinical Innovation, and the Cardiff and Vale University Health Board sponsor was Miss Maureen Fallon, the then Deputy Director of Continuous

Service Improvement. For the duration of the project, I mentored a senior manager in the NHS organisation.

5.2.2. Ethical approval

The Cardiff University School of Medicine Research Ethics Committee provided ethical approval (SM REC 16/6). Informed consent has been obtained from the key participants (e.g. Clinical Governance Manager, Organisational Sponsor) that I directly refer to in the case study.

5.2.3. What is a case study?

A case study is an established research approach used to “explain, describe or explore events or phenomena in the everyday contexts in which they occur”.(336)

5.2.3.1. Stages of case study development

Crowe et al.(336) outline the following stages in the development of a case study:

1. Defining the case;
2. Selecting the case(s);
3. Collecting and analysing the data;
4. Interpreting data; and,
5. Reporting the findings.

I will describe each stage in sections 5.2.3.2. – 5.2.3.6.

5.2.3.2. Defining the case

A case study can be defined in terms of the research question it seeks to address; for example, can healthcare organisations use learning from incident reports to improve patient safety in primary care? It is empirically informed by existing evidence which defines the starting context or problem. In my case study, best available evidence suggested incident reporting systems did not improve outcomes in organisations.(339) My working theory was QI tools could

be used to visualise patient safety incident report data,(343) and increase awareness of issues apparent in incident reports received by the organisation. In terms of context, Cardiff and Vale UHB recognised that improving patient safety in primary care was an emerging priority for Welsh Government and internationally, and an improvement agenda was needed for the organisation.

5.2.3.3. Selecting the case

The focus of the case study was on anti-coagulation since this was an exemplar of how the Clinical Governance team applied QI methods to an improvement priority identified from analysis of incident reports. This case study represents an opportunity to understand how methods originally intended for national-level analysis and improvement initiatives may be adapted, and whether effective in the local setting, with similar objectives.

5.2.3.4. Collecting and analysing the data

A range of quantitative and qualitative data was collected during the improvement project. Such data are summarised in Table 5.2 in terms of the improvement and organisational contexts it represents.

Table 5.2. Case study data sources and description of content

Source	Description
<i>Improvement context</i>	
MUSIQ self-assessment survey	A self-assessment survey called the Model for Understanding Success in Quality (MUSIQ) that was completed by the organisational sponsor, project team leader and the improvement coach before the project and at nine months.(344) The self-assessment tool explored multiple contextual domains to permit identification of areas of weakness for development by improvement team / sponsors in the organisation.
Improvement project protocol	A copy of the original improvement project protocol written with, and agreed by, the organisational sponsor and Clinical Governance Manager (see Appendix 14).
Monthly project reports	Monthly reports to comply with the assessment requirements of the Institute for Healthcare Improvement 'IA programme' containing quantitative run charts and Shewhart charts and explanatory narrative.(30)
Field notes	Field notes defined as, "shorthand reconstructions of events, observations, and conversations that took place in the field" taken during fortnightly face-to-face meetings with the team leader,(345) and at key meetings in organisation (e.g. Quality and Safety Faculty) and with the Local Medical Committee (a statutory representative organisation for GPs in the geographical area served by health board).(346)
<i>Organisational context</i>	
Patient safety incident reports	Review of the original patient safety incident reports submitted by GPs to the organisation and data management processes for those reports in the organisation.
Internal communications	Internal documents produced by the Clinical Governance Manager relating to the project.(347)

Data were analysed using a Framework Analysis, which required repeated reviewing and sorting of the voluminous and detail-rich data.(292) An existing theoretical framework developed by Senge (337), arguably the most influential text on the concept of the learning organisation, was used to examine emerging themes against five disciplines of a learning organisation (see Table 5.3).(189)

Table 5.3. Five disciplines of a learning organisation (189)

Dimension	Definition
Shared vision	To establish a clear sense of purpose. This includes having conversations to shape the emerging agenda and build shared understanding and commitment, motivate the sharing of aspirations, and identify and address reservation and resistance amongst staff.
Mental model	To identify beliefs, values, mind-sets and assumptions that determine the way staff think and act.
Personal mastery	To manage change relationships sensitively, acceptance of having beliefs and values challenged and to ensure change interactions and related behaviours are authentic, congruent and principled.
Team learning	Teams learn by sharing experience, insights, knowledge and skills with each other about how to do things better. Teams develop reflection, inquiry and discussion skills to conduct more skillful change conversations and activities e.g. utilising tools like PDSA cycles.
Systems thinking	To examine inter-relationships underlying complex situations and interactions rather than simplistic (and mostly inaccurate) linear cause-effect chains. This will allow teams to unravel hidden subtleties, influences, leverage points and intended/unintended consequences of change plans and programmes and leads to deeper, more complete awareness of the interconnections behind changing the system.

5.2.3.5. Interpreting data

My role as a QI coach to the organisation,(348) with a vested interest in the processes for maximising learning from incident report data, risked introducing bias to my interpretation of the case study data. I sought to maximise the input of key stakeholders in the organisation through sharing monthly project reports (September 2012 to July 2013) with the organisational sponsor and project team for their critical input.

A copy of the draft report was shared with key stakeholders for respondent validation purposes where I sought consensus, and alternative explanations, for the conclusions reached through one-to-one meetings with an executive director, a middle manager, and a GP in the health board.

5.2.3.6. Reporting the findings

I co-authored a conference poster for presentation at an international conference with members of the project team (Clinical Governance Manager) and organisational leadership (Deputy Director of Improvement, Medical Director, Clinical Director, and Chief Operating Officer). A copy of the final report submitted for assessment by the Institute for Healthcare Improvement was circulated within the organisation, and an oral presentation was given to the organisation's Quality and Safety Improvement Faculty (a quarterly meeting to celebrate innovation that is attended by the organisation's senior leadership).

5.3. Details of the case study

5.3.1. Background to the local incident reporting system

In 2010, integrated Health Boards that brought primary and secondary care together into the same organisation were formed throughout NHS Wales. There are 67 GP practices in the Cardiff and Vale University Health Board in South East Wales, United Kingdom. During the merger, GPs raised patient safety concerns about the primary and secondary care interface relating to discharge, prescribing and shared care. The Local Medical Committee (LMC), the statutory representative organisation for GPs practicing within the Health Board's catchment area, felt that concerns that had been communicated to the previous secondary care organisations had not been acted upon. There was no formal or reliable incident reporting process in place for GPs.

The Health Board and GP practices recognised the potential to improve patient safety through the quality of communication, interaction and cooperation between the sectors. In February 2012, leaders from the Health Board and the LMC agreed to launch a system to enable patient safety incidents to be reported from general practice.

The new process for reporting was:

- GPs reported incidents via a clinical letter addressed to the relevant Clinical Directorate to enable investigation and response and a copy was

sent to the Primary Care Divisional Director and the Primary Care Clinical Governance Manager;

- next, the Primary Care Clinical Governance Manager reviewed the content of the letter and coded a short free-text summary of the incident in a Microsoft Excel spreadsheet, the name of the GP practice, and the date received by the team (see screenshot of database in Microsoft Excel in Figure 5.1); and,
- finally, the Primary Care Clinical Governance Manager acknowledged receipt of the incident by writing back to the reporter and liaised with relevant departments to ensure action.

A	B	C
Practice	Date Reported	Incident
	24.01.12	Warfarin - Inadequate discharge with Warfarin patient, no notification
	02.05.12	Inappropriate discharge, low INR & Warfarin regime changed whilst inpatient but not communicated to surgery
	11.05.12	Inadequate discharge, Warfarin poor communication
	15.05.12	Inadequate discharge, Warfarin
	14.06.12	Warfarin Chart after prolonged admission not provided to GP making dosing on discharge potentially unsafe
	10.10.12	Warfarin - Inappropriate request to primary care to commence Warfarin
	04.03.13	Request to initiate Warfarin
	07.03.13	Warfarin - Incident re: note on results advising "Practice Phoned" about high result. Practice made enquiries and is confident that no one rang the practice. Lab apologised and undertook investigation and the patient has not suffered any harm. Practices asked if this could be noted but no further action required. Also monitoring charts are not being made immediately available from wards and are no longer being faxed through.
	18.03.13	Warfarin - Inappropriate request to commence warfarin Warfarin - Dr [redacted] asked Practice to commence

Figure 5.1. Screenshot of warfarin-related incidents in database

The reporting system received 192 reports from GPs between February 2012 and December 2013. The system was separate to the paper-based incident reporting system used in the Health Board's hospitals.

5.3.2. Reporting system challenges

Several challenges arose in the first 18 months of the reporting system's functioning concerning the analysis of reports and the ability of the Health Board to provide a timely response to the concerns raised by GPs. As a result, the rate of reporting from GPs had decreased and there was a sense of dwindling interest in the reporting system as a result of the delays in action. Several reasons underpinned this:

- A Clinical Directorate Manager for each specialty in the Health Board had the responsibility to review the content of a report and consider the improvement options.
- Incidents were being considered in isolation (at the Clinical Directorate level) and not in conjunction with other similar incidents. Variable lag times existed between the receipt of incident reports and reporting back to the GP about actions to prevent future occurrences. In some cases, a delay of up to three months existed.
- Difficulty prioritising issues using data in the incident report database.
- Reports often required telephone follow-up by the Primary Care Clinical Governance Manager for more detail.

5.3.3. What the improvement team in the Health Board did

I will now provide an overview of how the Health Board addressed challenges to develop and maintain a functioning incident reporting system.

5.3.3.1. My role as an improvement coach

As an Institute for Healthcare Improvement-trained Improvement Advisor, I coached the Primary Care Clinical Governance Manager to: consider what the key concepts for change were described in incident report data by using the PISA coding frameworks to code incidents and contributory factors and consider the implications for systems redesign; and, identify the key issues to be discussed and described in emerging driver diagrams.

5.3.3.2. Accountability and ownership

The Chief Operating Officer (COO) established a taskforce mandating all Clinical Directorate Managers and Clinical Directors attend. Constituency leads from the LMC were invited to attend. Following the first task force meeting, several changes were made to the way the Health Board's leadership learnt about patient safety incidents occurring in primary care:

- a forum comprising primary and secondary care professionals and the LMC was established to enable better communication and joint working between the University Health Board (UHB) and GPs;
- the Primary Care Clinical Governance Manager was required to 'identify trends' and write reports to the Medical Director, and those reports were reviewed via a standing agenda item at Executive Board and LMC meetings; and,
- a primary care nurse kept an incident log and tabled it for review at weekly meetings with the Clinical Board Nurses and COO.

Finally, members of the taskforce recognised the initial will demonstrated by the GPs to report incidents. To acknowledge their concerns, and in an attempt to demonstrate incident reporting can support systems improvement, a pilot QI project was agreed to support the development of the Health Board's processes to learn from incident reports.

5.3.3.3. A demonstration anticoagulation pilot project

Anticoagulation-related incidents were the most frequently reported issue to the reporting system. Each report concerning anticoagulation had previously been sent to the relevant Clinical Directorate for investigation. However, by combining all anticoagulation-related reports, the Primary Care Clinical Governance Manager could undertake a brief content analysis of 27 separate incidents (18 from an 8-month period from 15 different practices) which revealed five main issues when displayed in a Pareto chart (Figure 5.2). The chart demonstrates the descending frequency of issues in the bars, and a cumulative total of reports represented by the overlying line graph.

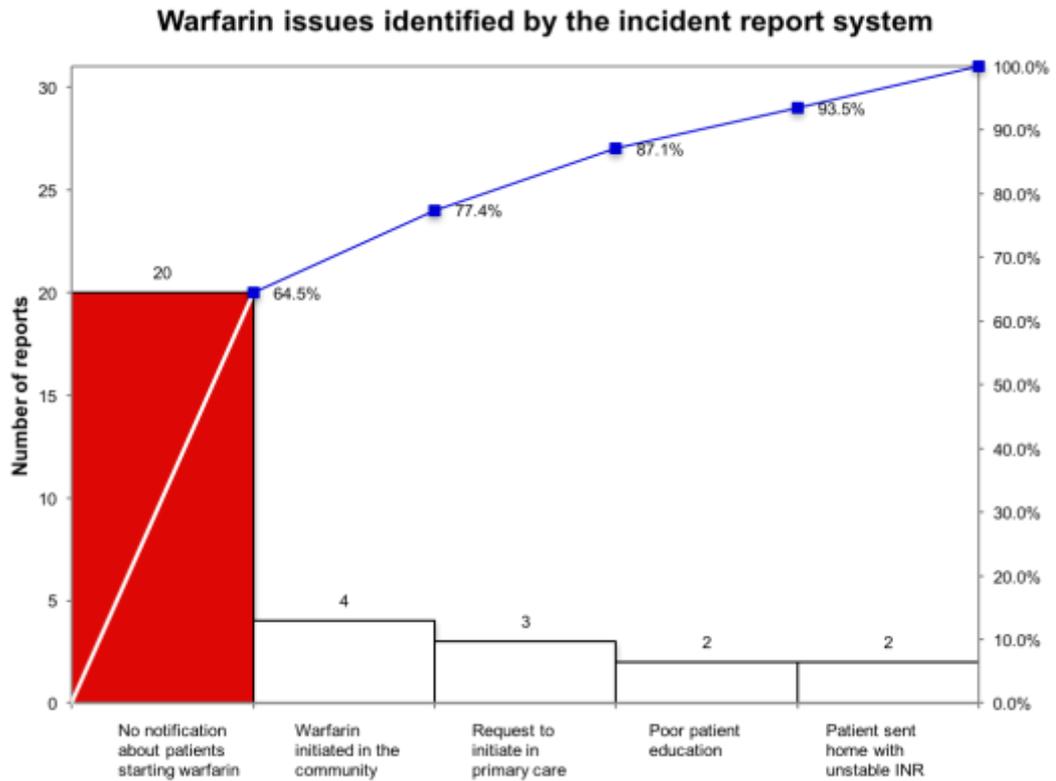


Figure 5.2. Pareto chart of warfarin-related issues *note: more than one issue identified in some reports*

Reviewing the incident reports in detail permitted the development of a first draft of a driver diagram. Three primary drivers, and related secondary drivers, were drafted based on the incident types and contributory factors identified in reports, and are summarised in a driver diagram (Figure 5.3).

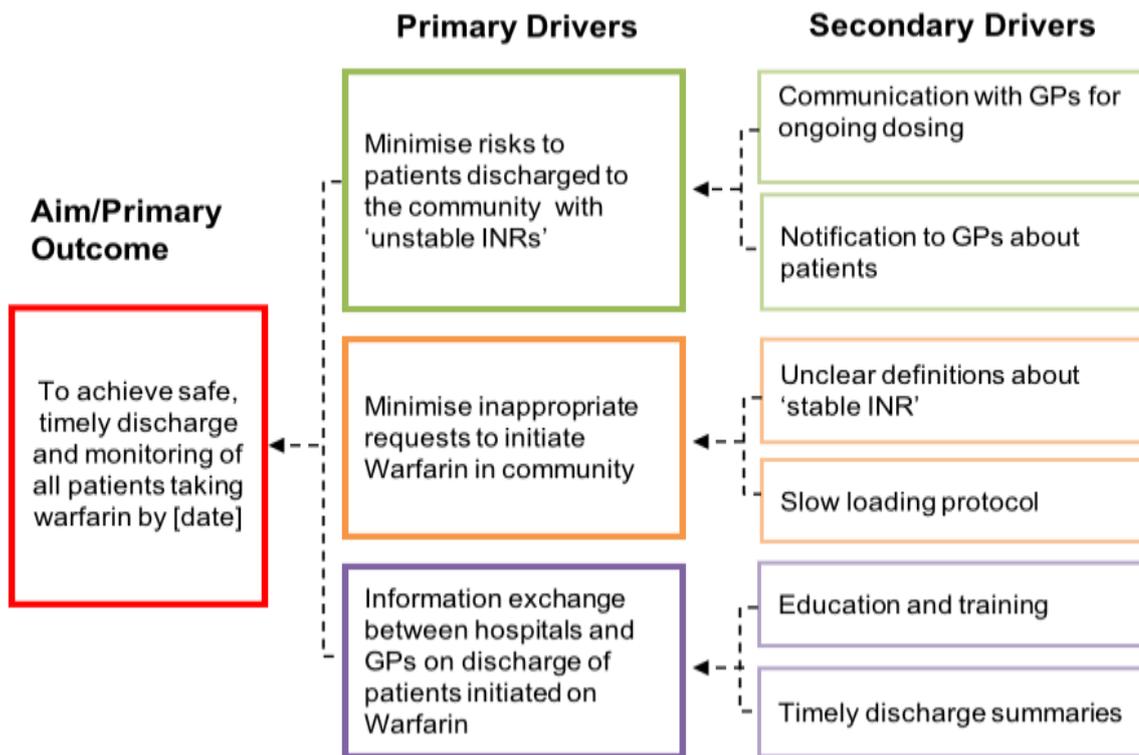


Figure 5.3. First draft of driver diagram (programme theory) for improvement of anticoagulation services

Findings from the incident reports were presented to hospital consultants at the grand round by the Medical Director. There, the consultants felt the delays in discharge were due to patients remaining in hospital to achieve 'stable INRs' and that this was not an issue that necessitated a hospital bed. They supported the development of primary care services for assuming responsibility for slow-loading warfarin. Next, a GP and secondary care forum with representatives from pharmacy and finance was convened to discuss options to mitigate the issues identified by GPs and hospital consultants. Those discussions were used to update the driver diagram (Figure 5.4) and permitted articulation of more specific and operational change concepts and ideas. For example, 'minimise risks to patients discharged to the community with unstable INRs' was updated to "Acute Rehabilitation Team to manage patients with 'unstable' INRs". The related change ideas for each 'secondary driver' became the basis of the QI project plans used by the Health Board to lead change in anticoagulation services.

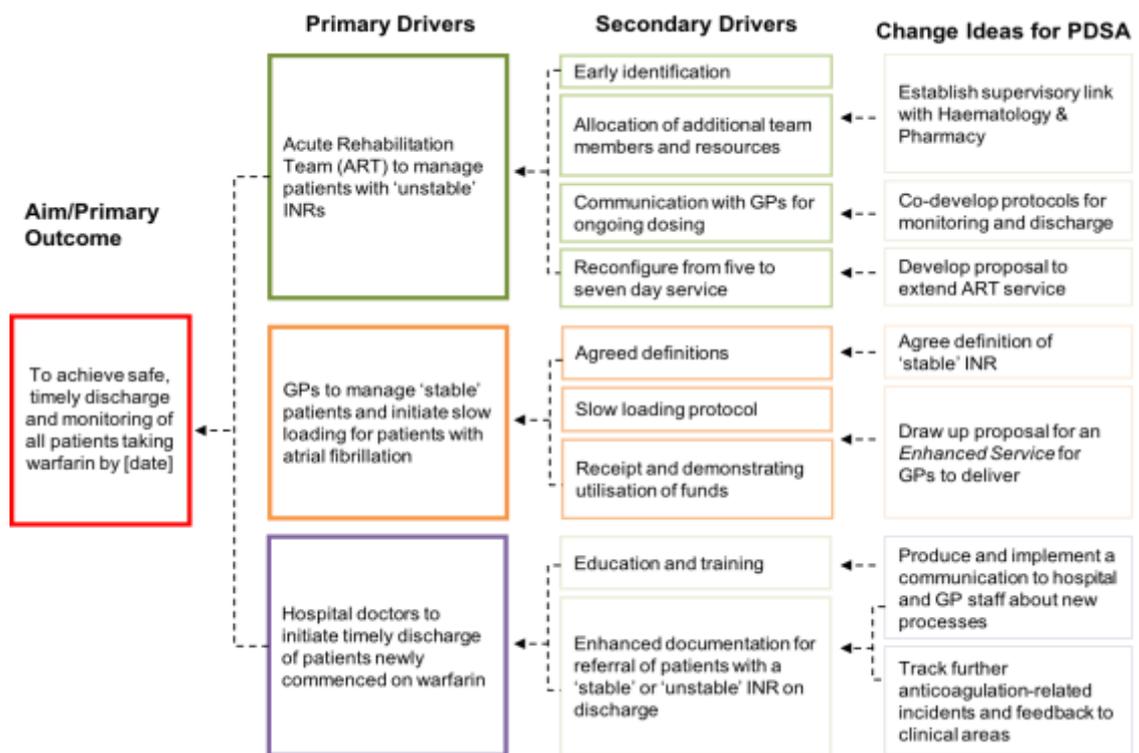


Figure 5.4. Updated driver diagram (programme theory) for improvement of anticoagulation services

5.3.3.3.1. Examples of Plan-Do-Study-Act (PDSA) cycles

A summary of the changes made by the team are listed in the 'Change Ideas for PDSA' column of the driver diagram (Figure 5.4). PDSA is short for 'Plan, Do, Study, Act'. This is a tool to structure and communicate plans for change by stating the objectives of each 'cycle' in terms of what will be done differently, predictions and identifying who is responsible for each process (i.e. 'plan'), carrying out the development or test and documenting problems and unexpected observations ('do'), analysing the data collected ('study'), and considering what has been learnt to inform future developments and tests ('act').(30) Throughout the project, some changes were made simultaneously, whilst others required a sequential approach where learning from one change informed the next (see Figure 5.5).

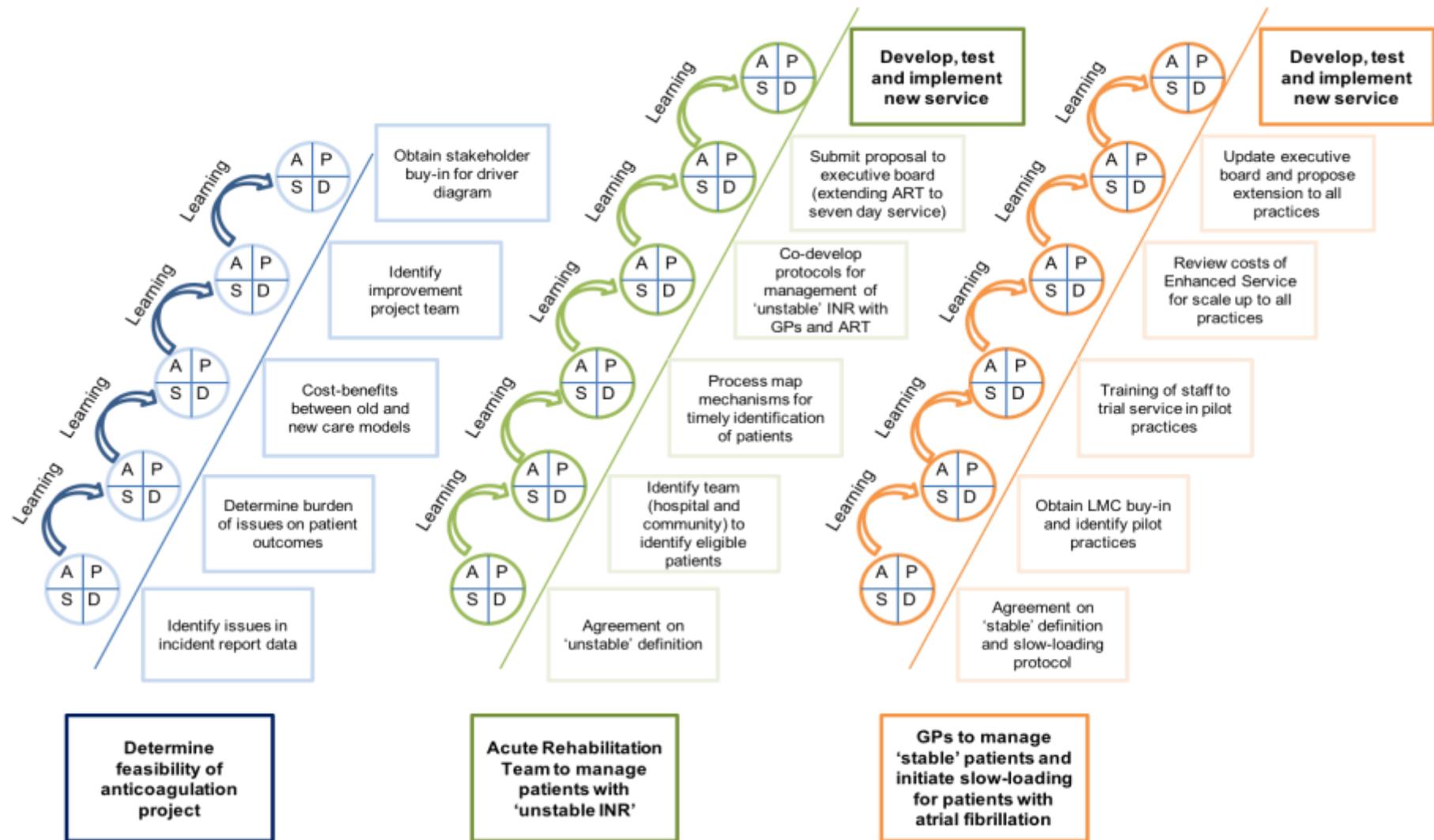


Figure 5.5. Summary of PDSA cycles

An example outcome from a PDSA includes a cost-benefit analysis of efforts to minimise warfarin-related incidents for patients. The full PDSA cycle is described in Appendix 15. In brief, to complete the PDSA cycle, the quality improvement team planned to collect data about existing practices (e.g. length of stay of patients started on warfarin) and their consequences, and considered how a new model of working would function (e.g. the number of trained staff required, anticipated cost of enhanced service provided by general practice, amongst other variables). Using administrative data, the Primary Care Clinical Governance Manager and an Anticoagulation Pharmacist identified 25 patients over a calendar month who had a delayed discharge whilst awaiting a 'stable INR'. The finance team estimated this cost to be £38,874 per month, with overall unnecessary hospitalisation costs being £466,488 per annum. Estimated costs were next drawn up for each of the proposed changes. The difference between existing practice and the proposed new models of practice demonstrated a potential cost saving of around £300k per annum (see Figure 5.6 for the breakdown of costs).

INR MONITORING SERVICES								
UHW - WEEKLY CLINICS (HAEM OUTPATIENTS)		Hrs/Clinic	Clinics/wk	Total weekly hrs	Cost/hr	Total weekly cost	Annual Cost	
	Consultant Haematologist	2.0	2	4.0	£50	£200	£10,429	
	Haematology SpR	2.0	2	4.0	£27	£110	£5,718	
	Pharmacist	4.0	2	8.0	£25	£200	£10,429	
	Pharmacy technician	4.0	2	8.0	£15	£120	£6,257	
STAFF COSTS, UHW							£32,833	
UHL - WEEKLY CLINIC (HAEM OUTPATIENTS)		Hrs/Clinic	Clinics/wk	Total weekly hrs	Cost/hr	Total weekly cost	Annual Cost	
	Consultant Haematologist	4.0	1.5	6.0	£50	£300	£15,643	
	INR Nurse	2.0	1.5	3.0	£22	£66	£3,435	
STAFF COSTS, UHL							£19,078	
TOTAL STAFF COSTS							£51,910	
DTOC IMPLICATIONS								
DTOC bed day pressures, per month							£38,874	
TOTAL ANNUAL BED DAY SAVINGS							£466,488	
IF SERVICE DELIVERED IN PRIMARY CARE								
PATHWAY 1 - INR				WTE				
Est cost to transfer stable f-up ptnts out to PC ES monitoring:				£	183.51			
average drug costs, per patient (warfarin)				£	47.67			
estimated no. patients / year					176			
					Consumables costs	£ 40,687.09		
					PATHWAY 1 TOTAL		£40,687	
PATHWAY 2 - SLOW LOADING ATRIAL FIBRILLATION (AF)				£				
dependent on "Level" of patient seen								
average cost per patient (Level 4)				£	120.00			
average drug costs per patient				£	5.50			
estimated no. patients / year					350			
					Consumables costs	£ 43,925.00		
					PATHWAY 2 TOTAL		£43,925	
PATHWAY 3 - ACUTE RESPONSE TEAM (ART)				£				
Community Nurse				£	2.0	75.0	£22	£1,650
							£86,036	
TOTAL STAFF COSTS							£86,036	
dependent on "Level" of patient seen								
average cost per patient (Level 4)				£	61.00			
average drug costs per patient				£	1.83			
estimated no. patients / year					300			
					Consumables costs	£ 18,850.00		
Coagucheck machines x2						£2,000.00		
						£ 20,850.00		
					PATHWAY 3 TOTAL		£106,886	
					PRIMARY CARE SERVICE DELIVERY TOTAL		£191,498	

Figure 5.6. Business case calculations comparing old and new models of INR monitoring

Once the pilot anticoagulation project launched, the Health Board communicated learning from PDSAs back to LMC representatives at the primary and secondary care forum. There is some evidence in the Shewhart chart in Figure 5.7 (a graph to examine data for special causes of variation) that the pilot project's initiation had some impact on increased reporting rates and in prompting practices that had not previously used the system to report. The overlying cumulative frequency chart (Figure 5.7) demonstrates this might have

contributed to a change in mindset for GPs that had not previously reported an incident to the reporting system.

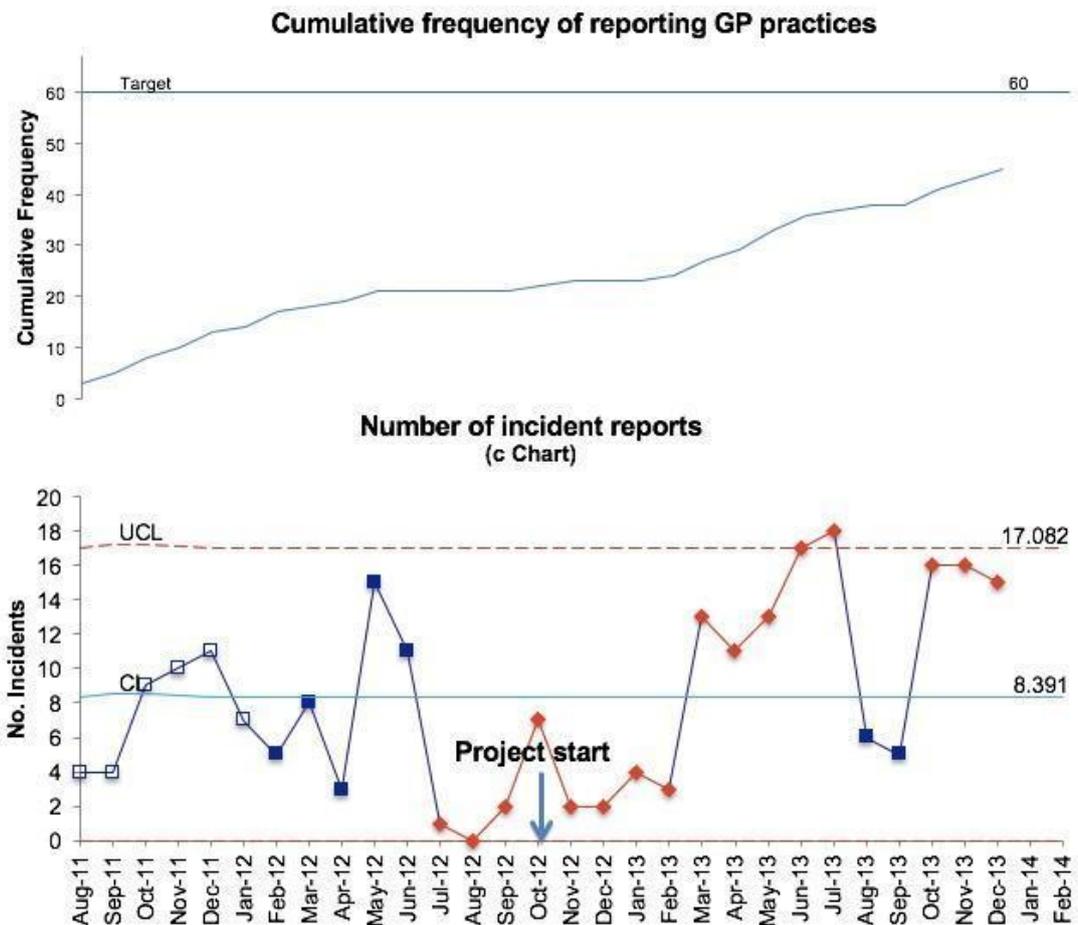


Figure 5.7. A control chart to demonstrate frequency of incident reports and an overlying cumulative frequency chart of the number of new reporting practices (red dots signify identified special cause variation)

The upper control limit (UCL) in Figure 5.7 represents the limits of process variation for the number of reports received. The chart demonstrates from October 2012, following initiation of the task force, there was evidence of 'special cause variation' (denoted with red dots adhering to the following rules suggestive of a non-random process: at least one point more than 3σ from the centre line and four out of five points more than 1σ from the centre line) which the team believed could be due to the increased number of new practices submitting incident reports which is apparent on the cumulative frequency chart

above.(349) The increase in reporting practices corresponded with the initiation and delivery of the pilot anticoagulation project (March 2013 onwards).

5.3.3.4. Outcomes from the project

The task force remains a fixture in the Health Board to pick up and respond to incidents and trends are captured via the incident reporting process and to agree a way forward to address issues. A formal report on patient safety incidents and investigative outcomes remains a standing agenda item at the LMC and UHB Executive Board. All general practices in the Health Board now deliver the enhanced service. A reimbursement of £120 for initiation / slow loading of warfarin, and £150 per annum per patient for ongoing management, has been agreed for the provision of INR monitoring and a warfarin dosing service. This direct enhanced service has since been extended across Wales, for all Health Boards and their general practices, via the General Medical Services Contract with effect from April 2017.

When asked, “What impact has the quality improvement project made in Wales?” a Senior Welsh Government leader replied:

“At the national level, there was some recognition of the need to update enhanced services but this work was a useful driver. This [project] described the systems we all acknowledge should be in place and allowed us to compare what was actually happening and showed us what needed to be updated.... It was also helpful to challenge any criticism of GPs, “they won’t change” as we could show that engagement improves as soon as systems are made to work effectively. [The work led in the Health Board] was a good example of a *once for Wales* approach...we don’t all need to repeat that learning.”

5.4. Analysis in relation to Senge’s five disciplines of learning

I have outlined the definitions for each of Senge’s five disciplines of learning in Table 5.3.

5.4.1. Establishing a shared vision for the project

The Health Board recognised that post-merger morale was low amongst the GPs. It demonstrated tangible engagement and action by its leadership in support of patient safety by initiating the COO-led task force. The Assistant Director of Improvement commented:

“Intervention was needed. The Health Board was taking months to acknowledge safety concerns raised by GPs. There were apparent bottlenecks in our communication processes to review and take action for each incident report. The task force enabled us to highlight those bottlenecks, restructure the way we reviewed progress and receive updates on actions being taken in each clinical directorate.”

The task force helped to establish a shared sense of purpose that the learning from the incident reports that GPs had taken the time to complete mattered to the Health Board. As the Assistant Director of Improvement, added, “These are the issues and solutions [they] have reported... the [Health Board] was listening to them.”

A first draft of a programme theory for change was developed from incident reports using PISA coding frameworks and related methods. This was the basis for the quality improvement team to subsequently co-develop (iterate / amend) the theory by inviting feedback from both primary and secondary care stakeholders. All improvement plans were agreed and signed off jointly by the LMC Chair and Medical Director which also imbued a sense of collaboration. To inform those decisions, multiple forums provided input to deepen understanding about the challenges faced by healthcare professionals in community and hospital settings.

“By being able to sort the reports into similar incidents and think about their underlying causes, it was possible to harness the perspectives of GPs, which I think as [a Health Board] we had never really done before, and create a sense of urgency for change.... One [member of staff] wrote

to me saying how this project was finally achieving what the [Health Board] had been talking about doing for upwards of ten years!” (Primary Care Clinical Governance Manager)

The driver diagram (Figure 5.4) was an effective tool for displaying the programme theory and for orientating different stakeholders (executives, managers, and clinical leaders) to the key concepts and ideas for change. Strong support emerged to proposed changes. The Primary Care Clinical Governance Manager reflected on where she believes the origins of this support emerged:

“We took a long-standing, seemingly intractable problem [warfarin-related safety incidents] and demonstrated we were listening to how this impacted the GPs. We summarised their ideas as plans for change in a single driver diagram instead of a lengthy written proposal.... [the stakeholders] liked seeing a summary of these complex issues on one page, it engaged them. The proposed ideas were their ideas.”

5.4.2. Inclusivity of multiple mental models

The driver diagram represented an attempt to portray a summary of problems with the existing system. Such a concise overview permitted each stakeholder group to consider their own experiences in relation to the issues presented. Task force meetings provided an opportunity for multiple stakeholders to assimilate the feedback gained from discussions and presentations to wider groups of professionals and agree by consensus on the plans described in the driver diagram.

The pilot QI project helped build a mental model (considered by Senge in terms of the conceptual frameworks that influence how we view the world and act in it)(189) of ‘what’s possible’ for the GPs, the leadership and the hospital professionals by undertaking a focussed analysis of incident reports and discussing what changes were needed. It was important to understand the

different perspectives on the problems identified by the incident reports; as a Senior Welsh Government leader described it:

“GPs tend to identify and deal with issues within their own sphere of influence; they are reluctant to spend time trying to address wider issues where timescales are slow and processes appear complicated”.

Bringing representatives from multiple stakeholder groups from the Health Board’s leadership and management, and a range of primary and secondary care professionals and leaders from disciplines such as medicine and pharmacy, permitted a combining of perspectives. The Health Board’s Patient Safety Manager commented, “...everybody who needed to be there to make a decision, take action to enact a change or to measure the impact of those changes, were all there each week.” The pilot project increased confidence in the value and utility of incident reporting systems for informing improvement agendas:

“...we noticed that once we started to acknowledge the concerns raised by the GPs and provided them with feedback about our plans for anticoagulation via their LMC representatives, new GP surgeries became vocal and started submitting their own incident reports. We were measuring the rate the reports were coming in and our charts suggested our activities were instilling confidence amongst GPs that had never previously reported an incident to the Health Board. [see Figure 5.6]”
(Primary Care Clinical Governance Manager)

5.4.3. Managing change relationships (personal mastery)

The improvement team used different formats of communication to disseminate learning. An emphasis on getting opinions on the proposed plans and willingness to accept additions and amendments demonstrated inclusiveness. Communications with GPs and hospital doctors were managed via their leaders who explicitly sought feedback on the proposed changes in the driver diagram. Identifying ‘big ticket’ opportunities for the QI project that emerged from their incident report data helped to secure early buy-in from GP and hospital leaders for the pilot project. Similarly, the creation of a business case based on staff

concerns and ideas for improvement, which also had cost-saving implications, secured commitment from senior leadership. A senior Welsh Government leader commented:

“As soon as the governance team showed real commitment to act the reporting increased, which gave the team more data to challenge areas within the hospital setting.... They also built a case about the risk and made it uncomfortable for [the Health Board] to ignore. I think this led to interest in solving the problem which was recognised as an organisational problem not a ‘GP Issue’...”

The COO mandated attendance at the task force for the Health Boards senior leadership. The Health Board’s response time to GPs, and the action arising from what was learnt, became an escalated priority for all leaders attending the task force.

“The meetings were regular, they were minuted, and each clinical directorate leader or representative had tasks to complete by the next meeting.” (Assistant Director of Improvement)

5.4.4. Team learning

A structured approach for developing and testing changes in practice called the Model for Improvement enabled focussed inductive-deductive learning cycles via PDSAs (Figure 5.5). Some PDSAs took several months to move from development to implementation in practice; for example, in October 2012 a definition of a stable INR was agreed with implementation of the new agreed definition in February 2013. Such developments and tests of change required negotiation, consensus, and such complex transactions required trust between leaders and representatives.

Nine reports described issues with management of patients with unstable INR or initiating warfarin in the community.

“Although they were few in number, the reports described nine less than optimal outcomes for our patients. You couldn’t overlook these nine essentially stories about patients that might have had excellent care

during their stay and at the final hurdle had their experience and safety compromised because of poor communication and unclear awareness by secondary care physicians about what was realistic and is delivered by primary care.” (Primary Care Clinical Governance Manager)

Although few in number, a PDSA was agreed to develop consensus around a definition of ‘stable’ INRs and a protocol for slow-loading in the community. Improvement team members with tacit knowledge were able to explain why such requests to ‘slow-load’ warfarin in the community were not feasible given the constraints on GPs to deliver such services safely. Changes ideas were identified that could enable community services to assume responsibility, and this informed the subsequent discussions about a contract to deliver an enhanced service in general practice. It also identified knowledge gaps in what secondary care clinicians presumed was possible in the community.

“If anybody was unclear about what we were doing or why we were doing it, they could read the PDSA sheets. [Appendix 15] These took me a long time to fill out at first but I’m glad I did it now because they were useful to share at meetings.... Brought us onto the same page...” (Primary Care Clinical Governance Manager)

5.4.5. Systems thinking

The project, and its leadership, demonstrated the benefits of seeking multiple perspectives whilst attempting to understand what and how the system could be improved in the interests of improved safety. The initial insights from incident reports became the basis of further discussions about what changes were needed to improve anticoagulation safety.

“The incident reports from GPs helped the consultants realise the implications of the actions by junior members of their team, and in some cases themselves.” Assistant Director for Improvement

The task force chaired by the COO was initially created to clear a backlog of unresolved safety incidents reported by GPs within the Health Board. Members of the task force were chosen since they were identified as being essential for

improvement in the departments where issues had been highlighted by GPs about secondary care services. The taskforce therefore played an important role in pushing forwards many challenging structural changes in the project. For example, securing the commitment from each Clinical Directorate to provide a named representative to receive reports demonstrates a will to support a timelier process of investigation, resolution of ongoing or outstanding issues, and feedback to the reporting clinician. The anticoagulation project helped convince stakeholders that using incident reports to inform improvement projects can be an effective means of engaging clinicians and identifying drivers for change. The task force comprised diverse representation from multiple hierarchical levels in the Health Board.

5.5. A model for local incident report-driven improvement projects

Drawing together the learning highlighted in this case study, combined with my previous work analysing homogenous volumes of incident reports (chapter 4), there are apparent stages (and related objectives) to support incident report-driven improvement. I have summarised these stages in Figure 5.8. The case study highlights the benefits that can be yielded from undertaking objectives 1 and 3 at the outset of an improvement project. Objectives 4-6 represent my post-hoc reflections on the benefits of updating and amending a programme theory arising from the activities to achieve objectives 1–3, and throughout the project. A scoping review of the literature was not undertaken for the project described in the case study. However, my subsequent research and development work highlights this can be beneficial for outlining existing options available to inform improvement plans.

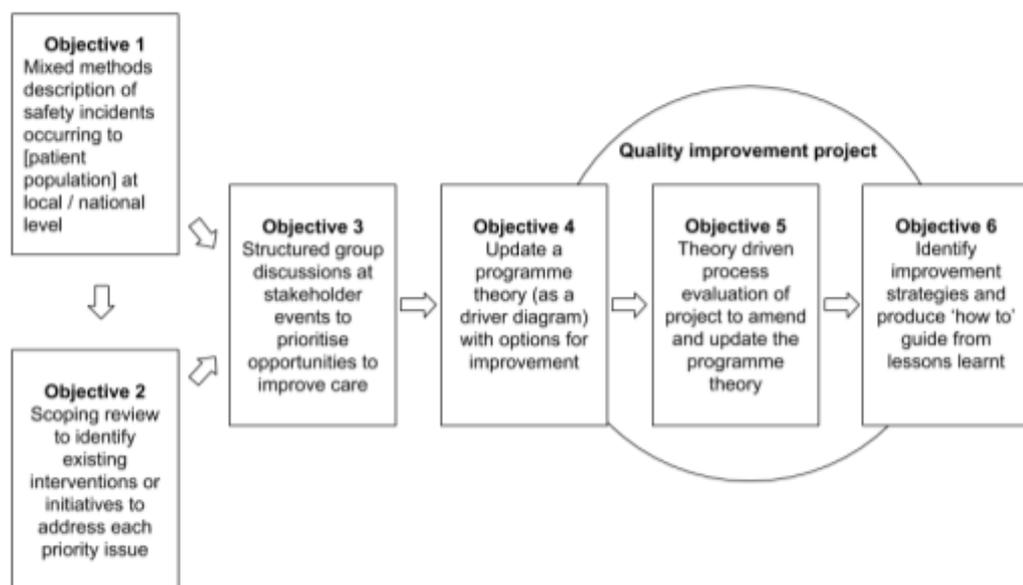


Figure 5.8. A model for an incident reporting system-driven patient safety improvement project

5.6. Conclusion

An analysis of incident reports at a local level, using a structured approach to analysis including the PISA coding frameworks and related methods, can be used to generate a programme theory for a QI project within a healthcare organisation. Initial themes identified from reports can be used to guide more in-depth discussions with relevant stakeholders. QI tools like a driver diagram can be used to invite key stakeholders to amend and update the theory. A model for incident report-driven improvement is proposed. Evidence exists to demonstrate how learning from incident reporting can support a healthcare organisation to work towards fulfilment of the criteria outlined in Senge's five disciplines of a learning organisation.

Chapter 6 – Discussion of methods

6.1. Overview of chapter

A structured, mixed methods process has been developed to generate learning from incident reports. An outcome of this process can be a programme theory for change. The coding and analytical process has been designed to be replicable in healthcare organisations. A QI tool called a driver diagram can summarise the emerging draft programme theory. Scoping reviews and QI methods to engage stakeholders can be used to update and amend the programme theory for change.

To begin to address objective 5 of my thesis, which is to: “Propose areas for future research and development to improve the ability to generate learning from patient safety incidents.”, I will reflect on the conceptual approaches taken to analyse patient safety incident report data, and I will describe the lessons learnt from the application of methods developed and / or applied to achieve study objectives 2-4 (objective 1 was discussed in chapter 2).

6.2. Reflection on conceptual approach

I have outlined the conceptual decisions made to address my research objectives in section 1.6.1 of chapter 1. In this section, I will now reflect on how:

- Dewey's [pragmatic] systematic approach to inquiry, aligned with the mixed methods paradigm, has encouraged a reflexive process of development and testing to promote learning throughout the thesis (objectives 1-5); and how,
- Reason's Trajectory of Accident Opportunity has served as the basis for aligning the concepts and definitions from WHO ICPS to process incident report data to identify priorities and generate learning for improving safety in general practice (objectives 2-4).

6.2.1. Dewey's systematic approach to inquiry

Dewey's approach promoted a philosophy of continuous improvement of several processes throughout the PhD within the context of the limitations of incident report data and the intended research objectives, particularly:

- the development of codes, their definitions and rules for application;
- a systematic approach to exploratory descriptive analysis;
- sensemaking of aggregates of incident reports to propose areas with the greatest need and opportunity for future intervention strategies to improve patient safety in general practice; and,
- efficient approaches to identify existing interventions and initiatives to inform the design of improvement projects.

6.2.1.1. Sources of learning

The pragmatic paradigm supported my intentions to learn from both development and application of ideas throughout the PhD. In relation to Dewey's systematic approach to inquiry (Figure 1.7 in chapter 1), many cycles of learning between beliefs and actions occurred in order to develop and apply

the methods to achieve the study objectives. I outline this learning in more detail in section 6.3.

My prior experiences of analysing incident report data,(350–352) and awareness of the debate concerning the limitations of these data amongst clinical and informatics communities,(183,353) influenced my judgements about the methodological approaches needed. Thus, I acknowledged those prior beliefs at the outset of the study, and sought to appoint a balanced professional advisory group to achieve consensus on issues that might be biased by my own principles and intentions. The professional advisory group was comprised of policymakers, health services researchers, primary care patient safety researchers, and human factors experts. My diverse group of (grant) collaborators included epidemiologists, academic GPs, statisticians and sociologists.

Meetings with collaborating colleagues and professional advisors, and experience from submitting and responding to peer review comments for pilot manuscripts submitted to journals, have advanced my ideas and understanding of the developed methods for generating learning from incident reports. The initial Professional Advisory Group meeting in Cardiff in July 2014 challenged my original analytical plans proposed to the National Institute for Health Research to address objectives 2 and 3. Pilot work which I conceptualised and supervised informed those discussions and has since been published in *Pediatrics*, *Vaccine*, the *British Journal of General Practice* and *PLOS Medicine*.(36,257,354,355) Further, my professional preparation as an Institute for Healthcare Improvement trained QI coach, and role in coaching an organisation to utilise the methods developed for analysis of large volumes of incident reports (chapters 3 and 4), has influenced my beliefs about the transferability of the methods developed (objectives 2-4) for use in healthcare organisations (chapter 5).

6.2.2. Reflection on Reason's Trajectory of Accident Opportunity

The conceptual basis of systems thinking as described by Reason provided a sound theoretical base to apply WHO ICPS concepts and definitions.(2,356) A structured ordering of codes was required to deconstruct incident report narratives whilst retaining their meaning (see Figure 6.1). The implied chronology of incidents with the trajectory was intuitive and permitted the application of the Recursive Module of Incident Analysis rules about the relationships of concepts.(288) Combined, this permitted training of multiple clinicians to simultaneously review reports with strong concordance.

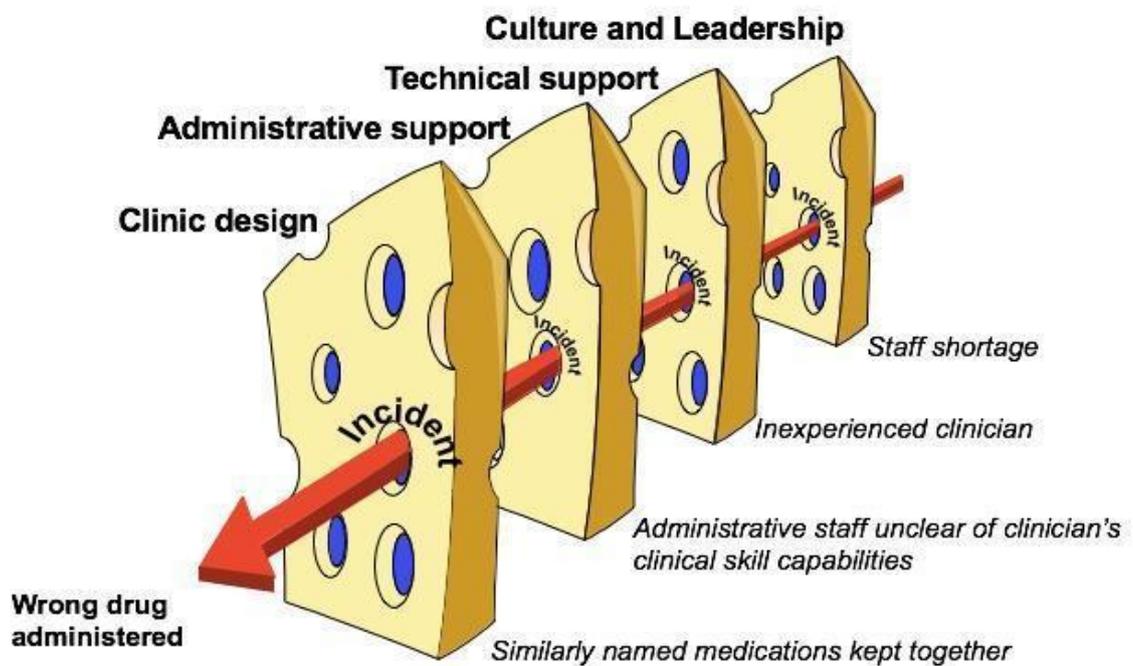


Figure 6.1. Trajectory of a patient safety incident applied to the Swiss cheese model

The Swiss cheese model was also helpful in the development of incident type and contributory factor classes. The concepts of 'contributory factor' and 'contributory incident' resulted in considerable overlap of classes and their inherent codes in early piloting. The holes in the cheese represent incidents arising from human error and contributory factors which are the system conditions in terms of influences from patient, staff, environment, organisational

policies, and equipment. Nine rules were used to conceptually organise the relationships between incidents, contributory factors and outcomes (see Table 3.4 in chapter 3). For example, “Rule 2: An incident can be a contributing factor to another incident” (as seen in Figure 6.1). The study team was supported by Mr Peter Hibbert (a human factors expert and one of the original developers of the Advanced Incident Management System) to make sense of those rules, apply them, and identify which codes belong in each class and why (described in more detail in section 6.3.2).

6.3. Learning from applying methods

A fundamental objective of this thesis was to develop methods to characterise the content of incident reports, and discussions within the coding team and the wider professional advisory group informed decisions about balancing the objectivity and subjectivity of reviewers (section 6.3.1); the development of the PISA coding frameworks aligned to WHO ICPS (section 6.3.2); and, the development of the data management system (section 6.3.3).

6.3.1. Trade-off between explicit and implicit judgements

A pilot analysis of applying the PISA frameworks to incident reports revealed they were often written in shorthand, and were jargon- and acronym-laden. This implied there could be some expectation from reporters for issues to be inferred by the healthcare professionals or managers reading and responsible for actioning the report.

There is a risk of confirmation bias when researchers analysing incident reports attempt to validate pre-existing hypotheses about the data by drawing on their clinical experiences. For example, seeking to identify the information in reports that would corroborate the contributory factors they had pre-conceived before fully reviewing the incident. Similarly, a risk of frequency bias exists when the researchers become familiar with particular contributory factors because they are observed most often.⁽³⁵⁷⁾ As Javaux, cited by Johnson,⁽³⁵⁷⁾ cautions, subsequent similar incidents are likely to be classified according to the

commonest codes used to describe incidents irrespective of whether an incident is actually caused by those factors. Similarly, recognition bias is possible when researchers have a limited vocabulary of codes to describe incidents which do not necessarily reflect the complexity or conditions of what is described.(357)

To achieve consistency in the application of codes, per the Recursive Model of Incident Analysis,(288) my collaborators and I decided that codes must represent what is explicitly stated in the narrative, not inferred by the clinical reviewer. The decision was based on an iterative approach involving regular discussions that drew upon our collective experiences of analysing incident reports and learning from the application of emerging coding frameworks to pilot samples of data. This approach minimised subjectivity and meant discordance discussions primarily concerned misunderstandings about definitions of codes rather than the interpretation of the incident report content. Overall, this process permitted informed decision-making about coding, training and quality assurance processes.

To capitalise on the 'soft intelligence' inherent within incident reports (described earlier in section 1.5), I believed it was important to utilise the clinical expertise of reviewers.(192) Once the most frequent and most serious incidents had been identified, clinicians were instructed to re-review the content of similar reports to aid interpretation of the relationships between codes. This permitted a clinician-oriented description of aggregated reports, as well as to identify apparent themes between similarly grouped reports. These were integrative and manifest themes that described the identified opportunities to intervene for systems improvement.

6.3.2. PISA framework development

Development of a comprehensive PISA coding framework, aligned with WHO ICPS, to characterise safety incident reports in general practice has permitted the description of events leading up to patient safety incidents, their reported contributory factors (human and system issues), and patient- and system-level outcomes. Four independent classes (a description of the incident, its

contributory factors and the type and level of harm) should provide sufficient minimal information for practising healthcare professionals to identify learning for improvements in future practice from the reports.

The manual coding of reports was a resource-intensive process in terms of the application of codes and the development of the code book. Codes within each class were inductively added and amended throughout the study, with fewer iterations needed towards the end of the study. Given the shared 'contributory' nature of contributory incidents and contributory factors, codes were assigned to the 'incident' or 'contributory factors' framework based on strict adherence to the definition of those concepts i.e. codes for descriptions of what happened were included in the incident framework, and codes for description of why an incident occurred in terms of circumstances, actions or influences were included in the contributory factors framework. Regular team meetings held to discuss such changes should be emulated by those responsible for the analysis of incident reports within healthcare organisations to permit a shared understanding of codes, their definition, and application.

The PISA coding framework was designed to be aligned with the conceptual framework for the WHO ICPS.(2) As demonstrated in chapter 2, multiple classification systems exist to characterise incident report data. Given their heterogeneity of codes and related definitions, there is a strong push from WHO for the uptake of ICPS to enable international comparison and identification of shared learning. Given its conceptual alignment, the PISA coding frameworks could be considered for uptake in healthcare systems internationally.

The pilot analysis and discussions with the professional advisory group carefully considered what classes from WHO ICPS were essential to characterise safety incidents occurring in general practice.(2) ICPS contains 10 high level classes with 48 inherent concepts. This was deemed too granular for application to incident report data (as opposed to other data such as root cause analysis reports) on account of incident reports containing free text description of 'what happened', 'perceived contributory factors' and 'actions to prevent recurrence'. Several more in-depth considerations were made during the development of the

coding frameworks. For completeness, to summarise this learning from my research, reflections are made on the Desiderata for the design of a controlled healthcare vocabulary outlined by Cimino (described earlier in Table 3.5 in section 3.1.6.2) in Table 6.1.

Table 6.1. Reflections on the Desiderata for the design of a controlled healthcare vocabulary. Modified from Cimino (298)

Desiderata	Learning from research
Concept orientation	The code name should clearly articulate its meaning.
Concept permanence	Given the exploratory nature of the study, this desideratum raises an important consideration about the content of the final coding frameworks for external users and how they should update / amend these. During the development and initial application of the classes to the incident report data, it was essential to iterate and capture the learning from empirical analysis of incident reports.
Meaningless concept identifier	The Trajectory of Accident Opportunity model is the conceptual basis for structuring and ordering the application of codes. Code-dependence is essential as it implies a relationship between codes for a given context. Hierarchical relationships are important for this purpose e.g. '7.1.4.2. Dose dependent drugs' is a 'child' of '7.1.4. Responding to results'.
Polyhierarchy	Polyhierarchy was deemed important providing it was clear how the definition of the code (e.g. administering) would differ given its relationship to the parent code (e.g. vaccine or drug).
Formal definitions	Semantic definitions underwent regular review, and as new reviewers joined the research group, their review / identification of definitions that were vague or ambiguous was sought.
No residual categories	Residual categories were created as exclusion categories. Given the purpose of the projects was to characterise the content of incident reports, this also required description of what was reported as an incident but was not deemed to be an incident by clinical reviewers. Understanding what gets incorrectly reported is an important learning opportunity and one which should be encouraged in healthcare organisations.
Multiple granularities	Other systems have enabled multiple levels of granularity, particularly for diagnosis, by incorporating for example, International Classification of Disease (ICD) codes into the

	coding frameworks.(195) There was no perceived benefit of adding this layer of complexity for the clinical reviewer given the research objectives and the perceived limited value added from this approach.
Multiple consistent views	A focus on essential classes to represent what happened, perceived reasons why and planned actions to prevent recurrence. Given the complex nature and variable descriptions in reports, we agreed it was acceptable that codes may appear in a different order in rare cases. It was, however, not acceptable for different codes to be present; for example, selection 'failure to call an urgent ambulance' instead of 'prescribing error'. Inter-rater reliability checks were undertaken for 20% of the total coding. This enabled focussed discussions about discordance concerning the type of patient safety incident, and largely identified any misunderstanding about code definitions. Where relevant, reviewers brought issues concerning vague or, ambiguous definitions to weekly meetings for discussion and, if appropriate, action. Discordance, and related inter-reliability calculations, could have been sought for additional variables like harm outcome and harm severity; this should be considered in future analyses of incident reports.
Representing context	The Recursive Model of Incident Analysis structured the application of codes and thus preserved the assertional and contextual knowledge present in narratives.
Graceful evolution	A regular (weekly) audit process was undertaken and a memo was created in the coding management system to update users about changes made to the coding frameworks.
Recognise redundancy	Frequencies of codes were examined. The situations in which those potentially redundant codes were used were examined and informed decisions about redundancy and deletion. If deleted, decisions were made about the re-coding of the reports affected.

6.3.3. Methods of analysis

6.3.3.1. Replicable coding management systems

Given the distributed and international nature of the project (members of my research team were in the UK, the USA and Australia simultaneously) and data security requirements, I commissioned the development of a bespoke data management system to support the iteration of frameworks and provide secure access to numerous concurrent reviewers, regardless of geographical location.

My brief to the informatician (Huw Evans) responsible for the development and maintenance of the 'PISA database' was to have a technical specification that could be replicable in healthcare organisations by an experienced information technology technician quickly and inexpensively. In total, the server and software cost no more than £5000 and utilised open source software.

The PISA server had the following functions:

- Centralised coding manual – this included a date-stamped log of changes made to the coding frameworks which all reviewers were required to review before starting each coding session. This kept reviewers up-to-date with changes made during any absences.
- Incident report flagging system – reviewers were encouraged to flag near misses, difficult cases, and interesting, unusual or rare cases. This worked well since interesting cases could be indexed to illustrate themes representing a large collection of similar reports. Difficult cases which required tacit knowledge of a medical specialty or healthcare discipline were discussed with healthcare professional colleagues with relevant expertise. A bank of helpful individuals were identified and this could easily be emulated in a healthcare organisation.
- Reflexive memo entry system – memos about observations or hunches emerging from the data, and ideas or rationales for new codes were recorded; this enabled the reviewers to continuously learn from each other and improve work processes.
- Discordance checks – each reviewer had a real-time list of reports to discuss with their second reviewer which enabled learning throughout the study and encouraged interaction between reviewers.
- Progress monitoring – given the large volume of reports, each reviewer could track their progress (number of reports coded) in relation to the other reviewers. This created healthy competition amongst the reviewers.

The PISA coding frameworks have since been used for a MPhil project focussed on paediatrics safety in primary care (I was lead supervisor to Dr Philippa Rees, Cardiff University) and two PhD projects focussed on medication safety (I am co-supervisor to Mr Khalid Muhammed MPharms, University of

Nottingham) and ambulatory dentistry safety (I am co-supervisor to Dr Eduardo Ensaldo-Carrasco BDent, University of Edinburgh). The generation of bespoke codes by investigators working on focussed speciality or discipline-specific investigations is encouraged. Currently, a quarterly review is undertaken to review additional codes being used by new investigators to consider updating or amending the main PISA coding frameworks.

6.3.3.2. Accessible methods

The methods of analysis were designed to permit future adoption in healthcare organisations by healthcare professionals or administrators with minimal training. Further work is now needed to develop and test the content and delivery of such training. Outcome formats from analysis (e.g. clustered bar charts) were also chosen to provide a logical account of how priority issues for possible intervention were identified. In addition, clinical expertise supported contextual interpretation and identification of the implications of the described safety incidents on patients and their families.

6.4. Strengths and limitations

A primary care coding framework, aligned with the WHO ICPS, has been empirically developed to assist in the generation of learning from patient safety incident reports (objective 2). Further, this is the first mixed-methods analysis of safety incident reports from general practice in England and Wales (objective 3). The PISA coding frameworks can be used with WHO ICPS, and my mixed methods analytical approach, can be applied to more focussed aggregates of similar data (e.g. vaccine incidents involving children in general practice)(36,343) to generate a programme theory for change which existing interventions or initiatives can inform (objectives 4a and 5, chapter 4). Organisations can also use this approach on smaller volumes of reports and use the programme theory to initiate a QI project (objective 4b and 5, chapter 5).

Noteworthy limitations exist and broadly relate to the quality of incident report data (section 6.4.1) the nature of the analytical findings (6.4.2), the limitations of scoping reviews (6.4.3) and biases in the generation of the case study (6.4.4).

6.4.1. Quality of incident report data

Reporting systems rely on data input (reporting) to generate learning. Safety incident-reporting systems rely on staff to write descriptions of incidents, including what happened and perceived reasons for why an incident occurred.(358) At a local level, these reports can inform the basis of recommendations to mitigate harm in practice, and at a national level these reports may be used to identify issues that would otherwise be overlooked. The information described in these reports can be understood as a form of 'storytelling' that represents the reporter's position, perspective and experience, regardless of whether or not the reporter witnessed the incident first hand.(359,360)

Around one-third of reports contained descriptions of contributory factors. The two-thirds of reports without contributory factors represent a major missed opportunity to learn from patient safety incidents. The relationships between contributory factors and similar types of incidents and contexts (i.e. manifest and integrative themes) can reveal potential areas to intervene to minimise the risk of future incidents. A total of 462 discrete NHS organisations uploaded at least one incident report, although over half of the reports originated from just 30 organisations (n = 7071, 51.6%). This implies that some organisations do not commonly report general practice safety incidents to the NRLS, or do not have mechanisms for receiving reports from general practice in its organisation (i.e. those with good reporting cultures are likely to contribute more than those without such cultures).(361,362). The number of reports excluded from the analysis suggests a sometimes misguided use of local reporting systems in terms of knowledge and understanding of its purpose. It is well recognised that incidents are under-reported, can represent only the 'tip of the iceberg' and can be limited in narrative content.(363) Although the NRLS accepts reports from patients and parents, few such reports were apparent in my data set.

Both the coding process and thematic analysis are open to personal interpretation of the data, and may be subject to confirmation bias. The team sought to minimise personal interpretation of the data in stage 1 by adhering to the nine rules of the Recursive Model of Incident Analysis and designating codes that represent what was explicitly stated in reports.(288) In addition, methodological rigour was ensured by keeping an audit trail of all coding-related decisions, holding weekly meetings to discuss analysis, and independent double-coding of 20% of reports, indicating a high degree of concordance.(364–366) The reliability of Cohen’s kappa indicated that researchers were applying the coding frameworks consistently. In stage 3 of the analysis, clinicians were encouraged to use their clinical expertise and judgement for the interpretation of reports aligned with priority issues identified by EDA.

In summary, my analytical process required the rigour of an objective and structured coding process in stage 1 to ensure confidence in the identification of priority issues in stage 2. To augment pragmatic, clinically meaningful learning for improvement, a thematic analysis was undertaken in stage 3 that drew on the clinical expertise of reviewers. The requirement for a clinical reviewer could limit transferability to healthcare organisations. Modifying existing organisational customs like Morbidity and Mortality Review meetings to include review of clusters of similar reports might offer a feasible means for integrating these processes into existing processes.

6.4.2. Nature of findings

My findings are hypothesis generating, inductive in nature and require testing and development by further research and QI activities. Reporting to the NRLS has increased in the last decade, providing large amounts of data from which to generate learning.(350,364,367) There may be other harmful incident types occurring in primary care that are under-reported by staff because of a fear of being reprimanded.(362) However, despite limitations from under-reporting and reporting biases, analyses of NRLS data have played an important role in

generating lessons to mitigate harmful incidents in other areas of clinical practice.(362,368,369)

Incident reporting is widely understood to be imperative for generating system learning that improves patient safety,(46,370,371) yet the literature demonstrates that patient safety incidents are under-reported.(363,372,373) As a result, there has been a great deal of interest in investigating barriers to incident reporting.(362,372,374) Fear of blame has been cited as a primary factor in the unwillingness of individual doctors to report incidents.(375,376) Waring (377) notes that some doctors 'referred to the excessive time required for form filling that could be better spent with patients or the menial nature of paperwork that was somehow beneath medical expertise'. Meanwhile, the literature also reports that some staff fail to recognise how completing incident forms will impact on practice- or organisation-level change.(377,378) These sociocultural determinants are broad, and the influence of each will vary between individuals and institutions. However, they illustrate that even when there are procedures in place to encourage incident reporting, and even when those policies clearly define which incidents need to be reported, there may be mitigating factors. These environmental and personal issues may affect whether or not an incident is reported, and when and how it is reported. It is evident that there are significant cultural and social factors that affect the processes of incident reporting in healthcare settings. Quality improvement efforts are now needed to enhance the functioning of incident reporting systems in healthcare organisations.

6.4.3. Scoping review limitations

Because of the lack of standardised terminology in the published and grey literature concerning vulnerable children, the scoping review search strategy comprised broad terms to achieve a high recall of interventions or initiatives. The 17 studies described interventions or initiatives aimed to improve an aspect of patient safety for vulnerable children. Narrow research studies that did not explicitly discuss change concepts and ideas were excluded. Quality assessment is not usually undertaken for scoping reviews, although for the

purposes of highlighting the diverse range of research and improvement project reports that can populate driver diagrams, I have categorised the included interventions or initiatives by study design in Table 4.7.(211)

The objective of the scoping review was to identify existing interventions or initiatives in order to inform the possible design (i.e. identified areas to intervene) for an improvement project. The purpose of the review is to identify change concepts, described in the descriptions of interventions, to minimise or mitigate contributory factors to patient safety incidents. Such change concepts are the basis of ideas (the operational and physical manifestations undertaken in practice) that can be introduced through QI projects in practice. For this reason, I have assessed the strength of described actions, in human factors terms, using a tool developed by the Veterans Health Association.(229) The tool is easy to use, and healthcare organisations should be aware of this by virtue of its inclusion in the Root Cause Analysis process, or at the very least appreciate the principle of designing better systems to enable humans to practise more safely.

Incident report analysis can inform a first draft of a driver diagram. The scoping review can support the update and amendment of the driver diagram. In chapter 4, an additional primary driver was added about 'leadership' given its predominant presence in the included literature. Similarly in chapter 5, and possibly the result of a smaller volume of reports, discussions with stakeholders enabled a more in-depth understanding of the issues originally identified from incident reports. Following analysis of incident reports at a local or national level, the driver diagram permits a concise summary of the learning from incident reports. Seeking the identification of themes from similar incidents minimises the risk of singling out incidents involving a small group of individuals.

6.4.4. Biases during generation of the case study

A case study can be generated in a number of ways, and this can be influenced by the epistemological stance of the researcher. Whilst my interest was in observing and describing how the organisation used its primary care patient

safety incident report data, my influence as a both an improvement coach and a patient safety researcher working to advance the utility of incident reports in organisations must be recognised.

I provided the Primary Care Clinical Governance Manager with training to undertake an analysis of incident reports, and development of a Pareto Chart and driver diagram. My idea to use incident reports to empirically inform the content of a driver diagram had emerged from my own pilot work and I was interested in applying this concept in a healthcare organisation. Typically, descriptive accounts of a unique phenomenon are referred to as 'intrinsic case studies'.(336) However, as an observer and coach, I was accruing insights which supported my understanding about how quality improvement teams could use incident reporting data in healthcare organisations, and appreciate how such knowledge can generate theory which can be used as a guide to support others to emulate such achievements in other settings. My approach was aligned with the pragmatic paradigm,(379) which has been described as a sound philosophical basis for participatory research which is inclusive of multiple approaches for generating learning in a practical, reflexive way.(380) This allowed me to generate knowledge about the social system, as well as advise on options to change it.(381) Marshall et al.(380) describe a 'researcher-in-residence' model where researchers position themselves as a "core member of a delivery team, actively negotiating a body of expertise which is different from, but complementary to, the expertise of managers and clinicians". Further work is needed to explore how participatory research can support organisations to maximise the ability to generate knowledge to improve patient safety.

My case study has required combined epistemological stances: a critical stance to question my own assumptions and influence, and an interpretative stance to understand individual and shared meanings of my observations in the wider organisational context.(336,382) Given the features of my participation in the project, to minimise bias, a copy of the draft report submitted for assessment by the Institute for Healthcare Improvement was shared with key stakeholders for respondent validation purposes where I sought consensus, and alternative

explanations, for the conclusions reached. I also co-authored a conference poster for presentation at an international conference with members of the project team (Clinical Governance Manager) and organisational leadership (Deputy Director of Improvement, Medical Director, Clinical Director, and Chief Operating Officer) and this enabled achievement of consensus about the conclusions arising from the project.

6.5. Conclusions about conceptual approach and methods

The pragmatic paradigm has provided a sound philosophical basis conducive to the development and testing of a structured, mixed methods process to generate learning from patient safety incident reports. The coding and analytical processes, computer hardware and software requirements, as well as the visual tools used to summarise analytical findings, should be transferable for use in healthcare organisations. Lessons learnt about the development of coding frameworks can be adopted by those seeking to develop their own frameworks aligned with the WHO ICPS. The PISA frameworks can be applied to generate learning about priority areas for patient safety improvement at a local and national level.

Chapter 7 – Discussion of practice implications

7.1. Overview of chapter

In chapter 6, I partly addressed objective 5 by discussing the strengths and limitations of my research, and I described methodological lessons learnt from the empirical development of primary care classification frameworks (objective 2). In this final chapter, I will explore the findings of my thesis in relation to the existing literature, and propose areas for future research and development identified from the national analysis of general practice incident reports (objective 3), a focussed analysis of aggregate national-level data (objective 4a) and the local utility of incident reports (objective 4b).

7.2. Main findings from thesis

I have demonstrated that methods, which align to the WHO International Classification for Patient Safety (ICPS), do not exist to deconstruct and enable sense making of the content of patient safety incidents reports from primary care (objective 1, chapter 2).

Using a repository of patient safety incident reports from general practice in England and Wales, I have empirically developed and tested coding frameworks aligned to ICPS (objective 2, chapter 3-5). This is the largest ever analysis of general practice patient safety incident reports (objective 3, chapter 3) and I have highlighted how: a structured approach, guided by definitions, for reviewing the content of incident reports can support the identification of reports describing actual patient safety incidents and highlight areas where the system is used for unintended purposes; examining the relationship between incidents and their contributory factor(s) provides a means of explaining why incidents might have occurred; and, incidents with similar outcomes such as serious harms can permit understanding deeper underlying contributory themes which are not necessarily apparent when considered in isolation. For example, several processes needing both quality improvement and research activity were apparent at a practice and organisational level, including: referral and discharge

processes; how physician decision making is impacted by administrative and information technology systems; cancer recognition and diagnosis; and, recognising signs of clinical (medical, surgical and mental health) deterioration.

Using a mixed methods process, that incorporates PISA coding frameworks (objective 2, chapters 3–5), I have generated learning from incident reports and identified priority issues to guide future improvement efforts. Further, I used an analysis of similar incident reports drawn from a national database to generate a programme theory for systems improvement and used scoping review methods to identify existing interventions which could enable mitigation of system weaknesses and redesign of processes for safer patient care (objective 4a, chapter 4). At a local level, I observed it was possible to use a structured mixed method approach to support the generation of a programme theory for a QI project within a healthcare organisation (objective 4b, chapter 5). From this, I have highlighted how QI tools like a driver diagram can be used to invite key stakeholders to amend and update the theory ahead of and during implementation of changes.

7.3. Discussion of findings in the context of current literature

I will discuss my findings described in chapters 3-5 in relation to the current literature, particularly to situate the relevance of my findings and related outputs (methods for analysing incident report data) within the WHO-led international agenda for patient safety incident reporting and learning systems.

7.3.1. Operationalising a common vocabulary for patient safety

WHO's initiative to develop the ICPS gave rise to an internationally accepted, common vocabulary to understand patient safety. More recently, in 2014, the WHO recognised there was a global scarcity of standards for reporting and learning from patient safety incidents. A *Minimal Information Model* for “minimal meaningful learning” from patient safety incidents was developed and tested in the interests of supporting countries to achieve a minimal standard for

collecting, storing, classifying, analysing and interpreting reports.(383) The uptake of these minimal standards are expected in all member states, with a big emphasis for resource constrained countries adopting and integrating these standards into the design of their new or current systems.

As recently as March 2016, the WHO convened representatives from 18 countries, with most representation from low- and middle-income countries, to support and advance discussions towards the development of their national reporting and learning systems. There is growing awareness that as resource-limited settings work to develop their own incident reporting systems, the surveillance and measurement processes they use to identify learning to improve patient safety will be critical. The coding framework and methods developed in my thesis are intended to advance these foundations laid by the WHO ICPS and *Minimal Information Model*.

7.3.2. Developing functioning incident reporting systems

My analysis of incident reports highlighted several limitations of the NRLS and the data it collects (described in more detail in section 6.4 in chapter 6). The large volume of reports that did not describe patient safety incidents suggests incident reporting systems in many organisations in England and Wales were being used for other unintended purposes. However, when patient safety incidents were described, just over one third of reports contained the detail needed about contributory factors to inform the design of safer systems. In this section, I will broadly describe the literature on improving the functioning of incident reporting systems in terms of the quality of incident report narratives (7.3.2.1) and the dissemination of learning (7.3.2.3). Methods for generating learning from incident reports were discussed in chapter 2.

7.3.2.1. Improving the quality of incident report narratives

In chapter 3, I demonstrated one in five reports from general practice (n = 3147, 23%) contained insufficient detail or did not describe a patient safety incident. This suggests the purpose of incident reporting is misunderstood, staff are not completing the incident report forms properly, or the reporting system is being

used for unintended purposes. Further, only one-third of the incident reports described reasons why the incident occurred, which significantly inhibits learning to improve future practice. Good quality reports are a prerequisite for learning.(384,385) The Francis Inquiry report reflects on the limitations of incident reporting systems and concludes they “cannot scrutinise all of the incidents reported“.(386) However, fewer more in-depth reports that contain descriptions of why the incident occurred, in terms of highlighting underlying system failures, could be less demanding of reporters and analysts, and potentially more insightful than numerous superficial reports.(387,388) This does not mean lengthy descriptions are needed; instead the report should contain enough essential detail needed to trigger an investigation in a general practice or other healthcare organisation.(389) Poor reporting rates amongst healthcare professionals is a commonly described issue; however, there are several descriptions of engagement efforts to increase reporting of clinically important incidents.(390–394) Further, specialty-specific (e.g. anaesthesia) incident reporting systems tend to generate better quality reports, which is often attributed to clinicians reporting for the benefit of colleagues and therefore providing more detailed reports.(385,395,396)

Reporting and learning systems rely on healthcare professionals to report, and be open about, patient safety incidents that they witness or are involved in.(397) Several papers and professional reports highlighted the importance of creating ‘a culture of safety’ within organisations,(221,398–406) defined by the WHO as the, “product of individual and group values, attitudes, perceptions competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation’s health and safety management”.(2) Organisations that openly claim to have or seek this culture largely do so through having a ‘no punishment’ policy for reporters. Where there have been breaches of such trust in the aviation industry, they have seen decreases in reporting; to address this, some aviation organisations have provided immunity from ‘non-criminal’ incidents and this has been a powerful incentive to report.(407)

Under-reporting is the ‘Achilles heel’ of incident reporting systems.(395,408) In

healthcare, fear of blame poses a significant barrier to staff fulfilling this duty and creates missed opportunities for systems learning and improvement.(47,409–411) Previous studies have demonstrated that when healthcare professionals report incidents, the narrative often reflects the fact that responsibility for the incident is placed on an individual through ‘person-blaming,’ rather than blaming the organisation or weaknesses in the system.(412) It is well acknowledged that uncertainty about the implications of reporting, not least the personal shame about involvement in a medical error, can create barriers to incident reporting and learning.(409,413)

The ‘second victim’ concept captures the experience of healthcare professionals who are involved in incidents and suffer psychological distress, directly from the stress of being involved in the incident and / or the collateral from blame attributed in the incident report or related review processes.(414,415) Many organisations support voluntary reporting mechanisms to encourage reporting of incidents deemed important for learning by staff.(221,239,398,400,404,406,416–422) Voluntary reporting is often considered essential for ‘creating a culture of safety’ where staff feel able to report incidents rather than being forced to report.(423) In contrast, mandatory requirements for reporting can often be limited to specific incident types which an organisation deems important to be detected, such as medication errors.(421,424–428) Neuspiel et al.(406) describe a multi-disciplinary approach where teams are encouraged to report incidents within their department for local-level learning, and a transparent review process is undertaken to determine their relevance for escalation beyond the team. Another example includes the University of Texas MD Anderson Cancer Centre’s ‘Good Catch Program’ which requests that staff “huddle” at the end of shifts to ensure any potential incidents are communicated to a lead member of staff.(429) They encourage competitive reporting of ‘good catches’ by rewarding frequent reporters. High performers are designated “patient safety champions”. This programme saw a dramatic increase in the volume of reports, evaluated by a before and after study design.(429)

7.3.2.2. Disseminating learning

As I have demonstrated in the case study in chapter 5, timely feedback to reporters is a characteristic of a successful incident reporting system.(430) This includes providing acknowledgement of the report, informing a reporter about resulting actions, and highlighting any recommendations aimed at reducing future incidents. Such feedback can be in the form of e-mails, reports or regular meetings. The improvement team in my case study realised different formats were needed for different stakeholder groups.(157,400,417,431,432) Harvard hospitals disseminate incident report findings between organisations for shared learning purposes; this includes highlighting the 'patient safety case of the week' which can be emailed to members or published.(417) Further, the most severe and frequent incidents are published along with their analyses and recommendations. Morbidity and Mortality meetings are also frequently used to present findings and disseminate learning about particularly concerning reports.(417)

The case study in chapter 5 highlights how analysis of incident reports at a local level can identify a focus for other methods like case note review and direct observation to enhance the organisation's understanding of the identified patient safety risks. This corroborates what has been found in other studies which conclude incident reporting systems offer one lens on patient safety, complementary to other methods for understanding patient safety risks.(433,434). The case study demonstrates how similar reports (e.g. warfarin-related incidents) can sensitise the leadership of an organisation to the variety of risks that might warrant further inquiry using other methods like case note review and observation of clinical tasks (e.g. pharmacists observing the administering of medicines). Several studies describe incident reports being discussed at ward rounds or clinical fora to glean more contextual information for action, and as a process to support clinical teams to own the problems and to buy-in to the changes deemed necessary to mitigate future similar incidents.(433–435)

A recent systematic review concluded that incident reporting systems can improve safety outcomes, although all authors of included studies acknowledged the difficulty in demonstrating a causal relationship since they

are often embedded within a wider programme of safety initiatives. There was some evidence of changes to clinical processes and insubstantial evidence of any cultural change or changes in mindset.(339) The case study (chapter 5) also culminated in a change in national-level policy for anticoagulation services in Wales, and also demonstrated an increasing reporting rate from GPs over the study period. Consistent with other studies,(436,437) the organisation in my case study did not evaluate the effectiveness of the changes introduced. Similar to other organisations, they were able to demonstrate process changes to remove the identified system weaknesses.(438–440) It is a credible achievement for the Health Board that their leadership efforts to implement GP-led warfarin slow-loading and management has been scaled up across Wales. A ‘Directed Enhanced Service for Oral Anticoagulation with Warfarin’ has been launched with financial remuneration for all GPs offering this service across Wales from April 12th, 2017.

7.3.3. Learning from patients

It was not possible to identify reports written by patients during the analysis of incident reports included in chapters 3 or 4. Cultivating conditions in which patients, parents and carers feel comfortable challenging healthcare professionals can prevent safety incidents.(441) Patients and healthcare professionals are now co-designing new models of care delivery that inform local improvement initiatives; there are now demonstrable examples of improvements in the parent–provider relationship increasing child safety.(442–444) Studies of patient reported safety incidents in hospitals suggest most patient-identified incidents are not detected by the hospital’s incident reporting system.(445,446) In several children’s hospitals in the United States, incident reporting mechanisms for parents to report safety concerns have highlighted how parents also identify incidents that go undetected, and overall parent reporting rates were higher than the hospital’s average staff incident reporting rate.(447)

Regulation 20 (duty of candour) of the *Health and Social Care Act 2008*

(Regulated Activities) Regulations 2014 outlines specific actions that healthcare professionals and their team must follow when an incident occurs, including informing patients about the incident, providing reasonable support, truthful information and an apology. The duty of candour, applied to patient safety, requires general practices to demonstrate:

- openness – a culture where incidents and complaints can be raised without fear of reprimand;
- transparency – sharing of information about what happened to staff, patients, the public and regulators; and,
- candour – any patient harmed by the provision of a healthcare service is informed, and an intervention is made where appropriate, regardless of whether a complaint has been made or questions have been raised about the safety of care.(397,448)

Several innovative approaches are emerging to involve patients in the mitigation of patient safety incidents. This includes providing patients with access to their medical records to reduce documentation discrepancies and appointment-related incidents, as well as to provide healthcare professionals with a safety net.(441) Such incidents could also be prevented by providing staff with better accessibility to unified records.(449) As care models for different patient groups change, investment is required to maximise patient understanding and empowerment to use those services,(450) and raise their patient safety concerns.

7.3.4. Identifying patients at high risk of harm in the community

In chapter 3, reports describing failures of timely diagnosis and assessment, the availability of treatments and care equipment, and lack of continuity of care following discharge often involved patients with social or medical issues that compromised their ability to access GP services. Exploring the accessibility of clinical services must be a priority for all healthcare organisations, and general practices should determine whether their existing telephone call-handling processes meet the needs and expectations of their patient population. In 2015, a randomised controlled trial by Campbell et al.(451) was not sufficiently

powered to detect differences in safety outcomes (in terms of patient mortality, emergency hospital admissions, and accident and emergency attendance rates) between same-day consultations with GPs/telephone calls, versus nurse-led computer-supported services or usual care. However, the accompanying process evaluation recognised the importance of culture, capacity and involvement of all practice staff when introducing such major changes to access. The authors recommended examination of Significant Event Audits (SEA) to explore safety outcomes.(452) My findings support this recommendation given the diversity of issues patients face while accessing clinical services; in particular, the need to focus future improvement efforts on vulnerable patient populations.

Patients recently discharged from hospital and those receiving end-of-life care in the community or requiring regular district nursing involvement frequently did not receive timely follow-up by community healthcare professionals. Exploring options to intervene early, to manage patients at home and to mitigate avoidable deterioration through proactive intervention is needed. Different options that could achieve this are described in NHS England's General Medical Services 'enhanced service' for vulnerable groups, which describes a complex intervention that includes same-day telephone consultations for patients at risk of unplanned hospital admission and timely follow-up by a healthcare professional in the practice on discharge from hospital.(453) Although there may be unclear benefits of standalone system changes such as telephone triage,(451,452) a synergy might be evident from new models that combine same-day telephone triage and risk stratification (or other options). Given the failures in care identified in chapter 3, my findings support the direction taken by NHS England to support GPs to develop and test new models of care delivery for the 'enhanced service' which could include: rapid response community nursing; support from mental health service providers; designated district nursing; additional discharge co-ordinator services; additional support for carers; and, targeted social-care services.(451) As I have previously discussed in chapter 1, given the largely social, rather than technical, nature of such interventions, an outcome-based evaluation is likely to determine a minimal or

null net effect. Thus, formative theory-driven evaluation options should be considered.(61)

7.3.5. Minimising risks from human factors

Most safety incidents are caused by a complex interaction of individual actions and system failures, with greater weight given to system factors.(356) Reason's Swiss cheese model describes how although human error cannot be completely avoided, incidents are frequently the result of multiple small errors within a failed system: "The important question is not '*Who blundered?*' but '*How and why did the defences fail?*'".(356)

A range of diagnostic errors was described in chapter 3. These incidents had both human and system contributory factors, and may have been errors of commission or omission. Croskerry et al.(454) describe a number of initiatives for mitigating specific cognitive errors in practice, in keeping with current literature around improving diagnosis and assessment by reducing dependence on flawless cognitive performance.(454,455) Schiff et al.(456) described the importance of adopting better multidisciplinary approaches, reducing pressure on clinicians to rely solely on their memory and clinical experience when making diagnoses, and instead supporting them by means of computerised and non-technological aids. This supports my thesis findings, which demonstrate that lack of knowledge, oversights and mistakes were frequently described staff factors contributing to patient safety incidents. Cognitive errors, which are often unexpected active errors of commission, complicate the process of improving patient safety; however, focusing on providing safe systems and safety-netting may help minimise patient harm when errors occur.(457)

Previous studies have highlighted the importance of streamlining systems for referral and discharge or follow-up, and using electronic systems to unify patient records.(458) Electronic systems are being developed to support a number of aspects of the diagnosis and assessment process. There is increasing support for the use of clinician decision support systems, to assist in managing consultations.(459,460) For example, a system proposed by de Wit et al.(461)

supports the management of polypharmacy in the elderly patient population. Whilst algorithms, guidelines and computer assisted diagnostic systems are sometimes advocated as debiasing strategies,(454,462,463) others have considered them to augment cognitive processes.(464,465)

Vulnerable patients were described within the reports analysed. Elderly patients, patients with acute illness or disability have an increased risk of patient safety incidents.(466) Such patients often have multiple comorbidities and run the risk that new pathologies will be overlooked as clinicians focus on existing diagnoses which can undermine the presentation of new pathology.(467,468) In addition, they may be less able to raise concerns about their care or lack agency in decision-making. Guthrie et al.(467) described polypharmacy and choice of acceptable care strategies as specific issues for patients with comorbidities yet to be addressed in policy.(467) Some credible resources exist to guide practitioners in managing this demographic group, particularly for minimising risks from polypharmacy.(469,470) Involvement of patients in training healthcare professionals, to improve management of the vulnerable, has been associated with improvements in patient satisfaction, with no clear detrimental effects.(471,472) Cross-linking electronic guidelines for the management of related disorders, and to aid recognition of red flags to minimise diagnostic overshadowing, is a further proposal for practice-level improvement to mitigate human error.(467)

Building IT infrastructure and functionality capable of sharing data between health- and social-care providers could support identification of predictors of risk and inform interventions to prevent future incidents.(473–475) In addition, efforts to transition existing written processes, and align existing electronic processes, could support healthcare professionals to have timely and reliable access to healthcare data needed for safer consultations and permit continuity of care across different health- and social-care sectors.

Based on my findings, several hypotheses have been raised about improvement of referral and discharge processes. The receipt of poor quality, and sometimes inappropriate, referrals received by district nursing teams is well

described,(476–479) and each unclear referral has been estimated to cause five hours of extra work for district nurse teams.(480) To overcome variability in referral processes, the development and testing of a single, unified electronic referral process with an agreed baseline of minimal information should be agreed between professionals in primary and secondary care settings.

NHS England and other organisations have previously reported that failures in communication processes can account for up to 33% of discharge-related safety incidents.(481,482) Electronic discharge documentation could prevent most paper-based administration failures,(483–485) and, across the UK, a process is underway to support 24-hour electronic discharge.(486–488) Accepted best practices, such as the Scottish Intercollegiate Guidelines Network discharge document, already exist.(489,490) In parallel, patient-held records could aid understanding about a recent hospital stay and follow-up plans.(491,492)

7.4. Implications for policy and practice

Actionable findings provide the basis for improvements and interventions, and should be evaluated in practice as to if, and how, they can best achieve the desired benefits for patient safety. I will consider the immediate implications for policy and practice informed by the inductive approach taken during my thesis. Thus, my findings should be considered in the context of the strengths and limitations of incident report data (described in chapter 6). These will be groups of recommendations that apply to general practices and their commissioning healthcare organisations, and for the wider healthcare system.

7.4.1. What can general practices do?

7.4.1.1. Establish a reporting and learning process in general practices

All members of the primary care team, including administrative staff, should have a knowledge and understanding of what patient safety is, and more specifically what a patient safety incident is, in the context of general practice.

Table 7.1 shows a range of incidents previously described in chapter 3; this table could be used to explore with a general practice team their existing knowledge and understanding of patient safety incidents. Reflecting on past incidents, as well as receiving feedback on incidents (described later), are also likely to improve future decision making.(465)

Table 7.1. Summary of patient safety incidents reported from general practice in England and Wales by Carson-Stevens et al.(493)

Communication with patients
<ul style="list-style-type: none"> ● Miscommunication e.g. inadequate safety netting advice ● Difficulties accessing clinical services e.g. telephone triage, message handling, appointments ● Parent-held records unavailable
Communication between professionals
<ul style="list-style-type: none"> ● Unavailable or inaccurate medical records e.g. paper notes from previous practice ● Delayed referrals e.g. erroneously completed referral, delayed decision to refer ● Information transfer between care providers e.g. delayed discharge summary or clinic letter
Diagnosis and assessment
<ul style="list-style-type: none"> ● Missed or delayed diagnosis ● Delayed assessment of care ● Delays assessing patients with serious mental health conditions ● Not identifying patients at risk of deterioration
Medication and vaccine
<ul style="list-style-type: none"> ● Errors in prescribing, dispensing and administering medicines and vaccines ● Complications with therapeutic drug monitoring processes
Investigations
<ul style="list-style-type: none"> ● Ordering inappropriate investigations to inform differential diagnosis ● Incorrect collection, or transfer, of specimens ● Administrative failures leading to delays, wrong results or failure to receive results ● Incorrectly interpreted results e.g. blood tests, imaging, other investigations
Treatment and equipment
<ul style="list-style-type: none"> ● Complications of procedures ● Malfunctioning and unavailability of care equipment e.g. pressure mattresses, oxygen, walking aids

The primary care team should be aware of the benefits of incident reporting at multiple levels, including:

- reflection on the incident by the reporter and enhanced professional development (individual level);
- identification of opportunities to undertake SEAs (practice level);
- collated reports at a Health Board or CCG can highlight local systems issues for change (system level); and,
- collated reports can help identify rare issues (national level).

Staff should know how to report a patient safety incident in the practice. A model for generating learning in general practice is proposed in Figure 7.1, and includes:

- initially risk-assessing what is reported and informing the relevant staff and patients (if appropriate) of the investigative or remedial action to be taken;
- discussing incidents as a practice team to decide on which incidents merit a SEA, or do not require a detailed inquiry and which should be reported directly to the commissioning organisation's incident reporting system; and,
- prioritising which patient safety issues should form the basis of QI activities in the practice.

Patient and staff feedback is essential throughout this learning process as a commitment to demonstrate a duty of candour.(448)

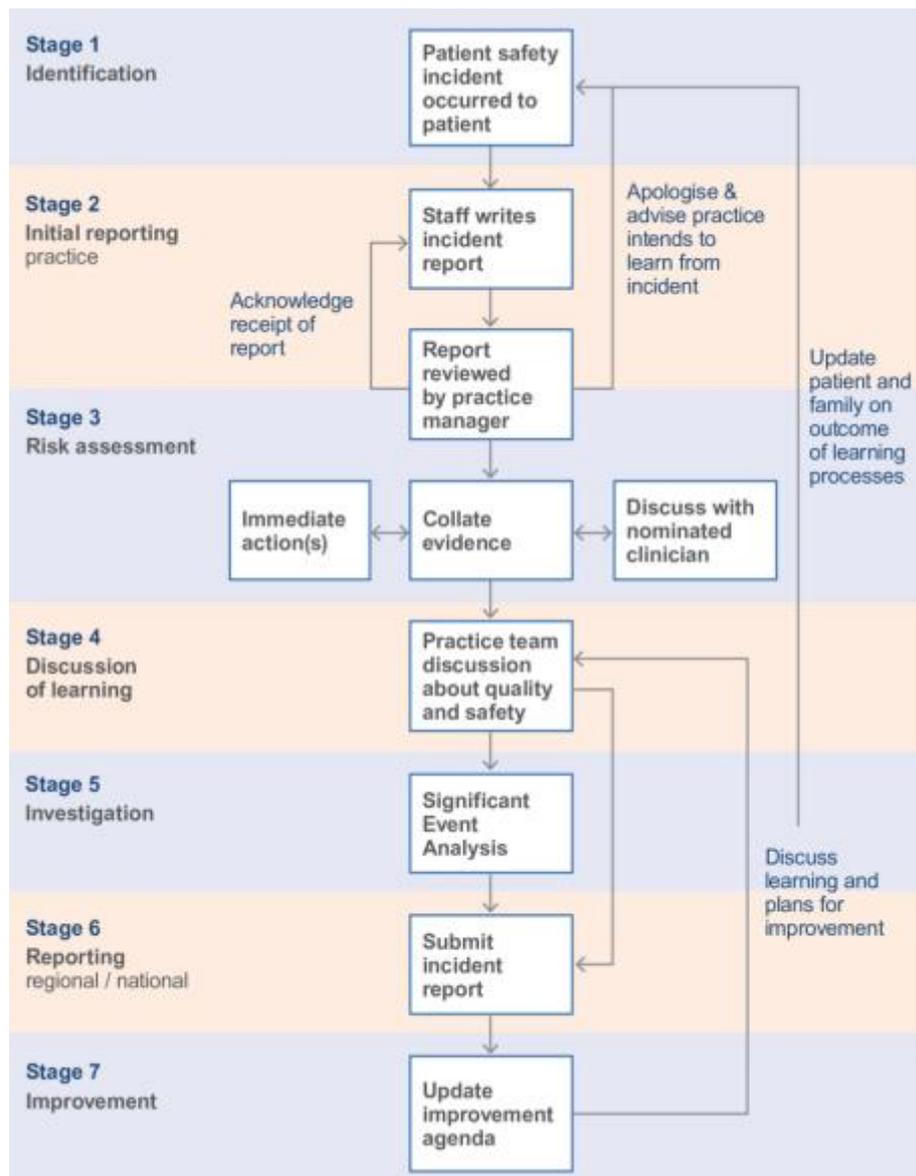


Figure 7.1. Stages of a Primary Care Patient Safety (PISA) Learning Model for Care Improvement (494)

GPs already dedicate resources to undertake SEAs, also called Significant Event Review or Audits,(495) and these are often used for (personal) appraisal processes. The SEA process brings together multiple sources of evidence, which enables a more complete representation of clinical activity to be generated to understand the patient safety incident.(496,497) SEAs inform improvement efforts in practice. However, not all incidents need a SEA. GPs and practice teams should also write patient safety incident reports about incidents that have not been subject to an in-house SEA. This includes incidents where the patient came to no harm, or where an intervention occurred before

harm could reach the patient (so called 'near misses'). These incidents will allow teams to identify and understand what processes are working well and which could be improved.

Practices should consider sharing SEAs for regional or national learning because they represent an opportunity for the NHS to learn how to improve the quality and safety of primary care. To support this commitment, policy makers need to be more explicit about how SEAs can be integrated into existing reporting systems (e.g. NRLS) for wider learning.(498)

Informed by the findings from my thesis, and related studies through which I have provided the lead supervision,(36,307,343,354,355,458,473,499) I have co-authored the RCGP 'Reporting and learning from patient safety incidents in general practice – a practical guide'.(494) The guide describes the range of patient safety incidents that occur in general practice (Table 7.1); provides examples of local- and national-level learning from the analysis of groups of similar incidents (as also described in chapters 3-5); and, outlines seven stages for learning from patient safety incidents in general practice (Figure 7.1), including when to undertake a Significant Event Analysis (SEA). An exemplar patient safety incident reporting form is proposed in the RCGP guide (Figure 7.2).(494) The incident report should provide essential information about what happened.

Following receipt of an incident report by a practice manager in general practice, Figure 7.1 recognises the informal inquiry often required to identify additional details such as the severity of harm outcome, to consider the risk of a similar incident recurring in the practice, and determine whether any immediate action is needed for the patient and their family. An initial review of the incident report by the practice manager is proposed to decide whether the report also requires review, for example, by a nominated quality and safety lead partner. Practices should agree on rules for escalating an incident report to the nominated partner. However, some incidents will come to light which have been generated by actions outside the practice such as in hospitals. For example, a patient may have developed an advanced stage cancer because a radiology

report went missing or was misinterpreted in the hospital; however, the error might only be detected when the patient attends for consultation with obvious signs or symptoms of cancer or has an investigation repeated a few months later. In these circumstances, whilst the practice will need to review the incident, the appropriate action would be to draw the matter to the attention of the medical director of the hospital as well as reporting the incident to the NRLS (in England and Wales).

The practice manager (and/or nominated partner) should decide whether the facts about the incident have been sufficiently determined and will be suitable for group discussion at the next quality and safety meeting, will require a Significant Event Audit, or both. If the incident is complex, it may benefit from a more structured investigation like a SEA. For example, a facilitated team-based discussion may be needed if the incident resulted from care received over multiple episodes by multiple GPs or the patient has a complex medical and social background. Similarly, for issues where input from representatives from secondary or tertiary services (e.g. opinion from Consultant Neurologist) would be beneficial, this might benefit from a SEA. Tools are suggested in the RCGP guide to help structure this process by considering the severity of harm and risk of recurrence (Figure 7.3).(494)

PISA Patient Safety Incident Reporting Form Template

Who	Where/When
Patient affected:	Location:
Person reporting incident (including job title):	Date/time of incident:
	Date/time reported to manager:
What	
Incident category type (please circle):	
<ul style="list-style-type: none">• Medication process• Diagnostic / clinical assessment• Investigation process	<ul style="list-style-type: none">• Communication process• Equipment• Other
What happened?	
Why?	
Was immediate action necessary? If yes please document below	
Were there any contributing factors? (e.g. system, staff, patient)	
What was the patient harm severity outcome? (please circle – refer to table on next page):	
<ul style="list-style-type: none">• No harm• Mild harm• Moderate harm	<ul style="list-style-type: none">• Severe harm• Death
What is the probability of recurrence? (please circle — refer to matrix on the next page)	
<ul style="list-style-type: none">• Extreme risk• High risk	<ul style="list-style-type: none">• Medium risk• Low risk
Actions to prevent recurrence and how this incident will be investigated?	

Figure 7.2. PISA Patient Safety Incident Reporting Form Template (494)

PISA Harm Severity Classification

Severity	Definition
No harm	An incident occurred but no harm was experienced by the patient.
No harm outcome due to mitigating action	Any incident that had the potential to cause harm to a patient but this was prevented, resulting in no harm.
Mild harm	<p>Patient was harmed with mild and short-term impact on physical, mental or social functioning; this includes requiring:</p> <ul style="list-style-type: none"> • minimal intervention/treatment e.g. antiemetic, oral antibiotic; or, • repeat of a minor procedure such as vaccination or insertion of contraceptive implant; or, • the patient or their loved ones experiencing transient emotional distress but no long-term consequences.
Moderate harm	<p>Patient was harmed causing a medium-term impact on physical, mental or social functioning; this includes requiring:</p> <ul style="list-style-type: none"> • medical intervention in the form of treatment e.g. intravenous fluids or antibiotics; or, • short-term hospitalisation for assessment and/or minor treatment in either A&E or a hospital ward; or, • the patient or their loved ones experiencing psychological difficulty of a more longstanding nature but not requiring formal treatment e.g. evidence of more longstanding anxiety, insomnia, or low mood.
Severe harm	<p>Patient was harmed causing a major long-term or permanent impact on physical, mental or social function or shortening of life-expectancy; this includes requiring:</p> <ul style="list-style-type: none"> • major medical or surgical intervention (most often delivered in a hospital setting) e.g. thrombolysis, cardioversion, any major surgery; or, • prolonged hospitalisation or admission to HDU/CCU/ITU; or, • the patient or their loved ones experiencing enduring psychological difficulty that requires specialist treatment e.g. evidence of chronic anxiety or depression or psychosis.
Death	On the balance of probabilities, death was caused or brought forward in the short term by the incident.

Probability as per Table 4	Harm severity as per Table 3				
	Death	Severe Harm	Moderate Harm	Mild Harm	No Harm
Frequent most weeks/months	4	4	3	2	2
Likely a few times a year	4	4	3	2	2
Possible may happen every 1—2 years	4	3	3	2	1
Unlikely possibility could occur in the next 5 years	4	3	2	1	1
Rare unlikely to reoccur	3	2	2	1	1

SAC Matrix [developed from VHA](#)

Each SAC matrix score from one to four has defined actions. Examples are provided here for illustration purposes and these must be amended for your own context, particularly agreed within your own practice and with your relevant commissioning body.

4 = Extreme risk – Immediate action required – Clinical Director of Primary Care / Clinical Governance Leads must be informed. Investigation must be commenced across primary and secondary care. Significant Event Analysis to be undertaken in practice. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.

3 = High risk – Notification to Clinical Director of Primary Care / Clinical Governance Leads. Significant Event Analysis (and where relevant a Root Cause Analysis) involving relevant primary care team members and respective department staff. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.

2 = Medium risk – Practice manager to aggregate data and Significant Event Analysis to be undertaken to inform an improvement project. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.

1 = Low risk – Practice manager to aggregate data. To be discussed at team-based meeting and decision needed about whether Significant Event Analysis will be undertaken to inform practice improvement. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.

Figure 7.3. PISA Harm Severity Classification matrix (494)

7.4.1.2. Identify at-risk patients

Practices can immediately explore their current processes for identifying patients who could be stratified to be at high risk of deterioration, unplanned admission or readmission following discharge from hospital. This should include multidisciplinary team involvement for undertaking the assessment of these patients to achieve integrated care. Several condition-specific risk stratification tools exist for coronary heart disease and diabetes.(500,501) More recently, a predictive risk-stratification tool has been developed for application to the general patient population to reduce unwarranted emergency admissions from community settings in Wales; the outcome of the step wedge cluster randomised trial is outstanding.(474,475)

7.4.1.3. Examine patient satisfaction in relation to perceived accessibility

Perceptions of barriers to clinical services should be explored with patients. First steps could include determining whether or not patients find existing telephone and call-handling processes meet their needs and expectations. All GP surgeries can immediately seek to appoint a patient representative(s), or even a “patient champion” staff member, to attend meetings to discuss process changes that will affect how patients use and interact with services.

7.4.2. What can commissioning organisations do?

7.4.2.1. Data-driven improvement

Practices must be supported to develop a learning culture by being encouraged to use their own data (e.g. SEAs and GP-related patient safety incident reports) to identify potential candidate areas for small, local QI projects. At a commissioning organisational level (i.e. Clinical Commissioning Group in England, Health Board in Wales), those responsible for clinical governance could support the identification of similar incident reports between practices in order to identify common system weaknesses and use those ideas to inform system redesign efforts to minimise future risk to patients. For example, if there is a sufficient volume of incident reports around a specific theme, a programme theory can be generated to outline apparent change concepts for a QI project.(343) As demonstrated in chapter 5, organisations should examine their

existing infrastructure for receiving reports and disseminating learning back to practice, and monitoring the success of those mechanisms.

The findings from my PhD thesis informed the agenda at an all-day event co-hosted by 1000 Lives Improvement and the Royal College of General Practitioners (RCGP) in Cardiff on March 7th, 2017. Representatives from each Health Board in Wales, including GPs, managers and other primary care healthcare professionals, attended the event and supported plans to establish a primary care patient safety 'community of interest' for Wales.(502) An opportunity exists to utilise local and regional groups of neighbouring general practices to share incident reports and SEAs on a regular basis, in the interests of identifying priority issues for improvement in local and regional services. Members of the community of interest might also identify in their own organisations the 'beacons' to which others can aspire. For example, general practices that have high patient satisfaction scores for different patient groups, including socially and medically vulnerable patients, could be identified and their models of delivery observed to determine whether or not there are best practices that can be shared widely. Preliminary discussions with the 1000 Lives Improvement leadership suggest the analyses presented in chapters 3–5, as well as additional published studies undertaken using my methods, will inform agenda- and priority-setting.

7.4.2.2. Prepare the workforce to report

There is a need to develop a culture of open reporting among healthcare professionals and staff in general practice. This must also extend to patients and carers. Clear mechanisms must exist for escalating concerns and reporting patient safety incidents. To ensure that incident reports can inform future improvement efforts, the workforce must be provided with patient safety education and training that increases understanding about the rationale for reporting and prepares them to be aware of human and system factors contributing to the incident. Previous reported educational interventions have covered the importance of incident reporting,(433,503–508) as well as guidance on how to report.(398,503–505,509–511) Such interventions could lead to more informative report narratives which could lead to enhanced systems

improvement capability. Despite a range of described educational interventions, these have not been formally evaluated to date.

Global education providers such as the United States-based Institute for Healthcare Improvement provide free access for student healthcare professionals and doctors in training to undertake courses on patient safety, which includes coverage of human factors and root cause analysis (a systematic, team-based inquiry used to investigate incidents in organisation).(229,512) National quality improvement learning programmes like 'Improving Quality Together' in Wales, already provide content on quality improvement methods for NHS staff.(513) This programme, and other reputable educational providers,(514,515) can disseminate patient safety education to NHS staff. With the support of a RCGP Spotlight Award, I have co-written e-learning modules for inclusion in the RCGP Online Learning Environment called "Patient Safety and Quality Improvement in Primary Care".(516)

Competencies around incident reporting may be best demonstrated via appraisal or revalidation processes. The GMC's appraisal and revalidation guidance recommends supporting evidence is required to demonstrate participation in activities to learn from patient safety incidents and quality improvement activities. The GMC guidance supports discussion about patient safety incidents (including those that result in no harm or were near misses) and states the purpose of the supporting information is to "illustrate events which may not have a serious outcome but highlight issues which could be handled with greater clinical effectiveness and patient safety, and from which lessons could be learnt."(517)

Using patient safety incidents to inform quality improvement activities creates an opportunity for GPs to demonstrate several appraisal and revalidation requirements stated in the GMC guidance, such as:

- "...participation in logging any incidents or events..."
- "...should be able to demonstrate that you are aware of any patterns in the types of incidents or events recorded about your practice and discuss any lessons learnt."

- “...participation in any clinical governance meetings where incidents or events and learning are discussed”
- “Discussion at appraisal should include any systematic learning from errors and events such as investigations and analysis, and the development of solutions and implementation of improvements.”

7.4.3. What can national bodies interested in patient safety do?

7.4.3.1. Support general practices to contribute to the National Reporting and Learning System

At present, in England alone, there are numerous channels to report patient safety incidents. These include the NRLS, the Care Quality Commission (CQC) in England, the National Clinical Assessment Service, the General Medical Council and locally at practice level through SEAs. The CQC also conducts routine inspections of general practices, and the registered manager in each practice should also notify the CQC about serious harm outcomes occurring to patients in the practice.(518) These systems do not communicate with each other, resulting in an incomplete national picture of patient safety in primary care. There is a need to create a single mechanism of data capture. Currently, in terms of mandatory data capture, the only incidents that must be reported are “never events”. A set of such events relevant to primary care, such as those developed by de Wet et al.(519), should be agreed by policy makers and tested for their feasibility in general practice.

An opportunity exists to better use the analysis of routinely available healthcare data, such as patient safety incident report data, to inform the designs of QI projects. The Five Year Forward View presents an opportunity to deliver the necessary system changes to bring patient safety in primary care to the fore.(520)

7.4.3.2. Co-ordinated expert analysis at a national level

To generate recommendations for practice from patient safety incident reports from primary care in England and Wales, I developed a mixed methods

approach that combined detailed data coding process, descriptive statistical analysis, and a thematic analysis of reports (chapter 3). New ideas and hypotheses emerged throughout each step of analysis. Subject matter experts also discussed findings and identified key areas for improvement.

Analysis of incident reports at a national level needs a combined enterprise between clinical, research and patient safety experts to regularly review the output of analyses, to corroborate with existing insights from research studies and improvement initiatives, and to develop potential action-orientated solutions with strong face validity among the profession. Involvement of the Royal Colleges in dissemination of learning will continue to be critical, particularly in terms of advocating the uptake of solutions by members and recognising NRLS contributions for appraisal purposes. However, the future of the England and Wales NRLS must be secured, in terms of providing both a means for national learning and the expertise and resources needed to undertake regular systematic inquiries of these data. The *Next Steps on the NHS Five Year Forward View* report describes a 'Patient Safety Incident Management system' which NHS Improvement will develop and deliver for all healthcare settings. This will be an updated version of the NRLS.(521) In the report, NHS England pledge to "make it easy and rewarding to record patient safety incidents, provide feedback, and enhance learning from what has gone wrong".

7.4.3.3. Support the development of global learning registries

To advance and accelerate the primary care patient safety agenda internationally, a global registry for incident reporting could support the ability to generate action-orientated outputs with strong face validity in the healthcare profession. The WHO has proposed a minimal information model to provide a dataset in all countries for sharing patient safety incident reports.(522) Efforts will then need to be made to ensure that incident reports from each country meet an acceptable standard to enable learning. National (and the proposed international) patient safety incident report systems should be designed to describe care failures and safety incidents, and be utilised to shape priorities for improvement. Similarities and differences may exist between incidents in different countries, across different contexts and gaining insight about rare

events is possible. Further, an opportunity exists to identify common system weaknesses that would benefit from combining the expertise and creative ideas for solutions from all contributing nations. Such systems should seek to corroborate the insights with existing research studies, develop potential solutions for application in practice, and share learning of the context-specific approaches to applying solutions.

7.4.3.4. Data linkages within and between health- and social-care services

The potential value of data linkage to evaluate the impact of patient characteristics on healthcare outcomes was demonstrated in a recent UK-wide enquiry into child mortality.⁽⁵²³⁾ As demonstrated by the characterisation of reports involving vulnerable children in chapter 4, insights for prioritising and designing future safety interventions could be gained by linking incident-reporting systems with electronic medical records and other public or social-care registries. This would enable the identification of incident reports relevant to specific groups. Sheikh et al.⁽⁵²⁴⁾ have outlined a strategy for healthcare IT in the NHS which has four key components: (1) devolve the decision-making processes about systems procurement to practising professionals; (2) consider offering modest financial incentives and highlight the penalties for non-adopters of such systems in the future; (3) governance to ensure safe sharing of data between providers; and (4) oversight from a national body to coordinate national efforts to implement advanced healthcare IT systems.⁽⁵²⁵⁾ Lessons from England's National Programme for Information Technology suggest that rigorous, independent evaluations of implementation efforts are needed.

7.5. Recommendations for further research and development

My thesis has generated several recommendations for further research and development which include the need to: corroborate learning with other primary care patient safety data sources (section 7.5.1); undertake wider characterisation of reports from primary care disciplines working in other community settings (section 7.5.2); utilise learning from analysis of NRLS data for systems improvement (section 7.5.3); and, adopting machine learning and natural language processing methods for incident report analysis (section 7.5.4).

7.5.1. Corroborate and gain additional insights from other patient safety data

Further research is needed to corroborate the findings from my thesis by examining other sources of insight about primary care patient safety data. In collaboration with Professor Tony Avery (my second PhD supervisor and chief investigator of the Avoidable Harm study: Understanding the Nature and Frequency of Avoidable Harm in Primary Care, Department of Health Policy Research Programme PR-R11-0914-11001), we are undertaking a case note review of general practice records to:

- estimate the incidence of avoidable significant harm in primary care in England;
- quantify, describe and classify the patient safety incidents that result in avoidable significant harm and their severity; and,
- identify ameliorable factors that, if addressed, could help reduce the incidence of avoidable significant harm in primary care.(526)

My thesis findings have informed the design of the Avoidable Harm study. For example, the PISA coding frameworks, particularly descriptions of incident types (what happened) and contributory factors (why did it happen) are being used to structure each case of identified avoidable significant harm. The study will be completed in December 2017 and will advise on the extent to which future assessments of avoidable harm in primary care could be made more

efficient through interrogation of electronic health records, and propose areas for intervention that might help reduce the incidence of avoidable harm.

As demonstrated by other groups working in hospital safety, complaints data could also be an additional source of primary care patient safety insight.(427,455,527) As mentioned previously, multiple organisations including medical defence unions also collect patient safety data in England and Wales (and other countries have similar set ups); a structured analysis of these data could also provide alternative, and complementary, opportunities to better understand primary care patient safety. Further, the new Healthcare Safety Investigation Branch launched in England in April 2017, will be undertaking up to 30 in-depth investigations of patient safety incidents per year. A structured approach to incident investigation could yield rich data on patient safety across a range of clinical settings to inform systems improvement.(528)

7.5.2. Analysis of reports from other primary care disciplines

In view of the findings described in chapters 3-5, the value of my potentially generalisable methods for interrogating and identifying learning from incident reports to inform systems improvements, should now be explored with reports from other primary care disciplines (e.g. community nursing, ambulatory dentistry). Classification methods that are pragmatic and flexible are needed for application in a range of settings for different purposes.(389) In addition to general practice, there are several other 'point-of-first-access' disciplines from primary care that have contributed > 200,000 reports, which include dentistry, pharmacy, health visiting, nursing and midwifery. In the same way that general practice reports were overlooked prior to this study, except for medication- and pharmacy-related reports, these reports have also never been systematically characterised. As the PISA coding frameworks and methods are utilised by health service researchers and healthcare professionals from different disciplines, it will be possible to learn how they should be amended to suit the needs of different professionals across the range of contexts of primary care delivery. I am co-supervising two PhD students that are using the PISA methods to characterise patient safety in other areas of primary care, these are:

- Mr Khalid Muhammad MPharm exploring incident reports from community pharmacy (with supervisors Dr Matt Boyd and Professor Tony Avery); and,
- Dr Eduardo Ensaldo-Carrasco BDent exploring incident reports from community dentistry (with supervisors Dr Kathrin Cresswell and Professor Aziz Sheikh).

Extending this work beyond the confines of general practice is an important next step to advance the field of primary care patient safety, and there is an obvious opportunity to obtain a more representative view of issues by analysing reports from other disciplines. Research being undertaken by Muhammad and Ensaldo-Carrasco, and studies led by my previous MPhil student Dr Philippa Rees (focussing on community-based healthcare to children), highlight the benefits of drawing a large sample of reports from each discipline.

In chapter 3 of my thesis, I outlined the nature and range of safety incident reports from general practice. I recognised more focused coding and analysis of general practice reports was needed, and several follow-on studies have been undertaken and completed. By analysing a greater volume of homogeneous reports from which to generate hypotheses, more in-depth insights into the potential contributory factors, and the likely changes (both concepts and ideas) that would be needed to enhance patient safety have already been undertaken for:

- primary care mental health;
- diagnosis and assessment;
- care of older adults;
- out-of-hours care;
- unwell children; and,
- vulnerable adults.

Reviews of the literature, and in more recent studies scoping reviews, have been undertaken to identify interventions and improvement initiatives that address the inductive priorities that have emerged from analysis. These studies

are currently being prepared for submission or have been published.(354,458,529,530)

7.5.3. Data-driven improvement agendas for primary care

Preventive quality and safety initiatives like the 1000 Lives campaign (now the 1000 Lives Improvement service) in Wales have claimed significant reductions in harm and mortality were made through reliable implementation of interventions in hospitals like 'care bundles' and 'checklists'.(531) Such campaign approaches to achieve improvement at scale have not been rigorously evaluated.(34,532) Further, the paucity of research and development of patient safety in primary care means there are few primary care-specific interventions for improving patient safety.(96) In the absence of extensive research and development about where and how to intervene to improve patient safety in primary care, countries like England and Wales can establish their own data-driven primary care patient safety and improvement agendas. Acting on these agendas does not require learning a new set of methods and tools for implementation. Primary care should capitalise on the considerable experience about implementation already accrued by organisations that improved safety in hospitals over the past decade.(64) My thesis also provides the foundations to base plans for incident report-driven systems improvements at a national level (chapter 4) and local level (chapter 5).

Wales has aspirations to be 'a data-driven system' which aligns with systems scientist, Peter Senge's concept of the 'learning organisation'.(189,533) Learning organisations require the supporting infrastructure for a range of activities and processes to create what is often described in healthcare organisations as a 'culture of learning'.(534,535) The 1000 Lives Improvement programme has established an infrastructure for enabling Health Boards in Wales to train their staff to be proficient in quality improvement methods via the Improving Quality Together programme,(513) and regularly organised learning environments to share learning about the successes and challenges of implementation. Based on findings from my thesis, I am advising the 1000 Lives Improvement on their plans for primary care in Wales.

I have previously discussed how the outcomes from analysis of incident reports can trigger more in-depth investigation inquiry in general practices or healthcare organisations, as well as empirically inform the initial programme theories for systems improvement.(183) The value of incident-reporting systems will be realised by healthcare professionals only when their contributions are acknowledged and acted on. Creating an open culture of incident reporting is needed in all care settings, and I recognise that this is still an ongoing challenge in hospital settings too. (183,353)

A range of research methods can be employed to study patient safety. Trigger tools can identify, within medical records, features suggestive of patient safety incidents.(536,537) Safety indices can be constructed from administrative data or regular data capture exercises like those advocated by the NHS patient safety thermometer,(538) to estimate what incidents occur and their frequency.(539) Methods such as significant event auditing and incident reporting systems can help understand why incidents occur. All such data can be used to inform a theory of what changes are needed to improve patient safety. Each offers an important, although incomplete, observation of the problem.(540)

My thesis demonstrates that analysis of incident reports at a local and national level can be used to generate programme theories of change to improve patient safety in primary care. That said, the collection, analysis and use of incident report data in healthcare remains problematic, with few healthcare systems demonstrating that they can learn to reduce risk for future patients.(339) Further research and improvement activity are needed to realise the value of using incident report analysis to empirically inform improvement agendas.

Primary care can accelerate the pace of its quality improvement agenda by using routine data sources like incident reports to identify local and national-level priorities. My colleague, Dr Huw Williams, will develop and test the model for incident reporting system-driven patient safety improvement (Figure 5.8, chapter 5). Williams has secured a RCGP Marie Curie Research Fellowship

(2017-2019) to undertake analysis of patient safety incident reports describing care received by palliative care patients from the out-of-hours general practice service. Williams will use the learning from incident reports and a scoping review of the literature to inform the content for discussion at stakeholder events. The purpose of the stakeholder events will be to determine the acceptability and feasibility of identified interventions with healthcare professionals in general practice (and wider). Further, the events will add depth and update the programme theory, by exploring the following:

- Which of the identified problems from national level analysis are relevant to practice in this health board?
- Which of the interventions identified in the scoping review are feasible in this setting and fits with the service as it exists currently?(33)

The programme theory will emerge as the basis of the QI project to be led by a large organisation in Wales. Williams will evaluate the QI project and update and amend the programme theory throughout the course of the project, and will identify improvement strategies and produce a 'how to guide' to describe the lessons learnt. If successful, this project will be an exemplar to demonstrate how a model for incident reporting system-driven patient safety improvement can be achieved and could be applied to the range of primary care problems described in section 7.5.2.

In Chapter 5, I demonstrated how a small volume of incident reports could be used to develop a driver diagram which could be taken to frontline stakeholders for discussion and iteration. In the case study, the tacit knowledge of healthcare professionals and managers was used to operationalise the change concepts identified from analysis of incident reports. In this situation, a scoping review may have identified several ways in which other organisations have previously tackled this well-established problem for patient safety in primary care. However, the improvement team had confidence in their change ideas for each change concept. In the absence of change ideas, an improvement team might consider a review of the published and grey literature to benefit from insights accrued by teams in other organisations. Individual general practices are unlikely to have the resources to undertake such searches. However, such

approaches might be relevant for problem issues that have been identified for multiple practices in a CCG or Health Board. Guidance for deciding on whether to undertake a scoping review, or another kind of structured review of the literature, should be developed; currently, decisions to commit to a literature review are largely influenced by resource and skill limitations, as well as beliefs held by the project team around what they expect to gain from the review. Educational providers like the British Medical Journal (BMJ) and RCGP Learning recognise this challenge. Internationally, BMJ launched 'BMJ Open Quality' as an online journal inviting case reports of quality improvement projects.⁽⁵⁴¹⁾ Nationally, the RCGP recognised that an online repository of primary care improvement solutions was needed and launched 'QI Ready' in March 2017.⁽⁵⁴²⁾ An online platform has been created to enable sharing of case studies and facilitate sharing of learning between a network of GPs and primary care professionals working to improve quality improvement in general practice.

7.5.4. Natural language processing

With the WHO now advocating wider use of patient safety incident reporting systems, and several low- and middle-income countries planning/ embarking on creating such systems, there is a pressing need for research to identify cost-effective automated approaches to data acquisition and analysis. The methods employed in my research have involved time-consuming manual analysis of these data undertaken by expensive, trained clinical analysts. This means that these methods cannot easily scale to low- and middle-income countries.

An opportunity exists, given that at least 13,699 reports have been manually coded, for the data set to be used to develop the technology capable of automating the analysis of incident reports. A solution to manual coding is to use Natural Language Processing (NLP) in conjunction with machine learning, which together can convert unstructured free text into structured knowledge autonomously.^(527,543–545) Such approaches demonstrate promise for the automation of categorising incident type.^(546–548) NLP offers a set of

informatics tools capable of transforming text into a structured format that can be used for research and improvement.

7.6. Conclusions

Despite over a decade of patient safety research in the hospital setting, incident-reporting systems have struggled to gain traction with the clinical community, and garnered little respect from the health information and research communities. Therefore, if healthcare professionals in general practices are to invest time and effort in reporting patient safety incidents, a robust method is needed to learn about risk and to generate strategies to minimise future patient risk. Those professionals will want to see results. An opportunity exists to support healthcare organisations to exploit their local data to generate learning from incident reports and inform their quality improvement agenda. This would enable each organisation to undertake their own diagnostics for improvement and prioritise the issues that matter most to their workforces.

Research included in my thesis is the first systematic analysis of safety incident reports from general practice reported to the NRLS. Using mixed methods, I have empirically developed a classification approach to enable coding of patient safety incident reports for the identification of the most common and frequent safety issues, as well as to understand the underlying clinical context reported by healthcare professionals. The four classes of data (incident type, contributory factors, level of harm and outcomes) represent the minimum data needed to identify learning to inform future practice improvement. Opportunities to prevent the issues underpinning the most commonly reported incidents, as well as those described as resulting in severe harm or death, were identified.

Recommendations have been made from this analysis by a multidisciplinary team of clinicians, researchers and patient safety experts.

To advance the field of patient safety in primary care, regular interrogation of routine data, such as incident reports, will be needed to inform the development of a national quality and safety agenda. Although there are recognised limitations of incident reporting system data, my research has generated

hypotheses through an inductive process that now requires development and testing through future research and improvement efforts in clinical practice. Using the issues that matter most to professionals to gain traction for buy-in could help to accelerate a culture of patient safety in primary care.

A structured analysis of local incident reports permitted local improvements to be developed and implemented (exemplar - anticoagulation safety). Similarly, a structured analysis of national-level data permitted identification of more systematic issues concerning general and recurring safety problems, and further work is needed to update and amend the programme theory by improvement activities in a range of contexts. However, variation currently exists in terms of report content and its ability to inform systems improvement. Maximising opportunities to learn from patient safety incidents via mandatory data capture and a national, co-ordinated effort to support organisations to build the capacity and capability of their workforce to report data for learning is needed.

Further work must now build on both deepening and broadening understanding of my thesis findings through methodological development, and wider characterisation of safety incident reports from primary care including scoping reviews for interventions and initiatives to address priorities. Finally, efforts to develop and test emerging programme theories in practice are needed and their effects on patient safety and experience need to be evaluated.

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Appendices

Appendix 1. Search strategy for scoping review (Chapter 2)

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)

- 1 Medical Errors/mt, pc, sn [Methods, Prevention & Control, Statistics & Numerical Data]
- 2 Quality Assurance, Health Care/mt, og, st, sn [Methods, Organization & Administration, Standards, Statistics & Numerical Data]
- 3 Risk Management/mt, og, st, sn [Methods, Organization & Administration, Standards, Statistics & Numerical Data]
- 4 Adverse Drug Reaction Reporting Systems/sn
- 5 Patient Safety/
- 6 Postoperative Complications/
- 7 Iatrogenic Disease/pc
- 8 Diagnostic Errors/mt, pc, sn [Methods, Prevention & Control, Statistics & Numerical Data]
- 9 Safety Management/mt, og, st, sn [Methods, Organization & Administration, Standards, Statistics & Numerical Data]
- 10 (medica\$ adj2 error\$).ab,ti.
- 11 (safety adj2 manag\$).ab,ti.
- 12 (surg\$ adj2 error\$).ab,ti.
- 13 (diagnostic adj error\$).ab,ti.
- 14 (iatrogenic adj disease).ab,ti.
- 15 malpractice.ab,ti.
- 16 (safety adj2 culture).ab,ti.
- 17 (near adj2 failure).ab,ti.
- 18 (near adj2 miss).ab,ti.
- 19 ((incident\$ or safe\$ or event\$) adj3 report\$).tw.
- 20 or/1-18

21 *Informatics/ or *Online systems/ or (system\$ or report\$ or scheme or organi\$ation or method\$ or technique\$ or procedure\$ or process\$ or approach\$ or structure\$ or classification or practice or admin\$ or method\$).tw.

22 20 and 21

Database: Embase Classic+Embase

1 medical error/ae, pc [Adverse Drug Reaction, Prevention]

2 *risk management/

3 adverse drug reaction/co, dm, ep, pc [Complication, Disease Management, Epidemiology, Prevention]

4 *patient safety/

5 *health care quality/

6 postoperative complication/ep, pc [Epidemiology, Prevention]

7 iatrogenic disease/

8 diagnostic error/pc [Prevention]

9 *Safety/

10 malpractice/

11 (medica\$ adj2 error\$).ab,ti.

12 (safety adj manag\$).ab,ti.

13 (surg\$ adj2 error\$).ab,ti.

14 (diagnostic adj error\$).ab,ti.

15 (iatrogenic adj disease).ab,ti.

16 safety culture.ab,ti.

17 (near adj2 failure).ab,ti.

18 (near adj2 miss).ab,ti.

19 ((incident\$ or safe\$ or event\$) adj2 report\$).tw.

20 or/1-19

21 online system/

22 (informatic\$ or system\$ or report\$ or scheme or organi\$ation or method\$ or technique\$ or procedure\$ or process\$ or approach\$ or structure\$ or classification or practice or admin\$ or method\$).tw.

23 21 or 22

24 20 and 23

Database: Wiley COCHRANE Library

- #1 medical error*:ab,ti
- #2 medication error*:ab,ti
- #3 "diagnostic error*":ab,ti
- #4 iatrogenic disease:ab,ti
- #5 malpractice:ab,ti
- #6 "safety culture":ab,ti
- #7 "near failure":ab,ti
- #8 "near miss":ab,ti
- #9 "patient safety":ti,ab
- #10 safety event report*:ti
- #11 safety manage*:ab,ti
- #12 "risk management":ti,ab
- #13 adverse drug reaction:ti
- #14 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13
- #15 system or method or procedure or process or approach or practice:ti
- #16 #14 and #15

Database: Science Citation Index Expanded

- # 3 #2 AND #1
- # 2 TI=(medical error OR medication error OR diagnostic error OR iatrogenic disease OR malpractice OR safety culture OR "near failure" OR "near miss" OR patient safety OR safety event report OR safety manage OR risk manage OR adverse drug reaction OR medication error OR diagnostic error OR iatrogenic disease OR malpractice OR patient safety OR risk management OR adverse drug event)
Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH
Timespan=All years
- # 1 Ti=(informatics or Online systems or system or report or scheme or method or technique or procedure or process or approach or structure or classification or practice)

*Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH
Timespan=All years*

Grey literature searching

The following search terms were inputted to website search engines: 'incident report,' 'safety,' 'patient safety,' and 'healthcare quality'. When over 1000 hits were retrieved, a member of the research team reviewed the first 100 records. Links to publications, research papers and central repositories of organisation reports were sought. In the instance of poorly constructed websites, the site maps were used to locate intended links. In addition to hand searching for website links, individual website search engines were utilised to identify additional material.

Appendix 2. List of the organisational websites relevant to patient safety searched for grey literature (Chapter 2)

- European Centre for Health Policy European Centre for Social Welfare and Policy Research Health Impact Assessment Database
- International Health Policy Library
- International Network of Agencies for Health Technology Assessment
- World Health Organization
- Centre for Study Health System Change
- Centers for Medicare & Medicaid Services Health Policy Institute
- National Center for Policy Analysis
- Institute for Healthcare Improvement
- U.S. Department of Health and Human Services
- U.S. Agency for healthcare Research and Quality
- U.S. National Institute of Health
- U.S. Dept. Veteran Affairs
- Monash Institute of Health Services Research
- Centre for Health Services and Policy Research (Australia)
- The Fraser Institute for Clinical Evaluative Sciences
- Australia Health and Aging
- Australian Policy Online
- Centre for Clinical Effectiveness (Monash University)
- Centre for Health Economics (Monash University)
- Manitoba Centre for Health Policy
- Centre for Health Economics (University of York)
- Centre for Reviews and Dissemination (University of York)
- Institute for Public Policy Research
- The King's Fund
- National Institute for Clinical Excellence
- Policy Studies Institute
- PROSPERO Database

- UK National Health Service
- UK Health and Wellbeing
- UK National Research Register

Appendix 3. Table of included studies (Chapter 2)

Title of paper	Study design	Authors	Country	Year	Journal	Discipline	Name of Classification	Classification
1000 anaesthetic incidents: experience to date	case study	R. Hugh James	UK	2003	Anaesthesia	Anaesthetics	Royal College of Anaesthetists' incident categories and RCA CIRS	Novel Classification
3,520 medication errors evaluated to assess the potential for IT-based decision support	retrospective cross-sectional	Binzer K1, Hellebek A.	Europe	2011	Studies in Health Technology and Informatics	Pharmacy and Pharmacology	Veterans Administration Severity Assessment Code	Novel Classification
A comparative analysis of incident reporting lag times in academic medical centres in Japan and the USA.	comparative analysis	Regenbogen SE, Hirose M, Imanaka Y, Oh EH, Fukuda H, Gawande AA, Takemura T, Yoshihara H.	North America	2010	Quality & Safety in Health Care	Unspecified	Novel classification	Not Explicit
A comparison of iatrogenic injury studies in Australia and the USA II: reviewer behaviour and quality of care	comparative analysis	Runciman WB, Webb RK, Helps SC, Thomas EJ, Sexton EJ, Studdert DM, Brennan TA.	Australasia	2000	International Journal for Quality in Health Care	Unspecified	Generic Occurrence Classification (GOC)	AIMS
A comprehensive overview of medical error in hospitals using incident-reporting systems, patient complaints and chart review of inpatient deaths.	mixed method	de Feijter JM, de Grave WS, Muijtjens AM, Scherpbier AJ, Koopmans RP.	Europe	2012	PLoS One	Unspecified	ICPS	ICPS
A novel error-reporting tool in pediatric intensive care	prospective cross-sectional	Kolovos NS, Bratton SL, Levy FH.	North America	2008	Journal of Healthcare Quality	Intensive Care	NCC MERP	NCC MERP
A physician-based voluntary reporting system for adverse events and medical errors.	descriptive	Weingart SN, Callanan LD, Ship AN, Aronson MD.	North America	2001	Journal of General Internal Medicine	Cardiology	Novel Classification	Novel Classification
A preliminary taxonomy of medical errors in General Practice	descriptive	S M Dovey, D S Meyers, R L Phillips Jr, L A Green, G E Fryer, J M Galliher, J Kappus, P Grob	North America	2002	Quality & Safety in Health Care	All	International Taxonomy of Medical Errors in Primary Care	International Taxonomy of Medical Errors in Primary Care (LINNAEUS)

A prospective analysis of critical incidents attributable to anaesthesia	prospective cross-sectional	Spittal MJ, Findlay GP, Spencer I.	UK	1995	International journal for quality in health care	Anaesthetics	Unspecified	Not Explicit
A review of medication administration errors reported in a large psychiatric hospital in the United Kingdom	retrospective cross-sectional	Camilla Malyn Haw, Geoff Dickens, Jean Stubbs	UK	2005	Psychiatric services	Psychiatry	NCC MERP	NCC MERP
A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005-2010)	retrospective cross-sectional	David H. Cousins, David Gerrett & Bruce Warner	UK	2011	British Journal of Clinical Pharmacology	Unspecified	NRLS classification	Novel Classification
A review of safety incidents in England and Wales for vascular endothelial growth factor inhibitor medications.	descriptive	Kelly SP, Barua A.	UK	2011	Eye	Other	Unspecified	NRLS
A string of mistakes: the importance of cascade analysis in describing, counting, and preventing medical errors.	prospective cross-sectional	Woolf SH, Kuzel AJ, Dovey SM, Phillips RL Jr.	North America	2004	Annals of Family Medicine	General Practice	International Taxonomy of Medical Errors in Primary Care	International Taxonomy of Medical Errors in Primary Care (LINNAEUS)
A system factors analysis of "line, tube, and drain" incidents in the intensive care unit.	retrospective cross-sectional	Needham DM, Sinopoli DJ, Thompson DA, Holzmueller CG, Dorman T, Lubomski LH, Wu AW, Morlock LL, Makary MA, Pronovost PJ.	North America	2005	Critical Care Medicine	Intensive Care	System theory	Novel Classification
A system factors analysis of airway events from the Intensive Care Unit Safety Reporting System (ICUSRS)	retrospective cross-sectional	Needham DM, Thompson DA, Holzmueller CG, Dorman T, Lubomski LH, Wu AW, Morlock LL, Pronovost PJ.	North America	2004	Critical Care Medicine	Unspecified	Novel taxonomy	Novel Classification
Accidents and incidents involving patients in a mental health service	retrospective cross-sectional	Anne Fairlie Richard Brown	UK	1994	Journal of Advanced Nursing	Psychiatry	Unspecified	Not Explicit
Adverse event reporting: lessons learned from 4 years of Florida office data.	retrospective cross-sectional	Coldiron B, Fisher AH, Adelman E, Yelverton CB,	North America	2005	Dermatologic Surgery	Surgery	Unspecified	Not Explicit

Adverse events and comparison of systematic and voluntary reporting from a paediatric intensive care unit.	comparative analysis	Balkrishnan R, Feldman MA, Feldman SR, Silas R, Tibballs J.	Australasia	2010	Quality & Safety in Health Care	Intensive Care	Unspecified	Novel Classification
Adverse events and near miss reporting in the NHS.	prospective cross-sectional	Shaw R, Drever F, Hughes H, Osborn S, Williams S.	UK	2005	Quality & Safety in Health Care	Acute Care	Unspecified	Not Explicit
Adverse events in plastic surgery	prospective cross-sectional	Z. Hassan and P.D. Hodgkinson	UK	2003	British Journal of Plastic Surgery	Surgery	Based on Wilson's generic taxonomy	Novel Classification
Adverse incidents, patient flow and nursing workforce variables on acute psychiatric wards: the Tompkins Acute Ward Study	retrospective cross-sectional	Bowers L, Allan T, Simpon A, Nijman H, & Warren J.	UK	2007	International Journal of Social Psychiatry	Psychiatry	NPSA scale	NRLS
Adverse occurrences in intensive care units.	retrospective cross-sectional	Abramson NS, Wald KS, Grenvik AN, Robinson D, Snyder JV.	North America	1980	JAMA	Intensive Care	Unspecified	Not Explicit
An analysis of Australian adverse drug events.	retrospective cross-sectional	Malpass A, Helps SC, Runciman WB.	Australasia	1999	Journal of Quality in Clinical Practice	Unspecified	Generic Occurrence Classification (GOC)	AIMS
An analysis of computer-related patient safety incidents to inform the development of a classification.	retrospective cross-sectional	Magrabi F, Ong MS, Runciman W, Coiera E.	Australasia	2010	Journal of the American Medical Informatics Association	Unspecified	AIMS	AIMS
An analysis of critical incidents relevant to paediatric anaesthesia reported to the UK National Reporting and Learning System, 2006-2008.	retrospective cross-sectional	MacLennan AI, Smith AF.	UK	2010	Paediatric Anaesthesia	Anaesthetics	NRLS	NRLS
An evaluation of departmental radiation oncology incident reports: anticipating a national reporting system.	retrospective cross-sectional	Terezakis SA, Harris KM, Ford E, Michalski J, DeWeese T, Santanam L, Mutic S, Gay H.	North America	2013	International Journal of Radiation, Oncology, Biology, Physics	Oncology and Radiology	Novel Classification	Novel Classification

An overview of intravenous-related medication administration errors as reported to MEDMARX, a national medication error-reporting program	mixed method	Hicks RW, Becker SC.	North America	2006	Journal of Infusion Nursing	Pharmacy and Pharmacology	NCC MERP	NCC MERP
Anaesthetic adverse incident reports: an Australian study of 1,231 outcomes	retrospective cross-sectional	Aders A, Aders H.	Australasia	2005	Anaesthesia and Intensive Care	Anaesthetics	Unspecified	Not Explicit
Analysis of errors reported by surgeons at three teaching hospitals.	mixed method	Gawande AA, Zinner MJ, Studdert DM, Brennan TA.	North America	2003	Surgery	Surgery	According to Vincent's "Framework for analysing risk and safety in clinical medicine"	Novel Classification
Anesthesia-related mortality and morbidity over a 5-year period in 2,363,038 patients in Japan	mixed method	Kawashima Y, Takahashi S, Suzuki M, Morita K, Irita K, et al.	Asia	2003	Acta Anaesthesiologica Scandinavica	Anaesthetics	Unspecified	Not Explicit
Antiretroviral medication errors in a national medication error database	retrospective cross-sectional	Gray J, Hicks RW, Hutchings C.	North America	2005	AIDS Patient Care and STDs	Pharmacy and Pharmacology	MEDMARX	Novel Classification
Application of data mining to the identification of critical factors in patient falls using a web-based reporting system.	retrospective cross-sectional	Lee TT, Liu CY, Kuo YH, Mills ME, Fong JG, Hung C.	Asia	2011	International Journal of Medical Informatics	Nursing and Midwifery	Unspecified	Not Explicit
Are sequential compression devices commonly associated with in-hospital falls? A myth-busters review using the patient safety net database	retrospective cross-sectional	Boelig MM1, Streiff MB, Hobson DB, Kraus PS, Pronovost PJ, Haut ER.	North America	2011	Journal of Patient Safety	Unspecified	PSN Harm Scores	Not Explicit
Audits and critical incident reporting in paediatric anaesthesia: lessons from 75,331 anaesthetics	retrospective & prospective cross-sectional	Sharon Wan, Yew Nam Siow, Su Min Lee, Agnes NG	Asia	2013	Singapore Medical Journal	Neonatal Care and Paediatrics	Unspecified	Not Explicit
Benchmarking surgical incident reports using a database and a triage system to reduce adverse outcomes.	prospective cross-sectional	Anthony C. Antonacci, MD, SM; Steven Lam, PA; Valentina Lavarias, RN, MA; Peter Homel, PhD; Roland D. Eavey,	North America	2008	Archives of Surgery	Surgery	Unspecified	Not Explicit

MD, SM

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 incident reporting system.	retrospective cross-sectional	Panesar SS, Noble DJ, Mirza SB, Patel B, Mann B, Emerton M, Cleary K, Sheikh A, Bhandari M.	UK	2011	Journal of Orthopaedic Surgery and Research	Surgery	Used NRLS codes to identify but then developed novel classification	Novel Classification
Cardiac surgery errors: results from the UK National Reporting and Learning System.	retrospective cross-sectional	Martinez, Elizabeth A. Shore, Andrew. Colantuoni, Elizabeth. Herzer, Kurt. Thompson, David A. Gurses, et al.	North America	2011	International Journal for Quality in Health Care	Cardiology	Novel classification	Novel Classification
Central or local incident reporting? A comparative study in Dutch GP out-of-hours services	quasi-experimental	Zwart DL, Van Rensen EL, Kalkman CJ, Verheij TJ.	Europe	2011	British Journal of General Practice	General Practice	ORCE procedure	Novel Classification
Characteristics of falls in a large academic radiology department: occurrence, associated factors, outcomes, and quality improvement strategies	retrospective cross-sectional	Abujudeh H1, Kaewlai R, Shah B, Thrall J.	North America	2011	American Journal of Roentgenology	Oncology and Radiology	Novel taxonomy	Novel Classification
Characteristics of medication errors and adverse drug events in hospitals participating in the California Pediatric Patient Safety Initiative.	prospective cross-sectional	Takata GS, Taketomo CK, Waite S.	North America	2008	American Journal of Health System Pharmacology	Neonatal Care and Paediatrics	NCC MERP	NCC MERP
Characteristics of medication errors with parenteral cytotoxic drugs	retrospective cross-sectional	A. FYHR, R. AKSELSSON	Europe	2012	European Journal of Cancer Care	All	NCC MERP	NCC MERP
Classifying Health Information Technology patient safety related incidents - an approach used in Wales.	descriptive	Warm D, Edwards P.	UK	2012	Applied Clinical Informatics	Unspecified	Unspecified	Novel Classification
Classifying laboratory incident reports to identify problems that jeopardize patient safety.	evaluation	Astion ML, Shojania KG, Hamill TR, Kim S, Ng VL.	North America	2003	American Journal of Clinical Pathology	Other	Novel Classification	Novel Classification

Clinical handover incident reporting in one UK general hospital.	retrospective cross-sectional	Pezzolesi C, Schifano F, Pickles J, Randell W, Hussain Z, Muir H, Dhillon S.	UK	2010	International Journal for Quality in Health Care	Unspecified	Datix Common Classification System (CCS)	Novel Classification
Collecting data on potentially harmful events: a method for monitoring incidents in general practice.	mixed method	Britt H, Miller GC, Steven ID, Howarth GC, Nicholson PA, Bhasale AL, Norton KJ.	Australasia	1997	General Practice	General Practice	Unspecified	Not Explicit
Common types of medication errors on long-term psychiatric care units	mixed method	Hiroto Ito, Syun Yamazumi	Asia	2003	International Journal for Quality in Health Care	Psychiatry	Unspecified	Not Explicit
Comparative outcomes analysis of procedures performed in physician offices and ambulatory surgery centers.	retrospective cross-sectional	Vila H Jr, Soto R, Cantor AB, Mackey D.	North America	2003	Archives of Surgery	Surgery	International Classification of Diseases, Ninth Revision	Novel Classification
Comparison of Intensive Care Unit Medication Errors Reported to the United States' MedMarx and the United Kingdom's National Reporting and Learning System: A Cross-sectional Study	comparative analysis	Wahr JA, Shore AD, Harris LH, Rogers P, Panesar S, Matthew L, Pronovost PJ, Cleary K, Pham JC.	North America	2013	American Journal of Medical Quality	Intensive Care	NCC MERP	NCC MERP
Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care in hospitals	retrospective & prospective cross-sectional	Michel P, Quenon J L, de Sarasqueta AM, Scemama O.	Europe	2004	BMJ	Other	Unspecified	Not Explicit
Contributing factors identified by hospital incident report narratives.	descriptive	Nuckols TK, Bell DS, Paddock SM, Hilborne LH.	North America	2008	Quality & Safety in Health Care	Unspecified	Novel Classification	Novel Classification
Critical incident reporting in anaesthesia: a prospective internal audit.	prospective cross-sectional	Gupta S, Naithani U, Brajesh SK, Pathania VS, Gupta A.	Asia	2009	Indian Journal of Anaesthesia	Anaesthetics	Unspecified	Not Explicit
Critical incident reports concerning anaesthetic equipment: analysis of the UK National Reporting and Learning System (NRLS)	retrospective cross-sectional	C. J. Cassidy, A. Smith, J. Arnot-Smith	UK	2011	Anaesthesia	Anaesthetics	NPSA scale	NRLS

data from 2006–2008

Critical incidents during anesthesia in a developing country: A retrospective audit	retrospective cross-sectional	Amucheazi AO, Ajuzieogu OV.	Other	2010	Anaesthetics Essays and Research	Anaesthetics	Unspecified	Not Explicit
Critical incidents in paediatric anaesthesia: an audit of 10 000 anaesthetics in Singapore	prospective cross-sectional	Tay CL, Tan GM, Ng SB.	Asia	2001	Pediatric Anaesthesia	Neonatal Care and Paediatrics	Unspecified	Not Explicit
Critical incidents related to cardiac arrests reported to the Danish Patient Safety Database.	retrospective cross-sectional	Andersen PO, Maaløe R, Andersen HB.	Europe	2010	Resuscitation	Cardiology	Novel Classification	Novel Classification
Developing risk management behaviours for nurses through medication incident analysis	mixed method	Maree Johnson, Duong Thuy Tran, Helen Young	Australasia	2011	International Journal of Nursing Practice	All	Novel Classification	Novel Classification
Diabetes medication patient safety incident reports to the National Reporting and Learning Service: the care home setting.	retrospective cross-sectional	Milligan FJ, Krentz AJ, Sinclair AJ.	UK	2011	Diabetic Medicine	Other	NPSA scale	NRLS
Diagnostic error in a national incident reporting system in the UK.	retrospective cross-sectional	Sevdalis N, Jacklin R, Arora S, Vincent CA, Thomson RG.	UK	2010	Journal of Evaluation in Clinical Practice	Unspecified	Unspecified	NRLS
Does critical incident reporting contribute to medication error prevention?	prospective cross-sectional	Bernhard Frey, Vera Buettiker, Maja I. Hug, Katharina Waldvogel, Peter Gessler, Daniela Ghelfi, Catherine Hodler, Oskar Baenziger	Europe	2002	European Journal of Paediatrics	Intensive Care	Novel Classification	Novel Classification
Does the implementation of an electronic prescribing system create unintended medication errors? A study of the sociotechnical context through the analysis of reported medication incidents.	prospective cross-sectional	Redwood S, Rajakumar A, Hodson J, Coleman JJ.	UK	2011	BMC Medical Informatics and Problem Solving	Pharmacy and Pharmacology	Novel Classification	Novel Classification

Double checking medicines: defence against error or contributory factor?	mixed method	Gerry Armitage	North America	2008	Journal of Evaluation in Clinical Practice	All	Novel Classification	Novel Classification
Drug error in anaesthetic practice: a review of 896 reports from the Australian Incident Monitoring Study database.	prospective cross-sectional	Abeysekera A, Bergman IJ, Kluger MT, Short TG.	Australasia	2005	Anaesthesia	Unspecified	Novel Classification	Novel Classification
Drug Errors and Related Interventions Reported by United States Clinical Pharmacists: The American College of Clinical Pharmacy Practice-Based Research Network Medication Error Detection, Amelioration and Prevention Study	prospective cross-sectional	Kuo GM1, Touchette DR, Marinac JS.	North America	2013	Pharmacotherapy	Pharmacy and Pharmacology	NCC MERP	NCC MERP
Effect of an anonymous reporting system on near-miss and harmful medical error reporting in a pediatric intensive care unit	case study	Mary Jo C. Grant, Gitte Y. Larsen	North America	2006	Journal of nursing care quality	Intensive Care	Novel Classification, definitions provided by 'To Err Is Human: Building a Safer Health System'	Novel Classification
Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients	comparative analysis	Marang-van de Mheen PJ, van Hanegem N, Kievit J.	Europe	2005	Quality & Safety in Health Care	Unspecified	Unspecified	Not Explicit
Electronic reporting to improve patient safety.	quasi-experimental	Tuttle D, Holloway R, Baird T, Sheehan B, Skelton WK.	North America	2004	Quality & Safety in Health Care	Unspecified	Novel Classification	Novel Classification
Endoscope decontamination incidents in England 2003-2004	retrospective cross-sectional	H.P. Gamble, G.J. Duckworth, G.L. Ridgway	UK	2007	Journal of Hospital Infection	Other	Unspecified	Not Explicit
Error in the delivery of radiation therapy: results of a quality assurance review	retrospective cross-sectional	Huang G1, Medlam G, Lee J, Billingsley S, Bissonnette JP, Ringash J, Kane G, Hodgson DC.	North America	2005	International Journal of Radiation, Oncology, Biology, Physics	Oncology and Radiology	Unspecified	Not Explicit
Errors and near misses in digestive endoscopy units.	prospective cross-sectional	Minoli, Giorgio. Borsato, Paolo. Colombo, Enrico.	Europe	2012	Digestive and Liver Disease	Other	Novel Classification	Novel Classification

Errors in a busy emergency department.	prospective cross-sectional	Bortoli, Aurora. Casetti, Tino. de Pretis, Giovanni. Ferraris, Luca. Lorenzini, Ivano. Meggio, Alberto. Meroni, Rudy. Piazzi, Lucia. Terruzzi, Vittorio. Fordyce J, Blank FS, Pekow P, Smithline HA, Ritter G, Gehlbach S, Benjamin E, Henneman PL.	North America	2003	Annals of Emergency Medicine	Anaesthetics	derived from the Model of the Clinical Practice of Emergency Medicine, a description of physician duties in emergency medicine	Novel Classification
Errors in the administration of intravenous medications in hospital and the role of correct procedures and nurse experience	prospective cross-sectional	Westbrook JI1, Rob MI, Woods A, Parry D.	Australasia	2011	BMJ Quality and safety	Nursing and Midwifery	Unspecified	Not Explicit
Errors in the treatment of hypertensive disorders of pregnancy and their impact on maternal mortality	descriptive	Zuleta-Tobón JJ, Pandales-Pérez H, Sánchez S, Vélez-Álvarez GA, Velásquez-Penagos JA.	Other	2013	International Journal of Gynaecology and Obstetrics	Obstetrics and Gynaecology	Unspecified	Novel Classification
Evaluation of an Anonymous system to report medical errors pediatric inpatients	comparative analysis	Taylor J A, Brownsten D, Klein E J, Strandjord T P	North America	2007	Journal Of Hospital Medicine	Neonatal Care and Paediatrics	Unspecified	Novel Classification
Evaluation of two methods for quality improvement in intensive care: facilitated incident monitoring and retrospective medical chart review.	retrospective & prospective cross-sectional	Beckmann U, Bohringer C, Carless R, Gillies DM, Runciman WB, Wu AW, Pronovost P.	Australasia	2003	Critical Care Medicine	Intensive Care	Generic Occurrence Classification (GOC)	AIMS
Every error counts: a web-based incident reporting and learning system for general practice.	retrospective cross-sectional	Hoffmann, B. Beyer, M. Rohe, J. Gensichen, J. Gerlach, F M.	Europe	2008	BMJ Quality and safety	Unspecified	International Taxonomy of Medical Errors in Primary Care	International Taxonomy of Medical Errors in Primary Care (LINNAEUS)

Factors Associated with Reported Preventable Adverse Drug Events: A Retrospective, Case-Control Study	case study	Beckett, Robert D. Sheehan, Amy Heck. Reddan, Jennifer G.	North America	2012	The Annals of Pharmacotherapy	Unspecified	NCC MERP	NCC MERP
Factors influencing the reporting of adverse perioperative outcomes to a quality management program	comparative analysis	Katz RI, Lagasse RS.	North America	2000	Anaesthesia and Analgesia	Anaesthetics	ASA Grading System	Novel Classification
Failures in transition: learning from incidents relating to clinical handover in acute care	retrospective cross-sectional	Thomas MJ, Schultz TJ, Hannafor N, Runciman WB.	Australasia	2013	Journal for Healthcare Quality	Acute Care	Novel taxonomy	Novel Classification
Falls among nursing home residents: an examination of incident reports before and after restraint reduction programs.	quasi-experimental	Ejaz FK, Jones JA, Rose MS.	North America	1994	Journal of the American Geriatric Society	Other	Novel Classification	Novel Classification
Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports.	retrospective cross-sectional	Healey, F. Scobie, S. Oliver, D. Pryce, A. Thomson, R. Glampson, B.	UK	2008	Quality & Safety in Health Care	Acute Care	Novel classification	NRLS
Falls: an examination of three reporting methods in nursing homes.	cohort study	Kanten DN, Mulrow CD, Gerety MB, Lichtenstein MJ, Aguilar C, Cornell JE.	North America	1993	Journal of the American Geriatrics Society	Other	Unspecified	Not Explicit
Feasibility of centre-based incident reporting in primary healthcare: the SPIEGEL study	prospective cross-sectional	Zwart DL, Steerneman AH, van Rensen EL, Kalkman CJ, Verheij TJ.	Europe	2011	BMJ Quality and Safety	General Practice	International Taxonomy of Medical Errors in Primary Care	International Taxonomy of Medical Errors in Primary Care (LINNAEUS)
Field Test Results of a New Ambulatory Care Medication Error and Adverse Drug Event Reporting System—MEADERS.	prospective cross-sectional	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,	North America	2010	Annals of Family Medicine	Anaesthetics	Novel Classification	Novel Classification

Tierney WM.

Five-year experience of critical incidents associated with patient-controlled analgesia in an Irish University Hospital	prospective cross-sectional	Ahmad I1, Thompson A, Frawley M, Hu P, Heffernan A, Power C.	Europe	2010	Irish Journal of Medical Science	Unspecified	Unspecified	Not Explicit
Frequency and nature of reported incidents during Emergency Department care	retrospective cross-sectional	Considine, J. Mitchell, B. Stergiou, H.E.	Australasia	2010	Emergency Medicine Journal	Anaesthetics	Novel Classification	Novel Classification
General surgical adverse events in a UK district general hospital-lessons to learn.	retrospective cross-sectional	Gurjar SV, Roshanzamir S, Patel S, Harinath G.	UK	2011	International Journal of Surgery	Surgery	Datix Common Classification System (CCS)	Novel Classification
Harmful medication errors in children: a 5-year analysis of data from the USP's MEDMARX program	retrospective cross-sectional	Rodney W. Hicks, Shawn C. Becker, Diane D. Cousins	North America	2006	Journal of Pediatric Nursing	Neonatal Care and Paediatrics	NCC MERP	NCC MERP
Hemovigilance network in France: organization and analysis of immediate transfusion incident reports from 1994 to 1998.	prospective cross-sectional	Andreu G, Morel P, Forestier F, Debeir J, Rebibo D, Janvier G, Hervé P.	Europe	2002	Transfusion	Other	Unspecified	Not Explicit
Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place	comparative analysis	Sisse Olsen, Graham Neale, Kat Schwab, Beth Psaila, Tejal Patel, E Jane Chapman, Charles Vincent	UK	2007	BMJ Quality and safety	Unspecified	Unspecified	Not Explicit
Human factors and medical IT systems: complex incident reporting systems and multiple IV infusions	mixed method	Colvin C, Baird P, Easty T, Trbovich P.	North America	2013	Biomedical Instrumentation and Technology	Pharmacy and Pharmacology	Novel Classification	Not Explicit
Human factors-focused reporting system for improving care quality and safety in hospital wards	retrospective cross-sectional	Morag I1, Gopher D, Spillinger A, Auerbach-Shpak Y, Laufer N, Lavy Y, Milwidsky A, Feigin RR, Pollack S, Maza I, Azzam ZS, Admi H, Soudry M.	Other	2012	Human Factors	Surgery	Approach developed by Gopher and Weil (1989)	Novel Classification

Identification and characterization of errors and incidents in a medical intensive care unit	prospective cross-sectional	J. GRAF, A. VON DEN DRIESCH, K.-C. KOCH and U. JANSSENS	Europe	2005	Acta Anaesthesiologica Scandinavica	Intensive Care	SAPS II, TISS-28, Australian Patient Safety Foundation Incident Form (simplified Therapeutic Intervention Scoring System)	Not Explicit
Implementation of an event reporting system in a transfusion medicine unit: a local experience	prospective cross-sectional	Usin MF, Ramesh P, Lopez CG.	Asia	2004	Malaysian Journal of Pathology	Other	Eindhoven Classification Model (PRISMA tool)	Eindhoven Classification Model
Improving the capture of fall events in hospitals: combining a service for evaluating inpatient falls with an incident report system	prospective cross-sectional	Shorr, Ronald I. Mion, Lorraine C. Chandler, A Michelle. Rosenblatt, Linda C. Lynch, Debra. Kessler, Lori A.	North America	2008	Journal of the American Geriatrics Society.	Other	Unspecified	Not Explicit
Incidence of adverse drug events and medication errors in Japan: the JADE study.	cohort study	Morimoto T, Sakuma M, Matsui K, Kuramoto N, Toshiro J, Murakami J, Fukui T, Saito M, Hiraide A, Bates DW.	Asia	2010	Journal of General Internal Medicine	Unspecified	Novel taxonomy	Novel Classification
Incident reporting at a tertiary care hospital in Saudi Arabia.	prospective cross-sectional	Arabi Y, Alamry A, Al Owais SM, Al-Dorzi H, Noushad S, Taher S.	Asia	2012	Journal of Patient Safety	Intensive Care	Novel Classification	Novel Classification
Incident reporting in one UK accident and emergency department.	case study	Tighe CM, Woloshynowych M, Brown R, Wears B, Vincent C.	UK	2006	Accident and Emergency Nursing	Anaesthetics	Novel Classification	Novel Classification
Incidents relating to arterial cannulation as identified in 7,525 reports submitted to the Australian incident monitoring study (AIMS-ICU)	prospective cross-sectional	Durie M, Beckmann U, Gillies DM.	Australasia	2002	Anaesthesia and Intensive Care	Intensive Care	Unspecified	AIMS
Incorrect surgical procedures within and outside of the operating	retrospective cross-sectional	Neily J, Mills PD, Eldridge N, Carney BT, Pfeffer D,	North America	2011	Archives of Surgery	Surgery	Safety Assessment Code (SAC) Matrix	Novel Classification

room: a follow-up report		Turner JR, Young-Xu Y, Gunnar W, Bagian JP.						
Influences observed on incidence and reporting of medication errors in anesthesia	prospective cross-sectional	Cooper L1, DiGiovanni N, Schultz L, Taylor AM, Nossaman B.	North America	2012	Canadian Journal of Anaesthesia	Anaesthetics	Unspecified	Novel Classification
Inpatient medical errors involving glucose-lowering medications and their impact on patients: review of 2,598 incidents from a voluntary electronic error-reporting database	retrospective cross-sectional	Amori RE1, Pittas AG, Siegel RD, Kumar S, Chen JS, Karnam S, Golden SH, Salem DN.	North America	2008	Endocrine Practice	Pharmacy and Pharmacology	Unspecified	Novel Classification
Insulin, hospitals and harm: a review of patient safety incidents reported to the National Patient Safety Agency.	retrospective cross-sectional	Cousins, David. Rosario, Catherine. Scarpello, John.	UK	2011	Clinical Medicine	Unspecified	Unspecified	Not Explicit
Integrating incident data from five reporting systems to assess patient safety: making sense of the elephant.	comparative analysis	Levtzion-Korach O, Frankel A, Alcalai H, Keohane C, Orav J, Graydon-Baker E, Barnes J, Gordon K, Puopulo AL, Tomov EI, Sato L, Bates DW.	North America	2010	Joint Commission Journal on Quality and Patient Safety	Unspecified	Novel Classification	Novel Classification
Integrating Incident Reporting into an Electronic Patient Record System	quasi-experimental	Haller G, Myles PS, Stoelwinder J, Langley M, Anderson H, McNeil J.	Australasia	2007	Journal of the American Medical Informatics Association	All	EPR	Not Explicit
Intensive care unit safety incidents for medical versus surgical patients: a prospective multicenter study	prospective cross-sectional	Sinopoli DJ, Needham DM, Thompson DA, Holzmueller CG, Dorman T, Lubomski LH, Wu AW, Morlock LL, Makary MA, Pronovost PJ.	North America	2007	Journal of Critical Care	Intensive Care	Novel taxonomy	Novel Classification
Interception of potential adverse drug events in long-term psychiatric care units.	prospective cross-sectional	Sawamura K, Ito H, Yamazumi S, Kurita H.	Asia	2005	Psychiatry and Clinical Neurosciences	Psychiatry	Unspecified	Not Explicit

Intralipid medication errors in the neonatal intensive care unit	retrospective cross-sectional	John Chuo, George Lambert, Rodney W. Hicks	North America	2007	Joint commission on quality and patient safety	Neonatal Care and Paediatrics	Unspecified	Not Explicit
Lag time in an incident reporting system at a university hospital in Japan	retrospective cross-sectional	Masahiro Hirose, Scott E Regenbogen, Stuart Lipsitz, Yuichi Imanaka, Tatsuro Ishizaki, Miho, Sekimoto, Eun-Hwan Oh, Atul A Gawande	Asia	2007	Quality & Safety in Health Care	All	Unspecified	Not Explicit
Learning from incident reports in the Australian medical imaging setting: handover and communication errors	retrospective cross-sectional	N HANNAFORD, C MANDEL, FRANZCR, C CROCK, K BUCKLEY, F MAGRABI, M ONG, S ALLEN, T SCHULTZ	Australasia	2013	British Journal of Radiology	Oncology and Radiology	AIMS	AIMS
Learning from prevented suicide in psychiatric inpatient care: An analysis of data from the national Patient safety agency	descriptive	Bowers L, Dack C, Gul N, Thomas B, James K.	UK	2011	International Journal of Nursing Studies	All	Novel classification	Novel Classification
Learning from Taiwan patient-safety reporting system.	mixed method	Lin CC, Shih CL, Liao HH, Wung CH.	Asia	2012	International Journal of Medical Informatics	Unspecified	Novel Classification	Not Explicit
Lessons learnt from incidents reported by postgraduate trainees in Dutch general practice. A prospective cohort study.	cohort study	Zwart DL, Heddema WS, Vermeulen MI, van Rensen EL, Verheij TJ, Kalkman CJ.	Europe	2011	BMJ Quality and Safety	General Practice	Adopted Dovey and Rubin for Dutch context	Novel Classification
Major sources of critical incidents in intensive care.	prospective cross-sectional	Welters, Ingeborg D. Gibson, James. Mogk, Martin. Wenstone, Richard.	UK	2011	Critical Care	Intensive Care	Unspecified	Not Explicit
Measuring falls events in acute hospitals- a comparison of three reporting methods to identify missing	RCT	Hill, Anne-Marie. Hoffmann, Tammy. Hill, Keith. Oliver, David. Beer, Christopher.	Australasia	2010	Journal of the American Geriatrics Society.	Unspecified	Unspecified	Not Explicit

data in the hospital reporting system.		McPhail, Steven. Brauer, Sandra. Haines, Terry P. Källberg AS, Göransson KE, Östergren J, Florin J, Ehrenberg A.	Europe	2013	European Journal of Emergency Medicine	Anaesthetics	Novel Classification	Novel Classification
Medical errors and complaints in emergency department care in Sweden as reported by care providers, healthcare staff, and patients - a national review.	descriptive							
Medical errors in primary care: results of an international study of General Practice	prospective cross-sectional	. Rosser W, Dovey S, Bordman R, White D, Crighton E, Drummond N.	North America	2005	Canadian Family Physician	General Practice	International Taxonomy of Medical Errors in Primary Care	International Taxonomy of Medical Errors in Primary Care (LINNAEUS) Not Explicit
Medication administration errors in Eastern Saudi Arabia	retrospective cross-sectional	Sadat-Ali M, Al-Shafei BA, Al-Turki RA, Ahmed SE, Al-Abbas SA, Al-Omran AS.	Asia	2010	Saudi Medical Journal	Unspecified	Unspecified	
Medication errors among acutely ill and injured children treated in rural emergency departments.	retrospective & prospective cross-sectional	Marcin JP, Dharmar M, Cho M, Seifert LL, Cook JL, Cole SL, Nasrollahzadeh F, Romano PS.	North America	2007	Annals of Emergency Medicine	Neonatal Care and Paediatrics	NCC MERP	NCC MERP
Medication errors and professional practice of registered nurses	prospective cross-sectional	Cecil Deans	Australasia	2005	Collegian	All	NCC MERP	NCC MERP
Medication errors in a paediatric teaching hospital in the UK: five years operational experience.	retrospective cross-sectional	Ross LM, Wallace J, Paton JY.	UK	2000	Archives of Disease in Childhood	Neonatal Care and Paediatrics	Unspecified	Not Explicit
Medication errors in anesthesia: an 8-year retrospective analysis at an urban university hospital	retrospective cross-sectional	Yamamoto M, Ishikawa S, Makita K.	Asia	2008	Journal of Anesthesia	Anaesthetics	Novel taxonomy	Novel Classification
Medication errors in children: A descriptive summary of medication error reports submitted to the United States pharmacopeia	descriptive	Elizabeth Cowley, Roger Williams, Diane Cousins	North America	2001	CURRENT THERAPEUTIC RESEARCH	Neonatal Care and Paediatrics	NCC MERP	NCC MERP
Medication errors in the ambulatory treatment of pediatric attention deficit	retrospective cross-sectional	Bundy DG1, Rinke ML, Shore AD, Hicks RW, Morlock	North America	2008	Joint Commission for the Journal of	Pharmacy and Pharmacology	NCC MERP	NCC MERP

hyperactivity disorder		LL, Miller MR.			Quality and Patient Safety			
Medication errors in the PACU: a secondary analysis of MEDMARX findings	retrospective cross-sectional	Rodney W. Hicks, Shawn C. Becker, Dina Krenzischek, Suzanne C. Beyea	North America	2004	dental injury	Anaesthetics	NCC MERP	NCC MERP
Medication errors involving oral chemotherapy	mixed method	Saul N. Weingart, Julio Toro, Justin Spencer, Deborah Duncombe, Anne Gross, Sylvia Bartel, Jeremy Miransky, Ann Partridge, Lawrence N. Shulman, Maureen Connor	North America	2010	Cancer	Oncology and Radiology	approach developed by Bates and colleagues in studies of adverse drug events in outpatient and hospital settings	Novel Classification
Medication errors related to transdermal opioid patches: lessons from a regional incident reporting system	retrospective cross-sectional	Iovborg, H., Holmlund, M., Hagg, S.	Europe	2014	BMC Pharmacology & Toxicology	Pharmacy and Pharmacology	WHO classification	ICPS
Medication errors reported to the vaccine adverse event reporting system (VAERS).	retrospective cross-sectional	Varricchio F.	North America	2002	Vaccine	Unspecified	Novel Classification	Not Explicit
Medication errors: a prospective cohort study of hand-written and computerised physician order entry in the intensive care unit.	cohort study	Shulman R, Singer M, Goldstone J, Bellingan G.	UK	2005	Critical Care	Intensive Care	based on definitions of what are medication errors and harm severity scales	Novel Classification
Medication errors: Experience of the United States Pharmacopeia (USP) MEDMARX reporting system	retrospective cross-sectional	Santell JP, Hicks RW, McMeekin J, Cousins DD.	North America	2003	Journal of Clinical Pharmacology	Pharmacy and Pharmacology	NCC MERP	NCC MERP
Medication errors--an enduring problem for children and elderly patients	retrospective cross-sectional	Zakharov S, Tomas N, Pelclova D.	Europe	2012	Upsala Journal of Medical Sciences	Other	Poisoning Severity Score and Anatomical Therapeutic Chemical Classification	Novel Classification

Medication safety: using incident data analysis and clinical focus groups to inform educational needs.	mixed method	Hesselgreaves H, Watson A, Crawford A, Lough M, Bowie P.	UK	2013	Journal of Evaluation in Clinical Practice	Unspecified	Novel Classification based on human error theory	Novel Classification
Medication-related patient safety incidents in critical care: a review of reports to the UK National Patient Safety Agency.	retrospective cross-sectional	Thomas AN, Panchagnula U.	UK	2008	Anaesthesia	Intensive Care	NPSA scale	Novel Classification
Mortality as an indicator of patient safety in orthopaedics: lessons from qualitative analysis of a database of medical errors.	descriptive	Panesar SS, Carson-Stevens A, Mann BS, Bhandari M, Madhok R.	UK	2012	BMC Musculoskeletal Disorders	Surgery	Novel Classification	Novel Classification
Moving and handling and patient safety: analysis of clinical incidents.	mixed method	Cornish J, Jones A.	UK	2012	British Journal of Nursing	Unspecified	Novel Classification	Novel Classification
Multicentered Study of model of anaesthesia related adverse events in Asia by incident report (The Thai Anaesthesia Incidents Monitoring Study): results	prospective cross-sectional	Charuluxananan S, Suraseranivongse S, Jantorn P, Sriraj W, Chanchayanon T, Tanudsintum S, Kusumaphanyo C, Suratsunya T, Poajanasupawun S, Klanarong S, Pulnitiporn A, Akavipat P, Punjasawadwong Y	Asia	2008	Journal of the Medical Association of Asia	Anaesthetics	Novel classification	Novel Classification
Narrativizing errors of care: critical incident reporting in clinical practice.	descriptive	Iedema, Rick. Flabouris, Arthas. Grant, Susan. Jorm, Christine.	Australasia	2006	Social science and Medicine	Unspecified	Novel classification	Novel Classification
National study on the distribution, causes, and consequences of voluntarily reported medication errors between the ICU and non-ICU settings.	retrospective cross-sectional	Latif A, Rawat N, Pustavoitau A, Pronovost PJ, Pham JC.	North America	2013	Critical Care Medicine	Unspecified	NCC MERP	NCC MERP
National study on the frequency, types, causes, and consequences of voluntarily reported emergency department	retrospective cross-sectional	Pham JC, Story JL, Hicks RW, Shore AD, Morlock LL, Cheung DS, Kelen GD,	North America	2011	Journal of Emergency Medicine	Anaesthetics	Unspecified	Not Explicit

medication errors.		Pronovost PJ.						
Near-miss events are really missed! Reflections on incident reporting in a department of pediatric surgery	prospective cross-sectional	Mattioli G1, Guida E, Montobbio G, Pini Prato A, Carlucci M, Cama A, Boero S, Michelis MB, Castagnola E, Rosati U, Jasonni V.	Europe	2012	Paediatric Surgery International	Surgery	Unspecified	Not Explicit
Nursing-related patient safety events in hospitals.	prospective cross-sectional	Liu Y, Zhao G, Li F, Huang X, Hu D, Xu J, Yao S, Zhang L.	Asia	2009	Journal of Huazhong University of Science and Technology	Nursing and Midwifery	Unspecified	Not Explicit
Patient safety challenges in a case study hospital--of relevance for transfusion processes?	mixed method	Karina Aase a, Sindre Høyland, Espen Olsen, Siri Wiig, Stein Tore Nilsen	Europe	2008	Transfusion and Apheresis Science	Unspecified	Novel Classification	Novel Classification
Patient safety events reported in general practice: a taxonomy	quasi-experimental	Makeham M.A.B., Stromer, S., Bridges-Webb C., Mira M., Saltman, D.C., Cooper, C. Kidd, M.R.	Australasia	2008	BMJ Quality and Safety	General Practice	TAPS taxonomy	Novel Classification
Patient safety event reporting in critical care: a study of three intensive care units.	prospective cross-sectional	Harris CB, Krauss MJ, Coopersmith CM, Avidan M, Nast PA, Kollef MH, Dunagan WC, Fraser VJ.	North America	2007	Critical Care Medicine	Intensive Care	novel classification	Not Explicit
Patient safety in midwifery-led care in The Netherlands	mixed method	Lucie L.M. Martijna, Annelies J.E. Jacobsa, Irma I.M. Maassena, Simone S.E. Buitendijkb, Michel M. Wensing	Europe	2013	Midwifery	Nursing and Midwifery	Eindhoven Classification Model (PRISMA tool)	Eindhoven Classification Model
Patient safety in orthopedic surgery: prioritising key areas of iatrogenic harm through an analysis of 48,095 incidents reported to	case-control study	Panesar S, Carson-Stevens A, Salvilla S, Patel B, Mirza S, Mann B.	UK	2013	Drug, Health Care and Patient Safety	Surgery	NRLS	NRLS

a national database of errors.									
Patient safety incident-reporting items in Korean hospitals.	retrospective cross-sectional	Hwang JI, Lee SI, Park HA.	Asia	2013	International Journal for Quality in Health Care	Acute Care	ICPS	ICPS	
Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency.	retrospective cross-sectional	Thomas AN, McGrath BA.	UK	2009	Anaesthesia	Intensive Care	NPSA scale	Novel Classification	
Patient safety incidents associated with equipment in critical care: a review of reports to the UK National Patient Safety Agency.	retrospective cross-sectional	Thomas AN, Galvin I.	UK	2008	Anaesthesia	Intensive Care	NPSA scale	Novel Classification	
Patient Safety Incidents Associated with Tracheostomies Occurring in Hospital Wards: A Review of Reports to the UK National Patient Safety Agency	retrospective cross-sectional	McGrath BA1, Thomas AN.	UK	2010	Postgraduate Medical Journal	Surgery	Novel taxonomy	Novel Classification	
Patient safety incidents involving neuromuscular blockade: analysis of the UK National Reporting and Learning System data from 2006 to 2008.	retrospective cross-sectional	Arnot-Smith J, Smith AF.	UK	2010	Anaesthesia	Anaesthetics	NPSA scale	Novel Classification	
Patient safety incidents reported by Finnish dentists; results from an internet-based survey	retrospective cross-sectional	Hiivala N1, Mussalo-Rauhamaa H, Murtomaa H.	Europe	2013	Acta Odontologica Scandinavica	Dentistry	WHO ICPS	ICPS	
Patient safety incidents associated with obesity: a review of reports to the National Patient Safety Agency and recommendations for hospital practice.	retrospective cross-sectional	Booth, C M A. Moore, C E. Eddleston, J. Sharman, M. Atkinson, D. Moore, J A.	UK	2011	Postgraduate Medical Journal	Other	Unspecified	NRLS	
Patterns in nursing home medication errors: disproportionality analysis as a novel method to identify quality improvement	retrospective cross-sectional	Hansen RA, Cornell PY, Ryan PB, Williams CE, Pierson S, Greene SB.	North America	2010	Pharmacoepidemiology & Drug Safety	Pharmacy and Pharmacology	NCC MERP	NCC MERP	

opportunities.

Pediatric Antidepressant Medication Errors in a National Error Reporting Database	descriptive	Rinke ML, Bundy DG, Shore AD, Colantuoni E, Morlock LL, Miller MR.	North America	2010	Journal of Developmental and Behavioural Pediatrics	Neonatal Care and Paediatrics	NCC MERP	NCC MERP
Pediatric safety incidents from an intensive care reporting system.	prospective cross-sectional	Skapik JL, Pronovost PJ, Miller MR, Thompson DA, Wu AW.	North America	2009	Journal of Patient Safety	Intensive Care	Novel Classification	Novel Classification
Perianesthetic dental injuries: analysis of incident reports.	retrospective cross-sectional	Givol N, Gershtansky Y, Halamish-Shani T, Taicher S, Perel A, Segal E.	Other	2004	Journal of Clinical Anaesthesia	Dentistry	Unspecified	Not Explicit
Perioperative Pulmonary Aspiration: An Analysis of 28 Reports from the Thai Anaesthesia Incident Monitoring Study (Thai AIMS)	descriptive	Klanarong S, Suksompong S, Hintong T, Chau-In W, Jantorn P, Werawatganon T.	Asia	2011	Journal of the Medical Association of Asia	Anaesthetics	Unspecified	Not Explicit
Preventable Mix-ups of Tuberculin and Vaccines: Reports to the US Vaccine and Drug Safety Reporting Systems.	retrospective cross-sectional	Chang S, Pool V, O'Connell K, Polder JA, Iskander J, Sweeney C, Ball R, Braun MM.	North America	2008	Drug Safety	Other	Unspecified	Not Explicit
Preventing medication errors in community pharmacy: frequency and seriousness of medication errors	retrospective cross-sectional	P Knudsen, H Herborg, A R Mortensen, M Knudsen, A Hellebek	Europe	2007	Quality & Safety in Health Care	Pharmacy and Pharmacology	definition of the medication process as applied by Andersen et al was used as a structure for coding and analysis	Novel Classification
Preventing medication errors in community pharmacy: root-cause analysis of transcription errors	descriptive	P Knudsen, H Herborg, A R Mortensen, M Knudsen, A Hellebek	Europe	2007	Quality & Safety in Health Care	Pharmacy and Pharmacology	Unspecified	Not Explicit
Preventing medication errors in long-term care: results and evaluation of a large scale web-based error	evaluation	Pierson S, Hansen R, Greene S, Williams C, Akers R, Jonsson M,	North America	2007	Quality & Safety in Health Care	Other	Unspecified	Not Explicit

reporting system.		Carey T.						
Problems and consequences in the use of professional interpreters: qualitative analysis of incidents from primary healthcare.	case study	Hadziabdic E, Heikkilä K, Albin B, Hjelm K.	Europe	2011	Nursing Inquiry	General Practice	Novel Classification	Novel Classification
Profiling harmful medication errors in an acute Irish teaching hospital.	retrospective cross-sectional	Relihan EC, Ryder SA, Silke B.	Europe	2012	Irish Journal of Medical Science	Pharmacy and Pharmacology	NCC MERP	NCC MERP
Providing feedback to hospital doctors about prescribing errors; a pilot study	prospective cross-sectional	Franklin BD1, O'Grady K, Paschalides C, Utley M, Gallivan S, Jacklin A, Barber N.	UK	2007	Pharmacy World and Science	Pharmacy and Pharmacology	Unspecified	Not Explicit
Quality assurance in radiotherapy: evaluation of errors and incidents recorded over a 10 year period.	prospective cross-sectional	Yeung TK, Bortolotto K, Cosby S, Hoar M, Lederer E.	North America	2005	Radiotherapy and Oncology	Oncology and Radiology	Unspecified	Novel Classification
Radiation Oncology Safety Information System (ROSIS)--profiles of participants and the first 1074 incident reports.	prospective cross-sectional	Cunningham J, Coffey M, Knöös T, Holmberg O.	Europe	2010	Radiotherapy and Oncology	Oncology and Radiology	Novel Classification	Novel Classification
Rates and types of events reported to established incident reporting systems in two US hospitals.	prospective cross-sectional	Nuckols TK, Bell DS, Liu H, Paddock SM, Hilborne LH.	North America	2007	Quality & Safety in Health Care	Unspecified	Harvard Medical Practice Study Categorisation	Novel Classification
Real-time registration of adverse events in Dutch hospitalized children in general pediatric units: first experiences	prospective cross-sectional	van der Starre C, van Dijk M, Tibboel D.	Europe	2012	European Journal of Pediatrics	Unspecified	Unspecified	Not Explicit
Recovery room incidents: a review of 419 reports from the Anaesthetic Incident Monitoring Study (AIMS)	retrospective cross-sectional	M. T. Kluger and M. F. M. Bullock	Australasia	2002	Anaesthesia	Anaesthetics	Unspecified	AIMS
Reported medication events in a paediatric emergency research network: sharing to improve patient safety.	retrospective cross-sectional	Shaw KN, Lillis KA, Ruddy RM, Mahajan PV, Lichenstein R, Olsen CS,	North America	2013	Emergency Medicine Journal	Neonatal Care and Paediatrics	NCC MERP	NCC MERP

Chamberlain JM.

Reporting drug errors in a British acute hospital trust	mixed method	Armitage G, Newell R.	UK	2007	Clinical Governance	Pharmacy and Pharmacology	NCC MERP	NCC MERP
Reporting of medical errors: an intensive care unit experience.	prospective cross-sectional	Osmon S, Harris CB, Dunagan WC, Prentice D, Fraser VJ, Kollef MH.	North America	2004	Critical Care Medicine	Intensive Care	Unspecified	Not Explicit
Reporting of sentinel events in Swedish hospitals: a comparison of severe adverse events reported by patients and providers	retrospective cross-sectional	Ohrn A, Elfström J, Liedgren C, Rutberg H.	Europe	2011	Joint Commission Journal on Quality & Patient Safety	Unspecified	Unspecified	Not Explicit
Retrospective analysis of medication incidents reported using an on-line reporting system	retrospective cross-sectional	Darren M Ashcroft Jonathan Cooke	UK	2006	Pharmacy and world Science	All	Novel Classification	Novel Classification
Retrospective analysis of mortalities associated with medication errors	retrospective cross-sectional	Phillips J, Beam S, Brinker A, Holquist C, Honig P, Lee LY, Pamer C.	North America	2001	American Journal of Health-System Pharmacy	Pharmacy and Pharmacology	NCC MERP	NCC MERP
Retrospective record review in proactive patient safety work - identification of no-harm incidents	retrospective cross-sectional	Schildmeijer K, Unbeck M, Muren O, Perk J, Härenstam K, Nilsson L.	Europe	2013	BMC Health Services Research	Unspecified	Vincent et al. 1998	Not Explicit
Review of patient safety incidents reported from critical care units in North-West England in 2009 and 2010.	retrospective cross-sectional	Thomas AN, Taylor RJ.	UK	2012	Anaesthesia	Intensive Care	NPSA	NRLS
Review of patient safety incidents submitted from Critical Care Units in England & Wales to the UK National Patient Safety Agency	retrospective cross-sectional	Thomas AN, Panchagnula U, Taylor RJ.	UK	2009	Anaesthesia	Intensive Care	NPSA scale	NRLS
Risk management in dermatology: an analysis of data available from several British-based reporting systems.	retrospective cross-sectional	Gawkrodger DJ.	UK	2011	British Journal of Dermatology	Other	Unspecified	Not Explicit

Safety in anaesthesia: a study of 12 606 reported incidents from the UK National Reporting and Learning System.	retrospective cross-sectional	Catchpole K, Bell M, Johnson S.	UK	2008	Anaesthesia	Anaesthetics	Novel classification	NRLS
Safety incidents in family medicine.	prospective cross-sectional	O'Beirne M, Sterling PD, Zwicker K, Hebert P, Norton PG.	North America	2011	BMJ Quality and Safety	General Practice	Unspecified	Not Explicit
Scrutinizing incident reporting in anaesthesia: why is an incident perceived as critical?	prospective cross-sectional	Maaløe R, la Cour M, Hansen A, Hansen EG, Hansen M, Spangsberg NL, Landsfeldt US, Odorico J, Olsen KS, Møller JT, Pedersen T.	Europe	2006	Acta Anaesthesiologica Scandinavica	Anaesthetics	Novel Classification	Not Explicit
Selected medication-error data from USP's MEDMARX program for 2002	retrospective cross-sectional	RODNEY W. HICKS, DIANE D. COUSINS, AND ROGER L. WILLIAMS	North America	2004	American journal of health systems pharmacy	All	NCC MERP	NCC MERP
Self harm in adult inpatient psychiatric care: A national study of incident reports in the UK	descriptive	Karen James, Duncan Stewart, Steve Wright, Len Bowers	UK	2012	International Journal of Nursing Studies	Psychiatry	Novel classification	Novel Classification
Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review	retrospective cross-sectional	Sari AB, Sheldon TA, Cracknell A, Turnbull A.	UK	2007	BMJ	Surgery	Novel taxonomy	Not Explicit
Serious hazards of transfusion (SHOT) initiative: analysis of the first two annual reports	prospective cross-sectional	Williamson LM, Lowe S, Love EM, Cohen H, Soldan K, McClelland DB, Skacel P, Barbara JA.	UK	1999	BMJ	Other	Novel taxonomy	Novel Classification
Seven hundred and fifty-nine (759) chances to learn: a 3-year pilot project to analyse transfusion-related near-miss events in the Republic of Ireland.	prospective cross-sectional	Lundy D, Laspina S, Kaplan H, Rabin Fastman B, Lawlor E	UK	2007	Vox Sanguinis	Other	Eindhoven Classification Model (PRISMA tool)	Eindhoven Classification Model

Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports.	prospective cross-sectional	Snijders C, van Lingen RA, Klip H, Fetter WP, van der Schaaf TW, Molendijk HA.	Europe	2009	Archives of Disease in Childhood	Intensive Care	PRISMA	Eindhoven Classification Model
Study of model of Anaesthesia Related Adverse Event by Incident Report at King Chulalongkorn Memorial Hospital	prospective cross-sectional	Narasethkamol, Arunchai. Charuluxananan, Somrat. Kyokong, Oranuch. Premsamran, Porntep. Kundej, Sarawut.	Asia	2011	Journal of the Medical Association of Asia	Anaesthetics	Unspecified	Not Explicit
Surgical case listing accuracy: failure analysis at a high-volume academic medical center	descriptive	Robert R. Cima, Curt Hale, Anantha Kollengode, James C. Rogers, Stephen D. Cassivi, Claude Deschamps	North America	2010	Archives of Surgery	Surgery	Novel Classification	Novel Classification
Technology-related medication errors in a tertiary hospital: a 5-year analysis of reported medication incidents	retrospective cross-sectional	Samaranayake NR, Cheung STD, Chui WCM, Cheung BMY.	Asia	2012	International Journal of Medical Informatics	Unspecified	Novel taxonomy	Novel Classification
Tenfold medication errors: 5 years' experience at a university-affiliated pediatric hospital.	retrospective cross-sectional	Doherty C, Mc Donnell C.	North America	2012	Pediatrics	Neonatal Care and Paediatrics	NCC MERP	NCC MERP
The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. The development and evaluation of an incident reporting system in intensive care	evaluation	Beckmann U1, West LF, Groombridge GJ, Baldwin I, Hart GK, Clayton DG, Webb RK, Runciman WB.	Australasia	1996	anaesthesia and intensive care	Intensive Care	Used a research and collaborative approach to design the incident report structure which then framed their analysis. Used clinical observation, theory, research and expert opinion	AIMS
The Australian Incident Monitoring Study. Air embolism--an analysis of 2000 incident reports	retrospective cross-sectional	Williamson JA, Webb RK, Russell WJ, Runciman WB.	Australasia	1993	Anaesthesia and Intensive Care	Anaesthetics	AIMS	AIMS

The Australian Incident Monitoring Study. Cardiac arrest--an analysis of 2000 incident reports	retrospective cross-sectional	Morgan CA, Webb RK, Cockings J, Williamson JA.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Crisis management--validation of an algorithm by analysis of 2000 incident reports	retrospective cross-sectional	Runciman WB, Webb RK, Klepper ID, Lee R, Williamson JA, Barker L.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Difficult intubation: an analysis of 2000 incident reports	retrospective cross-sectional	Williamson JA, Webb RK, Szekely S, Gillies ER, Dreosti AV.	Australasia	1993	Anaesthesia and Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Human failure: an analysis of 2000 incident reports	retrospective cross-sectional	Williamson JA, Webb RK, Sellen A, Runciman WB, Van der Walt JH.	Australasia	1993	Anaesthesia and Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Paediatric incidents in anaesthesia: an analysis of 2000 incident reports	retrospective cross-sectional	Singleton RJ, Ludbrook GL, Webb RK, Fox MA.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Patient awareness during anaesthesia: an analysis of 2000 incident reports	retrospective cross-sectional	Osborne GA, Webb RK, Runciman WB.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Physical injuries and environmental safety in anaesthesia: an analysis of 2000 incident reports	retrospective cross-sectional	Singleton RJ, Ludbrook GL, Webb RK, Fox MA.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Pneumothorax: an analysis of 2000 incident reports.	retrospective cross-sectional	Williamson JA, Webb RK, Van der Walt JH, Runciman WB.	Australasia	1993	Anaesthesia and Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Problems associated with vascular access: an analysis of 2000 incident reports	retrospective cross-sectional	Singleton RJ, Webb RK, Ludbrook GL, Fox MA.	Australasia	1993	Anaesthesia and Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Problems before induction of anaesthesia: an analysis of	retrospective cross-sectional	Ludbrook GL, Webb RK, Fox MA, Singleton RJ.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS

2000 incident reports

The Australian Incident Monitoring Study. Problems related to the endotracheal tube: an analysis of 2000 incident reports	retrospective cross-sectional	Szekely SM, Webb RK, Williamson JA, Russell WJ.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Problems with ventilation: an analysis of 2000 incident reports	retrospective cross-sectional	Russell WJ, Webb RK, Van der Walt JH, Runciman WB.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. Recovery room incidents in the first 2000 incident reports	retrospective cross-sectional	Van der Walt JH, Webb RK, Osborne GA, Morgan C, Mackay P.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. System failure: an analysis of 2000 incident reports	retrospective cross-sectional	Runciman WB, Webb RK, Lee R, Holland R.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. The capnograph: applications and limitations--an analysis of 2000 incident reports	retrospective cross-sectional	Williamson JA, Webb RK, Cockings J, Morgan C.	Australasia	1993	Anaesthesia and Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. The electrocardiograph: applications and limitations--an analysis of 2000 incident reports	retrospective cross-sectional	Ludbrook GL, Russell WJ, Webb RK, Klepper ID, Currie M.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study. The pulse oximeter: applications and limitations--an analysis of 2000 incident reports	retrospective cross-sectional	Runciman WB, Webb RK, Barker L, Currie M.	Australasia	1993	Anaesthesia & Intensive Care	Anaesthetics	AIMS	AIMS
The Australian Incident Monitoring Study: Which monitor? An analysis of 2000 incident reports.	retrospective cross-sectional	Webb RK, van der Walt JH, Runciman WB, Williamson JA, Cockings J, Russell WJ, Helps, S.	Australasia	1993	Anaesthesia and Intensive Care	Anaesthetics	AIMS	AIMS

The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. An analysis of the First Year of Reporting	prospective cross-sectional	Beckmann U, Baldwin I, Hart GK, Runciman WB.	Australasia	1996	Anaesthesia and Intensive Care	Anaesthetics	Unspecified	AIMS
The Australian Incident Monitoring Study: An analysis of 2000 Incident reports	prospective cross-sectional	Webb RK, Currie M, Morgan CA, Williamson JA, Mackay P, Russell WJ, Runciman WB.	Australasia	1993	Anaesthesia and Intensive care	Anaesthetics	AIMS	AIMS
The development of a system for the reporting, classification and grading of quality failures in the clinical biochemistry laboratory	prospective cross-sectional	O'Kane MJ, Lynch PL, McGowan N.	UK	2008	Annals of Clinical Biochemistry	Other	Novel Classification	Novel Classification
The epidemiology and type of medication errors reported to the National Poisons Information Centre of Ireland	prospective cross-sectional	NICOLA CASSIDY , EDEL DUGGAN , DAVID J. P. WILLIAMS , and JOSEPH A. TRACEY	Europe	2011	Clinical Toxicology	All	NCC MERP	NCC MERP
The frequency and importance of reported errors related to parenteral nutrition in a regional paediatric centre	retrospective cross-sectional	Narula P, Hartigan D, Puntis J.	UK	2011	e-SPEN, the European e-Journal of Clinical Nutrition and Metabolism	Other	NCC MERP	NCC MERP
The harm susceptibility model: a method to prioritise risks identified in patient safety reporting systems.	retrospective cross-sectional	Pham JC, Colantuoni E, Dominici F, Shore A, Macrae C, Scobie S, Fletcher M, Cleary K, Goeschel CA, Pronovost PJ.	North America	2010	Quality & Safety in Health Care	Other	Novel Classification	NRLS
The nature and causes of unintended events reported at ten emergency departments.	prospective cross-sectional	Smits, M. Groenewegen, P.P. Timmermans, D. R.M. van der Wal, G. Wagner, C.	Europe	2009	BMC Emergency Medicine	Anaesthetics	Eindhoven Classification Model (PRISMA tool)	Eindhoven Classification Model
The nature and causes of unintended events reported at ten internal medicine departments.	prospective cross-sectional	Lubberding S, Zwaan L, Timmermans DR, Wagner C.	Europe	2011	Journal of Patient Safety	Other	PRISMA	Eindhoven Classification Model

The recognition of critical incidents: Quantification of monitor effectiveness	prospective cross-sectional	Findlay GP1, Spittal MJ, Radcliffe JJ.	UK	1998	Anaesthesia	Anaesthetics	Adapted from Cooper et al. 1984	Novel Classification
The Thai Anaesthesia Incident Monitoring Study (Thai AIMS) of anesthetic equipment failure/malfunction: an analysis of 1996 incident reports	prospective cross-sectional	Kusumaphanyo C, Charuluxananan S, Sriramatr D, Pulnitiporn A, Sriraj W.	Asia	2009	Journal of the Medical Association of Asia	Anaesthetics	Novel classification	Not Explicit
The Thai Anaesthesia Incident Monitoring Study (Thai AIMS) of Post Anaesthetic Reintubation: An analysis of 184 incident reports	descriptive	Chinachoti T, Poopipatpab S, Buranatrevedhya S, Taratarnkoolwatan a K, Werawataganon T, Jantorn P.	Asia	2008	Journal of the Medical Association of Asia	Anaesthetics	Unspecified	Not Explicit
The Thai Anesthesia Incident Monitoring Study (Thai AIMS): an analysis of perioperative complication in geriatric patients	prospective cross-sectional	Tuchinda L1, Sukchareon I, Kusumaphanyo C, Suratsunya T, Hintong T, Thienthong S.	Asia	2010	Journal of the Medical Association of Asia	Anaesthetics	Unspecified	Not Explicit
The Thai anesthesia incident monitoring study (Thai AIMS): an analysis of perioperative myocardial ischemia/infarction	prospective cross-sectional	Ngamprasertwong P, Kositanurit I, Yokanit P, Wattanavit R, Atichat S, Lapisatepun W.	Asia	2008	Journal of the Medical Association of Asia	Anaesthetics	Unspecified	Not Explicit
The Thai Anesthesia Incident Monitoring study (Thai AIMS): perioperative arrhythmia.	prospective cross-sectional	Ngamprasertwong, P. Kositanurit, I. Yokanit, P. Lersirisopon, S. Pulnitiporn, A. Klanarong, S.	Asia	2009	Journal of the Medical Association of Asia	Surgery	Unspecified	Not Explicit
The Thai incident monitoring study (Thai AIMS) of desaturation: an analysis of 1996 incident reports	descriptive	Suksompong, S. Chatmongkolchat, S. Hintong, T. Klanarong, S. Cha-in, W.	Asia	2008	Journal of the Medical Association of Asia	Anaesthetics	Novel classification	Not Explicit
The Thai incident monitoring study (Thai AIMS) of suspected pulmonary embolism: an analysis of	descriptive	Virankabutra, T. Chularojmontri T, Kositanurit I, Charuluxananan S, Sriraj W,	Asia	2011	Journal of the Medical Association of Asia	Anaesthetics	Novel classification	Not Explicit

1996 incident reports		Punjasawadwong Y, Pulnitiporn A.						
The use of categorized time-trend reporting of radiation oncology incidents: a proactive analytical approach to improving quality and safety over time	prospective cross-sectional	Arnold A1, Delaney GP, Cassapi L, Barton M.	Australasia	2010	International Journal of Radiation, Oncology, Biology, Physics	Oncology and Radiology	State Severity Assessment Code	Novel Classification
Therapeutic errors among children in the community setting: Nature, causes and outcomes.	prospective cross-sectional	Mc D Taylor D, Robinson J, MacLeod D, MacBean CE, Braitberg G.	Australasia	2009	Journal of Paediatrics and Child Health	Other	NCC MERP	NCC MERP
Toward learning from patient safety reporting systems.	cohort study	Pronovost PJ, Thompson DA, Holzmueller CG, Lubomski LH, Dorman T, Dickman F, Fahey M, Steinwachs DM, Engineer L, Sexton JB, Wu AW, Morlock LL.	North America	2006	Journal of Critical Care	Intensive Care	informed by Vincent's framework	Novel Classification
Trend analysis of radiation therapy incidents over seven years.	trend analysis	Bissonnette JP, Medlam G.	North America	2010	Radiotherapy and Oncology	Oncology and Radiology	from from Ekaette's taxonomy	Novel Classification
Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System	retrospective cross-sectional	A Hutchinson, T A Young, K L Cooper, A McIntosh, J D Karnon, S Scobie, R G Thomson	UK	2009	Quality & Safety in Health Care	All	Novel Classification	NRLS
Voluntary electronic reporting of laboratory errors: an analysis of 37,532 laboratory event reports from 30 health care organizations	retrospective cross-sectional	Snydman LK, Harubin B, Kumar S, Chen J, Lopez RE, Salem DN.	North America	2012	American Journal of Medical Quality	Laboratory	Novel taxonomy	Novel Classification
Voluntary electronic reporting of medical errors and adverse events. An analysis of 92,547 reports from 26 acute care hospitals.	descriptive	Milch CE, Salem DN, Pauker SG, Lundquist TG, Kumar S, Chen J.	North America	2006	Journal of General Internal Medicine	Other	Novel Classification	Novel Classification

Voluntary medication error reporting program in a Japanese national university hospital	retrospective cross-sectional	Hiroyuki Furukawa, Hisashi Bunko, Fumito Tsuchiya, and Ken-ichi Miyamoto	Asia	2003	Annals of pharmacotherapy	All	Unspecified	Not Explicit
What do radiology incident reports reveal about in-hospital communication processes and the use of health information technology?	retrospective cross-sectional	Stewart MJ, Georgiou A, Hordern A, Dimigen M, Westbrook JI.	Australasia	2012	Studies in Health Technology and Informatics	Unspecified	ICPS	ICPS
Where failures occur in the imaging care cycle: lessons from the radiology events register	mixed method	D. Neil Jones, M.J.W. Thomas, Catherine J. Mandel, Grimm, N. Hannaford, Timothy J. Schultz, William Runciman	Australasia	2010	Journal of the American College of Radiology	Oncology and Radiology	AIMS	AIMS
Wrong intraocular lens implant; learning from reported patient safety incidents.	descriptive	Kelly SP, Jalil A.	UK	2011	Eye	Other	Unspecified	Not Explicit

Appendix 4. List of excluded studies (Chapter 2)

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Appendix 5. Protocol submitted for NIHR HS&DR 12/64/118

Protocol – version 2 (July 2013)

PROJECT TITLE

Characterising the nature of primary care patient safety incident reports in England and Wales: mixed methods study.

SUMMARY OF RESEARCH

Primary care is overdue its recognition as a threat to patient safety where over a quarter of a million UK patients will experience harm in this setting each year (Panesar, Carson-Stevens et al. in review). A WHO-commissioned review of primary care patient safety research highlighted a limited appreciation of the causal pathways underpinning patient safety incidents (PSIs) that arise and translate into harm, and a limited understanding about where and how to effectively intervene. Further, no studies have explained or even hypothesised reasons why some incidents are more commonly reported and what opportunities exist to prevent them (WHO 2012).

The National Reporting and Learning System (NRLS) contains over 47,000 PSI reports from frontline clinicians in primary care in England and Wales and is the largest repository of primary care reports in the world.

We propose a mixed-methods study to use the NRLS database to understand the nature and range of PSIs that have resulted in harm to patients in primary care. We will identify patient safety incident reports from primary care in England and Wales between April 2003 and June 2012. All incidents resulting in severe harm and death will be analysed, and a 25% random sample of reports with all compulsory fields and free-text incident descriptions completed (available for 99.9% of total reports). Reports will be exported to STATA (StataCorp LP, USA) for descriptive statistical analysis and NVivo (QSR International Pty Ltd, Australia) for thematic content analysis.

Key incident characteristics will be identified using descriptive statistics (objectives 1&2) whereby differences in proportions of demographics e.g. incident type, incident location, and patient characteristics with the severity of harm event will be assessed by Chi-squared and Fisher's exact tests, and t-test. Subsequent logistic regression modelling will evaluate relationships between those variables to harm outcomes in the data (objective 3). Attributes with statistically significant relationships with any level of harm will be organised by their strength of association.

Free-text descriptions will be characterised by thematic analysis (objectives 4 & 5). This requires 'sense making' of the reported story and eliciting human factors and organizational issues discussed within it (Reason 1990; Reason 1995; Vincent et al. 1998; Henriksen and Kaplan 2003). Free-text will be categorised according to the LINNEAUS Primary Care Patient Safety Incident Classification scheme to describe the content of each report (<http://www.linneaus-pc.eu>). This taxonomy has only previously been informed by a systematic review and expert consensus methods; we will therefore iterate the taxonomy based on empirical analysis of the England and Wales data. As categories are assigned e.g. 'wrong drug administered', similar cases can be identified and higher-level themes will emerge e.g. 'administration errors' (Cooke and Scobie 2009). Reports will be interrogated inductively. Two primary care doctors and a research nurse will undertake analysis independently. We will describe the content of the text, the context and characteristics of the incident; identify patterns or recurring themes in the data; and compare incidents with different characteristics.

We anticipate the research will benefit patients and the NHS by: characterising patient safety incidents - understanding the nature, range and potential contributory influences - that lead to harm in primary care for the first time; and identifying how reporting of incidents can be improved to facilitate future learning.

BACKGROUND AND RATIONALE

Patient safety in primary care – an overlooked priority

Around 1 in 10 hospital in-patients experience a patient safety incident during their care (de Vries et al. 2008). Unsafe care is thus responsible for a substantial, potentially preventable, burden of disease (Landrigan et al. 2010). Over the past decade, most of the research on patient safety has been based in secondary care where it has been demonstrated possible to identify patterns in errors and determine those most frequently leading to major harm and isolate those most amenable to prevention. Informed by those epidemiological studies, patient safety in secondary care is now in an era of implementing interventions. There is now recognition similar work is needed in primary care (WHO 2012).

Studies of risk and iatrogenic patient harm, however, pose substantial challenges in primary care given the heterogeneity in primary care provision. The challenges of safe primary care relate to the variety of healthcare professionals that intervene, the data they exchange (verbally and written), and the movement of the patient between these, as well as the episodic and decentralised nature of care. The discipline of patient safety relies on evidence that harm is due to a multifactorial chain of events (Institute of Medicine 1999; Reason 2000). The underlying assumption is that if systems (i.e. organisations and networks of organisations) and working conditions within these can be optimised, then the occurrence of patient safety incidents is less likely.

Frequency and causes of primary care patient safety incidents

Until recently there was no robust evidence on the frequency of errors in primary care (WHO 2012). Our meta-analysis of a subset of studies suggested that 1.0% (95% CI 1.0–2.0) of all patient encounters in primary care in high-income countries involved an error, with major harm resulting from 12.8% (95% CI 9.8–15.8) of these errors (Panesar et al. in review). Based on our estimates, of the 303.9 million consultations per annum in general practices in England alone (2008-9), approximately 4 million (1.3%) will involve a patient safety incident. Over half a million (12.8%) of these are likely to have resulted in substantial harm to patients. General practice consultations only represent a subset of the encounters in primary care so the actual burden from errors in this setting (i.e. pharmacy, nursing, dentistry, out of hours services, community hospitals) is likely to be substantially higher than these estimates suggest.

Our systematic review (Panesar et al., in review) also identified that few studies have hypothesised or explained the causes or contributing factors to patient safety incidents in primary care (Britt et al. 1997; Fischer et al. 1997; Bhasale et al. 1998; Holden et al. 1998; Woolf et al. 2004; Kostopoulo and Delaney, 2007; Mitchel et al. 2013). No such studies have occurred within the United Kingdom.

Patient Safety Reporting Systems

All methods to examine patient safety incidents in healthcare provide only a partial picture of the problem. Patient Safety Reporting Systems offer an avenue for frontline healthcare professionals and patients to report details about the patient safety incidents they have been involved in or witnessed. In England and Wales, the National Reporting and Learning System (NRLS) receives reports about any “unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS funded care”. The reported information can therefore be used to advance understanding about the magnitude and nature of preventable harm.

Leading experts recognise that despite limitations of reporting systems – underreporting, incomplete view of incident, and reporting biases – they provide multiple perspectives over time and form an integral part of routine monitoring in clinical practice (Vincent 2010). Underreporting is the Achilles’ heel of a patient safety reporting system, and only 47,000 reports (0.4% of the total number of NRLS reports) exist from primary care. This reflects a poor reporting culture from primary care staff in England and Wales in the past decade, and is probably a reflection of the national emphasis placed on patient safety in hospital settings (Panesar et al. 2009). Paradoxically, despite the large number of incident reports received by patient safety reporting systems like the NRLS, reporting systems have been shown to detect only about 6% of adverse events found by a systematic review of records (Sari et al. 2007). This represents a mismatch between what actually occurs in clinical care and what healthcare professionals report as a ‘patient safety incident’. The Francis report (2013) could dramatically influence the reporting

culture amongst primary care healthcare professionals, as well as what gets reported by them, since it states they must play a greater role in quality monitoring, and reaffirmed their role to report adverse events and suboptimal care. Demonstrating the benefits of the learning generated from patient safety incident reports will nurture this reporting culture (Leape 2002; Leape and Berwick 2005).

Supporters of Patient Safety Reporting Systems believe they are not being used to their full potential to benefit patients (Noble et al. 2011). National systems rely on patient safety experts methodically trawling through patient safety incidents by severity and frequency. For example, each incident reported as leading to death or serious harm is reviewed individually by trained clinical staff at the NHS Commissioning Board (formerly at the National Patient Safety Agency) and a range of outputs are produced to provide solutions to patient safety problems. These include one-page reports called *Rapid Response Reports*, quarterly data summaries and topic-specific information on topics such as preventing inpatient falls in hospitals. NRLS staff will frequently consult subject-matter experts from professional organisations such as the Royal Colleges. NHS organisations also have deadlines imposed on them by which time they should have implemented key findings from such reports. These have offered important insights that have helped to shape national policy – for example, for demonstrating the risks 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. (Cresswell and Sheikh 2008; Panesar et al. 2009)

Little attention, however, has centred on the development of methods for making use of the potential learning from the majority of incident reports that are not routinely analysed. Thus, it is unsurprising that no studies within primary care have undertaken a structured, systematic exploration of free-text description of patient safety incidents. Researchers have previously used descriptive statistics and thematic analysis to identify areas for intervention in secondary care including: prescribing and monitoring lithium therapy (Gerrett et al. 2010); reliable administration of insulin (Lamont et al. 2010); early detection of complications in surgical care (Healey et al. 2010; Lamont et al. 2011; Panesar et al. 2011); and essential care after an inpatient fall (Healey et al. 2011). In addition, clinical researchers have explored descriptions of patient safety incidents in anaesthesia and identified system deficiencies relating to practical procedures, communication of information to patients, verbal and written communication practices, and continuity of care (Catchpole et al. 2008; Cassidy et al. 2011). Their analysis also led to the development of an anaesthesia-specific incident report data collection form (Smith and Mahajan 2009).

EVIDENCE EXPLAINING WHY THIS RESEARCH IS NEEDED NOW

Primary care is overdue its recognition as a threat to patient safety. It poses unique challenges for the design of better quality systems of care delivery, given its heterogeneous models of

delivery and diversity of patients with a wide variety of undifferentiated complaints, uncertain diagnoses and multiple comorbidities (Makeham et al. 2008). Transferring lessons from advances made from over a decade of patient safety research in specialist care settings may therefore not be without problems. The underpinning evidence base, whether in terms of conceptual frameworks, epidemiology, or interventions all therefore potentially need to be developed in their own right (WHO 2012).

Our WHO-commissioned systematic review and Delphi expert consensus study (February 2012) highlighted the paucity of empirical work that explores the relationship between cause (the error) and effect (harm), and the underlying system failures that facilitate this relationship. Of the 193 primary studies and 14 systematic reviews included in the systematic review, most studies estimated the frequency of patient safety incidents and their associated burden. No studies hypothesise or explain the reasons why incidents occurred and what opportunities exist to prevent them through a systematic exploration of free-text descriptions made about the incidents.

In 2003, a major national investment was made to better understand patient safety incidents occurring in England and Wales called the National Reporting and Learning System (NRLS). The NRLS contains a free-text description of the event, perceived causative factors, and any planned actions made locally following the incident. Over 47,000 incident reports exist from primary care in England and Wales and these have never previously been systematically analysed. Such reports permit a retrospective 'window' on the healthcare system, providing a means of looking to the future, by identifying weaknesses of the system that are still present and could lead to further incidents involving patients (Vincent 2004).

Our proposed study will characterise a wide range of patient safety incidents that have led to harm, and demonstrate priority areas to focus the design of interventions, both in incident reporting, and system changes to enhance safety. This is an unexploited area within primary care patient safety, and post-Francis (2013) should serve to demonstrate the value of safety monitoring and frame the benefits of a reporting culture for doctors, nurses and patients in the NHS.

AIMS AND OBJECTIVES

We propose a mixed-methods study to use the NRLS database to understand the nature and range of patient safety incidents that have resulted in harm to patients in primary care.

We will undertake secondary quantitative and qualitative analysis of NRLS data from primary care to:

1. Describe the frequency of different types of patient safety incidents.
2. Describe incident characteristics such as patient age, gender, and ethnicity, geography, time

of day, and severity of harm.

3. Determine which characteristics are associated with different levels of patient harm.
4. Undertake a thematic content analysis of free-text qualitative data to describe the incidents, and iterate an existing taxonomy using empirical evidence based on these primary care-related incidents from England and Wales.
5. Map relationships between themes, i.e. categories of incidents and potential contributory influences, and elicit possible areas with opportunity for intervention.

RESEARCH PLAN / METHODS

We propose to undertake the study over 18 months. To address objectives 1-5, we will use descriptive statistical methods and thematic content analysis to interrogate a dataset of over 47,000 patient safety incidents reported to the NRLS from primary care.

Step 1. Organising and sampling data

All patient safety incident reports to the NRLS from primary care in England and Wales between April 2003 and June 2012 will be considered as the complete dataset. These include incidents from settings including GP surgeries, residential care homes, community pharmacies, opticians, out-of-hours services, hospices, and others. We include an overview of the NRLS and examples of its data in an attached appendix.

We will analyse 100% of reports on patient death or severe harm (sample size to be determined during Phase 1) as per previous work (Cousins et al. 2012; Panesar et al. 2012; Cooke and Scobie 2009). A random number generator will be used to identify a 25% random sample of all remaining reports. We chose 25% since it will represent approximately 12,500 reports that we judge to be a large volume of reports but realistic to analyse within the study timeframe. Based on our experience of incident report analysis at the former NPSA, and previous work (Panesar et al. 2012; Panesar et al. 2013), it is feasible to code approximately 100 reports per day, taking approximately 6 months to complete qualitative analysis (objectives 4&5).

Step 2. Statistical tests and modeling

Incident characteristics will be identified using descriptive statistics (objectives 1&2). Differences in proportions of demographics such as incident type, the incident location, and patient characteristics with the severity of harm event will be assessed by Chi-squared and Fisher's exact tests, with differences in means calculated by t-test. Subsequent logistic regression modeling will evaluate the relationships between incident type, incident location, and patient characteristics, to harm outcomes in the data (objective 3). Logistics odds ratios will be calculated to determine the odds of an event occurring; for example the odds of an event occurring in the out-of-hours clinic compared with all other settings. To rank the incident locations according to the degree of reported harm, we will calculate Harm Susceptibility Ratios, (Pham et al. 2010; Martinez et al. 2011) which are the odds of reported harm for each incident

location compared with the average odds of reported harm across all other incident locations. A Harm Susceptibility Ratio of greater/less than 1 for a particular variable indicates that incidents attributable to that location had higher/lower reported odds of harm compared with the average odds of reported harm for the cumulative incident types. Harm susceptibility ratios will be calculated from a random-effects logistic regression model that accounts for sources of variation in the data. We will undertake the same process for independent patient variables (e.g. age, gender, ethnicity) and incident characteristics using this approach. Attributes identified to have a statistically significant relationship with any level of harm will be arranged hierarchically in categories based on their strength of association.

Formal sample size calculations for quantitative analysis are not given at this stage of our Research Design since the final number of variables to be included in the regression model cannot be made a priori.

Step 3. Thematic content analysis

Free-text data will be characterised by thematic analysis (objectives 4 & 5). This requires 'sense making' of the story reported (Vincent et al. 1998; Henriksen and Kaplan 2003). The free-text will be categorised according to an existing Primary Care Patient Safety Incident Classification scheme (a taxonomy) in order to describe the content (i.e. what happened) of each patient safety report (LINNEAUS EURO-PC, <http://www.linneaus-pc.eu>). This taxonomy was informed by a systematic review and expert consensus; we will iterate this taxonomy based on our empirical analysis of the England and Wales NRLS data. As categories are assigned e.g. 'wrong dose administered' and 'wrong drug administered', similar cases can be identified and themes will emerge e.g. 'administration errors' (Cooke and Scobie 2009). Reports will be interrogated inductively. Secondly, the coding team will develop a separate coding framework for 'perceived causative factors' by eliciting human factors and organizational issues discussed within the reports.

Two primary care doctors and a research nurse, with backgrounds in qualitative research, will undertake analysis independently. This will allow us to describe the content of the text, context and characteristics of the incident, identify any patterns or recurring themes in the data, and to compare incidents with different characteristics. The analysis will be informed by human factors engineering principles to guide 'sensemaking', defined as "the active process of assigning meaning to ambiguous data", in order to identify the learning that can be used to inform improvements in clinical care (Reason, 1990; Battles et al., 2006).

In addition, the two assessors will independently review the harm designation based on the free text description and a third reviewer (a senior clinician) will resolve any disputes. This will require knowledge and understanding of the primary care context and to draw upon past experiences. The typology of harm proposed by Vincent and colleagues (2013) will be used,

and includes: treatment specific harm; harm due to over-treatment; general harm from healthcare; harm due to failure to provide appropriate treatment; harm resulting from delayed or inadequate diagnosis; and psychological harm and feeling unsafe. In addition, this approach is underpinned by the Institute for Healthcare Improvement's recommendation to review harm from the patient's point of view, asking, "Would you be happy if the event happened to you? If the answer is no, then likely there was harm." (Griffin and Resar, 2009:11)

We will take an inductive approach to thematic analysis; that is, as new ideas emerge from the analysis, interrogation of the dataset will seek to extend and add insight to our enquiry. We are unable to propose a sample size based on the inductive nature of our enquiry.

Study outcomes

- Detailed description of primary care Patient Safety Incident characteristics in England and Wales (objectives 1 & 2).
- Model of contributory influences underpinning Patient Safety Incidents in primary care (objective 3).
- Refinement of a primary care patient safety taxonomy using empirical England and Wales data (objectives 4&5).
- Candidate areas, prioritised for intervention development, to minimise the risk of healthcare-related harm (objectives 5).

DISSEMINATION AND PROJECT OUTPUTS

Communicate with reporting health organisations

This will be the largest study of its kind in primary care, and we anticipate it will serve as a stepping-stone for developing a range of interventions and approaches aimed at improving safety in this setting. The study will clarify the primary care contexts and aspects of care provision that need priority attention in high-income countries, and provide a greater understanding about how patient safety could be improved and identify interventions to limit patient safety incidents.

The impact of the study is potentially immediate, as it will provide evidence and priorities for the development of safer clinical practices across the UK, particularly knowledge and understanding of the actions and processes in daily work that influence the safety of patients. We will summarise our findings for dissemination to NHS organisations. Examples might include better training for primary care healthcare professionals in preventing commonly occurring incidents and improved organisational processes that detect potential incidents before they cause harm. Furthermore, because of our strong working links with the NRLS, we are ideally placed to feedback from this work to enhance the future reporting and analysis of primary care PSIs.

We anticipate our study will provide momentum for promoting a reporting culture in primary care via established improvement programmes in England and Wales. We will explore strategies for dissemination with the Advisory group, consisting of senior policy and operational representatives of both nations. It is likely that this will involve presentations at leading national conferences, as well as securing invitations to smaller seminars and local meetings to a variety of professional and lay audiences.

Peer-reviewed, open-access publications and conference presentations

The work is novel, and as with previous patient safety research led by members of our team (which has resulted in major publications in for example The Lancet, BMJ, PLoS Medicine) we anticipate a number of high profile publications from this work. We aim to demonstrate the value of qualitative analysis of free-text within incident reports to generate hypotheses about causal relationships. This could contribute a step-change in epidemiological study design for further work in primary care patient safety.

We will submit study outputs for oral presentation at the Society for Academic Primary Care annual scientific meeting, and the BMJ/IHI International Forum on Quality and Safety in Healthcare (Europe) and the IHI National Forum on Quality and Safety in Healthcare (USA).

Education and training of healthcare professionals and patients

We will deliver four regional training events (to be held in England and Wales) on the role of general practitioners in patient safety. We will seek Royal College of General Practitioners (RCGP) support and endorsement for the events and look to organise a session at the RCGP annual conference. Training days will be aimed at general practice registrars (those in their final year of training) and their trainers (those responsible for their supervision). Longer-term goals include the integration of 'patient safety reporting' as recognised demonstrable competencies within GP training and revalidation appraisals, and to support these via e-learning modules (e.g. BMJ Learning) and NHS Clinical Knowledge Summaries.

During those educational sessions, we expect to identify the critical points in care that compromise patient safety and elicit learning for feedback to frontline staff, patient groups, policy makers and managers. We believe our findings could be of interest to patient advocacy organizations and special interest groups; it is likely further work will involve galvanizing such energy around the prototyping and trial of a primary care-specific reporting form for patients.

PLAN OF INVESTIGATION AND TIMETABLE

The proposed study will run from Friday 1st November 2013 for a period of 18 months. Key events, and associated durations, are listed below.

(i) Recruitment of researchers and administration staff – Months 1-3;

- (ii) Qualitative software training – Month 3;
- (iii) Advisory group will meet via teleconference (months 9 & 18) and face-to-face (months 3 & 12).
- (iv) Study management group (all co-applicants) – monthly teleconference and face-to-face (month 3, 12 & 18).
- (v) Data extraction, checking, cleaning and organisation—months 2-4;
- (vi) Descriptive (statistical) analysis and thematic analysis—months 4-16;
- (vii) Report write up— months 17-18.
- (viii) Education sessions for stakeholders – month 18.

PROJECT MANAGEMENT

We have established a work partnership between Cardiff University, Imperial College London, University of Edinburgh and University of Nottingham. Our team comprises an international healthcare policy expert (Prof Sir Liam Donaldson); a senior epidemiologist and WHO Safer Primary Care programme chair (Prof Aziz Sheikh); a healthcare researcher, clinician and healthcare improvement educationalist (Dr Andrew Carson-Stevens); a NRLS methodological expert (Dr Sukhmeet Panesar); three patient safety researchers (Prof Anthony Avery, Prof Adrian Edwards, Dr Sharon Mayor); a patient co-applicant and the former RCGP Patient Engagement Chair (Mr Antony Chuter); a senior mathematician (Prof Paul Harper); and a medical anthropologist (Dr Luke Cowie) and senior medical sociologist (Dr Fiona Wood).

Dr Carson-Stevens and Professor Edwards are Co-Chief Investigators, and will be supported by a strong team of experienced co-applicants. Dr Carson-Stevens will oversee the management of recruited staff and ensure all milestones are met within the proposed timescale. In addition to the core team (described in Table 1 - below), recruited staff will facilitate this extensive programme of data analysis. We have also secured contributions from an academic general practice registrar at 1 day per week to support data analysis (costs covered by Cardiff University/ Wales Deanery).

We have adopted a matrix management approach to maximise the operational and intellectual contributions of all co-applicants. Dr Carson-Stevens and Professor Edwards will oversee the week-to-week running of the study with additional support from Dr Panesar and Cardiff-based colleagues (Dr Mayor, Dr Cowie and Dr Wood). The study management group (all co-applicants) will teleconference on a monthly basis and have 3 face-to-face meetings (months 3, 12, 18).

Advisory group

We have convened an advisory group to ensure independence of the work and advise on potential networks and initiatives for dissemination of study outputs. Advisory group members have influence and responsibility across the relevant specialist disciplines – research, service

delivery, healthcare improvement, clinical medicine, health policy – to ensure our research has immediate relevance and impact on patient safety in primary care within the UK and internationally. The Advisory group will meet face-to-face at months 3 and 12, with two teleconferences in the interim months 9 and 18.

The following colleagues have agreed to participate (indicated by *):

Prof David Bates, Harvard School of Public Health, USA*; Mrs Jan Davies, Head of Clinical Governance, Welsh Government*; Professor Jonathon Gray, University of Auckland, New Zealand*; Dr Karen Gully, Primary Care Lead in Welsh Government*; Dr Gareth Parry, Institute for Healthcare Improvement, USA*; Dr Maxine Power, Department of Health*; 1 General Practitioner, England*; Dr Donna Luff, Boston Children’s Hospital, USA*, and, at least 2 out of the 4 patient representatives will be present at each meeting.

APPROVAL BY ETHICS COMMITTEE

We plan to seek ethical approval from the Cardiff University School of Medicine Research Ethics Committee prior to study commencement. It is very likely that person-specific information has been removed locally (at healthcare organisations prior to submission of reports to the NRLS). Should such information be disclosed within a report and raise professionalism or patient safety issues, we will inform the relevant leads at the NHS commissioning board/NHS Wales that can institute the relevant clinical governance mechanisms, or the General Medical Council to instigate Fitness to Practise procedures as most appropriate, so that they can appropriately deal with those concerns.

PATIENT AND PUBLIC INVOLVEMENT

We have invited an experienced lay person/patient, Mr Antony Chuter, to be a co-applicant on this project. He has participated in all study planning meetings and has been consulted on all issues relating to PPI. Mr Chuter will contribute towards the design of patient-specific outputs, attend monthly study team meetings and will keep all lay participants updated by teleconference. The additional laypersons (Jillian Beggs, Kausar Iqbal and Susan Howe) all have prior lay representative experience and will support the project on a rotation at ½ day per month. This will ensure at least two laypersons are in attendance at each monthly study team meeting (Mr Chuter plus one other), and all will attend the Professional Advisory Group meetings. They will work alongside Mr Chuter and Dr Carson-Stevens at different phases of the study and attend training every 6 months. Initially this programme will include discussing their roles, the purpose of the project and ways to influence the study; and subsequent meetings will provide an opportunity to reflect together and bring items for discussion to feedback into the study, including interpretation of emerging results.

Applicant and % time commitment	Expertise	Operational contribution	Intellectual contributions
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Dr Andrew Carson-Stevens (50%)	Design and evaluation of healthcare improvement education/ NRLS analysis/ qualitative methods	Research design, liaising with NIHR, staffing, budget, advisory board, team meetings, engagement and publication strategy, supervision and mentoring of recruited staff, analysing and reporting data, 1 st draft of academic outputs.	Identification of candidate areas of clinical practice intervention and improvement in incident reporting process.
Professor Anthony Avery (2.5%)	Design and trial of patient safety interventions	Triangulating study findings with existing patient safety knowledge in key areas e.g. medication error.	Experience of development of primary care patient safety interventions.
Mr Antony Chuter (7.5%)	PPI	PPI Lead; equal partner in study.	Design of patient-specific study outputs.
Dr Luke Cowie (2.5%)	Qualitative methods	Advise on use of NVivo software/ contribute to coding as a non-clinician.	Advise on modelling of qualitative data.
Prof Sir Liam Donaldson (2.5%)	International health policy/ NRLS analysis	Liaison with Department of Health and international (WHO) healthcare policy leads.	Strategic actions and collaborations at the policy and service level.
Prof Adrian Edwards (10%)	Healthcare Improvement	Supervision and mentoring of Dr Carson-Stevens, research design, publication strategy, production of academic outputs.	Academic output and dissemination strategy; identification of candidate areas of clinical practice intervention.
Prof Paul Harper (2.5%)	Mathematical modelling	Database design and management; statistician supervision.	Modelling techniques and statistical analysis of quantitative data.
Dr Sharon Mayor (2.5%)	Harm measurement	Educational material development.	Development of educational materials for nursing and NHS manager groups/ interviews.
Dr Sukhmeet Panesar (10%)	NRLS analysis/ Patient Safety/ Public Health/ Quantitative methods	Liaison with the NRLS at NHS Commissioning Board; advise statistician on NRLS analysis; production of academic outputs.	Development of recommendations for NRLS and NRLS-specific interventions; modelling techniques of NRLS data.
Prof Aziz Sheikh (2.5%)	Patient safety research/ Epidemiology	Liaison with RCGP and WHO SPC programme.	Strategic actions and collaborations with international research community/ WHO SPC programme.
Dr Fiona Wood (10%)	Qualitative methods & medical sociology	Develop rigorous coding process; develop systems that will capture the learning from the methodological development.	Drafting of methodological-focussed study outputs and recommendations for qualitative analysis of patient safety incident reports.

Table 1. Expertise, Operational and Intellectual contributions of co-applicants

EXPERTISE AND JUSTIFICATION OF SUPPORT REQUIRED

The expertise, operational and intellectual contributions of each co-applicant are included in Table 1 (above). We request the following costs to support:

1. A clinical academic research team for interpretation of incident reports

Salary for 1 x Clinical Academic specializing in primary care medicine at 0.5 WTE for 18 months + 1 x Grade 6 research nurse with qualitative methods proficiency at 0.8 WTE for 18 months. A second primary care doctor has volunteered to contribute to this study at 1 day per week for 18 months (institutional costs covered by Cardiff University). Researchers with a clinical background will interpret the incident reports as medical terminology is often used and reports can describe a series of events without stating clearly what the incident was. This requires subject expertise to interpret the text, with an understanding of best practices in each case, to identify what went wrong. Such methods incorporate human factors engineering principles to guide sensemaking, defined as “the active process of assigning meaning to ambiguous data”, and identify the learning that can be used to inform improvements in clinical care. Thus, generalising (indexing and condensing of data) requires an understanding of the task being described, the context it occurs, and the nuances of clinical practice.

2. An experienced clinical academic study team from several subject disciplines

Funds for 7 x co-applicants AA, LC, LD, PH, SM, AS at 0.025 WTE. This study provides an opportunity to draw upon expertise from research, patient safety, health policy, as well as primary care clinicians and patients. We have built a team across several UK universities to incorporate the knowledge, skills and experience we believe necessary to deliver this study agenda. We have budgeted time for one-hour monthly meetings with one-hour preparation per meeting and three face-to-face meetings lasting approximately 8 hours.

Dr Panesar will work as a private consultant at 0.1 WTE (approximately half a day per week); he has extensive experience of modelling the NRLS dataset and will work closely with the recruited statistician and Prof Paul Harper; and will work with Dr Carson-Stevens to oversee analyses and produce academic study outputs.

Professor Edwards will contribute at 0.1 WTE as co-Chief Investigator. He will contribute supervision and mentoring of Dr Carson-Stevens (an early career researcher), and intellectual contributions to research design, publication strategy, and production of academic outputs.

Dr Wood will contribute at 0.1 WTE; she will work within the Cardiff-based team at half a day per week to guide the thematic content analysis coding process; work to develop systems that will capture the learning from the methodological development arising from this exploratory work; as well as oversee and partake in coding as a non-clinician. Dr Wood will also work closely with

team members responsible for statistical analysis and modelling of the data (Prof Paul Harper, Dr Sukhmeet Panesar & the recruited statistician).

Mr Chuter will contribute 1.5 days per month. Three lay members (Jillian Beggs, Kausar Iqbal, Susan Howe) will contribute at 0.5 days per month and attend study team and professional advisory group meetings.

3. Administration support

A grade 3 administrative assistant at 0.5 WTE for 18 months is required to plan and coordinate study team and professional advisory group meetings.

4. Descriptive statistical analyses and modelling expertise

A grade 6 statistician to lead on statistical analysis at 0.4 WTE for 12 months; Prof Paul Harper (co-applicant) will supervise this work.

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Appendix 6. List of collaborators for NIHR HS&DR 12/64/118

Collaborators (and co-authors of NIHR HS&DR report)

Peter Hibbert (Program Manager, Australian Institute for Health Innovation, Macquarie University) was a member of the PAG, provided human factors training to the study team and contributed to classification development.

Dr Huw Williams (Academic GP, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) undertook data coding and analysis, and contributed to study team discussions about study findings and policy and practice recommendations.

Dr Huw Prosser Evans (Academic F2 Doctor and Clinical Informatics Lead, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) designed and developed the analysis software and undertook data coding and analysis.

Dr Alison Cooper (Academic GP Fellow, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) undertook data coding and analysis.

Dr Philippa Rees (Research Assistant, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) contributed to the pilot analyses of data and development of the classification system.

Anita Deakin (Patient Safety Report Analyst, Australian Patient Safety Foundation) undertook data coding and contributed to the development of the classification system.

Dr Emma Shiels (Academic F2 Doctor, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) undertook data coding and analysis.

Dr Russell Gibson (Academic F2 Doctor, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) assisted with the analysis of coded data.

Amy Butlin (Medical Student, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) contributed to the pilot analyses of data and development of the classification system.

Dr Ben Carter (Lecturer in Medical Statistics, Division of Medical Education, School of Medicine, Cardiff University) provided statistical advice.

Paul McEnhill (Medical Student, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) contributed to pilot analyses of data and the development of the classification system.

Dr Hope Olivia Ward (Research Assistant, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) contributed to pilot analyses of data and the development of the classification system.

Dr Raymond Samuriwo (Lecturer in Adult Nursing, Primary Care Patient Safety Research Group, Division of Population Medicine, School of Medicine, Cardiff University) contributed to data analysis.

Antony Chuter (Independent patient) contributed to conceptualisation of the study design and study team discussions about study findings and policy and practice recommendations.

Professor Sir Liam Donaldson (Professor of Public Health, London School of Hygiene and Tropical Medicine) contributed to conceptualisation of the study

design and study team discussions about study findings and policy and practice recommendations.

Dr Sharon Mayor (Senior Lecturer in Healthcare Improvement, Division of Population Medicine, School of Medicine, Cardiff University) contributed to conceptualisation of the study design and study team discussions about study findings.

Dr Sukhmeet Panesar (Adjunct Assistant Professor, Department of Medicine, Baylor College of Medicine) contributed to conceptualisation of the study design.

Professor Aziz Sheikh (Co-Director, Centre for Medical Informatics, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh) contributed to conceptualisation of the study design and study team discussions about study findings and policy and practice recommendations.

Dr Fiona Wood (Senior Lecturer, Division of Population Medicine, School of Medicine, Cardiff University) contributed qualitative methodological input.

Appendix 7. Professional advisory group for NIHR HS&DR 12/64/118

Dr Karen Gully, Senior Medical Officer, Welsh Government.

Janet Davies, Patient Safety Advisor, Welsh Government.

Professor Nigel Sparrow, Senior National GP Advisor, Care Quality Commission.

Dr Gareth Parry, Institute for Healthcare Improvement and Harvard Medical School.

Dr Donna Luff, Boston Children's Hospital and Harvard Medical School.

Dr Meredith Makeham, Australian Institute for Healthcare Innovation.

Appendix 8. Aneurin Bevan University Health Board Research Risk Review Committee Review



Research and Development Department – Research Risk Review Committee

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Dr Andrew Carson-Stevens
[Redacted]
[Redacted]
[Redacted]
[Redacted]

26th November 2013

Dear Dr Carson-Stevens,

Title: Characterising the nature of primary care patient safety incident reports in England and Wales: mixed methods study.

Chief Investigator: Dr Andrew Carson-Stevens
Principle Investigator: Professor Adrian Edwards
ABHB R&D Reference Number: SA/410/13

The Chairman considered your project on the 26th November 2013.

The Chairman agreed that your study did not appear to pose any risk to the Health Board & agreed that your study be given a favourable opinion.

The Chairman also agreed that the study does not require approval by the Research Ethics Committee.

If you require any further assistance please do not hesitate to contact the Research and Development Office.

Yours sincerely

[Redacted Signature]

Mrs Jeanette Wells
Research and Development Manager
Research Risk Review Committee

Bwrdd Iechyd Aneurin Bevan yw enw gweithredol Bwrdd Iechyd Lleol Aneurin Bevan
Aneurin Bevan Health Board is the operational name of Aneurin Bevan Local Health Board

Appendix 9. PISA classification frameworks

A. INCIDENT DESCRIPTORS FRAMEWORK

1 ** ADMINISTRATION **

1.1 Filing system – information filed incorrectly

1.2 Message handling – errors in the taking and distributing of messages

1.3 Appointments – errors in managing appointments for healthcare

1.3.1 Primary care appointments

1.3.2 Secondary care appointments

1.4 Payment – errors in the process of healthcare payment systems

1.5 Ability to access healthcare professional – delays or unable to see healthcare professional

1.5.1 Home visits

1.5.2 Returning phone calls

1.5.3 Out-of-hours

1.5.4 Health visiting

1.5.5 Child and Adolescent Mental Health Services

1.5.6 Occupational therapy

1.6 Transfer of patient information – incorrect or inefficient transfer of patient information across healthcare systems

1.6.1 Between care settings

1.6.1.1 From primary to secondary care

1.6.1.1.1 Lost

1.6.1.1.2 Not sent

1.6.1.1.3 Incorrect/incomplete

1.6.1.1.4 Delayed

- 1.6.1.1.5 Illegible
- 1.6.1.2 From secondary to primary care
 - 1.6.1.2.1 Lost
 - 1.6.1.2.2 Not sent
 - 1.6.1.2.3 Incorrect/incomplete
 - 1.6.1.2.4 Delayed
 - 1.6.1.2.5 Illegible
- 1.6.1.3 Between primary care settings
 - 1.6.1.3.1 Lost
 - 1.6.1.3.2 Not sent
 - 1.6.1.3.3 Incorrect/incomplete
 - 1.6.1.3.4 Delayed
 - 1.6.1.3.5 Illegible

1.6.2 New diagnoses – incorrect or inefficient transfer of patient information from secondary care regarding new diagnoses

1.6.3 Appropriate follow up – incorrect or inefficient transfer of patient regarding necessary follow-up of patient. e.g. requirements for follow up screening or regular review

1.6.4 Involving out-of-hours – incorrect or inefficient transfer of patient information between in- and out- of hours services

1.6.5 NHS direct – incorrect or inefficient transfer of patient information between NHS direct and other services

1.7 Breaches of confidentiality – patient confidentiality breached via documentation error

2 ** DOCUMENTATION**

- 2.1 Medical records – errors involving patient’s personal medical records
 - 2.1.1 Record(s) unavailable – records could not be accessed when needed
 - 2.1.1.1 Red book
 - 2.1.1.2 General practice records

- 2.1.1.3 Child health records
- 2.1.1.4 Lost medical records

2.1.2 Care given but not documented – records did not contain documentation of care

2.1.3 Record not up to date or complete – information missing from record

2.1.3.1 Discrepancies between vaccine records

2.1.3.1.1 Red book

2.1.3.1.2 General practice records

2.1.3.1.3 Child health records

2.1.4 Inaccurate or unclear medical records / medical record error

2.1.4.1 Red book

2.1.4.2 General practice records

2.1.4.3 Child health records

2.2 Death certificates – errors concerning patient's death certificates

3 ** REFERRAL **

3.1 Human – human referral errors i.e. not system-based

3.1.1 Not performed when indicated – a person failed to refer when indicated

3.1.1.1 Delayed referral – errors in the timely referral of patients

3.1.1.1.1 Secondary care

3.1.1.1.2 Specialist care

3.1.1.1.3 Emergency care

3.1.1.1.4 Nursing

3.1.1.1.5 Social care

3.1.1.1.6 Health visitor

3.1.1.1.7 General practice

3.1.1.1.8 Child and Adolescent Mental Health Services

3.1.1.2 Referral not made when appropriate – referral decision-making error

3.1.1.2.1 Secondary care

- 3.1.1.2.2 Specialist Care
- 3.1.1.2.3 Emergency Care
- 3.1.1.2.4 Nursing
- 3.1.1.2.5 Health visitor
- 3.1.1.2.6 Social care
- 3.1.1.2.7 General practice
- 3.1.1.2.8 Child and Adolescent Mental Health Service
- 3.1.1.3 No follow up arranged – did not follow-up or were not asked to follow-up

- 3.1.2 Incomplete /incorrect referral – someone did not complete referral
- 3.1.3 Illegible referral – someone created an illegible referral letter/ document

- 3.1.4 Inappropriate referral to primary care – work inappropriately passed to primary care
- 3.1.5 Inappropriate referral – someone inappropriately referred a patient
- 3.1.6 Referral refused – someone refused to accept a referral of a patient

- 3.2 Administration
- 3.2.1 Not sent – letter of referral erroneously not sent by office
- 3.2.2 Delayed – letter of referral delayed at office level
- 3.2.3 Lost – letter of referral lost in the system
- 3.2.4 Not acted upon – referral successful but patient not seen by physic
- 3.2.4.1 Refused patient referral refused by receiving office
- 3.2.5 Inappropriate referral – referral made erroneously at office level
- 3.2.6 Social work referral issues – administrative errors in the social work referral process

4 ** DIAGNOSIS AND ASSESSMENT **

- 4.1 Diagnosis – errors in the process of identifying/ defining a patient’s illness
- 4.1.1 Missed diagnosis – failing to spot a particular illness
- 4.1.2 Wrong diagnosis – misidentifying the patient’s illness
- 4.1.3 Delayed diagnosis– not identifying an illness in a timely manner
- 4.1.3.1 Cancer
- 4.1.3.2 Emergency condition

4.1.3.3 Contagious condition

4.2 Insufficient assessment – not adequately assessing the patient clinically

4.2.1 Triage – errors in the process of assessing the severity of a patient's condition

4.2.1.1 By healthcare professional

4.2.1.2 By non-healthcare professional

4.2.2 History – errors in the process of taking a patient's medical history

4.2.3 Examination – errors in the process of examining patients

4.2.4 Identifying vulnerable or high-risk patient – failure to identify risky patients

4.2.5 Emergency vehicle use – inappropriate transfer vehicle used (e.g. private vehicle instead of ambulance)

4.2.6 Discharge planning – premature discharge and poor discharge planning

4.3 Delayed assessment – a delay in assessment for care or care adjunct

5 ** TREATMENT & PROCEDURES (excludes drugs/vaccines)

5.1 Clinical treatment decision – errors in decisions to treat or how to treat

5.1.1 No treatment given – inappropriate decision not to treat

5.1.2 Insufficient treatment given – failure to provide adequate treatment

5.1.3 Wrong treatment given – providing inappropriate treatment

5.2 Other non-medication treatment errors

5.2.1 Ordering treatments – wrong treatment ordered or treatment not ordered when appropriate

5.2.2 Implementation – error in conducting the correctly chosen process or procedure

5.2.3 Complication

5.2.3.1 Complication from execution of procedure

5.2.3.2 Adverse event suffered by patient as a result of treatment other than medication

5.2.4 Timeliness – treatment other than medication not administered in a timely fashion

5.2.5 Execution of care – error in choosing the correct process or procedure

5.2.6 Wrong anatomical side/site – administering treatment at the wrong site

5.2.7 Insufficient supply of treatment – not having adequate supplies to treat patients

6 ** MEDICATION & VACCINES **

6.1 Clinical treatment decision – errors in decisions to treat or how to treat with medications

6.1.1 No treatment given – inappropriate decision not to treat

6.1.2 Insufficient treatment – failure to provide adequate treatment

6.1.3 Wrong treatment given – providing inappropriate treatment

6.1.4 Treatment not ordered – failure to request an appropriate treatment

6.2 Medication prescribing – errors in the medication prescribing process

6.2.1 Wrong medication – patient was prescribed incorrect medication

6.2.2 Wrong patient – medication was prescribed for wrong patient

6.2.3 Wrong dose – medication was prescribed at incorrect dose

6.2.4 Wrong route – medication was prescribed for incorrect route

6.2.5 Wrong time – medication was prescribed for incorrect/ inappropriate time

6.2.6 Unsafe medication – medication prescribed was unsafe

6.2.6.1 Teratogenic

6.2.6.2 Contraindicated

6.2.6.3 Allergy

6.2.7 Wrong formulation – inappropriate formulation of medication was prescribed e.g. liquid versus tablet

6.2.8 Wrong number of doses – incorrect quantity of medication prescribed

6.2.9 Illegible/ unclear prescription – prescription document is unclear

6.2.10 Incomplete prescription e.g. brand not specified – prescription document not fully completed

6.3 Medication dispensing – errors in the medication dispensing process

6.3.1 Wrong medication – patient was dispensed incorrect medication

6.3.2 Wrong patient – medication was dispensed to incorrect patient

6.3.3 Wrong dose – medication was not dispensed at safe dose intended

6.3.4 Wrong route – incorrect dose of medication was dispensed

6.3.5 Wrong time – medication was not dispensed for appropriate time

6.3.6 Wrong formulation – medication was not dispensed as appropriate formulation e.g. liquid versus tablet

6.3.7 Not dispensed – medication was not dispensed

6.3.8 Allergy – dispensed to a patient with known allergy

6.3.9 Out of date – medication dispensed was out of date

6.3.10 Wrong label – medication was dispensed with wrong label

6.3.11 Wrong number of doses – wrong quantity of medication was dispensed

6.3.12 Inappropriate medication – medication dispensed was inappropriate e.g. for that specific patient

6.3.13 Wrong container – medication was dispensed in inappropriate container

6.4 Medication administration – errors in the medication administering process

6.4.1 Wrong medication – patient received incorrect medication

6.4.2 Wrong patient – patient received another patient's medication

6.4.3 Wrong dose – patient received incorrect medication dose

6.4.4 Wrong route – patient received medication via the incorrect route

6.4.5 Wrong time – patient took medication at incorrect time

6.4.6 Wrong formulation – patient took inappropriate medication formulation

6.4.7 Out of date – patient took out of date medication

6.4.8 Allergy – patient received medication they had a known allergy to

6.4.9 Medication not administered – patient did not receive medication

6.4.10 Reconstitution error – patient received inappropriately reconstituted medication

6.5 Monitoring medication – error in the process of monitoring dose-dependent medications, or those with side effects

6.5.1 Lack of monitoring – failure to appropriately monitor

6.5.2 Medication dose not appropriately adjusted – failed to appropriately act on monitoring

6.6 Adverse event – patient suffered a complication as a result of medication

6.6.1 Allergy – unknown that patient had any allergies

6.7 Drug omission – medication was erroneously not given to or not taken by patient

6.8 Patient overdose – patient self-administered overdose

6.9 Incorrect storage of medication – medication was not stored appropriately

6.10 Medication timeliness – medication was not commenced in a timely fashion

6.11 Vaccines

6.11.1 Vaccine prescribing – errors in the vaccine prescribing process

6.11.1.1 Wrong vaccine – patient was not prescribed appropriate vaccine

6.11.1.2 Wrong patient – vaccine was prescribed for wrong patient

6.11.1.3 Wrong dose – vaccine was not prescribed at appropriate dose

6.11.1.4 Wrong route – vaccine was not prescribed for appropriate route

6.11.1.5 Wrong time – vaccine was not prescribed for appropriate time

6.11.1.6 Contraindicated – vaccine prescribed was contraindicated

6.11.1.7 Wrong formulation – vaccine prescribed was of wrong formulation

6.11.1.8 Wrong number of doses – incorrect quantity of vaccines prescribed

6.11.2 Vaccine dispensing – errors in the vaccine dispensing process

6.11.2.1 Wrong vaccine – patient was not dispensed appropriate vaccine

6.11.2.2 Wrong patient – vaccine was dispensed for wrong patient

6.11.2.3 Wrong dose – vaccine was dispensed at incorrect dose

6.11.2.4 Wrong route – vaccine was dispensed for incorrect route

6.11.2.5 Wrong time – vaccine was not dispensed for inappropriate time

6.11.2.6 Wrong number of doses – incorrect quantity of vaccines were dispensed

6.11.2.7 Stored incorrectly – vaccines were not stored correctly

6.11.2.8 Out of date – expired vaccines were in storage

- 6.11.2.9 Not dispensed – vaccines were unavailable/ not dispensed
- 6.11.2.10 Wrong formulation – incorrect vaccine formulations were stored
- 6.11.2.11 Wrong label – vaccines were dispensed with incorrect labels
- 6.11.2.12 Contraindicated – contraindicated vaccine was dispensed

- 6.11.3 Vaccine administration – errors in the vaccine administering process
 - 6.11.3.1 Wrong vaccine – patient received incorrect vaccine
 - 6.11.3.2 Wrong patient – patient received another patient’s vaccine
 - 6.11.3.3 Wrong dose – patient received the incorrect vaccine dose
 - 6.11.3.4 Wrong route – patient vaccinated via incorrect route
 - 6.11.3.5 Wrong time – patient vaccinated at incorrect time
 - 6.11.3.6 Wrong amount – patient vaccinated with wrong number of doses
 - 6.11.3.7 Stored incorrectly – patient vaccinated with inappropriately stored vaccine
 - 6.11.3.8 Out of date – patient vaccinated with expired vaccine
 - 6.11.3.9 Contraindicated vaccine – patient vaccinated with contraindicated vaccine
 - 6.11.3.10 Not administered – patient not vaccinated
 - 6.11.3.11 Used/dirty needle – patient vaccinated using non-sterile needle
 - 6.11.3.12 Wrong site – patient vaccinated at wrong anatomical location
 - 6.11.3.13 Reconstitution error – patient vaccinated with inappropriately reconstituted vaccine

- 6.11.4 Adverse event – patient suffered a complication as a result of medication

- 6.11.5 Batch recall – a batch of vaccines recalled after use

- 6.12 Vaccine unavailable – unable to source appropriate vaccines

7 ** INVESTIGATIONS **

- 7.1 Laboratory – errors in the process of laboratory investigations
 - 7.1.1 Ordering – wrong test ordered or test not ordered when appropriate

7.1.2 Implementing – errors in the process of obtaining or processing a laboratory specimen

7.1.2.1 Mislabeled sample

7.1.3 Reporting – error in the process of physician receiving accurate test results including errors of delay

7.1.4 Responding to results – inappropriate response to a laboratory result

7.2 Diagnostic imaging – errors in the process of diagnostic imaging investigations

7.2.1 Ordering – wrong test ordered or test not ordered when appropriate

7.2.2 Implementing – errors in the process of obtaining or processing of a diagnostic image

7.2.2.1 Mislabeled request form

7.2.3 Reporting – error in the process of physician receiving accurate test results including errors of delay

7.2.4 Responding to results – inappropriate response to a laboratory result

7.3 Other investigations – errors in the process of other investigations

7.3.1 Ordering – wrong test ordered or test not ordered when appropriate

7.3.2 Implementing – errors in the process of obtaining or processing of other diagnostic investigation

7.3.3 Reporting – error in the process of physician receiving accurate test results including errors of delay

7.3.4 Responding to results – inappropriate response to a result of other investigations

8 ** COMMUNICATION **

These are human failures, and do not include breakdowns in the systems that are used to communicate information.

8.1 With patients or caregivers – errors in communication between physicians or healthcare professionals and patients or caregivers

8.1.1 Wrong advice given to patient or caregiver – includes information about accessing emergency services, self-management or safety netting

8.1.1.1 By healthcare professional

8.1.1.2 By non-healthcare professional

8.1.2 Failure to convey seriousness/urgency of patient condition

8.1.3 Consent errors – errors in the process of obtaining informed consent

8.2 Between healthcare professionals – errors in communication between healthcare professionals

8.2.1 Failure to convey seriousness/urgency of patient condition

8.2.2 Handover-related inadequacies

8.3 Between healthcare and non-healthcare professionals

9 ** EQUIPMENT **

9.1 Therapeutic adjunct provision – failures in the process of therapeutic adjunct provision

9.2 Insufficient supply – failure to adequately supply equipment or a lack of equipment

9.2.1 Stolen equipment

9.3 Failure of equipment – equipment failing to fulfill its purpose

9.3.1 Damaged

9.3.2 Faulty

9.3.3 Misused

9.3.4 Computerised Physician Order Entry

10 ** OTHER **

10.1 Professionalism

10.2 Environmental hazard

10.3 Transport issues

10.4 Failure to prevent fall/injury

10.5 Failure to follow up 'unwell' or vulnerable child

10.6 Failure to prevent pressure ulcer

B. CONTRIBUTORY FACTORS FRAMEWORK

1 ** PATIENT OR CAREGIVER FACTORS **

1.1 Geography – the area where patients live including its characteristics

1.1.1 Out of area – patient new to area

1.1.2 Access difficulties because of geography

1.2 Language – patient or caregiver unable to communicate in English

1.3 Behavior – the way in which patients or caregivers act or conduct themselves

1.3.1 Non-compliance – patient does not follow advice or instructions

1.3.1.1 Takes own discharge

1.3.1.2 Patient does not take medication as instructed or advised

1.3.1.3 Non-disclosure

1.3.1.4 Violent

1.4 Health - factors related to the patient's physical and mental health

1.4.1. Frailty – reduced physiological reserve, fragile

1.4.2. Disability

1.4.3. Allergy

1.4.4 Immunocompromised

1.4.5 Coagulation problems

1.4.6 Pregnancy

1.4.7 Epilepsy

1.4.8 Poor renal function

1.5. Knowledge – insufficient knowledge or inadequate application of knowledge

1.6. Looked-after child – child not in the care of their parents e.g. foster care

1.7 Age – child-specific factors

1.7.1 Weight-based dosing

1.8 Ethnicity – the child belongs to a certain social group

2 ** STAFF FACTORS **

2.1 Health – physical and mental wellbeing

2.1.1 Fatigue

2.2 Task – a piece of work to be done or undertaken.

2.2.1 Failure to follow protocol – not adhering to organizational guidelines

2.2.1.1 New protocol

2.2.2 Inadequate skill set/knowledge – insufficient knowledge of inadequate application of knowledge

2.3 Cognitive - includes abilities such as perception, learning, memory, language, concept formation, problem solving, and thinking.

2.3.1 Mistake – unintentional cognitive lapses

2.3.1.1 Distraction/ inattention/ oversight/forgot

2.3.1.2 Similar medication names/appearances confused

2.3.1.3 Similar patient names

2.3.1.4 Haste/ poor time management

2.3.1.5 Misread/ did not read

2.3.1.6 Patient ID label

2.3.2 Violation - deliberate breaking of a rule

2.3.3 Stress - mental or emotional strain

2.3.4 No or poor supervision or assistance of staff

2.3.5 Critical thinking – problem solving

3 ** EQUIPMENT / MEDICATION/ VACCINE FACTORS **

3.1 Poor design – impractical or in some way inadequate

3.2 Poor storage – impractical or inadequate storage

3.3 Poor packaging – impractical or inadequate storage

3.4 Failure of equipment/ medication/ vaccine – unable to fulfill its purpose

4 ** ORGANISATION FACTORS **

4.1 Protocols or guidelines – existing guidelines not fit for purpose

4.1.1 Mental health

4.1.2 Vulnerable patients

4.1.3 Investigations

4.1.4 Referrals

4.1.5 Epilepsy management plan

4.1.6 Asthma management plan

4.1.7 School care plan

4.1.8 Diabetic management plan

4.1.9 Palliative care plan

4.2 Interpreter services – communication aids to reduce language barriers

4.3 Continuity of care – issues with the co-ordination of services

4.3.1 Patient unknown to staff

4.3.2 Within primary care

4.3.2.1 Out-of-hours service

4.3.2.2 Registering with a general practice

4.3.3 Between secondary and primary care

4.3.4 Access block – cannot move a patient because there is no space

4.3.5 Locum/ agency staff

4.4 Working conditions – factors relating to the work environment

4.4.1 Staffing levels

4.4.1.1 Shift pattern

4.4.1.2 Insufficient numbers of staff

4.4.1.2.1 Doctors

4.4.1.2.2 Nurses

4.4.1.2.3 Allied health professionals

4.4.1.3. Sickness

4.4.2 Team factors

4.4.2.1 Culture

4.4.2.2 Inadequate leadership

4.4.2.3 Disagreement amongst teams

4.4.3 Busy/overloaded by work

4.4.4 interruptions

4.5. Education and training – insufficient education and training of staff

4.5.1 Supervision

4.5.2 Knowledge of others roles

4.5.3 Caregiver training

4.6 Service availability – a required service is unavailable

4.7 Long wait for service – unacceptable delays in service access

5 ** ENVIRONMENTAL FACTORS **

5.1 Care facility has poor access for emergency vehicles

C. OUTCOME FRAMEWORK

1 ** PATIENT HARM ** - direct harm to the patient physically or mentally

1.1 Clinical harm – impaired bodily function

1.1.1 Pain / discomfort

1.1.2 Swelling

1.1.3 Rash

1.1.4 Nausea

1.1.5 Redness

1.1.6 Bruising

1.1.7 Dizziness/ faint/ loss or altered consciousness

1.1.8 Bleeding

1.1.9 Changes in physiological parameters

- 1.1.9.1 Fever
- 1.1.9.2 Breathless
- 1.1.10 General deterioration/progression of condition
- 1.1.11 Pressure ulcer
 - 1.1.11.1 Pressure ulcer developed
 - 1.1.11.2 Pressure ulcer deteriorated
- 1.1.12 Other wound/ulcer
- 1.1.13 Admitted to the high dependency or intensive care unit
- 1.1.14 Seizures
- 1.1.15 Admitted to hospital/ visited emergency department
- 1.1.16 Infection
- 1.1.17 Migraine
- 1.1.18 Poor diabetic control
 - 1.1.18.1 Diabetic ketosis/ ketoacidosis
- 1.1.19 Developmental delay
- 1.1.20 Diarrhea
- 1.1.21 Emergency surgery
- 1.1.22 Liver failure
- 1.1.23 Constipation

1.2 Injury - tissue damage

- 1.2.1 Laceration
- 1.2.2 Perforation
- 1.2.3 Fracture
- 1.2.4 Skin tear
- 1.2.5 Pain / discomfort
- 1.2.6 Swelling
- 1.2.7 Redness
- 1.2.8 Bruising
- 1.2.9 Bleeding
- 1.2.10 Needle stick
- 1.2.11 Burn
- 1.2.12 Fall

1.3 Psychological / emotional distress – patient suffering

1.4 Death – the end of life

1.5 Cardio-respiratory arrest – inadequate circulation due to sudden cardiac failure and abnormal or absent breathing

2 ** PATIENT INCONVENIENCE ** - increased patient burden

- 2.1 Repeated tests / procedure / additional treatment
- 2.2 Delays in management (assessment or treatment)
- 2.3 Increased documentation
- 2.4 Financial implication
- 2.5 Repeated visits to/from health care providers
- 2.6 Unnecessary treatment
- 2.7 Extended hospital stay
- 2.8 Hospital admission

3 ** ORGANISATIONAL INCONVENIENCE ** - increased organisational burden

- 3.1 Increased documentation
- 3.2 Phone calls/follow-up
- 3.3 More equipment / supplies used
- 3.4 Delays in using facilities
- 3.5 Legal implication
- 3.6 Complaint made
- 3.7 Financial implication

Appendix 10. Definitions of vulnerable child

Definition	Source	Important concepts identified	Key terms
<i>Social</i>			
<p>“Vulnerable children are those – (a) who are unlikely to achieve or maintain, or have the opportunity of achieving or maintaining, a reasonable standard of health or development without the provision for them of social care services, (b) whose health or development is likely to be significantly impaired, or further impaired, without the provision for them of social care services, (c) who have a physical or mental impairment, (d) who are in the care of a public authority, or (e) who are provided with accommodation by a public authority in order to secure their well-being.”</p>	<p><i>UK Parliament, House of Commons, Welsh Affairs.</i></p> <p>Link: http://www.publications.parliament.uk/pa/cm200708/cmselect/cmwelaf/576/57605.htm</p>	<ul style="list-style-type: none"> – Will not achieve reasonable standard of health without provision of social care services. – Have mental or physical disability. – Provided accommodation or are in the care of a public authority. 	<p>Children in care, social care, foster care, social services, disability, public housing, social services, public authority, council housing</p>
<p>“A vulnerable child in this context is one who is not within the social care system, but where there are warning signals that the child is becoming at risk of harm. The child and his or her family is likely to be receiving help from one or more agencies, and while no single agency has identified a significant risk to the child, when information from all agencies is pooled, the picture that emerges indicates that there are many factors having a negative impact</p>	<p><i>Child and Maternal Health Observatory.</i></p> <p>Link: http://webarchive.nationalarchives.gov.uk/20170302100842/http://www.chimat.org.uk/resource/view.aspx?RID=164673</p>	<ul style="list-style-type: none"> – Not within the social care system. – Child or his or her family is receiving help from more than one agency. 	<p>Services, social worker, agency, agencies</p>

<p>on the child. While inter-agency data sharing to resolve child protection concerns is established, data sharing to identify these children who are earlier on in the process tends not to happen routinely in a similar way.”</p>			
<p>“Children most at risk of experiencing inequalities and poor life chances. Focus is on those whose experience of multiple, adverse, overlapping factors in their lives makes them vulnerable to significant risk of poor outcomes.”</p>	<p><i>National Child Bureau.</i> Link: http://www.ncb.org.uk/areas-of-activity/vulnerable-children</p>	<ul style="list-style-type: none"> – Multiple and overlapping experiences. 	
<p>“Vulnerable children are identified as having needs or circumstances that require particularly perceptive intervention and/or additional support. This includes children – (a) From low income backgrounds, (b) living with domestic abuse, adult mental health issues and substance abuse, (c) Children ‘in need’ or with a child protection plan, (d) Children who are in the care of the local authority (looked after children), or (e) Those with protected characteristics, as defined by the Equality Act 2010, including Gypsy and Traveller communities, minority ethnic groups or those from same sex parent families.”</p>	<p><i>Ofsted</i> Link: http://ww5.swindon.gov.uk/moderngov/documents/s69891/Childrens%20Centres%20-%20Appendix%203%20-%20Ofsted%20Definition%20of%20Vulnerability.pdf</p>	<ul style="list-style-type: none"> – Socioeconomically deprived. – Domestic abuse and child protection issues. – Mental disability. – Children in care. – Protected characteristic children have higher needs. 	<p>Low income, low socioeconomic class, poverty, traveller, minority, looked after children, greater needs, support</p>
<p>“Over one third of the children in the United Kingdom grow up in conditions of socioeconomic deprivation. In consequence they experience poorer health than their more affluent peers. Within this socioeconomically deprived population exist several groups of children</p>	<p>Webb, E. Children and the inverse care law. <i>BMJ</i>. 1998; 316(7144):1588. doi: http://dx.doi.org/10.1136/bmj.316.7144.1588</p>	<ul style="list-style-type: none"> – Large population of children in socioeconomic deprivation, predisposing to vulnerability. – Poorer access to healthcare. 	<p>Homeless, refugee, deprived, low socioeconomic class, marginalised, access, ethnic minority, poor access</p>

<p>and young people who are profoundly marginalized— (a) Homeless children, (b) Refugees, (c) Traveler communities, (d) Children in care. These groups have poor access to health services and as a result poor. Other groups, such as children from minority ethnic communities and adolescents, have poor access to services.”</p>			
<p>“Children and young people who are in need of support but are resilient. This includes children who are not suffering from an imminent risk of physical abuse or neglect and whose vulnerability does not reach obvious thresholds for statutory intervention. Young carers are an example where their resilient capabilities are frequently allowed to predominate in their assessment of their needs.”</p>	<p>Ward, H. and Rose, W. <i>Approaches to Needs Assessment in Children’s Services</i>. Gateshead. Jessica Kingsley Publisher; 2002.</p>	<ul style="list-style-type: none"> – Child carers can cope so are a hidden group to services. – Due to their coping underlying emotional needs are frequently. – Wide literature base on caregiving being detrimental to health. 	<p>Young carer, caregiver, needs, social care, mental, social exclusion, social isolation, care burden</p>
<p>“Orphans and Vulnerable Children (OVC) are children affected by HIV and AIDS by virtue of, among others, living in a household where one or more people are ill, dying or deceased, or which fosters orphans, and children whose care givers are too ill or old to continue to care for them. They often have more health needs than their peers.”</p>	<p>Tagurum, Y. <i>et al.</i> Situational analysis of orphans and vulnerable children in urban and rural communities of Plateau State. <i>Ann. Afr. Med.</i> 2015; 14(1):18-24.</p>	<ul style="list-style-type: none"> – Affected by HIV/AIDS. – Carers can no longer take care of them. – More health needs than their peers. 	<p>HIV, AIDS, orphans, household, unwell carers</p>
<p>“The loss of a parent through death or desertion is an important aspect of vulnerability. Additional factors leading to vulnerability included severe chronic illness of a parent or caregiver, poverty, hunger, lack of access to services, inadequate clothing or shelter,</p>	<p>Skinner, D. <i>et al.</i> Towards a definition of orphaned and vulnerable children. <i>AIDS and Behaviour.</i> 2006; 10(6):619-626.</p>	<ul style="list-style-type: none"> – Orphans are vulnerable. – Loss of parent or chronic illness of parent. <p>Poverty, hunger, lack of</p>	<p>Poverty, orphan, loss of parent, carer, adoptee, adopted, chronic illness, overcrowding</p>

overcrowding, deficient caretakers, and factors specific to the child, including disability, direct experience of physical or sexual violence, or severe chronic illness.”		shelter – e.g. stigma of low socioeconomic class, are all additional factors.	
“ A child whose parents are dead.”	<i>Oxford Dictionary</i>	<ul style="list-style-type: none"> – No parental care. – Are in care of public authorities or not in care at all. 	Orphan, loss of parent
<i>Mental</i>			
“Literature shows consistently increased levels of psychological morbidity among refugee children, especially post-traumatic stress disorder, depression, and anxiety disorders. The delivery of mental health care for these children is also different. There is particular concern for the plight of unaccompanied children.”	Fazel, M. and Stein, A. The mental health of refugee children. <i>Archives of Disease in Childhood</i> . 2002; 87(5):366-370.	<ul style="list-style-type: none"> – Stress from the country of origin, the migration and the resettling in foreign country is a traumatic experience. – Increased morbidity in this demographic. – Children as a group have greater dependence on outside sources for protection and care. 	Refugee, mental health, depression, anxiety, stress, refuge, dependant, culture, migration, immigration
“Many different factors affect the mental health of forcibly displaced children in the presence of substantial life challenges, such as perceived discrimination, being unaccompanied, poor finances, parental psychiatric problems.”	Fazel, M., Veed, R., Panter-Brick, C. and Stein, A. Mental health of displaced and refugee children resettled in high-income countries: risk and protective factors. <i>Lancet</i> .2012; 379(9812):266-282.	<ul style="list-style-type: none"> – As above – Parental psychiatric problems 	Discrimination, racism, lauguage, Low income Lower socioeconomic class, poverty, poor, parental mental illness, parental psychiatric illness
“Refugees resettled in western countries could be about ten times more likely to have post-traumatic stress disorder than age-matched general populations in those countries. Worldwide, tens of thousands of refugees and former refugees resettled in	Fazel, M., Wheeler, J. and Danesh, J. Prevalence of serious mental disorder in 7000 refugees resettled in western countries: a systematic review. <i>Lancet</i> . 2005; 365(9467):1309-1314.	<ul style="list-style-type: none"> – Age matched refugees have higher prevalence’s of PTSD. – It is seen in studies in varying 	Refugee, stress, low income, mental health

<p>western countries probably have post-traumatic stress disorder. Five surveys of 260 refugee children from three countries yielded a prevalence of 11% (7–17%) for post-traumatic stress disorder.”</p>		<p>countries.</p>	
<p>“Children with learning disabilities have a significantly reduced ability to understand new or complex information, to learn new skills (impaired intelligence) with a reduced ability to cope independently (impaired social functioning).”</p>	<p>Calder, M. and Hackett, S. <i>Assessment in Child Care</i>. 2nd edition. Dorset. Russell House Publishing. 2013.</p>	<ul style="list-style-type: none"> – Affected by the way they are perceived in the communities they live in. – Cannot cope independently. – Cannot learn new skills. 	<p>Learning disability, impairment, intellectual disability, learning difficulties, mental retardation, dyslexia, dyspraxia</p>
<p>“Children and adolescents with learning disabilities have high rates of mental health problems and behavioural difficulties. Comorbid disorders such as epilepsy, autism and attention-deficit hyperactivity disorder are common and overall there is more than a six-fold increased risk of mental illness.”</p>	<p>Emerson, E. and Hatton, C. Mental health of children and adolescents with intellectual disabilities in Britain. <i>The British Journal of Psychiatry</i>. Royal College of Psychiatry, London, 2007.</p>	<ul style="list-style-type: none"> – Conditions like autism are not illnesses but the resulting social isolation results in mental illness such as depression. 	<p>Depress, mental illness, isolation, epilepsy, autism, ADHD</p>
<p>“Children can feel afraid, anxious or guilty about their parent’s illness, and find it hard to make and keep friends. Mental illness can be difficult to understand and some children and young people fear that the same thing could happen to them. A mentally ill parent can behave in ways that can be confusing or distressing for children. Some children are more resilient than others and seem to cope better with their parent’s mental illness, understanding more of what is happening and supporting their parent with confidence. A child’s age, gender, temperament and intelligence are among a range of factors that affect a child’s resilience to this particular situation.”</p>	<p><i>Family Minded. Supporting Children in families affected by mental illness</i>. Barnardo’s. 2008.</p> <p>Link: http://www.barnardos.org.uk/family_minded_report.pdf</p>	<ul style="list-style-type: none"> – Uncertainty about their parents condition can cause anxiety, guilt and social isolation. – Ability to cope is affected. – Resilience is decreased which increases vulnerability. 	<p>Young carer, uncertain, mental illness, social isolation, distress, anxiety, mental handicap</p>

<p>“Children with learning disabilities were significantly more likely to: (a) Have poor general health, (b) Have been exposed to a greater variety of adverse life events (e.g., domestic abuse, serious accidents, abuse), (c) Live in poverty, (d) Have a mother who has mental health issues.”</p>	<p>The Mental Health of Children and Adolescents with Learning Disabilities in Britain. <i>Lancaster University</i>. 2007.</p>	<ul style="list-style-type: none"> – With learning disabilities have poorer health, and more adverse life events. – Higher chance of being in poverty. 	<p>Poverty, poor, abuse, adverse life events, learning disability</p>
<p><i>Physical (Disability)</i></p>			
<p>“Disabled children are not the same as one another but rather have their own individual needs and specific disabilities. To compare in other ways can result in their abuse being overlooked and assumed to be part of their ‘condition’ as research has shown injuries were accepted as an ‘inevitable feature of the child’s disability’ rather than the abuse inflicted on them.”</p>	<p>Wilson, K. and James, A. <i>The Child Protection Handbook</i>. 3rd edition. Elsevier. 2007.</p>	<ul style="list-style-type: none"> – Disability must be seen as individual. – Injuries are accepted as part of the disability incorrectly. – Legislation protecting from harm covers “harm suffered considered significant on the child’s health and development compared with what one could expect of a similar child’ which doesn’t work with disabled children. 	<p>Disabled, injury, injuries, wheelchair, aids, crutch, abuse, impairment, physiotherapy, physical handicap</p>
<p>“Deaf and disabled children are more likely to be abused than non-disabled children. They are particularly vulnerable to abuse because they are - (a) not offered the same protection as non-disabled children (b) often treated as different, and less likely to (c) receive adequate sex education or information about their own bodies</p>	<p><i>Safe Network</i> Link: http://www.safenetwork.org.uk/training_and_awareness/Pages/disabled_children.aspx</p>	<ul style="list-style-type: none"> – As above – Not educated specifically about their own bodies. – More isolated. – Less communication. 	<p>Communication, education, isolation, disabled, mobility</p>

<p>(d) generally more isolated, both physically and socially and also from mainstream facilities and services (e) less likely to have people who they can communicate with (f) Dependent on others for their most important needs, such as feeding, taking medication or their intimate care needs. ”</p>			
<p>“When a disabled child is referred to Children’s Social Care for assessment it can be for many reasons, ranging from practical service requests to concerns about significant risk of harm. These frameworks however were not initially designed with disabled children in mind. This has led to basic services being too intrusive and complex assessments lacking. This can lead to the views of the child not being listened to and in cases risks not understood and responded to.”</p>	<p>Calder, M. and Hackett, S. <i>Assessment in Child Care</i>. 2nd edition. Dorset. Russell House Publishing. 2013.</p>	<ul style="list-style-type: none"> – As above. – Inadequate frameworks, institutionalised discrimination. – Needs not met correctly. 	<p>Discrimination, needs assessment, occupational therapy, housing, stress,</p>
<p><i>Child Protection</i></p>			
<p>“Many children accept maltreatment as a "normal" family dynamic and do not recognize the need for help or intervention. While this may be particularly true for young children, older youth often report family violence as usual, expected, and part of their environment. Note: We are reminded that parents who were themselves raised with drugs and alcohol, domestic violence, or mental health issues often don't see their own histories as abusive. They were in fact vulnerable as children and are less likely to protect their own children without this realization.”</p>	<p><i>Ohio Child Welfare Training Program</i> Link: http://www.ocwtp.net/PDFs/CAPMIS/D.%20Child%20Vulnerabilities%20Reading.pdf</p>	<ul style="list-style-type: none"> – Children who grow up with abuse do not recognise it as abuse and thus do not seek out help. – Parents can be abusive without realising as they grew up used to abuse. 	<p>Abuse, maltreatment, harm, child protection, injury, stress</p>
<p>“Neglect is the failure of a parent to provide for the development of the child – where the parent is in a position to do so – in one or more of the following areas: health, education, emotional development,</p>	<p>Krug, E., Dahlberg, L., Mercy, J., Zwi, A. and Lozano, R. <i>World report on violence and health</i>. WHO. 2002.</p>	<ul style="list-style-type: none"> – Failure of parent to provide for the child where there is provision to do so. 	<p>Neglect, development, self-protection, abandonment, mistreatment, desertion, disregard</p>

<p>nutrition, shelter and safe living conditions. Neglect is distinguished from circumstances of poverty in that neglect can occur only in cases where reasonable resources are available to the family or caregiver.”</p>		<ul style="list-style-type: none"> – Distinguished from cases of poverty. 	
<p>“Children and young people on the Child Protection Register have been identified as being at risk of significant harm. This vulnerability has necessitated a multi-agency response with an identified child protection plan put in place. All key agencies involved with the child and family should be aware of the child protection plan in place.”</p>	<p><i>East Renfrewshire Child Protection Committee</i></p> <p>Link: http://www.eastrenfrewshire.gov.uk/CHttpHandler.ashx?id=3558&p=0</p>	<ul style="list-style-type: none"> – Children on this register are predefined as vulnerable. – Multi-agency responses are preset. 	<p>Protection plan, agency, response, harm, child protection register</p>
<p>“The term ‘child protection’ refers to preventing and responding to violence, exploitation and abuse against children – including commercial sexual exploitation, trafficking, child labour and harmful traditional practices. Child protection programmes also target children who are uniquely vulnerable to these abuses, such as when living without parental care, in conflict with the law and in armed conflict. Children subjected to violence, exploitation, abuse and neglect are at risk of death, poor physical and mental health, HIV/AIDS infection, educational problems, displacement, homelessness, vagrancy and poor parenting skills later in life.”</p>	<p><i>Child Protection Information Sheet. What is Child Protection?</i> UNICEF. 2006.</p> <p>Link: http://www.unicef.org/protection/files/What_is_Child_Protection.pdf</p>	<ul style="list-style-type: none"> – Child protection includes sexual, physical, emotional and financial abuse. – Those subject to this abuse are at risk of poor outcomes. 	<p>Child protection, abuse, neglect, sexual abuse, violence, conflict, homelessness, vagrancy, exploitation</p>
<p>“Preschool children who have been neglected or emotionally abused exhibit a range of serious emotional and behavioural difficulties and adverse mother-child interactions that indicate that these children require prompt evaluation and interventions”</p>	<p>Naughton, AM. <i>et al.</i> Emotional, behavioural, and developmental features indicative of neglect or emotional abuse in preschool children: a systematic review. <i>JAMA Peadiatric</i>. 2013; 167(8):769-775.</p>	<ul style="list-style-type: none"> – Neglected or abused children in their pre-school exhibit behavioural difficulties as they grow older. – Require additional evaluation 	<p>Abuse, emotional abuse, neglect, learning disability</p>

		and interventions.	
<p>“Child abuse is any action by another person – adult or child – that causes significant harm to a child. It can be physical, sexual or emotional, but can just as often be about a lack of love, care and attention. We know that neglect, whatever form it takes, can be just as damaging to a child as physical abuse. An abused child will often experience more than one type of abuse, as well as other difficulties in their lives. It often happens over a period of time, rather than being a one-off event. And it can increasingly happen online.”</p>	<p><i>NSPCC</i></p> <p>Link: http://www.nspcc.org.uk/preventing-abuse/child-abuse-and-neglect/</p>	<ul style="list-style-type: none"> – Cause significant harm. – Sexual, emotional, physical, neglect. 	<p>Significant harm, sexual, emotional, physical, neglect,</p>

Appendix 11. Comparison of scoping review methods

Amendments to the original Arksey & O'Malley scoping review approach

Amendment to Scoping Review method	Subject area	Summary of changes	Justification of changes
Anderson et al. 2008	Scoping studies in the commissioning of research in the organisation and delivery of health services	<ol style="list-style-type: none"> 1. Relate scoping studies to a particular health service context 2. Have multidisciplinary scoping teams 3. Give teams time to integrate diverse findings 4. Research commissioners must be explicit about the 	<ol style="list-style-type: none"> 1. Allows a more evidence-based approach to relating recommendations to context 2. Due to the wide-ranging nature of the findings it is necessary to have as wide a range of individuals on the scoping team in order to properly review the literature 3. A tight time scale prevents a more considered and comprehensive response 4. There has previously been a disconnect between

		aim and intended uses of scoping studies.	the literature in the review and the end recommendations as well as this, some reviews were missing recommendations about what to do next, the key purpose of a scoping study.
Davis et al. 2009	Scoping studies in nursing	No specific changes were made to the framework but the requirement to have a standardised and reproducible study was highlighted. The authors commented on the relative embryonic nature of such studies, particularly in the field of nursing, and stated that further development of the framework was required following further research.	Not applicable.
Grant et al. 2009	Generic research methods	No specific changes made to the framework but comments on limitations include that such studies cannot be used to recommend policy due to there being no weighing of the quality of the evidence presented.	Not applicable.
Levac et al. 2010	'Reviewing health evidence'	<ol style="list-style-type: none"> 1. Clarifying and linking the purpose and research question 2. Balancing feasibility with 	<ol style="list-style-type: none"> 1. The purpose of the study, together with the research question were not well enough linked in the original framework 2. The original framework was not well balanced

		<p>the breadth and comprehensiveness of the study</p> <p>3. Using an iterative team approach to selection of studies and data extraction</p> <p>4. Incorporating a numerical summary as well as qualitative summary</p> <p>5. Consideration of implications of findings to practice, policy or research</p> <p>6. Making the 'consultation with stakeholders' stage a compulsory stage</p>	<p>between feasibility and comprehensiveness and one may argue went into too much detail versus the need to be feasible</p> <p>3. The original framework did not see the selection process as iterative and may have missed out key studies versus this approach.</p> <p>4. To better summarise the data collected</p> <p>5. The original framework was not comprehensive enough in applying to the 'real world' the findings of the review</p> <p>6. The final step in the original framework often yielded very useful results and making it compulsory seems like an obvious development of the framework.</p>
Armstrong et al 2011	Cochrane Review of Scoping Studies	<p>This paper does not make any specific recommendations to the original framework, other than summarising the work of Levac et al (see above) and combining it with the original framework</p>	<p>The paper highlights the need for an evidence-based logical and reproducible procedure for conducting scoping reviews and highlights that if such studies are published they are highly useful for directing future research.</p>

Appendix 12. Search terms for vulnerable children scoping review

1. Medicat* error*
2. Abuse*
3. Neglect*
4. Child adj3 negl*
5. Child adj3 safeguard*
6. Child adj3 Prote*
7. Triag* adj3 error*
8. Triag* adj3 incident*
9. Clinical assessment adj3 error*
10. Patient assessment adj3 error*
11. Assessment adj3 safety incident
12. Diagnos* error*
13. Diagnos* incident*
14. Patient* record* adj3 error*
15. Medical record* adj3 error*
16. Referral* adj3 error*
17. Referral* adj3 safety
18. Referral* adj3 incident*
19. Communicat* adj3 error*
20. Communicat* adj3 failure
21. Communicat* incident*
22. Communicat* adj3 patient* safety
23. (1-22)/ OR
24. Drug adj3 error*
25. Drug adj3 program*
26. 24 OR 25
27. exp Child Health Services/ or exp Child, Preschool/ or exp Child/
28. Paediatric*
29. Pediatric*
30. exp Adolescent/ or exp Adolescent Health Services/

31. exp Infant/ Newborn/
32. (27-31)/ OR
33. Improve* adj3 interven*
34. exp Quality Improvement/
35. Error* adj3 prevent*
36. Safety adj3 improve*
37. Error* adj3 reduc*
38. (34-37)/ OR
39. Animals
40. Animal stud*
41. 39 OR 40
42. 23 AND 33 AND 38
43. 42 NOT 26 NOT 41
44. Looked adj3 after
45. Disab*
46. Learning adj3 di*
47. Vulnerab*
48. Psych*
49. Homeless
50. Maltreatment
51. Social adj3 services
52. Social adj3 care
53. Language
54. Developmental delay
55. (45-54)/ OR
56. 43 AND 55

Appendix 13. Data extraction sheet

Microsoft Excel - Included extracted studies for paper - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW DESIGN

Clipboard Font Alignment Number Styles Cells Editing

J2 : X ✓ ✗ fx Survey of users found that the program saved time, was easy to use, and helped to manage incident reports.

1	Author	Year	Title	Journal	Study Type	Primary or Secondary Care	Country	Vulnerability addressed	Intervention	Efficacy
1	Brenner E. and Freundlich M.	2006	Enhancing the safety of children in foster care and family support programs: Automated critical incident reporting	Child Welfare	Observational	Primary Care	United States	Social	Social workers to file reports for a number of predefined critical incidents with the system providing templates for follow-up that specify required information with a series of help screens.	Survey of users found that the program saved time, was easy to use, and helped to manage incident reports.
2	Chedoe I. et al.	2007	Incidence and nature of medication errors in neonatal intensive care with strategies to improve safety: A review of the current literature	Drug Safety	Review	n/a	Netherlands	Physical	Computerised Provider Order Entry	n/a
3	Chin M. et al.	2009	Health care quality-improvement approaches to reducing child health disparities	Pediatrics	Review	n/a	United States	Social	Key recommendations: examining performance data, measure and improve childhood health-related quality of life, use multidisciplinary teams with close monitoring of patients, incorporate families into interventions and introduce a quality improvement culture.	n/a
4	Deshpande G. et al.	2010	Computerised pharmaceutical algorithm reduce medication administration errors during simulated resuscitations	Journal of Pediatric Pharmacology and Therapeutics	Within-subject control	Secondary Care	United States	Physical	Pac2 tool, which assists in dosing calculations at the point-of-care by performing unit conversions and infusion rates based on patient characteristics and intended dose.	Improved nurses performance in drug calculations, increased accuracy in drawing up medication (p<0.0001), and identifying unsafe doses (p<0.0001).
5			Integrating mental health into	Journal of	Quasi-				Complete the DartScreen before	reems completing the DartScreen entered more neurosocial information (mean: 19.5

Sheet1

READY 100%

Appendix 14. Quality improvement project plan

Identifying opportunities to improve the quality of patient care in primary care via a functioning local reporting and learning system

What are we trying to accomplish?

Background: Primary care poses unique challenges for the design of better quality systems of care delivery, given its heterogeneous models of delivery and diversity of patients with a wide variety of undifferentiated complaints. For over a decade in healthcare, patient safety incident report systems have offered an opportunity to capture learning for improvement by understanding characteristics about events and contributory factors that led to incidents occurring. Leading experts recognize that despite limitations of reporting systems (underreporting, incomplete view of incident, and reporting biases) they provide multiple perspectives over time and form an integral part of routine monitoring in clinical practice. (Vincent 2010)

There has been little effort internationally to extend the advances made in hospital-based patient safety incident reporting to community settings (a model of a functioning reporting and learning system is proposed in Appendix A). Consequently, there is a poor reporting culture amongst healthcare professionals working in primary care in England and Wales (<0.05% of all total reports received by the National Reporting and Learning System between 2003-2013). Preliminary analysis of primary care incident reports from England and Wales over the past decade suggests that there is a misunderstanding amongst reporters about the purpose of reporting (i.e. around 40% percentage of reports contain little useful information to inform learning) as well as some confusion about what information needs to be included within reports (Carson-Stevens et al., unpublished).

Organisational activities to date: In 2012, GPs raised concerns about their inability to feedback system issues that were compromising the quality of patient care. CVUHB launched a reporting system for General Practitioners

(GPs) to enable better communication and joint working between the health board and GPs.

Over the past 9 months, the reporting process has been as follows:

- GPs report incidents via a clinical letter addressed to the relevant clinical area to enable investigation and response and cc'd to the Primary Care Divisional Director and the Primary Care Clinical Governance Manager;
- The Clinical Governance Manager log the reports and links with the reporter and relevant departments to ensure action;
- Clinical Governance Manager 'identities trends' and reports to CVUHB Medical Director, and a standing agenda item at CVUHB Executive Board and LMC (a statutory representative organisation for GPs practicing within CVUHB's remit) meetings.

CVUHB has 67 GP practice groups serving a population of over 500,000 patients at 92 GP surgeries (18 practice groups have more than one GP surgery) in the region. Only 32/67 GP practices are reporting incidents. Incidents solely relate to problems with secondary care (I.e. no primary care issues reported).

Organisational rationale for project: The project directly relates to Standard 23 for Health Services, 'organisations should ensure concerns are reported upon and expended to in an appropriate and timely manner'. Further, the incidents/near misses relating to the primary/secondary care interface impact directly on quality, safety and the patient and carer experience. A functioning reporting and learning system could mitigate risk by learning from interface incidents reported and improving systems and processes to avoid recurrence.

Financial considerations: There has been up to 15 reports, each requiring further investigation, generated in any one month; this has required considerable additional time from the Clinical Governance Manager and Medical Director. Incident trends will highlight the need to improve systems and service changes that will have financial implications (increase and decrease). But, trends could also lead to standardization of processes and reduce

variation. Likely complaints or claims could also reduce, and thus result in system savings (although existing system is not sensitive to detect financial benefit of avoided incidents).

Challenges with the existing system, include:

- Aimed solely at GPs and predominantly focused on 'what went wrong in the hospital'.
- No formal advice or guidance on what types of information to report for organisational learning (identifying what caused the problem, where it occurred, who needs to be involved in subsequent investigation and improvement efforts). Missing information often generates in the need to contact the busy reporter for further information and introduces delays in actioning and overall response.
- Popularity of reporting by GPs is placing resource pressures on Clinical Risk Manager overseeing paper-based system; for example, managing paper trail audit from initial receipt of letter, to actioning, to resolution of issues, follow up on missing information with the reporter, transcribing important information into a separate standalone database, and finally independent identification of trends.

Opportunities for system re-design, include:

- Convert to electronic system by integrating primary care reporting system into wider CVUHB used by all other clinical specialties.
- Integrating existing Significant Event Analyses (a technique to reflect on and learn from individual cases) undertaken at practice-level into the system for organisational level learning and wider national learning.
- Co-develop guidance and a report form (with prompts) with GPs based on their existing and ongoing experiences, best-available evidence on how to classify incidents in terms of data capture (i.e. what information is needed for organisational and wider national learning) and frequent local assessment of commonly missing variables of information.
- Co-develop a standard operating procedure with GPs, LMC, CVUHB Executive board to addresses *what to report* and exploring scope for extending definition of incident to include all relevant system-level quality

issues (not just 'patient safety incidents' that already has a clear definition) based on organisational and wider national agenda priorities.

- Consider processes for other healthcare professionals (community and practice based nurses, community midwives, pharmacists, et al.), as well as patients, to report to the system.
- Transfer insights from research (which includes early designs of audit tools for practical use by managers and clinicians to improve the quality of reporting).

Goals of improvement project

We aim to improve the quality of patient care in primary care at Cardiff and Vale University Health Board (CVUHB) by redesigning an existing local patient safety incident reporting and learning system to identify at least one priority area for improvement within the organisation. This will include achieving the following goals from Nov 1st to July 1st 2013:

- Increased overall incident reporting rate by 25%;
- Increased number of practices reporting (90% of total);
- At least 1 other healthcare professional (in addition to a GP) reporting from a practice from 10% of practices;
- At least 5% of practices advocating patients to report;
- Decrease time taken by risk management to action a report by 50%; and,
- Increase the quality of total incident reports by X%.

How do we know that a change is an improvement?

The following outcome (O), process (P) and balancing (B) measures and feedback (F) will be used to define the impact of the changes made.

Number of reports and reporting quality

- Total number of incident reports from GPs (O)
- Overall quality of incident reports from primary care at CVUHB (O)
- Number of identified issues for improvement (O)
- Number of issues informing improvement projects (O)
- Number of reports per practice (P)

- Quality of incident reports per practice (P)
- Number of reports by patients (P / O)
- Number of reports completed correctly (P)

Reporting process

- Duration between incident occurring and professional reporting it (P)
- Experience of reporters (F / B)
- Time taken to complete online form (P)

Risk management team handling of reports

- Time for risk management team to acknowledge report (P)
- Time for risk management team to complete investigation of each report (P)
- Time for risk management team to follow up missing or further information needed to action a report (P / B)
- Diversity of Healthcare Professionals (and patients) reporting (P)

Organisational feedback

- Time to provide feedback to reporters (P)
- Time to feed forwards to Executive meeting (P)
- Time to feed forwards to LMC meeting (P)
- Number of complaints (O)

What changes can we make that will lead to improvement?

See project driver diagram for change concepts and specific change ideas. A multidisciplinary team will lead this improvement project.

Project Driver Diagram

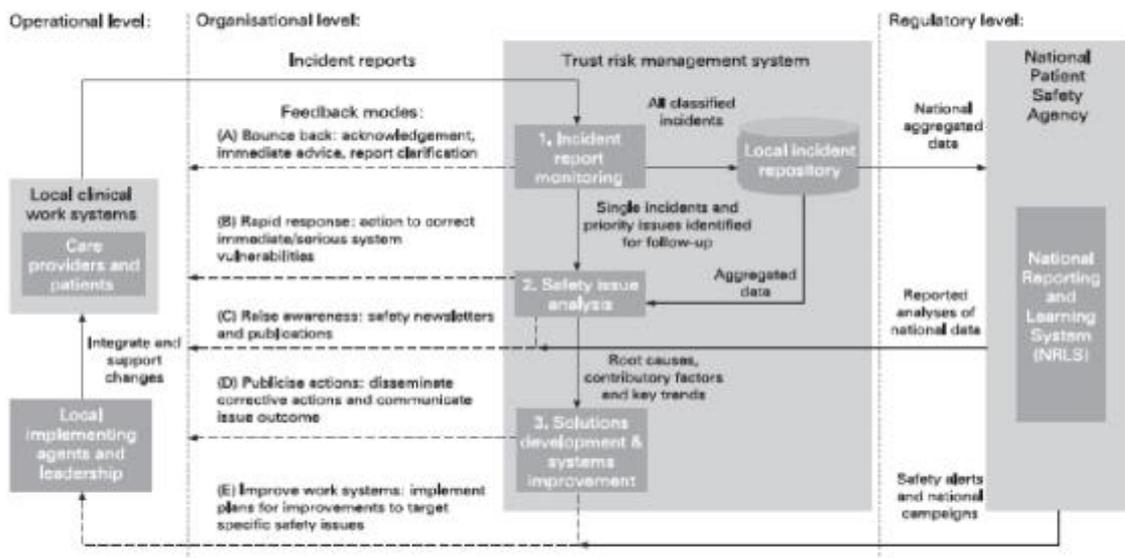
Primary Driver	Secondary Driver	Key Change Concept	Specific Change Ideas		
Functioning and Responsive Reporting and Learning System	Accessibility to report	User-friendly reporting	Inform first draft of form from evaluation of previous incident reports deemed 'high quality'		
			Develop form with stratified sample of high and low reporters		
			Ensure IT infrastructure in place to support set up of icons on desktop / intranet		
			Develop troubleshooting guide for IT issues		
	Efficiency of reporting process	Minimise duplication and ensure usefulness of information		Identify important variables of info with Risk Management team to commonly 'action a report' (Pareto Chart method)	
				Develop prompts based on 'high quality' reporting variables to focus reporting narratives	
		Identify balance between data quality and time to complete form			Regular team meetings to identify commonly missing information requiring f/up calls with reporters
					Evaluation of user experience
					Develop reported 'estimated time to complete form' measure
	Timely response	Response to report		Develop IT infrastructure to acknowledge report within 24 hours	
				Explore options for thematised responses to recognize importance of issue and educate the reporter in return	
SOP for verbal and written response from risk management team & escalation					
Action Grading System		Develop a grading system to determine			

			urgency for action			
			Track response time			
			Explore options for responses (automated or via other communication methods) based on urgency			
Healthcare professionals to provide descriptive, useful and timely incident reports	Education and Training to report	SOP of incident reporting	Determine by stakeholder ... what constitutes an incident and scope banding of reporting (i.e. issues with secondary care, primary care, all care)			
			Establish protocols/guidance for writing report			
			Guidance for accessing reporting system			
			Determine escalation procedures for urgent clinical issues			
	Increase Reporting Quality	Application of a quality scoring indicator	Develop quality scoring tool			
			Align quality scoring criteria with prompts			
			Look for variation in reporting quality by: GP Practice, practitioner, healthcare professional role			
			Identify low/... quality reporting practices and seek feedback re: understanding sources of variation			
			Create mechanism for feeding back data quality willing practices			
			Determine time lag between incident occurring and being reported			
			Develop Infrastructure to support the Reporting and Learning System	Leadership	Report themes/outcomes to key stakeholders:- - Patients - HCP - LMC - Executive Board; Representation of key stakeholders on project steering group	Develop format for learning outputs for each key stakeholder audience (including relevant outcomes)
						Stakeholder analysis of power/roles ratio

		Executive endorsement of reporting	Memos / forewords from CEO, consistent narrative at key events, organisational website and publications
		Incentives to report	Create excellence award' based on practices where most different types of health care professionals report, any efforts to encourage patients to report etc.
	National influences	Align with existing revalidation requirements for doctors	Encourage significant event audits (these are assessment undertaking by practitioners in-house in each practice) to feed into the reporting system too
		Quality checking by Government	Train Welsh Government staff to use quality scoring too (NB: interest already expressed to quality assure health board in this way)
		Seek to incorporate significant event analysis into Reporting and Learning Systems	Welsh Government to mandate all SEA's to be contributed locally and HB, level for learning purposes
		SOP for contribution to National Reporting and Learning System in England and Wales	Develop/Review Existing Criteria /process of 'when to report'
	Finance	Determine waste in terms of time currently taken to facilitate paper trail/ follow up of missing information by risk management team	Development of a realistic and manageable assessment of time to complete administrative tasks
		Cost-benefits analysis of staffing a patient (+clinician) reporting line	
		Report cost saved for those incidents triggering improvement/actions with established cost-effectiveness consequences known e.g. preventable	Work with Innovation and Improvement team to explore how this has been done previously; identify what could be done to support the identification of cost benefits within the existing measurement

		rehospitalisation	systems.
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Appendix A. Overview of a reporting and learning system at an operational, organisational and regulatory level (from Benn, J., Koutantji, M., Wallace, L., Spurgeon, P., Rejman, M., Healey, A., et al. (2009). Feedback from incident reporting: information and action to improve patient safety. *Qual Saf Health Care*, 18(1), 11-21.)



Appendix 15. Completed PDSA cycle



MODEL FOR IMPROVEMENT

DATE 3/01/2013

Objective for this PDSA Cycle: Undertake a cost-benefit analysis of efforts to minimise Warfarin-related incidents for patients.

Is this cycle used to develop, test, or implement a change?

Develop a change.

What question(s) do we want to answer on this PDSA cycle?

- What key issues have resulted in deleterious outcomes for patients?
- What costs are associated with those outcomes, and what would a monthly and annual extrapolation for the health board be?
- How could those key issues (sub-themes) inform opportunities to improve existing Warfarin services for patients?

Plan:

Plan to answer questions: Who, What, When, Where

ACS & SR to undertake thematic analysis of Warfarin-related incidents submitted over 12 months by 4/1/13.

Claire to order case notes of patients identified by pharmacy as discharged on Warfarin in a defined 2-week period by 7/1/13. SR and lead pharmacist for coagulation to undertake case-note review and identify potential deleterious outcomes jointly by 10/01/13.

NM to liaise with finance department re: cost of extra day stay and extrapolate potential monthly and annual costs by 13/01/13.

Discuss identified issues (sub-themes) at task force meeting and identify potential changes to inform Driver Diagram through group discussion by end of meeting on 13/1/2013. SR and ACS responsible for producing first draft of driver diagram to share with team by 15/1/13.

Predictions (for questions above based on plan):

- Identification of sub-themes will permit prioritization of common issues to focus change concepts/ideas.
- Delayed discharge is an expected outcome. Case note review could identify patients experiencing further iatrogenic harm as a result of their increased length of stay. Costs can be estimated for increased length of stay and common iatrogenic harms (e.g. VAP, HAI).
- The issues identified by the incident reports can become the focus of the change concepts and ideas for improving the care model.

Do:

Carry out the change or test; Collect data and begin analysis.

Finance team very forthcoming with figures and willing to be contacted to contribute to further calculations. Common issues identified by GPs in clinical incident reports heavily influenced discussions and focus of change ideas for a new model of care delivery.

Case note review required a structured tool to collect data. Pharmacy lead had previously used a modified trigger tool for this purpose. SR needed brief training to use the tool.

Study:

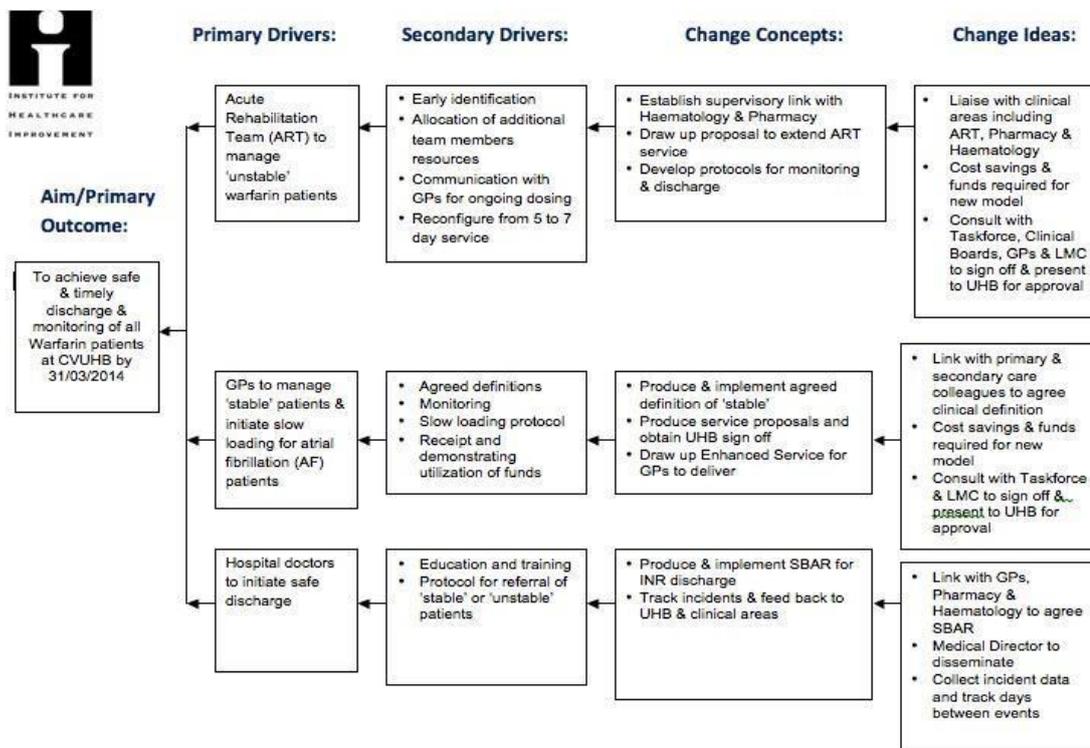
Complete analysis of data;

Case-note review for all in-patients admitted during a 2-week period in October 2013, of the patients on Warfarin who were discharged, 22% had a delay in discharge of at least 1 day (range 1-7 days) solely due to the need for in-patient INR monitoring. One patient developed a hospital-acquired pneumonia as a result of delayed discharge.

The reasons for discharge delay (sub-themes) included: poor secondary care understanding and communication of INR (tackled in May 2013 via the Warfarin SBAR), variation of 'stable' INR definitions (different INR protocols in place for acceptance of patients), and capacity for community-team to pick up 'unstable' INR patients.

This cost has been estimated as £38,874 per month, based on the 25 patients in this position, we estimate unnecessary hospitalization costs to be £466,488 per annum for the health board.

Further areas identified for improvement



Associated costs of existing services and estimates of new service (as per driver diagram): existing costs on top and new costs on the bottom.

INR MONITORING SERVICES							
UHW - WEEKLY CLINICS (HAEM OUTPATIENTS)							
	Hrs/Clinic	Clinics/wk	Total weekly hrs	Cost/hr	Total weekly cost	Annual Cost	
Consultant Haematologist	2.0	2	4.0	£50	£200	£10,429	
Haematology SpR	2.0	2	4.0	£27	£110	£5,718	
Pharmacist	4.0	2	8.0	£25	£200	£10,429	
Pharmacy technician	4.0	2	8.0	£15	£120	£6,257	
STAFF COSTS, UHW						£32,833	
UHL - WEEKLY CLINIC (HAEM OUTPATIENTS)							
	Hrs/Clinic	Clinics/wk	Total weekly hrs	Cost/hr	Total weekly cost	Annual Cost	
Consultant Haematologist	4.0	1.5	6.0	£50	£300	£15,643	
INR Nurse	2.0	1.5	3.0	£22	£66	£3,435	
STAFF COSTS, UHL						£19,078	
TOTAL STAFF COSTS						£51,910	
DTOC IMPLICATIONS							
DTOC bed day pressures, per month						£36,074	
TOTAL ANNUAL BED DAY SAVINGS						£466,488	
IF SERVICE DELIVERED IN PRIMARY CARE							
PATHWAY 1 - INR							
Est cost to transfer stable f-up ptnts out to PC ES monitoring: £ 183.51							
average drug costs, per patient (warfarin) £ 47.67							
estimated no. patients / year 176							
Consumables costs						£ 40,687.09	
PATHWAY 1 TOTAL						£40,887	
PATHWAY 2 - SLOW LOADING ATRIAL FIBRILLATION (AF)							
dependent on "Level" of patient seen							
average cost per patient (Level 4) £ 120.00							
average drug costs per patient £ 5.50							
estimated no. patients / year 360							
Consumables costs						£ 43,925.00	
PATHWAY 2 TOTAL						£43,925	
PATHWAY 3 - ACUTE RESPONSE TEAM (ART)							
Community Nurse							
WTE 2.0 75.0 £22 £1,650							
STAFF COSTS						£86,036	
dependent on "Level" of patient seen							
average cost per patient (Level 4) £ 61.00							
average drug costs per patient £ 1.83							
estimated no. patients / year 300							
Consumables costs						£ 18,850.00	
Coagucheck machines x2						£2,000.00	
PATHWAY 3 TOTAL						£ 20,850.00	
PRIMARY CARE SERVICE DELIVERY TOTAL						£191,498	

Compare the data to your predictions and summarize the learning

- The three common issues underpinning incident reports relating to Warfarin were identified. Secondary care clinicians understood the issues and identified opportunities to mitigate such issues occurring in the future.
- Costs estimated as a result of delayed discharges from the current model of anticoagulation services shocked the task force. Improving the service was recognized as a priority. One patient was identified as having preventable hospital acquired pneumonia as a result of her delayed discharge. Case note

review was useful although likely to identify more iatrogenic harms if undertaken with a larger sample. Costs can be estimated by ICD codes.

- Estimated costs have been drawn up to parallel the proposed primary drivers for the new anticoagulation service to demonstrate the potential cost saving of around £300k.

The cost-benefits analysis, and the first draft of a change model, will assist to build confidence amongst primary care (and secondary care) healthcare professionals in the value of incident reporting. This has generated an improvement project within/from an improvement project as anticipated.

Act:

Are we ready to make a change? Plan for the next cycle

Next steps include:

- Identify team members to lead the Warfarin improvement project (SR, NM included and ACS to continue as improvement advisor); *[System Improvement - 2ry Driver]*
- Feedback the proposed changes for testing to the LMC [primary care doctors group] to build will amongst GPs to report further incidents and demonstrate value of new reporting system; and, *[Issue Analysis – 2ry Driver] [System Improvement – 2ry Driver]*
- Highlight potential cost saving at next UHB Quality Improvement Faculty meeting to obtain CEO & Chair endorsement for project. *[Leadership (endorsement at board level) 2ry driver]*