Improving risk controls following root cause analysis of serious incidents in healthcare

Thesis submitted for the degree of

Doctor of Philosophy

at the University of Leicester

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2021

Abstract

Improving risk controls following root cause analysis of serious incidents in healthcare- Mohammad Farhad Peerally

Background
Root cause analysis (RCA) is widely used following healthcare serious incidents, but does not necessarily lead to robust risk controls. This research aimed to examine current practices and to inform an understanding of what good looks like in formulating and implementing risk controls to improve patient safety.

Methods
First, I undertook a content analysis of 126 RCA reports over a three-year period from an acute NHS trust, with the goals of characterising (i)the contributory factors identified in investigations and (ii)the risk controls proposed in the action plans. Second, I conducted a narrative review of the academic literature on improving risk control practices in safety-critical industries, including but not limited to healthcare. Finally, I undertook a qualitative study involving 52 semi-structured interviews with expert stakeholders in post-incident management, analysed using the framework method.

Results
Content analysis of serious incident investigation reports identified the preoccupation of RCAs with identifying proximate errors at the sharp end of care, neglecting wider contexts and structures. Most (74%) risk controls proposed could be characterised as weak and were poorly aligned with identified contributory factors. Together, the narrative review and the findings of the interview study suggested eleven features essential to addressing these problems: systems-based investigations; a participatory approach, skilled and independent investigators; clear and shared language; including patients' views; allocating time and space to risk control formulation; adding structure to risk control formulation; sustainable risk controls mapped to identified problems; purposeful implementation and better tracking of risk controls; a collaborative approach to quality assurance and improved organisational learning.

Discussion and conclusion:
RCAs as currently conducted, and the action plans that arise from them, are often flawed. The eleven features identified will be important in improving risk control formulation and implementation. To operationalise these features, there is a need for: professional and independent investigations, risk controls based on a sound theory of change, and improved cultures and structures for organisational learning.

Acknowledgements

As I write this acknowledgements section, I cannot help but look back at the last five years with feelings of satisfaction, pride and more importantly, gratitude towards numerous individuals and organisations without whose support this body of work would have never seen light.

First, I would like to thank the various participants in this study who have been very generous with their time and provided me with invaluable insights into their world, views and research. Interacting with them was a humbling, rewarding and enlightening experience, which reminded me of the importance of constantly striving to improve patient safety as a clinician and researcher.

I thank my funders, the Health Foundation, who demonstrated their commitment in my project and supported my development as an early career clinical researcher. My supervisors, Professor Mary Dixon-Woods, Professor Sue Carr, Professor Justin Waring and Professor Graham Martin have all been constant sources of inspiration and support, guiding me patiently throughout this journey. I thank Damian Roland whose wise words at the beginning of the PhD provided me with vital insight into life as a clinical academic. I am grateful to Moira Durbridge who unlocked many doors during the first few months of the PhD, and Carl Macrae who invited me at meetings where I could interact with both policymakers and academics interested in my area of research. I am also thankful to the SAPPHIRE department at the University of Leicester whose staff have welcomed me with open arms and were always available whenever I needed methodological guidance or just a chat over coffee. I cannot forget the role played by my clinical supervisors at the University Hospitals of Leicester and Kettering General Hospital, who were always flexible, allowing me time for academia, even when I returned to full-time clinical medicine.

I thank my friends and members of my family for their continuous support through thick and thin: my wife Nushra for always believing in me, my children Ayman and

Iqrah (who were not yet born when I began this PhD journey) for the daily joy they bring, my sister Warda for providing a listening ear and my parents and late grandmother for teaching me the importance of hard work.

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AAIB:	Air Accident Investigation Branch
AAR:	After-Action Review
CCG:	Clinical Commissioning Group
CDSS:	Computerised Decision Support Systems
CHFG:	Clinical Human Factors Group
CQC:	Care and Quality Commission
CV:	Curriculum Vitae
ED:	Emergency Department
EWS:	Early Warning Score
FMEA:	Failure Mode and Effect Analysis
HCA:	Healthcare Assistant
HFACS:	Human Factors Analysis Classification System
HOS:	Head of Service
HRA:	Health Research Authority
HRO:	High Reliability Organisation
HRT:	High Reliability Theory
HTA:	Hierarchical Task Analysis
HSIB:	Healthcare Safety Investigation Branch

IOM:	Institute of Medicine
ITU:	Intensive Treatment Unit
JDA:	Junior Doctors Administrator
LIIPS:	Leicestershire Improvement, Innovation and Patient Safety
M&M:	Mortality and Morbidity
MRSA:	Methicillin Resistant Staphylococcus Aureus
NHS:	National Health Service
NIHR:	National Institute of Health Research
NIOSH:	National Institute for Occupational Safety and Health
NPSA:	National Patient Safety Agency
NRLS:	National Reporting and Learning System
PASC:	Public Administration Select Committee
PEWS:	Paediatric Early Warning Score
RCA:	Root Cause Analysis
REC:	Research Ethics Committee
RN:	Registered Nurse
RTT:	Referral to Treatment
SBAR:	Situation-Background-Assessment-Recommendation
SI:	Serious Incidents
SOP:	Standard Operating Procedure

STAMP:	Systems Theoretic Accident Modelling and Processes
WHO:	World Health Organisation

1 Introduction

The US National Academy of Medicine (formerly the Institute of Medicine) has defined "patient safety" as the prevention of harm to patients,[1] and highlighted the need for different components of a healthcare system to work together to prevent errors, learn from past ones and create and sustain an environment which promotes safety. To that end, in the last 20 years, many practices with origins in other safety critical industries have been adopted in healthcare to improve patient safety. An important example is the conduct of structured investigations by healthcare organisations following patient safety incidents.[2, 3] The purpose of such investigations is to provide an insight into unsafe practices within an organisation. Charles Vincent, who developed the first organisational investigation framework (discussed in more detail in section 2.2.2.2), used in the NHS, suggested that these kinds of investigations would offer a "window on the system",[4-6] with a view of developing error-reduction strategies.

One particularly common approach used to investigate more serious incidents (SIs) in healthcare where patients were harmed or could have been seriously harmed, is root cause analysis (RCA).[2-4, 7] Using multiple information-gathering and analytical tools, RCA seeks to construct an understanding of what happened and why, in order to develop actions aiming to prevent future incidents.[2, 3] In the UK, the use of RCA to conduct incident investigations can be traced back to the early 2000 with the publication of a report entitled "An organisation with a memory". In this same report's executive summary, Sir Liam Donaldson, who was then Chief Medical Officer in England said, *"…such failures often have a familiar ring, displaying strong similarities to incidents which have occurred before and, in some cases almost exactly replicating them. Many could be avoided if only the lessons of experience were properly learned."*[8]

RCA is now used widely, across multiple healthcare systems.[3, 9-11] It is resource-intensive, requiring teams of investigators to build an anatomy of past events through staff interviews and statements, reviews of clinical notes, patient and relatives statements and workforce rotas, amongst other sources. Nicolini et al. report that the

practice of RCA in healthcare organisations allows a sense of "closure" for leaders of the organisation where the incident occurred and to achieve "control" over what are found to be deviations from expected practice.[12]

Despite its widespread use, it remains unclear whether RCA consistently leads to improvements in patient safety.[13, 14] Researchers (amongst whom I count myself),[13, 15-17] and policy makers[10, 18] have reported multiple concerns regarding the efficacy of serious incident investigation in healthcare organisations, as currently performed. For example, one concern is that the conduct of an RCA following a serious incident had become an "end in itself", as opposed to a "means to an end" (formulating and implementing strong actions to prevent future incidents and organisational learning).[12]

Since the publication of "An organisation with a memory", public inquiries into patient safety concerns at an organisational level such as the Mid Staffordshire reports[19, 20] and other reviews into patient safety across the wider NHS[18, 21] have identified that healthcare organisations must get better at investigating incidents and learning from them. One of the more widely discussed cases is that of the death of 18-year-old Connor Sparrowhawk, who drowned in a bathtub after suffering from a seizure while an inpatient in a mental health assessment unit.[22] The Mazars review, which followed on from the investigation, found that lessons from similar past incidents in the same trust were not always turned into recommendations and that the links between findings of investigations and recommendations were poor.[23] A parliamentary inquiry into how serious investigations are investigated in the NHS similarly questioned whether locally conducted investigations were consistently able to identify the right breadth and depth of contributory factors to incidents, and in turn whether they were able to generate and implement actions robust enough to prevent future incidents.[18]

While the healthcare literature is rich in research describing and critiquing the process of investigating incidents[12, 24, 25] and the types of factors leading to particular types of incidents,[26-31] less is known about how actions or risk controls are generated and implemented following an incident investigation. Understanding those factors

influencing the formulation and implementation of risk controls following investigations is important for multiple reasons: to ensure that the time and effort spent investigating incidents are not wasted, improve the ability of healthcare organisations to address identified hazards, share good practice, and ultimately reduce the recurrence of similar incidents.

The overarching aims of the study I report here are to construct an analysis of how actions (also referred as "risk controls" in this thesis) are formulated and implemented following serious incident investigations in healthcare, and to identify what needs to be done by individual healthcare organisations and regulators to improve risk controls (I provide a more detailed outline of research aims, objectives and questions in section 2.7 and Chapter 3). In so doing, this project aims to improve organisational responses to hazards identified through incident investigations in healthcare and ultimately improve patient safety. The specific research questions this thesis aims to answer are as follows:

1. How well suited are currently proposed risk controls to the problems identified through root cause analysis of serious incidents?

2. What are the influences on the formulation and implementation of risk controls following serious incident investigations in healthcare?

3. How can the formulation and implementation of risk controls following root cause analysis of serious incidents be improved in healthcare?

Previous research has shown that the activities involved in investigating incidents and analysing areas of risk are deeply social processes, involving interactions between multiple stakeholders: investigators, regulators, staff involved in incidents, patients, relatives, clinical and technical experts.[12, 24, 32, 33] I started this project with the assumption that the processes of formulating and implementing risk controls would at least be equally characterised and influenced by dynamic social factors, which necessitate an understanding of individual and collective behaviours and experiences.

The research questions, as set out above, particularly lent themselves to qualitative approaches (see Chapter 3), which would allow me to construct meaning from the experiences and opinions of those involved in the process of formulating and implementing risk controls following serious incidents.

Another assumption which informed my approach to answering the above research questions was the belief that healthcare, as a sector, can still learn from certain practices in place in other safety critical industries (such as aviation, energy, transport) when investigating incidents, generating and implementing actions. I used this assumption with care, as I am very aware that healthcare has its own set of unique complexities which differentiate it from other industries. Oversimplified comparisons between healthcare and other safety critical industries, exemplified by a "drag and drop" approach to reproducing improvement practices between industries can "provoke considerable frustration and scepticism among clinicians."[34] Nonetheless, previous research in both healthcare and other safety critical industries have demonstrated similar concerns when translating investigation findings into actions, and implementing them.[13, 35, 36] Thus, so long as contextual, cultural and structural differences between industries are accounted for,[34] I believe that much can be learnt from the experience of other safety critical industries (see Chapters 6 and 7).

1.1 Personal motives

One of the first things I did when I started this PhD journey was to document my reasons for dedicating the next few years of my life to this research project. I felt that it was important to curate my own beliefs relating to the subject I was studying and how they would influence my interpretation of the research findings. Many emotions, fuelled by my past and current experiences as a junior doctor, educator and researcher lie behind my motivations for doing this doctoral project, with the three predominant ones being frustration, curiosity and excitement.

When I began this PhD journey at the end of 2015, I was a junior doctor at the beginning of my specialty registrar training in Gastroenterology and General Medicine.

I had already been a medical student, foundation doctor and core medical trainee and had rotated through several hospitals and departments in South Yorkshire and the Midlands. I was what Sir Robert Francis, in his inquiry into the failings at Mid Staffordshire NHS trust would describe as the “eyes and ears” of the healthcare system.[20] This description would certainly resonate with my own experience: I had consistently witnessed and at times been part of teams of clinicians who regularly did our utmost best in our attempts to deliver high level care to patients. Yet, I also witnessed instances when patient safety was compromised despite those efforts.

As a clinician, how most departments responded to adverse events frustrated and perturbed me deeply. Even when adverse events were classed as serious enough to be investigated, there was no consistency in the quality of the response and learning was haphazard. The same problems recurred across departments, putting patients at risk of avoidable harm. Occasionally, healthcare professionals were blamed implicitly or explicitly. A case that sticks to mind is that of a patient whom I had looked after as a core trainee. On admission, he had wrongly been prescribed methotrexate (a drug used in rheumatoid arthritis which can affect the bone marrow) on a daily basis instead of weekly. The mistake was picked up by the pharmacist after the patient had two doses of the drugs. The patient came to no harm, which was good. The response of the department and the organisation was mixed.

I sought comfort from the fact that the organisation had systems in place to detect the incident and perform a structured investigation into the potential causes leading to the incident. Simultaneously, I was troubled by the measures that were put in place in response to the incident as they created multiple other problems. The trainee doctor who did the prescription had to undergo retraining and assessments of their prescribing skills, and the nurse who administered the drug was not allowed to do any unsupervised drug administrations for a few weeks, after which they had to undergo a period of retraining and assessments. The whole ward developed a policy where nurses could not be spoken to by other members of staff during their drug rounds, which unfortunately overlapped partly with the doctors’ ward round. The result was a

nurse and a doctor who, individually, were demoralised, and ward rounds with no nursing input. Meanwhile, the chances of other clinicians and nurses making the same mistake again probably remained the same.

My professional and personal interest in the conduct of incident investigations and the responses following the investigations was further fuelled by my roles as an educator and novice researcher. During my academic clinical fellowship in medical education between 2011 and 2014, I developed and evaluated a multi-disciplinary simulation programme based on real-life serious incidents that had occurred in the trust I worked in.[37] Critically reviewing serious incident reports and corresponding action plans with a view of reproducing the events was a hugely valuable exercise, making me question why investigators came to the conclusions they did and leading me to speculate on why they suggested particular actions.

I became curious about the social activity of investigating incidents (which is a process alien to most healthcare professionals) and eager to understand what influenced assumptions and deductions made during investigations and ultimately how they affected recommendations. These motives set the foundation for this research study. I was particularly directed towards understanding how the formulation and implementation of risk controls (termed collectively as the "risk control process" in the rest of the thesis) following serious incident investigations in healthcare could be improved. To progress this goal, I undertook three workpackages, as outlined in Chapter 3:

1. Workpackage 1: Qualitative analysis of serious incident investigation reports and action plans
2. Workpackage 2: Improving risk controls following incident investigations in healthcare- A narrative review of practices from safety critical industries.
3. Workpackage 3: Semi-structured interviews with stakeholders in the investigation of incidents and the risk control process in safety critical industries

1.2 Thesis outline

In this section, I provide an outline to the thesis by introducing the content of each chapter.

In Chapter 2, using the literature, I look at the burden of patient safety incidents in healthcare and introduce some important theoretical concepts describing the evolution of thinking about patient safety incidents. I outline how some major failures in healthcare have shaped the process of serious incident investigation in healthcare organisations, with a focus on the NHS. I focus on the practice of root cause analysis in healthcare, the theory behind it, its merits and limitations. Finally, I look at the limited data available on the effectiveness of risk controls generated following root cause analyses and explore the challenges faced in healthcare when generating and implementing risk controls following incident investigations based on evidence from the literature.

In Chapter 3, I outline and justify my methodological approach to answering the following research questions:

1. How well suited are current proposed risk controls to the problems identified through root cause analysis of serious incidents?
2. What influences the formulation and implementation of risk controls following serious incident investigations in healthcare?
3. How can the formulation and implementation of risk controls following root cause analysis in healthcare be improved?

I introduce the methods used to collect and analyse data for each workpackage within an ethical governance framework. Finally, I provide a reflective summary of my thoughts when conducting the semi-structured interviews (workpackage 3).

I report the findings of workpackage 1 in Chapters 4 and 5. First, in Chapter 4, I report the findings of a content analysis that I undertook of serious incident investigation

reports over a three-year timeframe across different specialties in a large acute NHS trust. I used a modified human factors analysis and classification system framework (HFACS) to identify contributory factors across incidents. I show that most contributory factors to incidents identified during investigations were those occurring at the front-line of healthcare delivery (such as decision-based errors), with organisational factors (such as staffing or organisational culture) identified less often. I discuss some of the factors influencing the breadth and depth of findings from serious incident investigations, including the methods used to investigate incidents and the expertise and seniority of those tasked with investigating incidents.

In Chapter 5, also using content analysis, I identify different risk controls generated from the action plans of serious incident investigation reports. I describe seven broad themes, each describing a family of risk controls. I identify that investigators often used a "sticking plaster" approach to addressing risk. They focused primarily on corrections at the front-line and failed to make recommendations to address hazards at the organisational level or those beyond the remit of the organisation. These findings highlight the importance of identifying factors influencing the formulation and implementation of risk controls following serious incident investigations.

Chapter 6 is a narrative review of the literature from healthcare and other safety critical industries to identify lessons relevant to healthcare when formulating and implementing actions following incident investigations (workpackage 2). I identify themes describing approaches from healthcare and other safety critical industries that could potentially improve the risk control process in healthcare.

In Chapter 7, I report the results of a semi-structured interview study with stakeholders from healthcare and other safety critical industries involved in incident investigations and the risk control process following investigations with a view of developing a better understanding of real-life influences when formulating and implementing actions (workpackage 3). Using the results of Chapter 6 as a sensitising framework, alongside an inductive approach, I identify seven features from the

interview data relevant to improving the formulation and implementation of risk controls following incident investigations in healthcare.

Of note, I argue that, for healthcare organisations to conduct better local investigations of incidents and implement stronger risk controls, they need to be supported by technical and social infrastructure at a sectoral level, which, among other things, could sustain intra and inter-organisational learning.

In Chapter 8, I combine the findings of Chapters 6 and 7 to outline eleven key features of stronger risk controls following investigations, the challenges frustrating the implementation of these features and potential solutions to address these challenges. I bring together the findings of Chapters 4 to 7 and organise them into three broad considerations. First, I argue that robust risk controls result from robust investigations, which cannot occur without empowering investigators with autonomy and expertise. Second, I discuss the role of theories of change when designing risk controls and consider what this may look like practically. Third, I elaborate on the need to develop a better understanding of how learning occurs following incident investigations.

2 Background

This chapter sets the context of the thesis by looking at the issue of adverse events in healthcare and how healthcare systems currently aim to respond to them. The chapter is divided into five sections. Section 2.1 introduces the scale of adverse events in healthcare worldwide. In section 2.2, I describe some important theoretical concepts, with practical relevance to the modern understanding of how incidents occur in complex sociotechnical systems, including healthcare. Next (section 2.3), I discuss how such incidents that resulted in major healthcare scandals have shaped the practices of incident reporting and investigation, with a focus on the NHS. In section 2.4, I focus on the practice of root cause analysis in healthcare as a means of investigating and analysing incidents, outline its strengths based on its theoretical underpinnings, and explore the limitations of its use in healthcare. Finally, section 2.5 looks at the available evidence in the literature describing the effectiveness of risk controls generated following root cause analyses and the challenges faced in healthcare when generating and implementing risk controls.

At this stage, two definitions need to be clarified: adverse events and incidents or patient safety incidents. In the context of this thesis, an adverse event is defined as an event that leads to unintended harm to one or more patients rather than the harm being due to the underlying condition of the patient(s).[1] A patient safety incident or incident relates to any unexpected event which led or could have led to harm to one or more patients.[3]

2.1 The scale of adverse events in healthcare

Some of the early estimates of the likely scale and burden of adverse events were published in the early 1990s through the Harvard Medical Practice study in the US.[38] The researchers retrospectively reviewed over 30,000 randomly selected hospital records from patients in New York State in 1984 and found that adverse events occurred in about 4% of hospitalisations. The landmark US Institute of Medicine (now National Academy of Medicine) report *"To Err is Human: Building a Safety Health*

System" used the study as the basis of its estimate that there were between 44,000 and 98,000 preventable deaths per year from adverse events related to the delivery of healthcare.[7] The prevalence of adverse events has since been estimated in other studies from Europe, Australia, New Zealand and North America. Through retrospective case note reviews, these studies have consistently shown that around 10% of patients experience some form of adverse event during in-hospital care,[39-43] and up to half of these events are preventable, according to a systematic review.[44]

The message from the IOM report and other studies[11, 39, 41, 42, 44] looking at the scale of adverse events in healthcare is clear: adverse events constitute a significant burden to patients, families and healthcare systems.[7] Researchers have demonstrated that patients suffering from adverse events stay in hospital for longer, with an estimated additional cost of £1 billion per year in lost bed days.[11] There are over 1.4 million patient safety incidents (defined by NHS England as any unintended or unexpected incident which resulted or could have resulted to harm to one or more patients receiving healthcare[3]) reported nationally to NHS England, with more than 10,000 classed as serious, based on their level of harm or their potential to have caused serious harm.[18]

These incidents are investigated in-depth by individual organisations and on occasions by national bodies to generate lessons for the wider NHS.[18] For patients and their families, the impact of these serious incidents may include death, life-changing injuries and other physical, financial and psychological sufferings.[45] Serious incidents contribute to significant emotional drain on the members of staff involved in incidents (sometimes referred to as the "second victims" in patient safety research),[46] as evidenced by the results of a survey of more than 3000 physicians[47] and an interview study of staff members previously involved in incidents.[48] Organisations may suffer reputational damage[49] as seen in the aftermath of some major NHS scandals[20, 50] and financial strains as a result of extra bed days.[11]

Given the scale and burden of adverse events in healthcare, understanding their underlying causes is thus, of both logical and moral importance. Developing such an

understanding is far from straightforward since the delivery of healthcare depends on a multitude of people, technologies and subsystems which interact with each other constantly in an ever changing way, often with different goals.[51] In that light, healthcare has many similarities with other safety critical industries, such as aviation, nuclear and the process industries: they operate as complex sociotechnical systems (discussed in more details in section 2.2).[51, 52] In the next section, I explore the evolution of thinking around how incidents occur in such systems.

2.2 Understanding how incidents occur in healthcare and other complex socio-technical systems.

In this section, some important theoretical concepts with practical relevance to the modern understanding of how incidents occur in complex sociotechnical systems including healthcare are discussed. I introduce the concept of a sociotechnical system and describe the different theories of accident causation, based on the varying complexity of individual sociotechnical systems.

The need for a common understanding of how accidents happen in complex sociotechnical systems such as healthcare is fundamental, as it underpins the assumptions made during incident investigations. These assumptions ultimately influence the causes identified and the solutions proposed. In the context of this thesis, a "system" is defined as a purposeful collection of connected components, which can be sub-systems working together to achieve a goal.[51] Healthcare is understood as a "sociotechnical system": one which functions through interactions between humans and technical components (procedures, equipment, knowledge) within a particular environment.[51]

2.2.1 Simple linear models in simple stable systems

One of the first theories of accident causation described in the literature is the Domino theory by H.W. Heinrich in 1931.[53] It is based on the principle that accidents are caused by a chain of connected but discrete event types. Thus, the last event (or domino) is the injury caused by the accident, which only occurs because of the events

(or falling dominoes) preceding it. Five discrete factors explain each event in the accident sequence: 1) ancestry or the social environment (the user's inherent preponderance to safety or the wider culture of the organisation towards safety); 2) the user's fault or trait, such as anger, carelessness, lack of knowledge; 3) the unsafe acts or conditions, such as lack of planning, equipment failures; 4) the accident; 5) the injury.[52, 53] Figure 2.1 provides a representation of the Domino model.

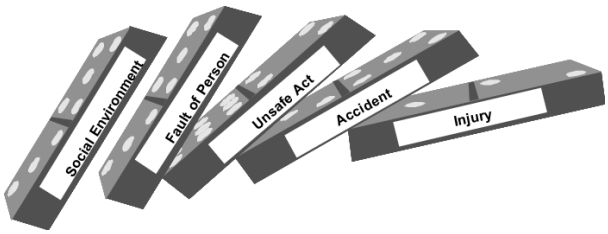

Figure 2.1 Heinrich's Domino Model of Accident Causation (From: Qureshi et al. Proceedings of the twelfth Australian workshop on Safety critical systems and software and safety-related programmable systems)[52]

This model is based on an assumption of clear cause and effect and works best when trying to understand causation in simple and stable systems,[52, 54] such as a production line. Since the outcome of the model is that there is always a clear, singular and identifiable root cause (the first domino in the model), the model may be much less well suited to explaining how accidents occur in systems where multiple sub-systems interact dynamically.[52] The model rather simplistically suggests that safety in a system can be enhanced by *"removing a domino"* or by *"spacing the dominos further apart*".[54]

2.2.2 Complex models in complex socio-technical systems

Plsek and Greenhalgh describe healthcare as a complex adaptive sociotechnical system[55] with the following properties:

1. Fuzzy boundaries. Members of the system (healthcare practitioners, patients, administrators, regulators, etc) change all the time and may belong to different systems simultaneously.

2. Internalised rules. Mental models are dynamic, yet internalised to members of the system, and may not be understood by others outside the system.

3. The members of the system and the system itself are adaptive to local changes. Their behaviour can change over time to suit contemporary needs.

4. Embedded network. Systems are often embedded within other systems. Their mutual relationships and behaviours may change over time, resulting in tension which may be resolved, may require new approaches to problem-solving or may remain unresolved.

5. Self-organisation within the system can happen naturally within the system to re-establish order.

6. Non-linear relationships between sub-systems and unpredictable behaviour.

Numerous industries, such as aviation, nuclear, petrochemical and the military amongst others, share these characteristics with healthcare. In such complex systems, accidents may be seen as an emergent or "normal" feature. Sub-systems may interact with each other in unpredictable or complex ways and failure in one sub-system may spread across the wider system through the intimate connections between sub-systems.

These two phenomena have been described as *"interactive complexity"* and *"tight coupling"* respectively by Charles Perrow in his seminal work on "Normal Accidents".[56] While the nuclear industry was used as a prime example of such complex systems by Perrow, healthcare exhibits some similar properties. The delivery of healthcare relies on the interaction of multiple actors, including regulators, managers, clinicians from different departments, amongst others, as well as with a variety of technologies. The actions of each of these actors are, more often than not, tightly connected (i.e. the actions of one actor changes the context for other actors)[55, 57] and control of the system is not the responsibility of one or a few actors but is instead decentralised throughout the system.[58]

Turner's work on man-made disasters was perhaps one of the first academic explanations on how accidents in particular industries can be explained by events beyond those that are immediately visible.[59] Turner postulated that man-made disasters could be studied to prevent their recurrence as they demonstrate common incubating patterns. During these incubation periods, discrepant events may develop unnoticed until an accident happens. The reasons for these accidents are not purely technical but may also result from organisational and management issues.[59] Turner's contributions set the scene for subsequent theories of accident causation in complex systems.

2.2.2.1 James Reason's Swiss Cheese model

Perhaps the model that has had the biggest influence on the understanding of incidents in complex systems, and in particular healthcare, is James Reason's Swiss Cheese model (see figure 2.2).[60, 61] Discussing accidents such as the Chernobyl nuclear disaster, Reason developed an organisational model of accident causation in complex systems. The model accounts for the interconnection of several subsystems which can each contribute to the system failing as a whole (see figure 2.2).[60] Using this model, organisations are conceived as being composed of numerous layers of "defences in depth" or barriers that prevent a potential hazard from reaching the users at the sharp end. Each layer is represented as a slice of Swiss cheese, within which multiple failures (or holes in the Swiss cheese) may be present. These holes are constantly *"opening, shutting, and shifting their location*".[62] Accidents happen when the holes line up, allowing for an error trajectory to be created, thereby connecting hazards with staff at the front-line.

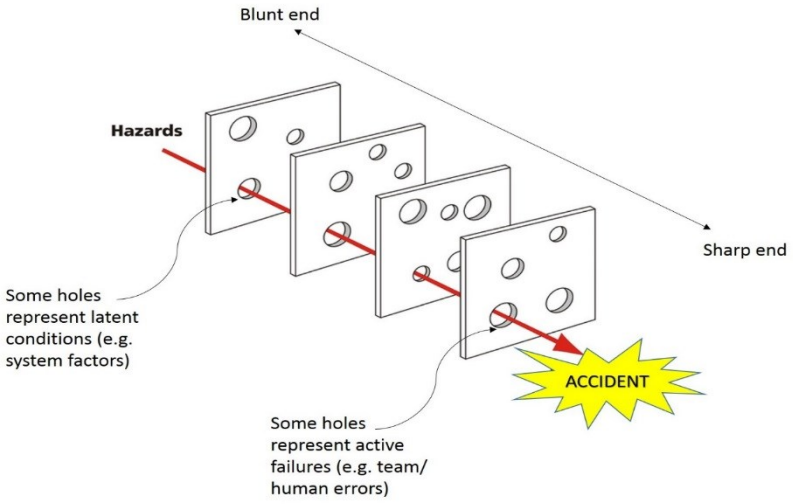

Figure 2.2 - Reason's Swiss Cheese model. (From: Reason et al. BMJ 2000)[62]

Failed or absent defences (or holes in the slices of cheese) occur for two types of reason: active failures at the sharp end and latent conditions at the blunt end. Active failures are those unsafe acts made up of slips, lapses, mistakes and violations by staff in direct contact with patients or the system.[62] Active failures are typically visible and easily identifiable, as their occurrences lead to immediate consequences. An example could be a nurse administering the wrong dose of a particularly toxic medication.

The acts making up active failures are often a result of numerous other latent factors within an organisation that, in contrast to active failures, often lie silent for days, months or even years. Latent conditions have been described as the *"resident pathogens within the system"* by Reason.[62] They happen due to strategic decisions made by regulators, management, designers and supervisors or when they fail to make decisions. The existence of such factors contrives to facilitate the occurrence of error-provoking situations. Examples of latent conditions based on the above example of wrong dose administration might include poorly designed drug charts or medication labels, unsafe staffing, lack of training.

On their own, each condition may not lead to an accident, but when combined, the probability of an accident increases. While Perrow argued that accidents themselves are inevitable in complex organisations with tightly coupled sub-systems, Reason

argued that it is the preceding active failures and latent factors that may be unavoidable: having the right barriers in place to prevent them from leading to an adverse event is therefore, Reason argues, the appropriate focus of attention.[56, 62, 63]

2.2.2.2 Vincent's Organisational Accident Causation Model

Numerous frameworks of accident causation have been developed in healthcare settings based, one way or another, on Reason's Swiss Cheese model. Examples include the Eindhoven classification, WHO patient safety classification and the Australian Incident Monitoring System (AIMS).[64-66] Lawton et al.'s systematic review of factors contributing to patient safety incidents in secondary care helped to develop the Yorkshire Contributory Factors Framework, which also relies on a classification of active and latent failures.[67] The model most widely used in the NHS is the Organisational Accident Causation Model (figure 2.3), developed by Vincent et al.[68] It has strongly influenced how incidents should be investigated in the NHS, as described in NHS England's Serious Incident framework.[3]

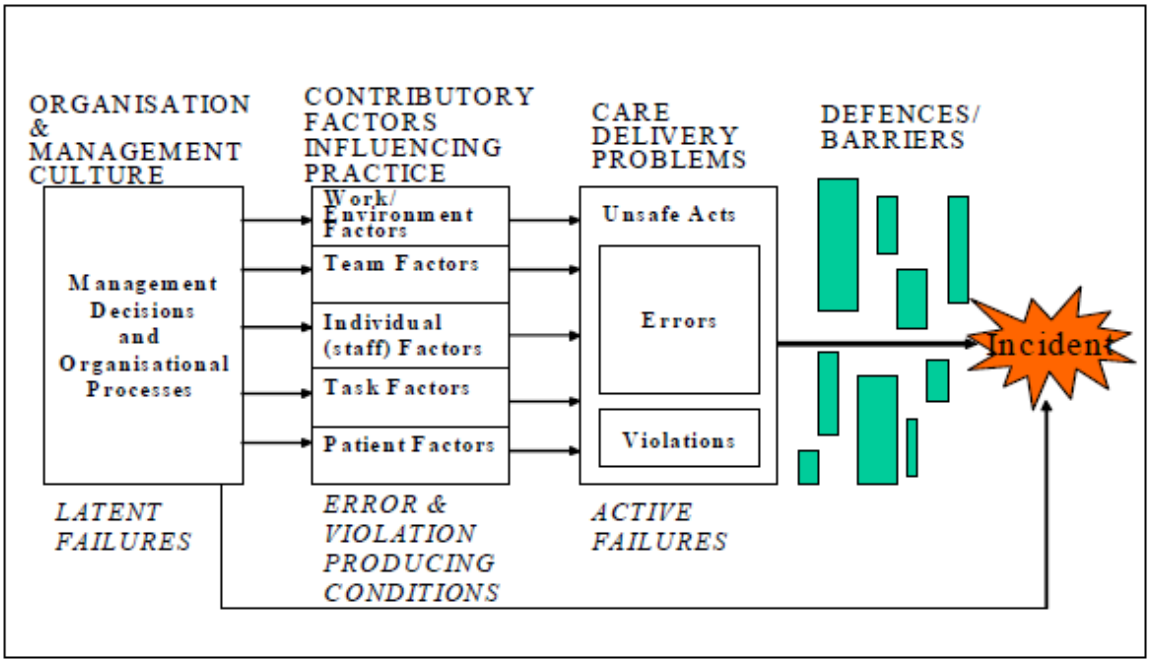

Figure 2.3 - Organisational Accident Causation Model (From Vincent. Patient Safety 2006)[68]

Vincent et al. describe three different layers where failures or error-producing conditions may arise. First, care delivery problems are the active failures at the sharp end. These failures happen because of error and violation-producing conditions which the authors label as *"contributory factors".* Such conditions include team factors (e.g. poor communication, lack of supervision), patient factors (e.g. disease complexity, language barriers), task and technology factors (e.g. unavailability of protocols, poorly designed cognitive aids), staff factors (e.g. lack of training, physical wellbeing), work environment factors (poor staffing levels, poorly maintained equipment).

These contributory factors occur within a wider context, shaped by managerial decisions and organisational processes. Contributory factors may take the form of organisational contexts (e.g. financial resources, organisational policies, safety culture) and wider institutional factors (e.g. regulatory context, structure of the NHS). The organisational accident causation model also includes the presence of barriers to prevent active failures from leading to adverse events. These mechanisms of defence may exist as physical barriers (such as a locked window), barriers reliant on human action (such as two persons confirming the dose of a drug before it is administered), natural barriers (such as distance) and administrative controls (such as procedures).[5]

2.2.2.3 The Human Factors Analysis and Classification System

Another accident framework based on Reason's Swiss Cheese model is the Human Factors Analysis and Classification System (HFACS), which was originally developed for accident analysis in aviation.[69] One of the rationales for developing this model was the absence of taxonomies of latent conditions and active failures in Reason's Swiss Cheese Model.[69] HFACS provides a taxonomy of failure modes across four different levels: unsafe acts, preconditions for unsafe acts, unsafe supervision and organisational influences. Each level has different categories, which in turn consist of several sub-categories corresponding to aspects of human behaviours or properties of components of the system which may contribute to an error. HFACS is summarised in figure 2.4 on page 22. Investigators are intended to systematically go through each level to identify factors contributing to the incident.

The lowest tier of HFACS, *unsafe actions or errors* represent actions at the sharp end of a system. They may take the form of normal accepted behaviours that ultimately fail to lead to the desired outcome (errors), or they may be the result of intentional departures from accepted practices (violations or lack of compliance).[70]

Errors may take three different forms. *Errors of decision* relate to instances when the wrong decision is made due to lack of information, knowledge or experience. *Skill-* or *action-based errors* occur during the execution of familiar tasks. Such actions are often seemingly automated in practice but are susceptible to failures of memory or attention. *Perceptual errors* relate to those actions which are a result of sensory degradation (e.g. not hearing an instruction from a colleague or misreading a drug label). Consequently, healthcare providers may subconsciously substitute missing information with the wrong inputs. *Violations* represent intentional departures from accepted practice. They may be *routine*, such as habitual workarounds, which tend to be known to the leadership of an organisation, practised by many in an organisation, and might not generally be dangerous. Diller et al. use the example of driving 5mph above the speed limit to illustrate a routine violation. On the other hand, *exceptional violations* represent wilful disregard to accepted practices and rules that are particularly risky, are not accepted by the leadership of an organisation and are generally not done by others in an organisation. A corresponding example would be driving 100mph over the speed limit.[70]

The second level of HFACS focuses on the factors that immediately predispose to the occurrence of the unsafe act at the sharp end. They are termed *preconditions for unsafe acts* and refer to the most proximal rationale to why an unsafe act was performed. Three different subtypes are described by Diller et al.[70] First, *environmental factors* relate to how the environment within which a healthcare worker operates, contributes to error. Examples include issues pertaining to technology or the physical environment (such as lighting, layout of clinical area). Second, *personnel factors* include issues relating to failures in *communication*, *coordination*, *planning* and the *fitness for duty* (such as lack of rest). Third, *condition of*

the operator describes situations where the operator is incapable to perform the task required due to adverse mental, physiological states or chronic illnesses. This subtype overlaps closely with *fitness for duty*.

The third tier of HFACS includes factors relating to the role of leadership or supervisors in the occurrence of an adverse event and have been divided into four subtypes by Diller et al.[70] First, *supervisory factors* may take the form of *inappropriate oversight* of the work performed by more junior staff by not providing adequate training or the right level of professional guidance. Second, supervisory factors may also include issues relating to *poor operational planning* whereby there is a failure to adequately plan how a team or department is organised or assess the hazards associated with an operation. Third, those in charge of operations may *fail to correct known hazards*, thereby allowing unnecessary known risk. Finally, supervisors may also show disregard to existing rules and regulations within an organisation (*supervisory violations*).[70]

The final level of HFACS refers to factors at the *organisational level.* Decisions at the upper echelons of management may directly or indirectly affect leadership decisions within individual departments and performance at the sharp end. Three different subtypes of organisational factors are described. *Resource management* includes factors relating to human and financial resources and hardware availability for adequate functioning of an organisation. *Organisational climate* includes factors relating to the working atmosphere within an organisation and the safety culture. *Operational processes* refer to issues with how processes are meant to happen within an organisation. They include inadequate *operations* (structured systems in place to deliver care), *inadequate procedures* (such as standard operating procedures) and the *oversight* of safety within an organisation.[70, 71]

HFACS has been adapted and validated in numerous other industries,[72-77] as well as healthcare.[70, 78, 79] ElBardissi et al. published the first HFACS framework that was modified to the specifics of healthcare, though their data was only applied in the context of cardiac surgery.[79] Diller et al. further expanded on ElBardissi's work and developed an extended HFACS based on numerous incidents across multiple incidents

in numerous specialties in the US.[70] The same framework has been applied to surgical never events[78] and refined to the specifics of anaesthesiology.[80]

HFACS appeals in two ways to the healthcare risk management community. First, HFACS allows users to classify contributory factors into multiple domains and subdomains, which may allow mapping of trends and themes across incidents.[81] It has thus been successfully used to identify contributing human factors from aggregated analyses of incident reports across multiple surgical never events[78] and different types of adverse events from a single healthcare system.[70] Second, it offers some familiarity to users in healthcare because of its origins in Reason's Swiss Cheese model, which, as discussed above, is already widely used in healthcare.

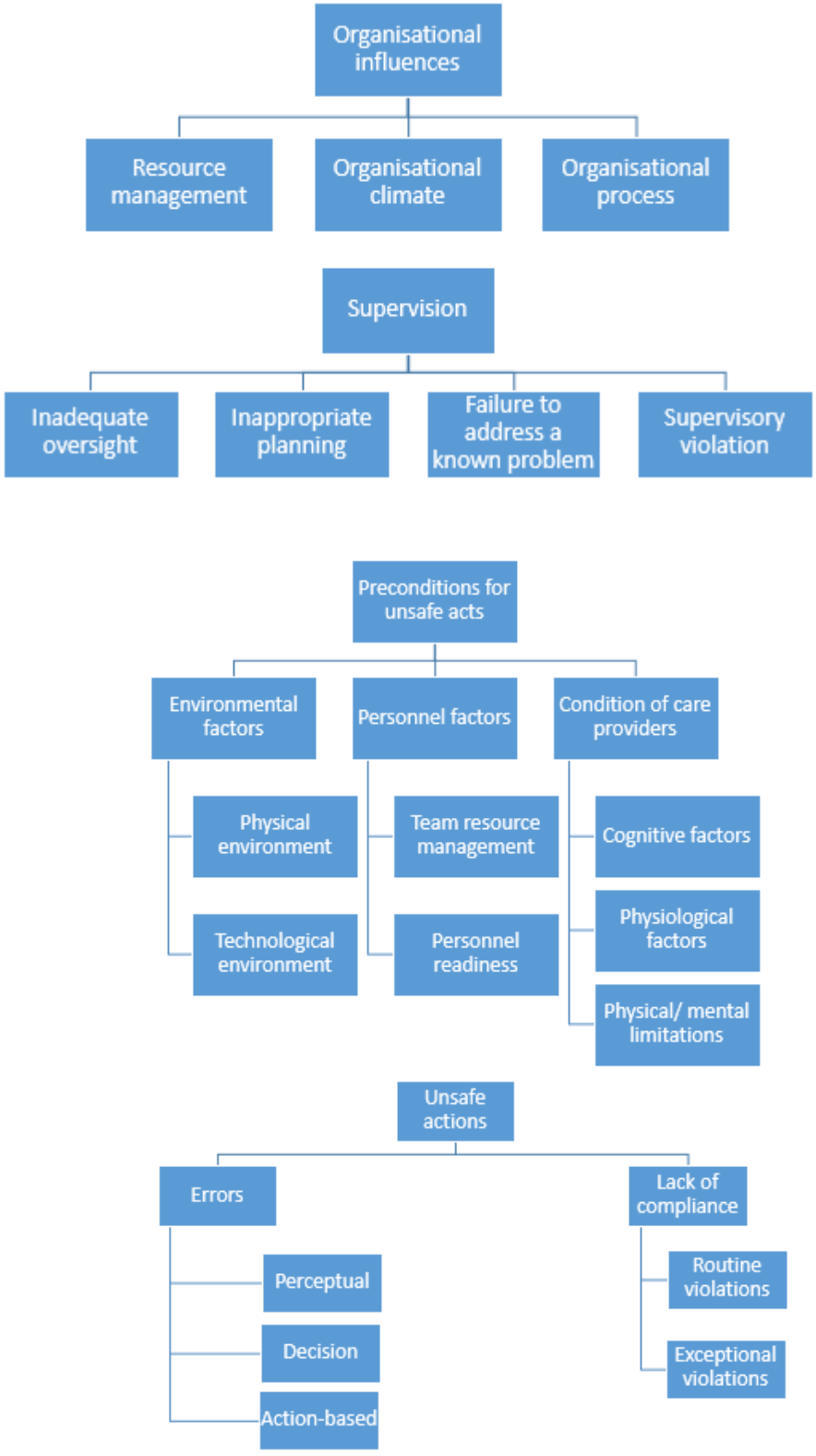

Figure 2.4 - The Human Factors Analysis and Classification System (From Diller et al. American Journal of Medical Quality.2014)[70]

2.2.3 Systems-based models of accident causation

Newer paradigms of accident causation draw on systems theory and embrace some of the properties of complex systems apparently not fully accounted for in Reason's Swiss Cheese model.[82-85] The systems-based approach in particular contends that properties of a complex organisation (or system) can only be appreciated when viewing the system as a whole. Thus, components of a system or sub-systems should not be analysed separately. Instead, the interactions between sub-systems must be accounted for. The approach views accidents as an emergent phenomenon arising from the unpredictable and non-linear interactions between components of the system. These sub-systems maintain their current state through feedback loops or constraints.[86] Accidents are then thought to occur as a result of inadequate control of these constraints between the different subsystems (people, social, organisational structures, automated activities, hardware and software).[52, 84]

Rasmussen's risk management framework was one of the earliest systems-based models of accident causation in complex systems.[83] It accounts for the various levels (e.g. government, regulators, company, company management, staff, and work) within a system which produce and manage safety. Safety is seen as an emergent trait arising from the interactions between constituents at each of these levels. As shown in figure 2.5, the functioning of lower levels in the framework is dependent on decisions made at high levels while information from the lower levels feedback to the higher levels to inform the responses to the decisions made. Rasmussen's model sees accidents as a result of normal variations in behaviour. Rasmussen argues that complex systems require a system-oriented approach based on functional abstraction rather than structural decomposition.[83]

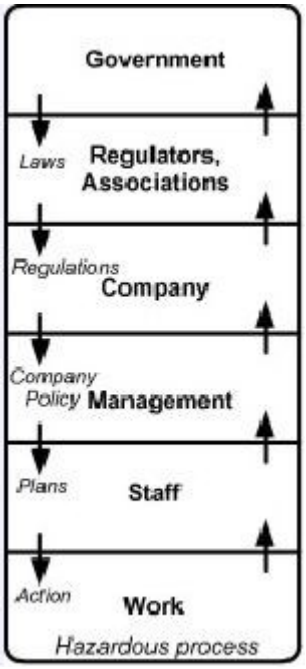

Figure 2.5 - Rasmussen's Risk Management Framework (From Rasmussen. Safety Sci 1997)[83]

A more recent example of a systems-based approach to accident causation is Leveson's Systems Theoretic Accident Modelling and Processes model (STAMP).[84] Leveson expanded on Rasmussen's risk management framework to develop a constraints-based socio-technical model that views systems as being made up of hierarchies of controls and constraints, with higher levels imposing constraints on levels below. There is also a feedback mechanism where the appropriateness of the constraints and controls are conveyed from a lower to higher levels (see figure 2.6).[81, 84] STAMP has an associated taxonomy, which, unlike HFACS, is quite generic. It is not as widely used among safety practitioners in high risk industries as other accident models,[81] perhaps because of its high level of abstraction.

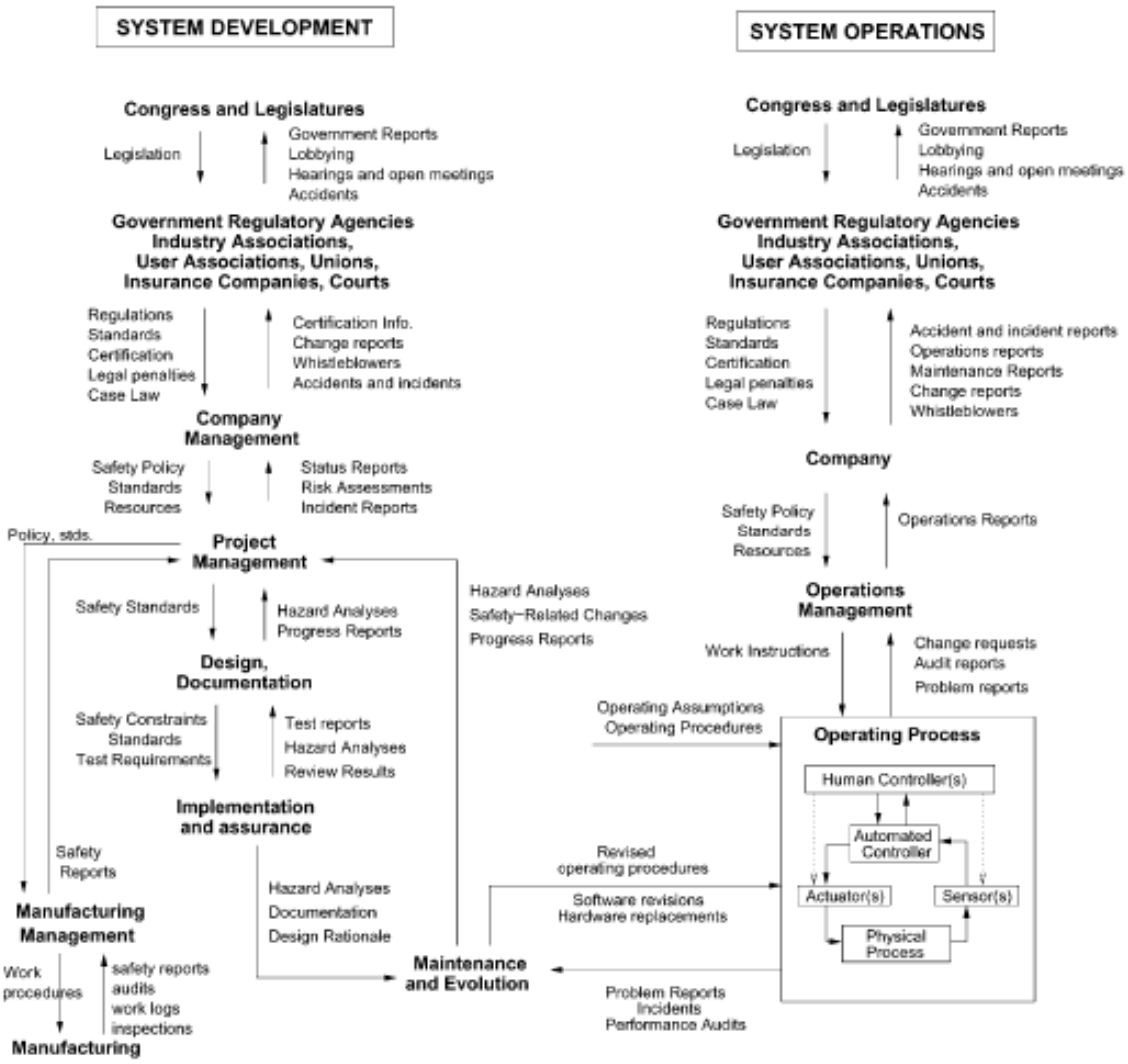

Figure 2.6 - STAMP's controlled failure taxonomy and generic control structure (From: Leveson. Safety Science.2004)[84]

In summary, accident models have matured from focusing on the solitary operations of individuals at the sharp end to models looking at the system as a whole, while simultaneously appreciating the role of regulators, legislation and safety culture. Despite the diversity of approaches, some models are more widely used than others, with those based on complex linear systems such as the Swiss Cheese model the most commonly used in safety critical industries,[87] including healthcare.[2, 3] As a result, the techniques that are used to dissect incidents often aim to identify active and latent factors causing or contributing to the occurrence of an incident—i.e. they are often

couched in the language of Reason's model. In the next section, I review the evolution of the practice of incident investigations in healthcare, with a focus on the NHS.

2.3 Patient safety incidents, incident reporting and investigations

In this section, I discuss the importance of learning from past incidents and how past healthcare scandals have shaped the process in the NHS. I then explore the practice of incident investigations within and across organisations.[8]

2.3.1 The need to learn from past incidents

When discussing the process of learning, it is important to understand what is meant by "learning".[88] At its most basic level, learning is considered to be any change in knowledge, which can manifest itself as a development of new knowledge or the confirmation of existing knowledge. The concept of learning can be approached from different angles, based on particular assumptions about knowledge and learning.

Learning can happen at three different units: the individual, groups or organisations.[89] I have mostly referred to the process of learning at an organisational level in this thesis, which I broadly consider to be a change in an organisation's knowledge[90] with potential to influence individual and group behaviour[91-93] and ultimately the wider organisation's performance.[94]

One way such learning can happen is through systematic understanding of past incidents. In their collection of case studies on organisational learning following major industrial accidents, Hale et al. propose that past incidents can be seen as gifts[95] offering valuable insights into unsafe operations. They create opportunities for mindful reflection,[96] to foster conversations around risk among relevant stakeholders and thereby bring improvements to technology, mental models and the organisation's and the overall sector's behaviour.[92] Thus, a better understanding of past incidents through well-conducted investigations might allow questioning that would motivate members of an organisation to review and improve working practices or adopt newer

models more appropriate to the new reality of the world constructed following the knowledge obtained after an incident.[92, 97]

In the UK, major NHS scandals in the 1990s fuelled the rise in political, clinical, academic and public attention to patient safety incidents.[50, 98, 99] One of the most significant scandals led to the Bristol public inquiry, chaired by Professor Ian Kennedy QC, which looked into the deficiencies in paediatric cardiac surgery at the Bristol Royal Infirmary between 1984 and 1995 following the deaths of 29 babies.[50] Problems were identified at numerous levels, including poor teamwork, communication, organisational culture, and individual and organisation accountability. A noteworthy aspect of the inquiry was how the investigation was conducted. The investigating team started by looking into the wider context surrounding how healthcare was organised and delivered in the units involved before focusing on specific events and individuals. This approach enabled the Bristol inquiry to report on the influence of the wider system (including the culture, working environment, organisation of healthcare) on the performance of individuals.[50]

Perhaps one of the most important policy documents which helped shape the patient safety landscape in the UK was the government commissioned report, entitled “An organisation with a memory”.[8] Led by Sir Liam Donaldson, the UK Chief Medical Officer at the time, it looked more specifically at how the process of learning from adverse events could be operationalised in the NHS.[8] While the tone of the document’s content was non-judgemental, the picture the report painted of the state of the processes in place at the time for the NHS to learn from failure was rather bleak. The team behind the report found evidence that incident reporting did not happen in a consistent manner in NHS trusts and organisations varied widely in their capability to capture incidents and investigate them.[8, 100] Key recommendations from “An organisation with a memory” included the strengthening of local reporting schemes for adverse events and near misses, introduction of a national reporting system, and an improvement in the quality of the investigation of adverse events, in particular by adopting practices in place in other high risk industries such as aviation.[8]

A summary of the new approach to responding to adverse events as recommended in the report is outlined in Table 2.1.

Past	**Future**
Fear of reprisals common	Generally, blame-free reporting policy
Individuals scapegoated	Individuals held to account where justified
Disparate adverse event databases	All databases coordinated
Lack of feedback to staff on outcome of investigations	Regular feedback to front-line staff
Individual training dominant	Team-based training common
Focus on individual error	Systems approach to hazard identification and prevention
Short term fixes	Actions that focus on prevention and risk reduction
Incidents viewed as isolated events	Potential for replication of similar adverse events recognised
Lessons from investigation aimed towards team involved only	Recognition that wider lessons may be relevant to others
Passive learning	Active learning

Table 2.1 - A new approach to responding to adverse events in the NHS (adapted from: Donaldson et al. Clinical Medicine (2012)[8])

The UK Government accepted all of the report's recommendations.[101] As a result, the National Patient Safety Agency (NPSA) was established in 2001 as an independent

arm's-length body to the Department of Health, with a mandate of identifying issues relating to patient safety in the NHS and finding potential solutions.[8] One of the key roles of the NPSA was to develop and disseminate an integrated approach to learning from adverse events and near misses through a National Reporting and Learning System (NRLS).[101, 102]

2.3.2 Incident reporting

The NRLS was founded on the following key principles: mandatory reporting of adverse events and near misses by individuals and organisations; confidential and accessible reporting; blame-free reporting; simple usability with comprehensive coverage; and systems learning at local and national levels. These principles drew their foundation from practices in other safety critical industries, in particular the aviation industry where confidential incident reporting to a national database was already a common and valued practice, going back more than 40 years.[103] System-wide learning following the analysis of such reports is dependent on what Macrae describes as a *"deeply embedded and widely distributed social infrastructure of inquiry, investigation and improvement."*[104]

Though the NPSA was disbanded in 2012, the NRLS continues. Since its inception, the NRLS has grown into a repository of 10 million patient safety reports consisting of incidents of varying degrees of harm, arguably making it the largest database of patient safety incidents in the world.[105] The NRLS collects patient safety incident reports across England and Wales with the aim of facilitating the analysis of patient safety concerns at national level. The main source of incident reports included in the NRLS is local incident reporting systems.

Staff members from individual NHS trusts can report any patient safety concerns or near misses in their local incident reporting system, irrespective of the level of harm associated with the event,[68] and these are uploaded onto the NRLS. The reports are meant to inform the development of local actions to address identified hazards and national interventions such as patient safety alerts.[106] Similar incident reporting and

learning systems operate in other countries. Examples include the Advanced Incident Management System in Australia and the Danish Patient Safety Database.[107, 108]

One of the key functions of an incident reporting system is to identify those incidents which require deeper investigations in order to address areas of risk and generate learning.[104] The practice of investigating the more serious incidents is now common practice in most healthcare systems in high-income countries, including the UK.[8, 108, 109] In the next section, I discuss which incidents are deemed serious enough by individual healthcare organisations to warrant an in-depth investigation and introduce the principles underpinning serious incident investigation within the UK context.

2.3.3 Serious incidents and never events

In the NHS, only incidents that are classed as "serious incidents" are required to undergo a structured local investigation. NHS England defines serious incidents as those adverse events with significant or potentially significant consequences to patients, families and carers[3] without providing a prescriptive list of events that should be classed as serious incidents. Instead, NHS England provides some general principles in terms of what may constitute a serious incident (see appendix A). A serious incident may range from a near miss which did not result in any harm to an adverse event (or a series of related adverse events) which resulted in the death of a patient (or multiple patients).[3] Fewer than 1% of patient safety incidents in the NHS are investigated by individual trusts as SIs, which equates to about 10,000 per year.[18]

An important specific type of serious incident is a "never event". The term was originally introduced in the UK in 2009 by Lord Ara Darzi in the report "High Quality Care For All- NHS Next Stage Review Final Report"[110] to describe those events with potential for catastrophic outcomes that are also deemed to be wholly preventable through strong systemic protective barriers.[111] The list has been updated every year; a list of never events from 2015/16 is provided in appendix B. Examples include wrong limb surgery and wrong route administration of chemotherapeutic agents.

Under present arrangements, once an event has been identified as a serious incident requiring investigation by a trust, the patient safety team within the trust notifies their local clinical commissioning group (CCG) within 72 hours. The team then works with the CCG to confirm the level of investigation required, as outlined below. When an investigation is completed, the investigating team from the trust submits a final report and action plan to the CCG who has the responsibility to review and feedback to the trust.[3]

NHS England's serious incident policy, operational at the time I started the PhD in 2015, outlines seven key principles underpinning SI investigations in the NHS, as shown in Table 2.2.[3]

Principle	**Description and rationale of principle**
1. Being open and transparent	To ensure that patients, families and carers are made aware when an incident has happened, that they are kept up to date with the investigation and that they are satisfied with the actions being taken.
2. Being preventative in the approach	The focus from investigations should be on learning what went wrong, with the aim of implementing barriers to prevent recurrence. Thus, a serious incident investigation differs from a coroner's inquiry or an investigation by a regulatory body (such as the General Medical Council, Nursing and Midwifery Council or Care Quality Commission). It does not set out with the purpose of apportioning blame to individuals but instead advocates *"justifiable accountability".*
3. Being objective	To minimise bias, investigators should not be responsible for the care of the patients affected by the incidents and

	should not be working directly with the members of staff involved in the incident.
4. Being timely and responsive	The SI investigation process should ideally happen within a relatively strict timeframe. First an incident must be reported on the local incident reporting system, and it should be ensured that the commissioners and other relevant parties such as the police and safeguarding professionals are made aware of the incident within two working days of its occurrence. Serious incidents should also be logged on to NHS England's web-based serious incident management system within two days. An initial report of the basic facts of the incident and an outline of the scope of the investigation should be made available to the commissioner within 72 hours. The organisation where the incident happened then has 60 working days to appoint an investigation team, conduct the investigation, identify causes to the incident, generate an action plan and produce a report. Extension requests are acceptable if justifiable, and often desirable if it would lead to a clearer investigation and report. Investigators should be available to deal with queries within the scope of the investigation from commissioners, patients or their representatives in a timely fashion.[112]
5. Systems-based investigations	Serious incident investigations should be conducted in a way that recognises that clinical incidents occur within a wider context. Thus an investigation should not simply identify the more visible errors and omissions committed by front-line staff members but should, more

	importantly aim, to detect those latent organisational factors which often remain silent and unnoticed but which fundamentally create the environment for individuals to commit mistakes.[61]
6. Being proportionate	The resources dedicated to an incident investigation should be proportional to the potential degree of learning from the incident. Some incidents may require only one individual in the investigating team (with collaboration of others when required). Such concise internal investigations are termed Level 1 investigations.[3] Other incident investigations may require a multi-professional effort including, in some instances, subject experts from other organisations if the expertise is not available locally. These comprehensive internal investigations are termed Level 2 investigations. In rare instances, some incidents may require Level 3 independent investigations. Examples include cases where multiple organisations are involved or in complex and highly sensitive incidents where the validity of an internal investigation may be questioned.[3]
7. Being collaborative	Investigations may span the care of a patient from primary care to secondary care. The different organisations have a duty to be co-operative with the investigative team.

Table 2.2 – Seven principles underpinning serious incident investigations in the NHS (NHS England.2015)[3]

Applied collectively, these principles inform serious incident investigators in the NHS of what a good serious incident investigation should look like. Paradoxically, none of

these principles relate to the ultimate goal of incident investigations: taking actions to mitigate future recurrence and dissemination of learning.

The risk that the investigation of safety hazards by healthcare organisations may be at the expense of solving them is a key motivator to this thesis. In order to understand this problem further, in the next section, I look at the current state of incident investigations in the NHS with a critical lens based on findings from major policy documents.

2.3.4 The current state of incident investigations in the NHS

Since the creation of the NRLS, the number of incidents submitted to it has increased year on year.[113] These reporting rates have not, however, necessarily translated into meaningful and actionable information on priorities for improvement,[20, 105] suggesting that the health sector's ability to learn from failure and secure improvement has remained limited. Numerous policy documents such as Sir Bruce Keogh's review into trusts with higher expected mortality ratios, Sir Robert Francis's report into the failings at Mid Staffordshire Trust And Professor Don Berwick's review into the state of patient safety in the NHS have commented on the ongoing failure to learn from past incidents, especially at an organisational level.[20, 21, 114]

The preamble to those policy documents has often been personal stories of poor care from patients, families and carers. As discussed in Chapter 1, one of the most high profile recent examples was the death of Connor Sparrowhawk in 2013 while he was an inpatient in a unit operated by Southern Health NHS Trust.[23] Connor, who had learning disabilities and epilepsy, was found unconscious in a bath in the unit and died shortly after. A subsequent post-mortem confirmed he had drowned, most likely as a result of an epileptic seizure. The death was initially deemed to be due to natural causes by the trust. An independent investigation eventually commissioned by the trust, following a campaign by Connor's family, found the death to have been entirely preventable.[115] In 2015, the coroner judged that there had been multiple failures in his care, including neglect. NHS England later commissioned a review of all deaths of patients with mental health conditions and learning disability at the trust over the

previous four years. The report (2015) found concerns with the inconsistent identification of incidents, the poor quality of investigations and lack of lessons learnt from past investigations.[23]

The public inquiry into failings at Mid-Staffordshire NHS Foundation Trust had, in 2013, already identified poor incident reporting, little staff confidence in the local incident reporting and learning system, lack of feedback from investigations to front-line staff, poor quality investigations and repetitions of similar incidents.[20] The independent investigation into failures in providing safe care in the maternity services at Morecambe Bay NHS Trust, which led to the deaths of eleven babies and one mother, similarly highlighted, in 2015, issues with the serious incident investigation process at the trust.[116] The government-commissioned review into 14 trusts with persistently high mortality rates by Sir Bruce Keogh found, in 2013, further evidence of poor quality investigations and limited dissemination of lessons learnt from failures across all trusts. Ultimately, the lack of learning led to the recurrence of similar types of adverse events.[114]

The Care and Quality Commission (CQC) conducted two reviews into how NHS trusts were identifying, investigating and learning from patient's deaths (Learning from serious incidents in NHS Acute hospitals, CQC 2016[117] and Learning, candour and accountability, CQC 2016[115]). They found concerns at various levels: variable involvement of families and carers during investigations, inconsistent thresholds to report and investigate deaths, poor quality investigations focusing on individuals rather than systems, variable strengths of recommendations, a lack of a structure in place to ensure recommendations are acted upon and learning shared across organisations.[115, 117]

The similarity in findings from these different reviews and inquiries into serious incident investigation practices in different NHS trusts, separated in time and space, provided the context to a 2015 Public Administration Select Committee (PASC) report into incident investigations in the NHS.[18] The report argues for the NHS to build capacity to carry out good quality independent incident investigations, nurture an

open and honest reporting culture, develop a clear line of accountability for actions being taken following investigations and for better sharing of lessons. In order to best operationalise many of these principles, the report concluded that there was need to set up a national independent patient safety investigation body, akin to the aviation equivalent, the Air Accident Investigation Branch (AAIB).[18]

Named the Healthcare Safety Investigation Branch (HSIB),[18] it has been operational since April 2017 and is led by the former head of the AAIB, Keith Conradi. The HSIB aims to carry out up to 30 independent investigations per year into incidents occurring in the English NHS with an immediate emphasis on learning and pattern recognition across incidents.[118, 119] It is able to make recommendations based on its investigations to any stakeholders including NHS trusts, regulators, equipment manufacturers and educational and training boards.[119] However, local incident reporting and investigation will remain a mainstay of the NHS, since the new body will only be able to tackle a tiny fraction of all incidents.

In this chapter, so far, I have discussed the scale of adverse events in healthcare, I have elaborated on the evolution of thinking on how incidents occur in complex socio-technical systems and have looked at how the practices of incident reporting and investigation are carried out in the NHS. I have shown, using examples of multiple policy documents that there is a lack of lessons learnt from past incidents within and across organisations. To develop a better understanding of why the learning from incidents is constrained, in the next section, I discuss the method (root cause analysis) used to conduct serious incident investigations in most healthcare organisations, its logic and associated difficulties faced when conducting RCAs in the context of healthcare.

2.4 The use of root cause analysis in healthcare

Root cause analysis can be broadly understood as a method of structured risk identification and management in the aftermath of adverse events.[120] While a step-by-step guide on how to conduct an RCA following an incident is beyond the scope of this

chapter, this section will aim to outline the background to the adoption of root cause analysis in high risk industries before focusing on its use in healthcare. The use of RCA as an example of how healthcare is trying to achieve high reliability will be described. Finally, some of the challenges facing the usage of RCA in the context of healthcare will be discussed.

RCA is not a singular modus operandi. Rather, it encompasses a toolbox of techniques (such as timelines/cause and effect charts, brainstorming techniques, change analysis, barrier analysis, use of a contributory factor framework, fishbone diagrams, five whys, accident fault trees) that addresses three facets of an incident being investigated: a description of what happened, an understanding of why the event unfolded as it did, and how it, and similar problems, can be prevented from happening again.[35]

Some of the basic tools of RCA were first developed in the field of engineering and total quality management in the 1950s. The "five whys", which consists of asking "why" sequentially up to five times to identify the root cause of a problem, can be traced back to the Toyota Production System.[121] In the 1970s, the Federal Aviation Administration in the US established the Aviation Safety Reporting System to conduct its safety management. A number of analytical techniques in the RCA toolbox were subsequently developed to standardise and strengthen the incident analysis process and are nowadays used in multiple safety critical industries.[122-124]

In a review of methods of investigation and analysis in high-risk industries, Woloshynowych et al. commented that the variety of techniques in the RCA toolbox made it a particularly strong investigation and analytical technique and proposed that, if used appropriately, RCA could be used to identify system weaknesses.[11] In such high risk organisations, safety is thus achieved by using the outputs of the investigations to change, adjust, adapt practices, technologies and processes.[63]

2.4.1 Root cause analysis as a manifestation of high reliability theory in healthcare

In this section, I discuss the logic behind the use of RCA as a means of analysing incidents in safety critical industries, with a focus on healthcare. The background to

the use of RCA in healthcare specifically stretches back to the establishment of the Veteran Affairs National Centre for Patient Safety in the USA.[2] The organisation pioneered the adoption of high reliability theory (HRT) as an approach to addressing and reducing preventable errors in healthcare.[7] HRT examines how high reliability organisations (HROs) attain high levels of safety despite operating in environments (such as aviation and nuclear power) where the potential for errors is high and the consequences of these errors often fatal. HRT studies have sought to explain how. They suggest that HROs are attentive to risk and have through time, developed strong cultures of broad vigilance.[125-129] These organisations also exhibit collective mindfulness, which is indicated by a focus on failure, sensitivity to operations, a commitment to resilience, expert-led decision making and a reluctance to simplify interpretations of risk.[96, 128, 130] In contrast to the pessimistic approach in Perrow's Normal Accident Theory, which tends to position accidents as normal and unpredictable events in complex socio-technical systems, HRT argues that high reliability organisations can function safely despite inherent hazards embedded in complex systems, with a particular role for learning from past failures.[131-133]

At the heart of this focus on organisational learning are event analysis techniques such as RCA. In the context of healthcare, the practice of RCA is meant to facilitate the formation of ad hoc natural networks of multi-disciplinary staff to investigate unanticipated safety incidents. RCA is expected to provide a platform for discussion and appraisal of current clinical practices through specialist-led decision-making by field experts (in the context of healthcare, clinicians and upper level managers).[12, 25, 131] Such conversations allow for collective mindfulness by contributing to the development of a shared "big picture" of clinical operations.[134]

Through the appropriate use of tools such as barrier and change analysis, the aim of RCA is to uncover latent conditions contributing to error-prone situations, thereby acknowledging that hazards may lie deep within organisational structures.[61, 134] In so doing, RCA is intended to allow the medical field to *"turn the medical gaze in upon itself"* and analyse its own practices with a critical lens.[25] Such level of reflexivity, if

appropriately conducted, is an elemental feature of the organisational resilience observed in HROs. The conduct of RCA in healthcare is intended to improve the ability of organisations to recover from unexpected events by learning from the reasons for past failures, generating actions to prevent their recurrence and incorporating lessons learnt into the organisational make-up.

2.4.2 Current practice of root cause analysis in healthcare

Since it was first introduced in the US healthcare system, RCA has grown to become a primary method of incident analysis following patient safety incidents in many high-come nations.[2, 3, 135-137] In the UK, thousands of staff have been trained in conducting RCA.[138] The training typically includes a focus on the London Protocol as described by Taylor-Adams and Vincent.[5] An interesting point of note is that the authors labelled their approach a "systems analysis" as opposed to a "root cause analysis" to highlight the focus in identifying failures at the macro level of the organisation.[5]

Despite the re-titling, the principles of the approach are firmly based on RCA. The accident investigation and analysis process flowchart from the London Protocol is summarised in figure 2.7.[5] The approach advocates the conduct of the investigation by a small team of professionals including experts in incident investigation, senior management, senior clinicians, external expert and someone not involved in the incident who knows how the department works. Facts should be gathered from different sources such as medical records, interviews and statements and a timeline of key events established. The care delivery problems (specific actions or omissions by staff members) and contributory factors are then identified using the various RCA tools. Finally, recommendations are generated and an action plan drawn up.[5, 12]

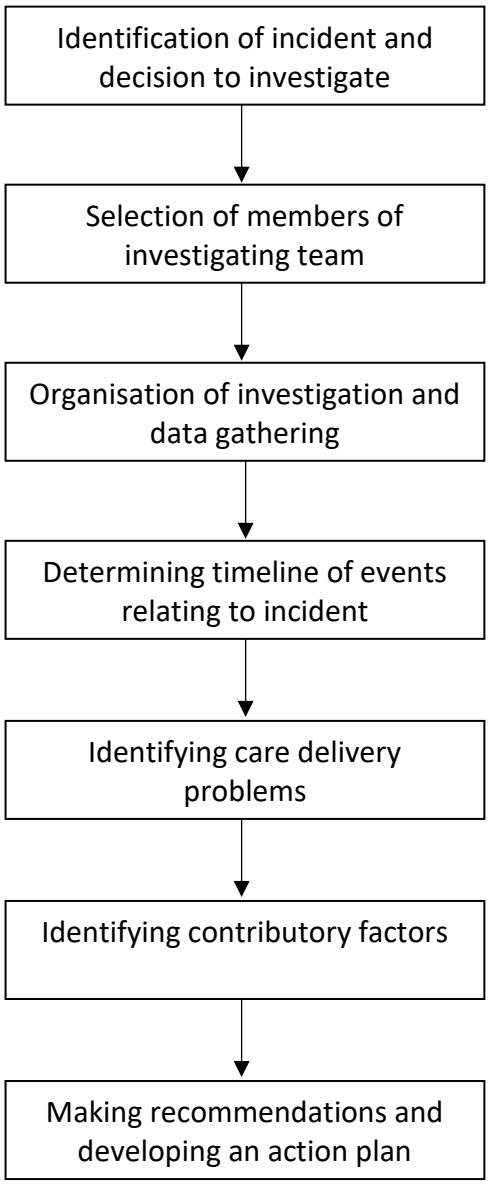

Figure 2.7 - Accident investigation and analysis process flowchart

Similar processes are in place in healthcare systems other than the NHS.[2, 136] In the US, the RCA approach is mandated by the Joint Commission and by state statutes for investigation of sentinel events.[2] The Queensland Health Patient Safety Centre and New South Wales Health in Australia have adapted their RCA processes on the US model as well.[14, 139]

The practice of RCA has been increasingly reported in the academic literature; Figure 2.8 illustrates the rise in medical publications available on the academic database SCOPUS with “root cause analysis” as keywords between 2001 and 2019. While some of these articles report on the improvements in patient safety following root cause analysis of specific event(s), there is also a growing consensus in the academic literature that the potential of RCA has remained under-realised in healthcare.[13, 35] Its use has been limited by paying insufficient attention to what makes it work in other safety critical industries, and without adequate customisation to the specifics of healthcare.[13] As a result, the use of RCA in healthcare has faced numerous translational frustrations akin to the piecemeal implementation of other safety initiatives borrowed from other safety critical industries.[104, 140] In the next section, I assess some of the constraints which have limited the impact of RCA in healthcare.

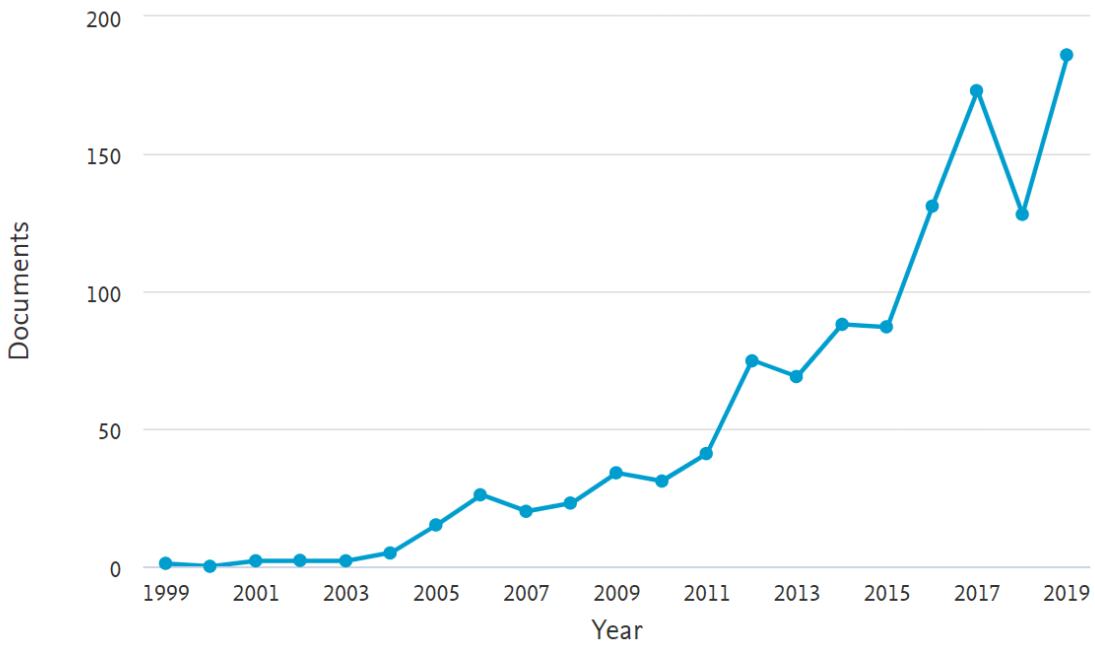

Figure 2.8 - Number of academic outputs in the medical literature with "root cause analysis" as keyword on SCOPUS

2.4.3 Constraints facing the RCA process in healthcare

In this section, I look at some of the difficulties in conducting an RCA, focusing on the constraints located at the level of the context within which it is used in healthcare. I discuss many of these challenges in a viewpoint article I authored which was published in BMJ Quality and Safety.[13]

RCAs in healthcare operate within numerous organisational and cultural constraints which may limit their effectiveness.[13] Nicolini et al. conducted an 18-month ethnographic study in two large acute NHS trusts in the UK to understand the challenges faced by incident investigators when conducting RCAs. The authors found that there were problems to overcome right from the very beginning of the investigation itself. For example, clinicians were often apprehensive about providing information during the investigations.[12] One reason was the cultural perception of incident investigation amongst clinicians as an intrusion into their established practices.[12] The data collection process was also found to be hampered by the need to arduously scour through numerous information sources ranging from staff rotas to hospital notes, which were often of poor quality.[12, 32] The rigour of the analytical phase was influenced by the quality of the conversations happening during the investigation and the relationships between the individuals involved in these conversations.[122]

Thus, for incident investigations to be of high enough quality, individuals with the right expertise need to be conducting these investigations. Unfortunately, this is not always the case during RCAs in healthcare. The lack of expert accident investigators was highlighted in the Public Administration Select Committee inquiry into the investigation of clinical incidents in the NHS.[18] In contrast, accident investigations in other safety critical industries are often led by safety or reliability engineers, skilled in systems thinking, cognitive interviewing and human factors engineering.[13]

A further problem with the current practice of RCAs is goal displacement: because the final investigation reports of the RCA are of interest to commissioners and regulators of services, they may inadvertently become the RCA's end-product as opposed to

being seen as the beginning of a learning cycle. Nicolini et al. found that incident investigation teams may end their analysis once they have reached a cause of mutual convenience in the quest to make the report look good.[12] The focus was on the report's apparent precision and style, even if it meant editing out causes (and thus solutions) that were deemed to be beyond the remit of the organisation.[12]

Perhaps the biggest challenge, however, is ensuring that the RCA actually leads to risk controls that reduce the possibility of harm occurring in the future. Many of the challenges influencing a good investigation and analysis of incidents also have an impact on the quality of risk controls recommended, as discussed below.

2.5 Risk controls following root cause analysis of serious incidents in healthcare

So far, I have shown that past serious incidents occurring in healthcare are investigated with the intention of improving patient safety. The analysis of such investigations is usually performed using the principles of root cause analysis. The conduct of a serious incident investigation is, however, limited by numerous constraints, many at the organisational or cultural level. For incident investigations to improve safety, investigators need to formulate and implement robust risk controls, based on the findings of investigations. In this section, I look at the effectiveness of those risk controls based on evidence from the literature and assess some of the challenges faced in healthcare when generating and implementing them.

2.5.1 Effectiveness of risk controls generated following RCAs in healthcare

A previous systematic review of studies on the effectiveness of corrective actions generated following RCA found limited literature on whether such actions led to improvement in patient safety.[14] Only three studies were found reporting clinical outcome as measures of effectiveness of corrective actions from root cause analyses.[141-143] In the first of these, a preoperative risk assessment tool and standardised preoperative procedure were implemented following an RCA of a patient's death where the main cause was found to be the failure to communicate

anaesthetic risk. Mortality decreased from almost 5% to 1% in the three years after implementation of the actions.[141]

In another study, Perkins et al. conducted a review of multiple RCAs of patient deaths with liver transplants and found that 50% of deaths over a five-year period could be attributed to issues with patient selection. Following the introduction of an enhanced pre-transplant evaluation protocol and education programmes with regular measurements of effectiveness, the authors were able to demonstrate an improvement in patient survival from 81% to 93%.[142] In a third example, Rex et al. reported on a statistically significant reduction in adverse drug event rates following the introduction of a number of actions to address care delivery and systemic problems identified following the introduction of an RCA programme across the organisation.[143] A more recent study has also demonstrated the effectiveness of multi-faceted interventions based on outcomes of RCAs of wrong intraocular lens implants.[144]

2.5.1.1 The hierarchy of risk controls

To facilitate the task of formulating risk controls, the risk management community (mostly outside of healthcare) has developed a framework to assist in the task of generating risk controls: the hierarchy of risk controls (see figure 2.9 below).[145, 146] It has its roots in engineering and occupational safety[147] and aims to provide a chronological list of categories of risk controls in order of assumed effectiveness.[148]

The hierarchy of controls is based on three basic principles.[146, 149-151] First, incidents are a result of exposure to particular hazards. Thus, risk controls aiming to eliminate the underlying hazard(s) are deemed most effective.[146, 150] Second, humans are deemed fallible. Therefore, risk controls which rely less on human interventions, such as forcing functions, are considered more effective as there is less scope for human error.[147] Third, measures at the top of the hierarchy (such as elimination of a hazard or substitution of a hazard) are deemed to be more effective at reducing risk, but also harder to design and implement than those at the bottom of the hierarchy (such as administrative controls e.g. training, reminders).[147, 150] One such model, as developed

by the National Institute for Occupational Safety and Health (NIOSH)[147] is shown in figure 2.9.

The need to design effective interventions in a resource-constrained, yet high risk environment, such as healthcare, might be seen to argue for the use of a hierarchy of risk controls when deciding on actions following identification of root and contributory causes. A modified version of the hierarchy of risk control, based on the above model was developed by the US Department of Veteran Affairs National Centre for Patient Safety in 2001 (see Table 2.3) to aid incident investigators in generating risk controls.[2, 10]

Research using the hierarchy of controls to categorise interventions proposed following incident investigations and prospective risk analysis in healthcare settings has consistently shown that most interventions are administrative in nature.[9, 146, 151] Accordingly, these controls were considered weak: Hibbert et al. for example, commented that "such weak recommendations are less likely to result in effective and sustainable changes to reduce the probability of a similar event recurring."[9] Similarly, the authors of a systematic review into the types of risk controls generated following incident analyses published in the literature demonstrated that 78% of controls were administrative in nature and warn that such interventions *"might do more harm than good."*[146]

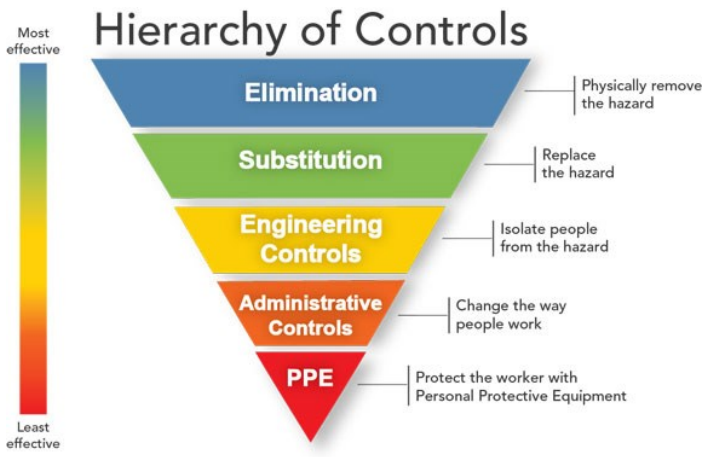

Figure 2.9 - Hierarchy of controls as used by NIOSH 2015[147]

	Action category	Example
Stronger actions	Architectural/ physical changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing that can only be connected the correct way.
	Simplify process	Remove unnecessary steps in a process
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff
Intermediate actions	Redundancy	Use two registered nurses to independently calculate high-risk medication dosages.
	Increase staffing/ decrease workload	Make float staff available to assist when workloads peak during the day.

	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/ reduce distractions	Provide quiet rooms for programming patient-controlled-analgesia pumps.
	Education using simulation-based training	Conduct patient handoffs in a simulation lab, with after action debriefs.
	Checklist/ cognitive aids	Use pre-induction and pre-incision checklists in operating rooms.
	Eliminate look and sound-alikes	Do not store look-alikes next to one another in the unit medication room.
	Standardized communication tools	Use read-back for all critical lab values.
	Enhanced documentation	Highlight medication name and dose on intravenous bags.
Weaker actions	Double checks	One person calculates dosage, another person reviews their calculations.
	Warnings	Add audible alarms or caution labels.
	New procedure or policy	Remember to check intravenous sites every 2 hours.
	Training	Demonstrate the hard-to-use defibrillator with hidden door during an in-service training

Table 2.3 - Veteran Affairs hierarchy of risk controls (From RCA squared. National Patient Safety Foundation 2015)[10]

The problem of suboptimal risk controls following incident investigation in healthcare remains common.[12, 146] Not all risk controls formulated following RCAs lead to improvement.[13, 26, 35, 146, 152] A major focus of this thesis is to understand what strong risk controls following serious incident investigations look like. In the next section, I explore some of the challenges faced in improving patient safety when formulating and implementing risk controls following serious incident investigations based on available evidence in the literature.

2.5.2 What are the challenges faced in healthcare when generating and implementing risk controls following incident investigations?

Many risk controls introduced following incident investigations fail to control risk adequately. Some studies have looked into the link between the types of corrective actions and improvement in patient safety and have demonstrated an endemic tendency of investigators to settle for administrative and what are traditionally viewed as weaker and shorter-term solutions (such as reminders).[12, 26, 146, 152] Such weaker solutions typically focus on the more malleable and visible symptoms of the problem as opposed to addressing the latent factors leading to the problem and have been shown to contribute to more harm in some instances. For instance, Mills et al. looked at 1738 actions recommended from RCAs of inpatient falls and adverse drug events and found that those based on training and education alone correlated negatively with measures of improved outcomes. On the other hand, actions focusing on technological changes and clinical processes were found to be the most effective.[26, 152]

A literature on the reasons for the challenges in healthcare to formulate and implement strong risk controls is now emerging. In this section, I describe the current challenges faced by investigators when formulating risk controls following incident investigations, and by those healthcare workers tasked with implementing them based on a review of the literature. The work done in writing this section has led to two peer-reviewed publications: a viewpoint article in BMJ Quality and Safety[13] (Peerally et al. The problem with root cause analysis. BMJ QS 2017) and a commentary

on the Agency for Healthcare Research and Quality website[15] (Peerally et al. Root cause analysis gone wrong. AHRQ PSNET 2018).

2.5.2.1 Limited models of accident causation and analysis

The first challenge relates to the suitability of current methods used during investigations and analysis of incidents. Root cause analysis-based incident investigations using methods such as the London protocol[5] focus on breaking down the overall healthcare system into different components and analysing each component independently.[5, 67] Leveson et al. suggested that such methods centring on structural decomposition of systems may discount the overall 'messiness' of systems.[153] As a result, proposed actions often focus on the micro level (at the departmental or individual level) and are rarely aimed at the meso (extra-departmental) or macro levels (across hospitals).[12, 154] Incident investigations using methods solely based on linear models may fail to account for the functional characteristics of the system as a whole by ignoring how sub-systems influence each other.[85, 153, 155]

A key problem associated with addressing each cause in isolation is that of "risk migration", which describes the situation where a risk control implemented without accounting for its effect on the wider system may lead to future unintended negative consequences.[156] This problem has been identified in case studies in healthcare risk management showing that incidents investigated using tools favouring a temporal narrative, such as the fish bone diagram, may not produce a systemic view of events.[157, 158]

2.5.2.2 Multiple asynchronous risk controls

Addressing each causal factor identified in an investigation in isolation may lead to a large number of uncoordinated actions generated from the ever-increasing number of incidents reported and investigated.[104] Using safety data from a US-based tertiary academic centre, Kellogg et al. showed that nearly 500 actions were generated from 106 incident reports.[17] Pham et al. explained the high number of actions as a consequence of the tendency for investigators to go *"a mile wide and an inch deep*

rather than an inch wide and a mile deep" during investigations.[159] Further, actions arising from incident investigations compete with those from other internal and external assessments and investigations, ranging from recommendations of local audits to those mandated by regulatory bodies.

The consequence is that organisations may have to deal with too many recommendations, some of them contradictory,[160] thereby creating a strain on management and operations. Based on research in nuclear and process industries, Carroll warned that such practices might impede learning through *"fragmentary, myopic and disparate understandings of how the work is accomplished".*[161] Additionally, as identified by numerous authors studying healthcare systems in different countries (English,[12] Swedish[154] and Australian[24]), even when multiple risk controls were generated from incident investigations, they tend to be primarily focused at the local level.

2.5.2.3 Lack of expertise

Next, the translation of identified causal factors into effective actions is a particular challenge in healthcare.[13, 24, 146] Card et al. argued that in industrial (non-healthcare) settings, a good understanding of risk following incident investigations leads to the formulation of effective risk controls.[146] Such a seamless flow from the diagnostic stage of risk (incident investigations) to the treatment of risk (formulation and implementation of risk controls) is harder to achieve in healthcare. In a qualitative study of managers' views on the quality of recommendations produced from investigations, Iedema et al. reported that recommendations tend to primarily focus on addressing the symptoms of bigger systemic problems,[24] not on resolving the problems themselves.

One possible reason, as discussed in the parliamentary inquiry into the state of healthcare safety investigations, was that healthcare safety investigators were often clinicians and managers, who were not always equipped with the required expertise in safety science.[18] On the other hand, training to develop such skills is part of the education of engineers who conduct investigations in non-healthcare settings. Card et

al. thus concluded in their systematic review that effective risk controls in healthcare did not necessarily result from incident investigations, even when the latter were deemed to be of high quality.[146]

2.5.2.4 Bureaucratic filters

Recommended actions from investigations may be processed through a bureaucratic filter with numerous trade-offs, before being finalised and implemented.[12, 24, 162] In an ethnographic study of incident investigation practices, Nicolini et al. showed how the need to reach consensus amongst multiple stakeholders in the incident investigation process, along with the drive to produce a presentable report, led to important and necessary actions at organisational level (such as managerial changes) being edited out due to their contentiousness.[12]

This situation, where multiple factors external to the findings of the investigation influence the design and implementation of actions is important to recognise and has aptly been described by Lundberg et al. as *"what you find is not always what you fix"*.[36] One reason why it may occur arises from professional and hierarchical differences among members of the investigative panel during the conduct of incident investigation meetings, resulting in the dominance of the voices and opinions of some members, notably senior physicians or managers, at the expense of the views of junior front-line staff.[12] In other instances, potential recommendations were not considered because they fell outside the remit of the healthcare organisation where the incident occurred.[12, 13]

2.5.2.5 Lack of engagement with relevant actors

There was also evidence that the quality of risk controls is constrained by lack of engagement of relevant staff from both the sharp (front-line staff) and blunt ends (management) of an organisation where an incident has occurred.[12, 24, 160]. In a qualitative study of senior managers, Iedema et al. reported that some risk controls were formulated but are later rejected by senior layers of management as unachievable. The result was often patchy implementation of risk controls,[24] linked partly to poor managerial continuity at an organisational level.[154] Another reason for

the gap between recommendation and implementation was the lack of information on the feasibility of implementing actions from front-line staff.[160] For instance, Anderson et al. reported on the relative lack of opportunity for frontline staff from the departments where incidents occurred to voice their views before the implementation of actions and the resultant feeling that actions were being imposed by investigators and regulators, who might not understand the complexities of day to day clinical work.[160]

2.5.2.6 Lack of follow-up of actions

Finally, healthcare organisations often struggled to routinely track the implementation and evaluate the effectiveness of risk controls generated from incident investigations.[160] Interview studies on incident investigation practices showed that healthcare practitioners relied on informal methods such as team discussions to assess implementation.[160] This meant that healthcare organisations might not be aware which actions required further resources for successful implementation, thereby failing to recognise which actions were effective and could be used more widely. Importantly, the healthcare sector also failed to recognise which risk controls worked in particular contexts and which ones did not. As a result, risk controls which had been proven not to work but were easy to implement, might prevail as shown by aggregate analyses of incidents by Mills et al.[26, 163]

The problems identified above limit the potential for healthcare incident investigations to lead to strong and sustainable risk controls. For healthcare incident investigations to be more than just a procedural ritual in the aftermath of an incident, strategies need to be identified to facilitate the processes of risk control generation and implementation following identification of causal factors. Table 2.4 below lays out each of these problems and lists out some of their potential consequences.

Problems with risk controls following incident investigations in healthcare	**Consequences of problems**
Limited models of accident causation and analysis	Focus on micro-level actions Systemic causes often remain unidentified and unaddressed Risk migration not accounted for
Too many actions, which may not work in synchrony	Strain on management and on front-line Risk migration
Lack of skilled expertise among investigators	Difficulty identifying the right causal factors Difficulty translating causal factors into effective actions
Professional hierarchies in investigation panels	Some solutions edited out
Lack of engagement of actors from the sharp and blunt ends	Poor implementation due to lack of resources Poor implementation due to lack of understanding of feasibility
Lack of follow-up of risk controls	Lack of organisational oversight on risk controls requiring further resources for successful implementation Lack of organisational and sectorial awareness of effectiveness of risk controls in particular contexts

Table 2.4 - Problems with risk controls generated from incident investigations in healthcare and respective consequences.

2.6 Summary and approach to thesis

In this chapter, I have looked at how multiple scandals, public enquiries and policy documents in the UK have prompted recognition of the need for serious incidents to be investigated in healthcare for the wider sector to learn lessons and not repeat mistakes of the past. I have summarised some of the models used to understand how such incidents happen in complex socio-technical systems, such as healthcare. Based on these models, I have explored how root cause analysis has been promulgated by policy makers as the means of choice for investigating incidents. I have further discussed how, though based on sound theoretical principles, RCA has nonetheless been constrained in its purpose of improving patient safety by numerous cognitive, organisational and cultural barriers. I have shown that previous research has questioned the strength of risk control coming out of RCA investigations and outlined some of the reasons why the risk control process in healthcare may be particularly challenging.

Healthcare is not alone in facing such challenges. Other safety critical industries, such as aviation, nuclear, petrochemical amongst others, have also used RCAs and other accident investigation techniques to improve how they learn from incidents and their safety.[36, 164-166] Yet, they have also faced issues when moving from investigation of incidents to the formulation and implementation of risk controls. For instance, the risk control process has been found to receive less organisational attention[166] compared with data collection and event analysis in the aftermath of incidents in such high risk organisations and research has also highlighted the tendency to identify weak solutions to complex problems.[36, 167] In light of the analogous concerns when moving from incident analysis to action planning in all safety critical industries, part of this thesis will also review principles and practices in place across all such high risk industries (including healthcare) when developing and implementing risk controls following incident analyses, with a view of identifying lessons relevant to healthcare.

2.7 Research aim

As discussed in this chapter so far, over the last twenty years, researchers have focused significantly on understanding and improving the process of incident investigations in healthcare. Less attention has been paid to how strong risk controls might be established following investigations. To improve the processes of formulating and implementing risk controls following serious incident investigations in healthcare, it is important to appreciate how these processes currently take place in healthcare and which factors influence them.

Accordingly, the aim of this study is to build a detailed understanding of how risk controls are formulated and implemented following incident investigations in healthcare and what can be learned from expert views on risk controls, with a view of informing "what good looks like" for the risk control process following serious incident investigations in healthcare. The motivation behind this study is to facilitate healthcare organisations in developing and implementing robust risk controls following investigations, assist commissioners, regulators and others in assessing the strength of risk controls proposed by individual trusts and contribute to the wider evidence-base on effective risk control post-incident investigation. In so doing, this project aims to improve organisational responses to hazards identified through incident investigations in healthcare and ultimately improve patient safety.

3 Methods

3.1 Introduction

In this chapter, I describe the research methods used to answer the research questions identified below. I explain the rationale for choosing those methods and define my approach to data analysis. I also provide an overview of how the research was conducted within an ethical governance framework.

To achieve the aim of the research as set out in section 2.7, the content of the thesis aims to answer the following research questions:

1. How well suited are currently proposed risk controls to address contributory factors identified through root cause analysis of serious incidents?

2. What influences the formulation and implementation of risk controls following serious incident investigations in healthcare?

3. How can the formulation and implementation of risk controls following root cause analysis of serious incidents in healthcare be improved?

Based on those research questions, the specific research objectives were as follows:

1. To identify contributory factors identified in reports of root cause analysis of serious incidents in healthcare

2. To identify the range of risk controls generated following root cause analysis of serious incidents in healthcare.

3. To identify the types of risk controls formulated by the investigating team to address particular categories of contributory factors.

4. To review the literature on high risk, high reliability organisations to identify current thinking about developing and implementing risk controls following incident investigations and provide the basis for sensitising constructs to be used in analyses.

5. To explore features influencing the successful formulation and implementation of risk controls following serious incident investigations in healthcare, based on opinions of multiple stakeholders in incident investigations from high risk industries, including healthcare.

In order to answer the research questions and achieve the objectives, this doctoral project was arranged into three workpackages. First, to understand the common contributory factors of serious incident investigations, the proposed risk controls and the latter's suitability in addressing the identified contributory factors, I performed content and thematic analyses of serious incident investigation reports and corresponding action plans from a large acute NHS trust (Trust A).

Second, I undertook a narrative review of the literature from safety critical industries (including healthcare) with the aim of identifying lessons relevant to healthcare for the generation and implementation of risk controls following serious incident investigations in healthcare, based on evidence from the literature. This review helped, among other things, to generate sensitising constructs that could be used in later analyses.

Third, semi-structured interviews with multiple stakeholders in accident investigation from healthcare and other safety critical industries were conducted to better understand approaches to risk control generation and implementation following incident investigations and factors influencing them. In Table 3.1 below, I summarise the research objectives addressed using which work package.

Workpackage	Research objectives
Workpackage 1: Qualitative analysis of serious incident investigation reports and action plans	To identify contributory factors identified in reports of root cause analysis of serious incidents in healthcare. To identify the range of risk controls generated following root cause analysis of serious incidents in healthcare. To identify the types of risk controls formulated by the investigating team to address particular categories of contributory factors.
Workpackage 2: Improving risk controls following incident investigations in healthcare- A narrative review of practices from safety critical industries.	To review the literature on high risk, high reliability organisations to identify current thinking about developing and implementing risk controls following incident investigations.
Workpackage 3: Semi-structured interviews with stakeholders in the investigation of incidents and the risk control process in safety critical industries	To explore the features influencing the successful formulation and implementation of risk controls following serious incident investigations in healthcare, based on opinions of multiple stakeholders in incident investigations from high risk industries, including healthcare.

Table 3.1 - Research objectives and workpackages.

3.2 Workpackage 1: Qualitative analysis of serious incident investigation reports and action plans

The first workpackage was a qualitative analysis of serious incident investigation reports and corresponding action plans from a large acute NHS trust (Trust A) over a three-year period. This workpackage aimed to address three research objectives, as outlined in Table 3.1 above:

1. To identify contributory factors identified in reports of root cause analysis of serious incident investigations in healthcare.
2. To identify the range of risk controls generated following root cause analysis of serious incidents in healthcare.
3. To identify the types of risk controls formulated by the investigating team to address particular categories of contributory factors.

Serious incident investigation reports and their action plans (including risk controls) are the written outputs of internal investigations conducted by teams of investigators, as described in sections 2.3.3 and 2.4.2. These reports follow a prescribed format as outlined by the serious incident framework[3] from NHS England (see appendix C). Of note, each investigation report covers an individual incident. These documents aim to identify factors contributing to incidents, and to recommend implementable risk controls to address those factors. I aimed to use a sample of these reports as a source of data.

Using incident investigation reports as source data for research is not novel. Previous researchers have used investigation reports as part of ethnographic approaches to study the practice of investigations,[6, 12, 24] others have used them to perform aggregated analyses of similar types of patient safety incidents (for example falls[26]) or of incidents occurring in individual specialties (such as intensive care[30]). A few others have used investigation reports and action plans to investigate the types of risk controls coming from serious incident investigations.[9, 17] I planned a rather different

approach. I aimed to use multiple investigation reports alongside their corresponding action plans across multiple specialties for different event types to identify the range of contributory factors and risk controls across different incidents from multiple specialties and make inferences about the suitability of particular risk controls in addressing the contributory factors identified in the reports. The findings from this work package are described in Chapters 4 and 5.

3.2.1 Data collection

A search was carried out in July 2016 from a secured computer on Trust A's intranet-based risk management software (DATIX®, now known as RLDATIX®).[168] A filter was applied to facilitate my search for serious incidents reported to the CCG matching the criteria set out in Table 3.2.

Serious incident reports dealing with pressure ulcers, Methicillin Resistant Staphylococcus Aureus (MRSA) bacteraemia, Clostridium difficile and other incidents related to healthcare associated infections were excluded. The reasons for these exclusions were several. First, within the organisation of the trust, investigations of pressure ulcers and healthcare associated infection related incidents are usually led by different teams (tissue viability and infection control respectively), which operate separately to the patient safety team responsible for conducting the investigations of all other serious incidents. The investigation reports and action plans are often kept in separate databases, which I did not have access to during the study. Second, given the very specialised and distinctive nature of these particular incidents, they are also investigated using bespoke templates,[169, 170] different from the ones used to investigate other patient safety incidents. Third, many organisations used to indiscriminately and inappropriately report and investigate all grade 3 and 4 pressure ulcers as serious incidents.[171] Ongoing serious incident investigations were also excluded.

Inclusion Criteria	Exclusion Criteria
All serious incident investigation reports reported to the local Clinical Commissioning group between 01/01/2013 and 31/12/2015	Pressure Ulcers. MRSA bacteraemia, Clostridium difficile and other healthcare associated infections. Ongoing investigations.

Table 3.2 - Inclusion and exclusion criteria.

3.2.2 Setting and sampling strategy

A criterion-based purposive sampling strategy,[172] outlined in Table 3.2, was used to identify all accessible serious incident reports over a three-year period (2013-2015) from Trust A. During that time-frame, Trust A consistently featured in the top quartile in terms of reporting rates of incidents amongst all acute NHS trusts in England, UK.[173] Trust A was a large teaching hospital, providing numerous specialist and sub-specialist services, with over 10,000 staff and looking after over one million patients per year. It followed the serious incident reporting process, investigation techniques and reporting templates set out by the NHS Serious Incident framework policy.[111]

3.2.3 Data storage and data security

Patient and staff details involved in the serious incidents were already anonymised in the serious incident reports made available to me. Data was stored on a secured drive at Trust A accessible only to named members of the research team.

3.2.4 Data analysis

All serious incident reports included in the study were analysed using the principles of content analysis,[174] (discussed in more details in the sub-section below (section 3.2.4.1)) to identify contributory factors across multiple incident investigation reports.

Corresponding action plans that were included in the study were analysed using the principles of both content[174] and thematic analysis.[175] Below I describe what content

analysis and thematic analysis entailed in the context of this workpackage, and how I analysed the data using three broad stages (open coding of serious incident reports and action plans, content analysis of contributory factors from serious incident reports and content and thematic analysis of risk controls from action plans).

3.2.4.1 Content analysis

Content analysis has roots in textual analysis in mass media research[174, 176] and has been increasingly used in health research.[177-180] The method is particularly useful in *"…simplifying and reducing large amounts of data into organised segments."*[174, 181] It involves establishing categories, followed by counting the number of instances each category occurs across numerous sources.[174] Thus, content analysis allowed me to categorise contributory factors and risk controls and determine their respective frequencies. Through the process described below (see section 3.2.4.3), I modified existing contributory factors and risk controls frameworks from the literature, allowing categorisation of contributory factors and risk controls into particular domains. Categorisation using this method was achieved using a coding rule book, which was precise enough to allow replication of the coding by a second coder (Sue Carr, a member of the supervisory team).

Some researchers have highlighted that the apparent simplicity of content analysis comes with drawbacks. Concerns include the risk of prioritising content over context, as single words get categorised, thereby losing an understanding of how, where and why the words were used. Second, qualitative researchers have highlighted that content analysis might amount to a quantitative analysis of qualitative data.[174, 182] I recognised these concerns as potentially reducing the richness of the qualitative data on offer from the investigation reports and action plans to mere numbers. In order to counter these issues, I coded whole paragraphs, as opposed to single words, to allow a better understanding of context, and provided annotations which contained my thoughts based on the coded data, which I reviewed once coding was completed before starting the analysis. When reporting the findings of the content analysis of contributory factors, I described how the contributory factors manifested themselves,

any particular patterns across serious incidents and provided textual excerpts where relevant.

3.2.4.2 Thematic analysis

While the investigation reports were analysed using content analysis as described above, the action plans were analysed using both content and thematic analysis. Using thematic analysis, I was able to group risk controls across incidents together into broad themes,[183] based on shared characteristics.

Thematic analysis is described as the most commonly used qualitative data analytic method in healthcare research.[182] It involves the grouping of data into themes and aims to describe how themes may be interconnected.[183] These themes emerge through "careful reading and re-reading of the data".[184]

To undertake the work, I used Braun and Clarke's six step procedure for thematic analysis (see Table 3.3) to identify recurring themes. Each theme was inductively derived and described a family of risk controls operating similarly to address identified hazards.[183]

Phase	Procedures involved in each step
1. Familiarisation with data	Reading and re-reading, noting initial codes
2. Generating initial codes	Coding relevant features in text systematically
3. Searching for themes	Grouping codes into themes
4. Reviewing themes	Checking if themes work across whole data set.
5. Defining and renaming themes	Refine themes based on captured excerpts, appraise interesting points in each theme and organise theme into a coherent story.
6. Producing the report	Final decision on themes and relevant extracts. Report writing.

Table 3.3 - The six steps of thematic analysis as per Braun and Clarke (2006)[183]

Based on the thematic analysis, I made inferences on the suitability of proposed risk controls in addressing identified contributory factors. In the next section, I describe how data from serious incident investigation reports and actions plans were analysed (using content and thematic analyses) in three stages.

3.2.4.3 The three stages of data analysis of serious incident reports and action plans.

Using a combination of content and thematic analyses, data analysis of the serious incident reports and action plans was performed in three stages, which involved both inductive (using data to generate ideas) and deductive (categorising data based on existing evidence) approaches.[175] The combination of both approaches is widely used

in qualitative research.[185-187] I found the combination of both approaches particularly useful as it allowed me to employ existing frameworks from the literature, and expand them further based on initial findings from an inductive approach.

3.2.4.3.1 First stage: Open coding of serious incident reports and action plans

First, using an inductive approach (where we allowed themes to emerge from the data without the use of any a priori framework),[188-190] two researchers (myself and a member of the supervisory team – Sue Carr) independently analysed a sample of 60 serious incident investigation reports and corresponding action plans by reading and re-reading them to ensure familiarity with the data and performed open coding[189, 191] of both contributory factors and risk controls. Two preliminary set of codes (one for contributory factors and the other for risk controls) were generated by combining the codes independently generated by each coder.

3.2.4.3.2 Second stage: Content analysis of contributory factors from serious incident reports

The second stage involved further analysis of the contributory factors identified in the serious incident reports as implicated in serious incidents using a content analysis approach.[174, 176] As described above, content analysis involved establishing categories of contributory factors, and counting their number of occurrences.[174] Coding was based on a modified human factors analysis and classification system framework (HFACS [70]- see figure 2.4 in section 2.2.2), enriched with the open codes identified in the first stage. The resulting framework was then further modified in an iterative manner through interaction with successive serious incident reports and the final framework (modified HFACS- see figure 3.1) applied to all included serious incident investigation reports to identify contributory factors.

For the purposes of this study, an excerpt from the serious incident investigation report was coded as a contributory factor if it was identified as a hazard in the report, and it led or could have led to an adverse event. Figure 3.1 shows the broad categories in the final framework (modified HFACS). The framework was utilised to provide an analytical lens when applied to all the included investigation reports. More details of

each coded category and how the framework differs from the HFACS framework developed by Diller et al, is available in Appendix D.

Coding of 5% of the sample of data set was checked by a second researcher (Sue Carr), resulting in minor adjustments of the coding framework.

3.2.4.3.3 Third stage: Content and thematic analysis of risk controls from action plans

In the third stage, I analysed the risk controls reported in the action plans in the incident reports in my dataset using a modified version of the Veteran Affairs hierarchy of controls.[10] The original Veteran Affairs hierarchy of controls was introduced in section 2.5.1.1 and Table 2.3. First, I modified the Veteran Affairs hierarchy based on the open codes identified in the first stage, and then further revised it in an iterative manner following interaction with successive action plans. The final framework (modified hierarchy of risk controls) used is available in appendix E and was applied to the entire dataset. Coding of 5% of the sample of dataset was checked by one of the supervisors (Sue Carr), resulting in no changes to the coding framework.

Using the "matrix coding" function on NVIVO, I coded each risk control against a category of contributory factor which the risk control was aiming to address. This function allowed me to identify the types of risk controls commonly formulated by investigating teams to address particular categories of contributory factors.

As discussed in section 3.2.4.2, I then grouped risk controls across incidents together into broad themes,[183] based on shared characteristics and how they aimed to address particular hazards. Each theme contained a "family" of related risk controls. For example, I labelled a theme including the following risk controls: training, reflection, assessments and feedback as "improving individual or team performance".

The three stages of data analysis were facilitated using the computer data analysis software NVIVO. I found the use of the software quite straightforward and intuitive. It

allowed me to organise my coding trees and facilitated comparisons across codes. In so doing, I found that NVIVO facilitated the translation of codes into cross-cutting themes.

3.2.4.4 Descriptive statistics

Simple descriptive statistics, including percentages, median and interquartile range (Q1-Q3) were used to identify the frequencies of the types of serious incidents, departments involved, degree of harm experienced by patients, and the occupations of members of the investigating teams. Each "type" of incident was used to group multiple incidents which shared a common nature, based on how the incident manifested itself (such as an unexpected death or an inpatient fall) or the most visible problem reported before the incident was investigated (such as delay in diagnosis).

3.2.5 Ethical considerations

The study received approval (project number 6545) from the clinical audit and service evaluation team in Trust A.

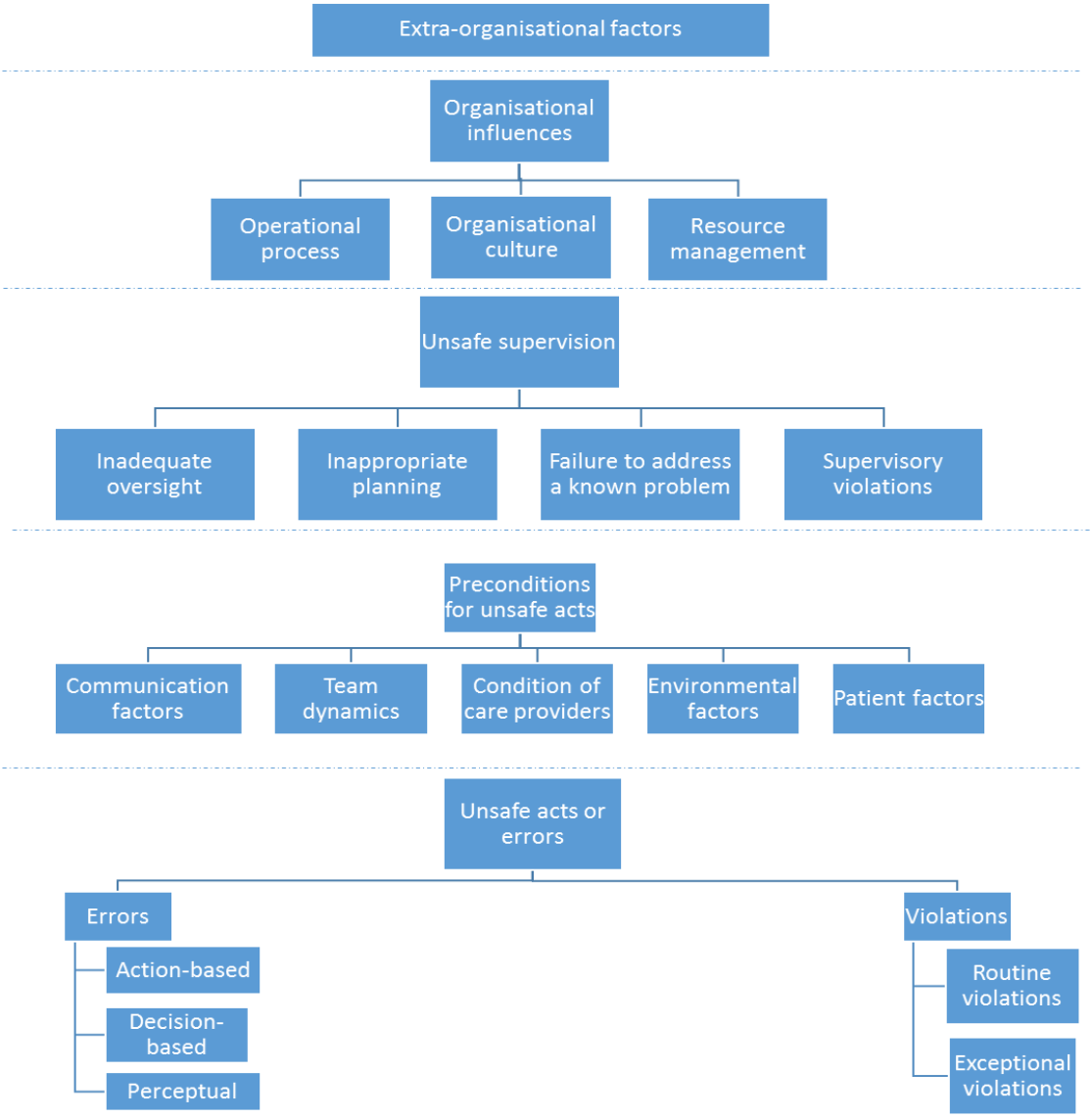

*Figure 3.1 - Final HFACS framework applied to data set**

*see Appendix E for a detailed version of the final HFACS framework applied to the data set

3.3 Work package 2: Improving risk controls following incident investigations in healthcare- A narrative review of practices from safety critical industries.

As discussed in sections 2.3 and 2.4, the last 20 years have seen sustained efforts at policy level and in academia to improve safety through the adoption of numerous practices already in place in other high risk sectors such as aviation and the process industries.[2, 8, 68, 102] Such practices, implemented to variable extent and effect, have included the use of root cause analysis as a toolbox of techniques for investigating incidents and the creation of structured hospital and nationwide incident reporting systems in order to learn from past incidents. While the aim of such risk management practices is to promote organisational learning and prevent the occurrence of future similar adverse events, as discussed in section 2.4.3, the evidence is lacking to suggest that incident investigations effectively and consistently lead to improvements in patient safety.[13, 14] As a result much time and resources are spent reporting[104] and investigating incidents[13, 24, 35, 146] without successfully translating identified causes into effective and actionable risk controls, thereby thwarting the learning that can be generated from the outputs of incident investigations.[17, 146]

The second work package comprised a narrative review of literature from healthcare and other safety critical industries with the aim of identifying practices and approaches that might be used to improve the formulation and implementation of risk controls following incident investigations in healthcare. The diverse nature of the available literature and the need to synthesise studies taken from multiple disciplines and conducted using differing methods made a narrative review, rather than a formal systematic review, more appropriate and more practically feasible.[192, 193]

A narrative review involves an academic summary of findings from relevant literature, accompanied with an *"interpretation and critique"*.[194, 195] As used in this thesis, it

involved the *"selection, chronicling and ordering of evidence to produce an account of the evidence."*[195] As a research method of synthesising secondary research, it has been criticised for its perceived lack of transparency.[195] In order to reduce bias and provide clarity on how literature was selected and reviewed, in the next section, I discuss the search strategy, inclusion and exclusion criteria and how the most important themes from the included literature were identified.[196] Findings of the narrative review are presented in Chapter 6.

3.3.1 Search strategy

I devised a search strategy, and refined it following feedback from my supervisors. The search strategy aimed to identify academic literature from healthcare and other safety critical sectors (such as aviation, transport, military, process industries, etc.), discussing approaches taken to formulate and implement risk controls following incident investigations. Figure 3.2 illustrates the overall search strategy.

3.3.1.1 Search strategy of academic literature

To identify academic literature, a search of numerous literature databases (SCOPUS, Embase, Psycinfo, Pubmed and CINAHL) was conducted on 15/04/2018. The search terms included:

(implement* OR design* OR formulat* OR *generat*) AND ("risk control" OR "risk mitigation" OR "risk management" OR "action*" OR "recommendation*" OR "CAPA") ("root cause analysis" OR "RCA" OR "accident* investigation*" OR "incident* investigation*")

To identify additional articles, the reference lists of included articles were hand searched.

3.3.1.2 Study inclusion and exclusion criteria

Academic literature published in English after 1990 was included in the review. The year 1990 was used as cut-off, as previous research has shown that this was when a

significant body of research relating to patient safety incidents began to emerge in the literature.[197]

A broad, inclusive approach prioritising relevance over rigour was used to maximise the capture of relevant literature. As such, peer-reviewed commentaries and reviews, along with book chapters, were also included. Specifically, academic literature discussing the following issues were included in the review:

1. Approaches to the generation of risk controls following incident investigations.
2. Approaches made to maximise the implementation of risk controls following incident investigations.

Articles were excluded if their sole aim was to discuss:

1. Root cause analysis or other accident investigation techniques without discussing the risk controls process following investigations.
2. Technical details specific to particular safety critical industries which are not applicable to healthcare.

3.3.2 Search results

The initial search from the academic literature databases, performed on 15/04/2018, yielded 1091 articles. After review of titles and abstracts based on the inclusion and exclusion criteria, 160 articles remained. After deduplication, 94 unique articles were identified, out of which 30 articles were included in the final review after reading the full-texts, and selection based on the inclusion and exclusion criteria. As shown in the modified PRISMA diagram below (figure 3.2), 19 additional articles were identified from a secondary search involving a manual search of the reference lists of the articles identified through the database searches and a citation search. In total, 49 articles were included for analysis in the final review.

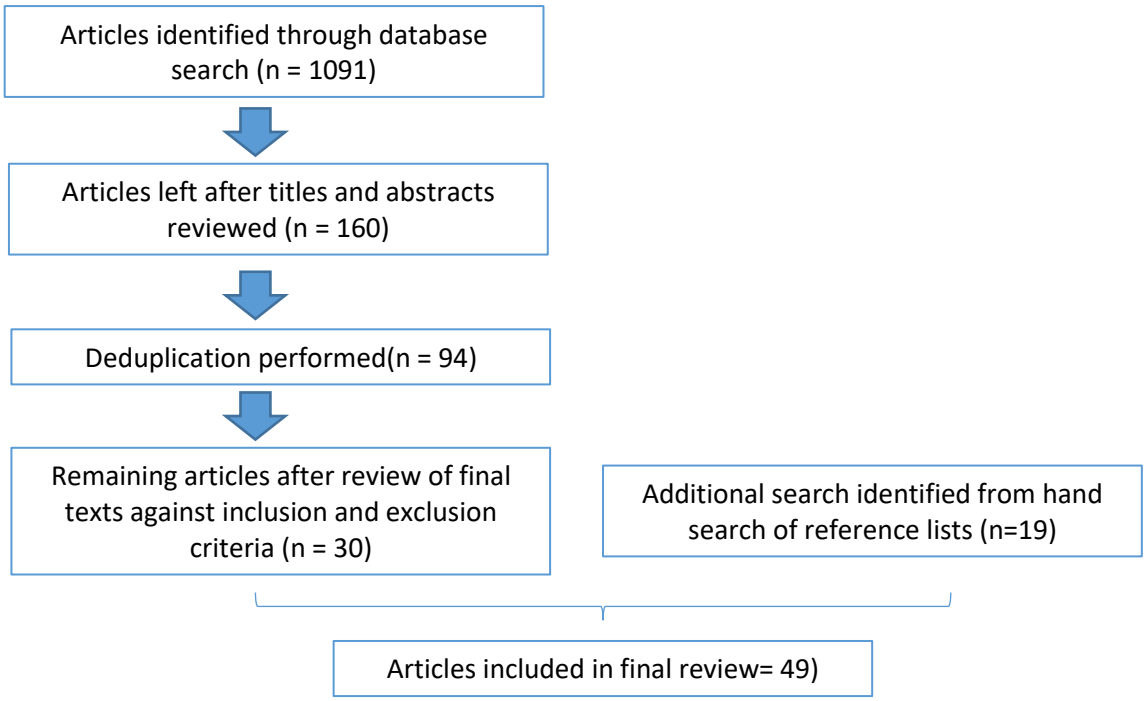

Figure 3.2 - Search strategy for narrative review

3.3.3 Synthesis of included literature

The synthesis of the included literature was an iterative process, involving the use of thematic analysis[183] to identify important practices and/or approaches when formulating or implementing risk controls following incident investigations. The themes described in the results section emerged from a process of reading and re-reading the articles to familiarise with key concepts followed by discussing key themes with supervisors. The themes were allowed to develop inductively, i.e. without applying a set of a priori codes to the included literature. These inductively derived themes were further discussed at supervisory meetings and enriched to develop the resulting thematic categories as described in Chapter 6. The included articles were then re-read and analysed using the thematic categories as a guiding framework.

3.4 Workpackage 3: Semi-structured interviews with stakeholders in the investigation of incidents and the risk control process in safety critical industries

Workpackage 3 involved semi-structured interviews with stakeholders who were experienced in the process of incident investigations in their sectors across healthcare and other safety critical industries. The goal was to understand what different stakeholders in incident investigation and risk control from both healthcare and other safety critical industries perceived as factors influencing the formulation of strong risk controls and how risk controls generated following incident investigations could be successfully implemented.

3.4.1 Participant inclusion criteria

The stakeholders were purposively sampled to include serious incident investigators in healthcare, expert accident investigators from other safety critical industries, commissioners responsible for reviewing serious incident investigation reports and action plans, NHS staff responsible for implementation of action plans from SI investigations and academics who have previously published on patient safety and/or incident investigation in safety critical industries. I interviewed each participant once, with each interview lasting for about an hour.

Participants included: (1) serious incident investigators in healthcare, (2) UK commissioners who have to review and provide feedback on serious incident investigation reports and their action plans, (3) academics who have previously published on patient safety and/or incident investigation in safety critical industries (4) accident investigators from other high risk industries (5) NHS staff responsible for implementation of action plans from serious incident investigations. These five groups of professionals were chosen as they include those who perform serious incident investigations and often generate action plans in healthcare (i.e. serious incident

investigators), those who need to endorse the quality of the action plans (commissioners), those who research the practice of incident investigation and the response following incidents (academics), those who are experts at investigating accidents in complex high risk, high reliability organisations (i.e. accident investigators from other high risk industries) and those who are provided with recommendations from serious incident investigations and their action plans and tasked with implementing risk controls on the front-line (NHS staff responsible for implementation).

More specifically, participants were recruited if they met the following criteria based on their role:

(a) Serious incident investigators

As noted earlier, serious incident investigators do not form a professional group of their own in healthcare. Instead, they come from several different backgrounds. Serious incident investigators tend to be senior clinicians, senior nurses, patient safety officers and risk managers. Thus, the inclusion criteria were kept quite wide to include any of these professionals who were involved, on average, in conducting more than two serious incident investigations per year.

(b) Commissioners

These were individuals working for CCGs who had formal responsibility for reviewing and approving serious incident reports and action plans generated by NHS trusts. An example might include the head of patient safety of a CCG.

(c) Academics

Academics included researchers who had published in the field of patient safety and/or accident investigation in safety critical industries.

(d) Expert accident investigators from other industries

These included individuals who routinely performed accident investigation in

other high risk, high reliability industries (such as aviation, defence, chemical, nuclear, etc).

(e) NHS staff responsible for implementation of action plans

This group of participants comprised NHS staff who had experience in gathering the resources required for execution of recommendations generated from serious incident investigations and tasked with implementing one or more risk controls from action plans. These participants comprised senior clinicians, senior nurses or operational managers.

3.4.2 Participant identification and recruitment

I identified participants by matching them against the inclusion criteria outlined in the section above. I designed a poster and a standard email invitation template which included the background and aim of the project (see Appendix F). Information on the research team was provided, including details on how to get in touch. The potential benefits and reach of the project were outlined. The poster was attached to the invitation email to potential participants known to the SAPPHIRE research group and disseminated via the Leicestershire Improvement, Innovation and Patient Safety unit (LIIPS) network, the Clinical Human Factors Group (CHFG) and the Health Foundation Alumni newsletter. The poster was also disseminated using social media (LinkedIn and Twitter) and a project website https://www2.le.ac.uk/departments/health-sciences/research/soc-sci/research-projects-1/do-you-conduct-supervise-review-or-research-accident-investigations-in-a-safety-critical-industry. To increase recruitment, snowball sampling[198] was used with each participant asked to provide details of any colleague(s) who met the inclusion criteria.

The following search strategy was used on SCOPUS and Web of Science to identify abstracts of papers published by relevant academics: (“Accident investigation” OR “incident investigation” OR “root cause analysis” OR “RCA”). Academics meeting the inclusion criteria were emailed using the contact details provided in the abstracts or through their official emails, if publicly available. To recruit accident investigators from other industries, relevant accident investigation boards were contacted (such as

the AAIB), through contacts and social media. NHS staff responsible for the implementation of action plans were identified from two large acute NHS trusts (Trust A and B). They were recruited using contacts, email distributions and the LIIPS network.

3.4.3 Sampling

Recruitment started in October 2016 and ended in May 2017. At the beginning of the study, I was hoping to recruit at least six participants from each stakeholder group, which would allow a sample size of at least 30 participants. I estimated such a sample size would allow theoretical saturation to be reached. Charmaz defines theoretical saturation as the stage in qualitative analysis where new insights stop emerging from analysis of further sources.[189] As this number could only be known once analysis has started, I kept a fairly open mind on the number of participants I needed to recruit and kept an eight-month recruitment window as outlined above. To account for those declining participation or drop-outs amongst, I aimed to contact at least 60 potential participants.

3.4.4 Study procedures

3.4.4.1 Interviews

The interview was framed around an interview topic guide, which was semi-structured (the final version is available in Appendix G). This guide was generated based on the research questions and on findings from the literature review, in particular, the challenges faced in healthcare when generating and implementing risk controls (section 2.5.2). The semi-structured format allowed the right balance between covering topics I felt were essential in answering my study questions, while also allowing participants space to steer the interview to cover domains which they considered important.

Given that my participants were from diverse geographical regions, including outside the UK, I conducted the interviews by telephone. While acknowledging that telephone interviews may have restricted my ability to pick up on non-verbal cues[199] during the

interview, I found the ability to conduct interviews by telephone particularly useful. It allowed me to recruit busy clinicians, who could accommodate me more readily in their busy schedule and facilitated recruitment of participants not bound by geographical boundaries.

I conducted two telephone mock interviews with colleagues to test the duration and flow of the interview and ensure questions were framed appropriately. The topic guide was modified to include feedback from the two mock interviews. During the course of the study, the topic guide was further modified to include recurring topics covered by participants, not initially covered by the topic guide.

3.4.4.2 Consenting

Once contact was made with potential participants, they were sent a participant information sheet with further information on the study and a consent form (Appendix F) for them to sign and return electronically. Participants were made aware that they could withdraw from the study at any time.

3.4.4.3 Data handling and security

Two electronic databases were kept on a secured drive in an encrypted laptop for recording purposes to ensure accuracy and avoid duplication of work. The first database included details of potential participants who had been screened as meeting the study inclusion criteria and subsequently contacted. The second database included details of participants who had consented to be part of the study. Personal details of the participants (name, role, emails, phone numbers, names of institution), corresponding unique study numbers and interview dates were kept in the enrolment log books.

The interviews were performed by phone in a private room and recorded using an encrypted voice recorder. Audio files were stored on an encrypted drive at the University of Leicester until professional transcription was complete. The audio files were then deleted once the transcripts had been reviewed for accuracy. Identifiable details of participants and institutions in the interview transcripts were anonymised.

Electronic versions of the transcript were stored on a secured drive, accessible only to the study team. Any printed transcript or section of a transcript was kept in a folder in a locked cupboard in a secured room in the university department's offices.

3.4.5 Data analysis

Transcripts of the interviews were analysed thematically using the principles of framework analysis.[175] This analytical method has roots in applied policy research and offers an adaptable, yet also systematic means of approaching and analysing data through the use of clearly documented and interconnected stages (see Table 3.4) as described by Ritchie and Spencer.[175]

The framework method allowed me to reduce large quantities of textual data into organised chunks. This process was facilitated using NVIVO. In Table 3.4, I summarise the steps involved in analysing data in this workpackage.

1	Familiarisation	This included immersion into a sample of data. I read and re-read five interview transcripts, noting down key ideas coming from the familiarisation process.
2	Coding	I applied a combination of deductive (using the results of the narrative review as sensitising constructs[189] along with findings from the wider literature) and inductive codes (new codes based on the interview data) to each transcript in succession, up to a total of 20 transcripts. Codes were discussed with the supervision team at two different points in time during this stage and the coding trees subsequently refined. I found discussion of the coding structure with my supervision team particularly useful as they approached the data from different perspectives.
3	Indexing (applying the framework to the data)	I grouped codes together into broad categories, which I defined clearly and applied the resulting analytical framework to multiple transcripts in succession. The analytical framework was updated with new codes as they emerged the data.
4	Charting	I generated a framework matrix of themes by rearranging coded data and used illustrative quotations to provide context to the codes.
5	Mapping and interpretation	Finally, I mapped connections between different themes to identify and explore relationships.

Table 3.4 - Stages of framework analysis. From Ritchie et al.2002. Qualitative Data Analysis for Applied Policy Research[175]

3.4.6 Ethical considerations

The interview study received ethical approval from the University of Leicester Research and Ethics Committee (6964-mfp6-healthsciences) on the 26th of July 2016, after review of the study protocol, consent form, participant information sheet and invitation email. No patient was involved in this study.

The participants were NHS staff and academics. It did not require approval from the NHS REC as per guidance from the NHS HRA website as it did not involve patients or carers. A copy of the results of the decision tool from the NHS HRA website is available in Appendix H. The tool itself can be accessed on the following link: http://www.hra.nhs.uk/documents/2013/09/does-my-project-require-rec-review.pdf.

The study was also deemed to meet the criteria for service evaluation by the Clinical Audit and Service Evaluation team at Trusts A (project reference 8388e) and B (project reference17-015Q).

3.4.7 Reflective practice

During the course of the interview study, I kept a reflective log, which I found useful to help structure my thoughts when designing the study and interpreting the findings. The content of the log included both successes and challenges, along with the feelings they engendered in me when navigating through the multiple steps of the interview study. Some of these thoughts and feelings are particularly relevant to the methods chapter and have influenced how I modified my approach to recruitment and conducting interviews.

I was pleasantly surprised by the readiness of the first group of participants contacted across all five stakeholder groups to be interviewed. The recruitment rate at the beginning of the interview study was high. The first tranche of participants mostly included healthcare incident investigators and academics, recruited through personal contacts and word of mouth. This recruitment peak was soon followed by a plateau which made me slightly uncomfortable in terms of ability to achieve my recruitment goals. In retrospect, I believe this plateau was due to the initial peak in response

following dissemination of email and newsletters as outlined in section 3.4.2. I used the time resulting from this "recruitment lull" to familiarise myself with the transcripts and initiate the first set of open codes. It also gave me space to reflect on the content of my interview topic guide.

To ensure that a holistic view of participants' varying perspectives was captured during the interview, I made different subsections of the topic guide more relevant to individual stakeholder groups. As described by Green et al., paying close attention to initial interviews allowed me to understand what worked well and what did not work.[200] A particular early addition to my interview technique which I found especially helpful when reviewing interview transcripts before analysing was a diary capturing my immediate thoughts following the interview.[200] Given that many of my initial participants were healthcare incident investigators, understanding their "world's view" of how incidents were investigated and how they came up with risk controls was particularly useful. An early amendment to the topic guide was to include questions encouraging participants to describe real-life instances when investigations led to strong risk controls and compare them with other instances when they felt investigations led to weak risk controls.

Green et al. suggest the use of "community groups" as an effective means of increasing recruitment to interview studies.[200] In order to increase recruitment of participants across all five stakeholder groups and generate a representative sample beyond the SAPPHIRE research group's personal contacts, I reached out to two particular groups: the Clinical Human Factors Group (CHFG) and the Health Foundation Alumni.

The CHFG is a charity that works with clinicians and experts in human factors to promote the use of Human Factors Science to improve patient safety. The Health Foundation Alumni group comprises current and past fellows sponsored by the Health Foundation who study or have studied means to improve healthcare. Both networks included a mention of my research study in their newsletters, which helped me recruit at least six more participants. I recognised that the exclusive use of such a sampling

strategy would have limited my sampling frame to participants interested in human factors and improvement science. Thus, to ensure a wider representative sample, I also regularly retweeted an invitation to my study and used snowball sampling by asking participants to suggest names of potential participants, including those who may or may not share the same views as themselves.

Finally, I was aware of the limitations of conducting interviews by telephone/electronic audio and actively sought to address them. As a very visual person, I initially found it frustrating not to be able to read the facial expressions and body language of my participants. To try mitigate this issue, I often found myself asking my participants how they felt about particular situations they were describing. While not completely replacing the visual cues that I would have gathered in a face-to-face interview, asking my participants about their feelings at strategic points during the interview allowed me to better understand their perspective. Occasionally, it enabled me to change the pace of the interview to accommodate for their feelings, such as when they were discussing things they felt particularly strongly about.

Other concerns with the use of audio interviews included the problem of technical glitches. Often unpredictable, they seemed to happen mostly when doing voice calls using the internet. After doing two such interviews, both interrupted at least three times for issues with internet connections, I stopped using such “voice over internet protocols” software and only used standard telephonic connections, which were more reliable. While there were some clear drawbacks to using telephone or audio interviews, I also found some notable advantages. First, they were useful to access participants across continents, which would have been both logistically and financially difficult through face-to-face interviews. Second, I managed to recruit busy clinicians who would allocate me time between their busy clinical schedule more readily by phone. Third, it allowed me to make notes without worrying about maintaining eye contact during the interviews.

3.5 Summary

In this chapter, I have described the methods I have used to answer the study questions of the thesis. Where relevant, I have included justifications for the methods used. I have provided a reflective account of my thoughts on how I went about conducting the interview study, which was a very significant component of my thesis. In the next four chapters, I discuss the findings of the research I conducted using the above described methods.

4 What are the contributory factors to serious incidents in healthcare? A content analysis of serious incident investigation reports from a large acute NHS trust between 2013 and 2015

4.1 Introduction

Previous patient safety research has highlighted the burden of harm caused by unsafe care.[7, 8] As previously discussed (see section 2.4), in the NHS, reported serious incidents are investigated using RCA to identify areas of risk, with a view to putting risk controls in place to reduce or eliminate potentially avoidable harm.[2, 3] Analysis of single incidents allows individual contributory factors related to single events to be identified but does not provide a systemic view of an organisation's vulnerability to recurring adverse events.[201] Aggregated analysis of multiple incidents, on the other hand, enables organisations to prioritise resources to implementing those risk controls which aim to address recurring contributory factors across multiple incidents, including those events that may seem more disparate at the surface.[13]

Using incident investigation reports as source data, previous research on the topic has focused on aggregated analyses of similar types of incidents (such as falls,[26] adverse drug reactions[163] or inpatient suicides[152]) and on incidents from individual specialties (such as palliative care,[202] general practice,[203] intensive care,[30] or orthopaedic surgery[204]). Less is known about common factors contributing to serious incidents

across multiple specialties in acute secondary care institutions. With this in mind, in this chapter, I report the results of a content analysis of 126 serious incident reports from RCA investigations conducted in a large acute NHS trust between the years 2013 to 2015 inclusive. The aim was to identify contributory factors from serious incident investigation reports across multiple serious incidents within a single organisation using a modified HFACS framework.

The methods used to address the aim of this study are discussed in more details in section 3.2. In summary, using an inductive approach, myself and Sue Carr (a member of the supervisory team) independently analysed a sample of 60 serious incident investigation reports and performed open coding of contributory factors. We generated a combined set of preliminary codes of contributory factors. This step was followed by a content analysis of contributory factors from 126 serious incident investigation reports, reported to the CCG between 01/01/2013 and 31/12/2015, using a modified HFACS framework, which was enriched by the initially generated codes and further modified in an iterative manner following interaction with successive serious incident investigation reports. The final framework (see figure 3.1 and Appendix D) was applied to all included serious incident investigation reports. Separately, I also used simple descriptive statistics to report findings on the types of incidents, departments, professional roles of investigators and patient outcomes.

As described above, to enrich the content analysis of contributory factors further, I not only report the numbers and percentages of the categories of contributory factors identified. I also include descriptions of how the contributory factors manifested themselves and provide accounts of any particular patterns I could identify across serious incidents. These findings are illustrated with textual quotes from serious incident investigation reports, where relevant.

4.2 Results

The findings of this study are organised in two broad categories. First, I use descriptive statistics to report demographic and outcome data on the incidents. Second, I

describe the findings of the content analysis of the contributory factors of the serious incident investigation reports reviewed by applying a modified HFACS framework (see section 3.2.4.3 and Appendix D), to the serious incident investigation reports. In particular, I report the frequencies of different categories of contributory factors, explore how they manifest at each level of the modified HFACS hierarchy and illustrate them with relevant excerpts quoted from the included sample.

4.2.1 Demographics of serious incident reports reviewed

One hundred and twenty-six serious incident investigation reports, reported to the local CCG by Trust A between 01/01/2013 and 31/12/2015, met the inclusion criteria for my study and were available for review, including six never events. Thirty-six serious incidents were reported in 2013, 50 in 2014 and 40 in 2015.

I identified 25 different types of incidents. As described in section 3.2.4.4, an incident "type" consisted of multiple incidents sharing a common nature, based on how they manifested (such as an unexpected death or an inpatient fall) or based on the most visible problem reported before the incident was investigated (such as delay in diagnosis). Each serious incident was categorised to one type only.

The two most frequently occurring types of incidents were inpatient falls (15 incidents, 12%) and delayed or missed diagnosis of other (non-cancer) condition (15 incidents, 12%). The top ten most frequent types of incidents are shown in Table 4.1. A tabular summary of the frequencies of all the different typologies is available in Appendix I.

Types of incident	Number	Percentage
Fall	15	12%
Delay/ missed diagnosis of non-cancer condition	15	12%
Unexpected death	14	11%
10 times or more drug error	12	10%
Failure to recognise deteriorating patient	12	10%
Delay/ missed diagnosis of cancer	9	7%
Delay in following up patient/ not followed up	8	6%
Capacity issues (bed)	6	5%
Wrong implants	5	4%
Inappropriate treatment	4	3%

Table 4.1 - Ten most common types of serious incidents from investigation reports generated between 2013 and 2015.

Emergency medicine (18%) and Obstetrics and Gynaecology (15%) were the two specialties most commonly involved in the serious incidents' investigation reports reviewed. Fourteen serious incidents (11%) involved two or more specialties. Table 4.2 shows the five departments most commonly involved in the sample reviewed and a tabular summary of the frequencies of all the specialties involved is available in Appendix J.

Specialties	Number	Percentage
Emergency Medicine	23	18%
Obstetrics and Gynaecology	19	15%
Radiology	11	9%
Paediatrics and neonates	11	9%
Ophthalmology	7	6%

Table 4.2 - Five most common specialties involved in the serious incident investigation reports reviewed.

The degree of harm, as reported in the serious incident investigation reports, for the patients involved, is shown in Table 4.3. Death was the most frequent outcome (37 cases, 29%). Each incident investigation report was assigned one outcome only. Those incident investigation reports where multiple patients with different degrees of harms were involved were assigned the most serious degree of harm. Organ damage or loss of organs (such as amputations, fractures, head injuries, etc.) occurred in 35 cases (28%) and delays in diagnosis or treatment without evidence of long-term damage to organs occurred in 20 cases (16%). Twenty-seven cases (21%) resulted in no harm.

Effect on patient	Number	Percentage
Death	37	29%
Organ damage/ Loss of organs	35	28%
- Fracture	12	10%
- Brain/ head injury	6	5%
- Visual loss	4	3%
- Removal of organ	4	3%
- Other	4	3%
- Amputation	3	2%
- Burns	1	1%
- Paraplegia	1	1%
None	27	21%
Delay in diagnosis/ treatment	20	16%
Psychological	2	2%
Unknown	2	2%
Risk of future complications	1	1%
Transient physiological compromise	1	1%
Decreased functionality	1	1%

Table 4.3 - Degree of harm patients were subjected to, based on serious incident investigation reports reviewed, among those incidents which had occurred between 2013 and 2015.

The teams who had undertaken the investigations at Trust A comprised mostly senior members of clinical staff and representatives from the trust's patient safety team (see

Table 4.4). Human factors specialists (2%) and junior members of staff, such as junior doctors (2%) and nurses in non-senior roles (2%) rarely formed part of investigation teams. A complete table with all the different professional roles of staff involved in the serious incident investigations reviewed is available in Appendix K.

Professional roles of investigators	Number of incidents	Percentage
Patient safety team	115	91%
Clinical consultants	109	87%
Senior nurses and matrons	85	67%
Clinical managers	65	52%
Non-clinical managers	41	33%
Specialist nurses	16	13%
Midwives	14	11%
Radiographers	13	10%
Human Resource representatives	11	9%
Pharmacists	7	6%

Table 4.4 - Ten most common professional roles of investigators present in serious incident investigation reports reviewed.

In the next section, I report the frequencies of the different factors contributing to the serious incidents using the modified HFACS framework, explore each level of the framework in more detail and provide examples of recurring themes at each level of HFACS, using textual excerpts from the serious incident investigation reports. Definitions of each level of HFACS are provided in more details in section 2.2.2.3 and Appendix D.

4.2.2 Content analysis of contributory factors using the modified HFACS framework

The median number of contributory factors I identified using the modified HFACS framework was four (Q1-Q3: 2-7). I identified a total of 701 contributory factors across the 126 incidents reviewed. The frequencies and percentages of the different categories of contributory factors, based on the application of the modified HFACS framework to the data set, are shown in Table 4.5.

The most common tier of contributory factors I identified was *unsafe actions or errors* (282 references across 99 incidents), followed by *preconditions for unsafe acts* (223 references across 91 incidents). I identified *organisational factors* 115 times across 59 incidents and supervisory factors 73 times across 40 incidents. I identified an extra tier to the framework when compared to the HFACS framework reported by Diller et al.[70] to account for *extra-organisational factors*, which I identified in eight instances across seven incidents.

Modified-HFACS level	Number of incidents	Percentage of total number of incidents	Number of references* across all incidents	Percentage of total number of references
Unsafe actions or errors	99	79%	282	40%
Errors	79	63%	162	23%
Decision-based	62	49%	117	17%
Action-based	26	21%	36	5%
Perceptual	8	6%	9	1%
Lack of compliance	59	47%	120	17%
Routine violations	46	37%	79	11%
Exceptional violations	30	24%	41	6%
Preconditions for unsafe acts	91	72%	223	32%
Environmental factors	56	44%	92	13%
Communication factors	49	39%	80	11%
Patient factors	27	21%	33	5%
Condition of staff	8	6%	10	1%
Team dynamics	6	5%	8	1%
Supervisory factors	40	31%	73	10%
Inappropriate planning	24	19%	36	5%
Inadequate oversight	16	13%	26	4%
Failure to address a known problem	6	5%	6	1%

Supervisory violations	5	4%	5	1%
Organisational factors	59	47%	115	16%
Operational process	41	33%	56	8%
Resource management	38	30%	53	8%
Organisational culture	5	4%	6	1%
Extra-organisational factors	7	6%	8	1%

Table 4.5 - Number of contributory factors across different levels of the modified-HFACS framework.

** Each reference denotes an occasion where I identified a contributory factor in the incident investigation report.*

4.2.2.1 Unsafe actions or errors

Unsafe actions or errors represent actions by health care providers at the sharp end and they may take the form of errors or intentional disregard of rules and policies (lack of compliance).[69, 70] I identified unsafe actions, errors and lack of compliance in 79% of incidents (282 times across 99 incidents). The frequencies of the different forms of unsafe actions and errors are outlined in figure 4.1.

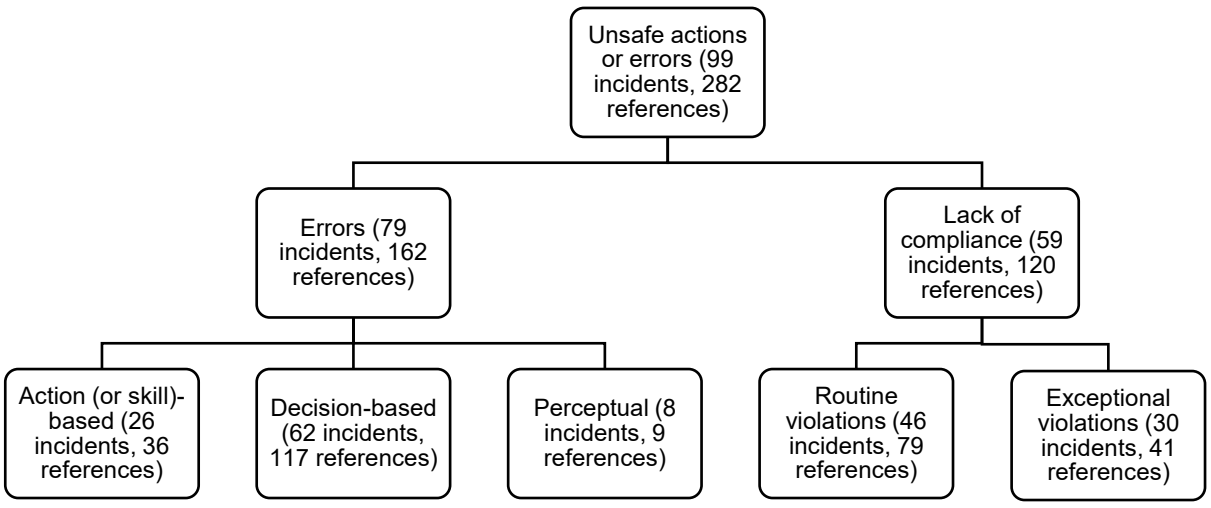

Figure 4.1 - Different types and frequencies of unsafe actions or errors

4.2.2.1.1 Errors

Errors, defined as mistakes, unintentional slips and lapses (action-based errors) or conscious actions that proceeds as intended but were inappropriate for the situation (decision-based errors),[70] were identified 162 times across 79 incidents. The most common subtype of errors was decision-based errors (117 references, 62 incidents). They comprised mistakes where the language in the investigation reports implied that the actions of staff proceeded from intention but were subsequently found not to have been appropriate for the situation. Such errors related to instances of inadequate clinical decision-making, for example due to poor judgement and cognitive biases.

> *"The investigation team were in agreement that bearing in mind a plan had already been made at approximately 10:00 that if there was further deterioration of the CTG [cardiotocography] then delivery should be by caesarean section... the decision for delivery should have been made at 10:45. However it appeared that there was a reluctance to make the decision for delivery even though there were increasing signs of both maternal and foetal compromise."* (Source E-12)

> *"… [the patient] attended the Emergency Department … with a sudden onset of paraesthesia in both lower limbs. Routine bloods were collected which showed raised lactate … however; there was no raised temperature or increased heart rate noted which would have been further clinical indications of an infection (sepsis). The medical management was that of sepsis and possible discitis (infection in the intervertebral disc space). The sepsis pathway was commenced due to the working diagnosis… there appears to be no consideration made that the condition maybe vascular in nature rather than a septic … condition."* (Source E-19)

> *"The investigation team felt that the medical assessment focussed on confirming the diagnosis of common peroneal nerve injury rather than ruling out other causes for the presenting symptoms. The documentation was*

considered a clear assessment of common peroneal nerve dysfunction but lacking in detail about the vascularity of the limb." (Source E-20)

Inadequate decisions occasionally resulted from poor appreciation of how the organisation ran. Weak understanding of operational processes was not an issue isolated to a particular group of professionals. Instead, it was identified among staff operating across the hierarchical spectrum, at both the sharp and blunt ends of care. Ignorance of procedures related both to rarely used processes and those used in the day-to-day functioning of clinical operations. When explored further, reasons for such lack of procedural awareness appeared on occasion to relate to the inadequacy of induction programmes.

"The usual process is for the Junior Doctors Administrator (JDA) to forward the Curriculum Vitae's (CV) to the Head of Service (HOS) from the Locum Bookers Service …The HOS would then be prompted by the JDA to complete and return the checklist detailed in the Temporary Staffing Policy. In this instance, the JDA was unaware of this process, and therefore did not ask the outgoing HOS to complete this task. The HOS was also unaware of this requirement." (Source E-14)

"There was also an issue that the Sonographer did not appear to understand the screening pathway as some patients were not sent for blood tests after their scan." (Source E-43)

Decision-based errors manifested in several different ways, such as inadequate assessments, diagnoses or treatment plans. Inadequate clinical assessments were particularly an issue when evaluation of clinical features involved a subjective measure (such as levels of pain) or when physiological parameters or patients' clinical risk factors changed during an admission (such as a patient's risk of falls).

"The patient was assessed as being a category 4, which means patients are seen in time order. The investigation team felt that based on the severity of

the patient's pain, she should have been triaged as a category 3, which means she would have been seen more urgently." (Source D-09)

"[the patient's] condition was changing, and this was not clearly identified by the nursing staff. The ED notes show that he was cooperative and communicating with staff whilst in the ED, however by 04.45hrs he was upside down in the bed, incontinent of urine and naked, asking to be left alone. Had the nursing staff referred to the ED notes they would have recognised this change." (Source D-47)

Examples of decision-based errors concerning treatment plans related to both the timeliness and the appropriateness of clinical decisions. A recurring feature across such instances was the silence in investigation reports regarding the reasons underpinning the clinical reasoning of staff at the time.

"However, although the patient's heparin was stopped following the fall, the clopidogrel was not stopped until the following day. The combination of heparin and clopidogrel increase the risk of internal bleeding and so it was the view of the investigation team that the clopidogrel should have been stopped on the day of the fall." (Source D-41)

"Mrs AB was still on a course of oral Co-Amoxiclav …but in breach of the requirement for IV antibiotics as set out in the Sepsis Pathway, IV antibiotics were not commenced until …[2 days later] …when IV Co-Amoxiclav was prescribed (the Sepsis 6 Pathway recommends consideration of Meropenem if severe sepsis is suspected)." (Source E-39)

Action-based errors were detected 36 times across 26 incidents. These errors were defined as unintentional slips and lapses made during the execution of seemingly familiar tasks. Two broad overarching themes were identified among action-based errors. First, they related to errors made during the calculation, prescription, selection or administration of medications or other treatments which operators were familiar

with. Second, they included slips and lapses which occurred during the assessment, monitoring and scoring of patients' physiological parameters.

> *"Doctor A considered that she knew the dose of the drug required and the calculation was considered straightforward so did not need to consult a reference guide or use a calculator. The recommended dose of intravenous Furosemide is 1mg/kg. The baby's weight was 0.73kg, therefore the dose prescribed should have been 0.7mg. However, the dose actually prescribed was 7 mg. Therefore, prescribed at 10x the recommended dose."* (Source D-33)

> *"Later scrutiny of the EWS* (Early Warning Score) *identified that the score had been miscalculated prior to discharge and was actually 5; a score of 5 necessitates a senior clinical review within one hour of detection of abnormality."* (Source E-21)

Such action-based errors occurred despite controls in place to prevent or reduce the risk of their occurrence, such as checklists and guidelines. For example, over the course of two years, two patients in my sample had the wrong lens inserted during cataract surgery. Though the locus of the errors differed in each instance, controls to prevent the occurrence of such errors were present and were either not used or did not work.

> *"… the Consultant Ophthalmologist went into the adjoining room, opened the cupboard and selected a [lens of a particular power]…Prior to the procedure, the Operating Department Practitioner performed the 'Time Out' phase of the checklist during which the patient's name, Date of Birth, [Unique identifying number] and correct surgical site mark was confirmed … the Consultant Ophthalmologist was asked if they had chosen the correct make and power of Intra Ocular lens … The ophthalmologist confirmed they had picked the lens and written the model and power of the lens on the white board in Theatre, in accordance with the protocol in place. There was no 'visual' check performed at*

this time in respect of looking at the lens packaging alongside the power of lens documented in the medical records [resulting in the wrong lens being used]." (Source C-26)

"In line with the Intraocular Lens Protocol, the Ophthalmic Fellow circled their lens choice (lens A) on the biometry form. The lens which the Ophthalmic Fellow should have circled, (lens D) was in the box directly adjacent to (lens A). The circling of lens A was done in error by the Ophthalmic Fellow." (Source E-52)

The third category of error identified was perceptual errors (nine references, eight incidents). These errors were due to wrong information perceived by staff. Such errors were visual in nature, with important clinical information being missed or misinterpreted by staff. Medication prescribing and administration and reporting of radiological imaging were activities susceptible to such errors. An important consideration made when perceptual errors were detected was the influence of external factors (such as design issues, environment, mental condition of the operator) on the occurrence of the perceptual error.

"At 18:00 the patient was administered an evening dose of insulin by Nurse- B who had checked the medication with an agency nurse. It was recorded … that 64 Units had been given. Both nurses …misread the prescription, reading 6U as 64…they did not recognise that an error had occurred… In other words what the nurse thought they saw, wasn't what was actually written because their mind constructed a different pattern with data." (Source E-18)

"The chest x-ray … was reviewed which showed a left upper lobe nodule that was a likely cancer. This was missed at the time of initial reporting by the radiologist…The incident occurred due to an error of individual perception on the part of a locum consultant radiologist operating within their regular field of practice. The lung cancer was mis-reported…. interruptions may have disrupted the individual's concentration" (Source E-44)

4.2.2.1.2 Lack of compliance

Unsafe acts also included violations, which were distinct from the three subtypes of errors discussed above. Violations or instances of poor compliance with established rules and norms comprised intentional departures from accepted practice.[70] They were of two broad types:

1. Routine violations: This category included those practices that had become routinised as workarounds (bending the rules),
2. Exceptional violations: This category included seemingly one-off departures from accepted practice, which would generally not be acceptable by peers and seniors according to the investigation report. I identified violations in 47% of incidents (120 times across 59 incidents).

I identified routine violations (79 references, 46 incidents) more commonly than exceptional ones (41 references, 30 incidents). Routine violations involved poor documentation practices and non-compliance with written policies and guidelines. In neither case were rationales for such work arounds explored in investigation reports.

> *"The standard of record keeping whilst Ms X was on ward [AB] and prior to the caesarean section was poor, with the majority of documentation within the maternal notes being retrospective."* (Source E-12)

> *"…the red tags holding the bundles of swabs together were not routinely included in the swab counts at the time of the incident. This requirement is outlined in the Trust's Swab Policy and has been included for some time, certainly when the Lead Nurse for Theatres sent an e-mail dated [a few months before] asking colleagues to disseminate the revised policy."* (Source D-45)

Exceptional violations related to failures to perform critical job activities, such as responding to emergencies or acting upon results in a timely fashion. The tone of the language used in the investigation reports enabled me to make a judgement regarding

whether violations were routine or exceptional. For instance, use of words such as "unacceptable" gave a clear notion of the seemingly unjustified, thus exceptional nature of the action or inaction. Despite the gravity of such violations, none were found during the investigations to have proceeded from intent to harm the patient. As with routine violations, the reasons underpinning those deviations from expected practice were not explored in the incident reports.

> *"The intravenous fluids were prescribed by the [Registrar] at 06.45hrs but these were not commenced by the Registered Agency Nurse. The Agency Nurse indicated on handover to the Day Shift at 07.30hrs that they could not locate a drip stand to do this. It is reported that drip stands were available on 3 vacant beds in the same bay and some mobile ones were available in the storeroom. It is unacceptable that the prescribed fluids were not administered for such a prolonged period of time."* (Source D-47)

> *"There was a twelve-hour delay in reviewing the x-ray and this is clearly unacceptable."* (Source C-39)

When exceptional violations were identified, investigators often used the "incident decision tree" tool. This tool, based on the work of James Reason,[205] was originally adapted by the National Patient Safety Agency[206] for the purposes of healthcare incident investigations. It provides an algorithmic method to determine whether incidents were due to a system issue or a human error. Importantly, it prompts investigators to consider whether the actions of staff were caused by more organisationally engrained factors, and whether another staff member of the same experience and qualification would act in a similar manner if placed in the same situation. There was a degree of arbitrariness regarding when the use of the incident decision tree was required (used 76 times across 55 incidents). Its use was not limited to instances of violations but was also used for other slips, mistakes and lapses.

> *"The Incident Decision Tree tool was used when reviewing the actions of this HCA and it was the view of the investigation team that the HCA showed poor*

judgement and that other HCAs would not act in similar way in the same circumstances." (Source D-03)

"The patient should have been reviewed [by the junior doctor] *an hour after commencing on the Sepsis pathway and prior to being transferred into [the Emergency Department Unit]. Following an interview with the junior doctor, conducted as part of the investigation process the doctor's performance was assessed by a senior ED Consultant and patient safety coordinator using an Incident Decision Tree."* (Source E-07)

4.2.2.2 Preconditions for unsafe acts

Preconditions for unsafe acts referred to those factors associated with the individual, team or the immediate environment where the individual or the team operates, which led to unsafe actions or errors.[69, 70] Such factors were identified in 72% of cases (223 times across 91 incidents). I identified five different categories of preconditions for unsafe acts: failures in communication, issues relating to team dynamics, environmental factors, patient factors and those issues relating to the mental and physical condition of the care providers. The frequencies of the different subcategories of preconditions for unsafe acts are outlined in figure 4.2. Each category is discussed below, with relevant textual excerpts.

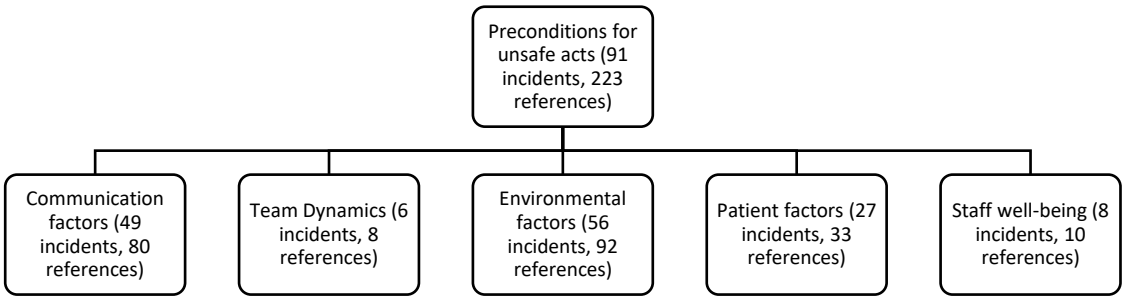

Figure 4.2 - Different types and frequencies of preconditions for unsafe acts

4.2.2.2.1 Communication factors

I identified failures in communication as a contributory factor when the *content* of the information exchanged was found to be deficient, the right people (*audience*) were not involved or the *outcome* of the exchange of information was not achieved. These factors have previously been described as key considerations when studying group interactions in complex social settings.[207] Communication failures were identified in 39% of all cases (80 instances across 49 incidents). The frequencies of each category of communication failure, their percentage occurrence compared to all incidents or references where communication failures were identified along with illustrative examples are shown in Table 4.6.

Type of communication failure*	**Number of incidents (%)**	**Number of references (%)**	**Illustrative example**
Audience	30 (61%)	41 (51%)	*"Initially contact was made with the speciality administrative and management staff; instead the Consultants should be contacted directly via switchboard."* (Source E-14)
Content	19 (39%)	23 (29%)	*"The referral from the GP did not mention the patient's history of TB* [Tuberculosis] *and so the radiologist was not aware of this when reporting on the x-ray..."* (Source E-08)
Outcome	15 (31%)	18 (23%)	*"However, despite efforts by the anaesthetist asking him subtly*

			to stop, the locum Consultant continued." (Source E-14)

Table 4.6 - Types of communication failures.

There were common examples of poor communication at all organisational levels (micro, meso and macro). Communication issues between members of the same team (micro- 46 instances, 31 incidents), such as shift handovers, were by far more common than those between members of different departments (meso- 24 instances, 19 incidents) or organisations (macro- 10 instances, 9 incidents). Failures in communication at macro level did, however, occur between Trust A and multiple other organisations, including primary care, other hospitals, private institutions and other emergency response services such as the police and ambulances. Lack of structures to facilitate the smooth exchange of information at all organisational levels was identified by the investigators as leading to the loss of information or the exchange of incomplete information.

> Macro: *"The investigation team identified there is currently no method of recording communication about referrals from other hospitals."* (Source D-05)
>
> Meso: *"It was also reported that a hard copy of the MRI report was sent to the named consultant; however, the named consultant did not receive this report."* (Source E-04)
>
> Micro: *"There is no evidence of any written or face to face handover between ED and [the admission unit] nursing staff. The investigation team has established that there is no formal process for handing over patients; this depends on whether an ED nurse accompanies the patient on transfer."* (Source D-15)

Even when existing structures to facilitate information exchange (such as discharge summaries, prefilled templates, handover systems) were in place, investigators identified failures in communication across all three organisational levels.

Macro: *"On examination of the handover patient record transfers Mrs XX's information was present on a handover sheet in June 20xx. However, this was declined* [by Trust A] *and returned back to* [private organisation N] *due to the lack of information provided. This referral should have returned the following week, but this did not happen."* (Source E-31)

Meso: *"According to the* [Acute Upper Gastrointestinal Bleed] *proforma the ED senior should have contacted the on-call Gastroenterologist and ITU if the blood pressure dropped below 90mmHg following 2 units of blood and reassessment, and before transfer to [the admissions unit]. ITU support was not requested until* [almost three hours later]. (Source E-21)

Micro: *"The weekly Consultant handover includes sharing information concerning new admissions/acute issues only, due to the high volume of patients on the surgical wards…in this case… [the patient's] ischaemic deterioration…was not communicated at these handovers."* (Source E-39)

In the instances when investigators probed into the rationales for these communication failures, a recurring finding was lack of training among staff members to use systems in place. Such training deficiencies were identified in relation to some of the most widely used tools in healthcare, such as the World Health Organisation (WHO) checklist.

"…It was believed that staff in the Children's Hospital had previously agreed to use [an electronic system] which informs staff on who is waiting for a bed, what their diagnosis is, what investigations they are waiting for, etc. However, although the [electronic system] is uploaded onto all of the Children's computers in [the Admission Unit], the staff had not been instructed on the use of [the electronic system]." (Source E-40)

"The team undertaking consent… had not undergone the required training in relation to consent or the WHO Checklist to meet the requirements of [the

trust] policies…There is no Education Lead currently... Therefore, no training needs analysis has been undertaken and there is no structured programme for ensuring that training needs are met." (Source E-05)

There were examples of communication failures at the micro level across professional boundaries (e.g. between nurses and doctors or between managers and nurses) and within the same profession, both horizontally (at the same level of the hierarchy) and vertically (across different hierarchical levels). Poor communication resulted in loss of situational awareness and thwarted the development of a shared mental model of evolving clinical situations.

"…it is evident that the decision (by the consultant) *to change from a grade 2 to a grade 1 caesarean section was not communicated effectively to all clinical staff involved. This resulted in some staff working at increased speed whilst others did not realise that there was an urgent need to deliver the baby as soon as possible. Some staff focused only on their role whilst others were multi-tasking. As a consequence, team working was not effective, and staff were uncoordinated in their approach."* (Source E-12 Ref 1)

"However, delays in the tasks allocated to midwives resulted in knock on delays in Ms X's transfer and lack of communication at handover meant the urgency for continued foetal heart monitoring and a medical review was not appreciated." (Source E-12 Ref 2)

4.2.2.2.2 Team dynamics

Though not often identified by investigators (5% of incidents), another noteworthy problem leading to breakdowns in teamwork were issues relating to team dynamics (eight references across six incidents). Difficulties in working together as a team emanated from ineffective leadership from staff members in positions of power (such as consultants, managers, senior nurses), resulting in a tense working environment, lack of mutual support and ultimately affecting patient care both directly and indirectly.

"…managers and clinicians have struggled to work together effectively at times – this seems to go back to a number of occasions where the Trust / management team have wanted to disinvest the service (for strategic reasons) and the clinical team has wanted to expand the service. This tension seems to have forced a wedge between some members or functions of the team…A lack of whole team working contributed to the issues reported with some staff working in isolation and experiencing difficulty when trying to find support." (Source E-49)

"When [the patient] had severe bleeding … the investigation team considered there was a lack of team working when assessing and managing the wound problems. Surgeon (2) was initially trying to deal with the problem when surgeon (1) arrived and proceeded to attempt to control the bleeding. The patient transferred to theatre, but it is reported that surgeon (1) appeared to prefer to seek advice from outside the Trust rather than from experienced colleagues within [Trust A]. This was identified in a recent independent review of the […] service…" (Source D-29)

4.2.2.2.3 Environmental factors

I identified numerous (92 references across 56 incidents) environmental factors which were reported to affect performance of staff working at the sharp end of healthcare, contributing to human errors and unsafe situations. I categorised these factors as physical (27 references, 22 incidents), technological (30 references, 26 incidents) or cultural in nature (8 references, 8 incidents).

Physical environment factors included those issues relating to the settings within which patient care was planned or delivered. One recurring physical environmental factor was the high level of activity in clinical area(s) leading to overstretched resources. These circumstances happened especially when care was delivered out of hours and affected the capacity of individuals and departments to deliver care safely and promptly.

> *"The capacity situation on both sites was full within the assessment areas. The flow throughout the organisation was poor hence patients were waiting within the Emergency Department. The requirement for monitored beds was extremely high hence the option was considered for patient to be accommodated at site Y."* (Source D-06)

While clinical activity in a unit varied with the time care was delivered, other hazards pertaining to the physical environment were more constant. Examples include poor layout of clinical areas and uncomfortable working conditions (such as poor ventilation). These constraints promoted distractions and interruptions, thwarted staff's situational awareness and challenged staff's ability to deliver optimal patient care.

> *"The work environment may have had an impact on the Consultant's levels of concentration with some individuals finding the room uncomfortable, with the temperature being noted to be difficult to control. Interruptions within the hot reporting zone [an area where radiologists report urgent scans and x-rays] are very significant with regular disturbances made to radiologists in the middle of reporting sessions."* (Source D-36)

> *"The layout of [Emergency Department Unit] makes observation of the seating area difficult by the Nurse Coordinator and there is limited ability to observe the seating area from the nursing station"* (Source E-51)

Technological factors were divided into three broad categories. The first subtype related to paper-based record systems, such as checklists and medical records. Trust A operated a primarily paper-based medical documentation system, which presented numerous challenges identified in the investigation reports. In particular, issues with their availability when needed and the ease with which they went missing were highlighted.

"Records should have been made available to [the unit] and would have explained the issues that the patient had been experiencing in the run up to his holiday. In this case only part of the records were provided (blood test results only) ..." (Source E-41)

"The [patient's] clinical condition and the management plan were discussed at the … multidisciplinary meeting…However, the pink proforma which is completed as a result of the meeting was not filed in the notes." (Source C-10)

Some paper-based checklists and questionnaires, even when used appropriately, were found to be deficient in content. As a result, they did not fulfil their purpose as safety barriers, highlighting potential gaps in their design.

"The equipment was successfully swapped over, but the theatre ECG electrodes were not removed. This was an oversight during the checking process as there is no prompt on the MRI safety questionnaire." (Source D-04)

The second subtype comprised problems pertaining to the design and usability of software. A recurring theme was the multiplicity of electronic systems in use across the NHS, compounded with the lack of interoperability between these systems in use in different hospitals. There were variations even in the use of software in different specialties within the same trust, making the transfer or retrieval of vital clinical information onerous and at times impossible.

"The investigation team identified the difficulty of obtaining the MRI images from another hospital due to non-compatible IT systems." (Source D-05)

"If a patient has a pre-existing medical condition, information would be gathered by the ED staff using the discharge letters on the [electronic system A]. However, cardiology letters are currently not kept on [electronic system A] but are stored on a separate… drive." (Source E-40)

The third subtype included issues relating to the design and usability of medical devices and other hardware required to assist healthcare practitioners in planning and delivering healthcare. These issues, such as poorly designed equipment, were beyond the remit of the organisation itself. For example, the statement below was quoted almost verbatim in at least two incidents in the intensive care unit.

> *"An IVAC 597 volumetric infusion pump was used in this incident…One of the issues with this piece of equipment is that it is easy to programme incorrectly, exacerbated by the fact that when the equipment is first switched on, the screen displays the rate previously programmed (which could be 100 due to intravenous fluids being administered via this device). There is no alarm system to indicate to the user that an error in programming has been made…"* (Sources C-19 and C-21)

Other design issues had in fact been previously identified as high risks both locally and nationally, but had not been addressed in Trust A.

> *"On the day of the incident, the nurse reported being distracted by multiple conflicting priorities and therefore was rushing to complete the request. This led to a human error of the nurse connecting the lines incorrectly…Epidural connections are compatible with IV connectors."* (Source D-33)

I defined local cultural factors as those issues relating to (usually) taken-for-granted rules and norms that staff used in order to organise and deliver care in a way that worked for them. These norms were widely accepted in the department where staff worked but occasionally led to unsafe practices, such as variations in the practice of double-checking medications and how the WHO checklist was used.

> *"The investigatory process has determined that it is not routine practice on ITU for two nurses to complete the whole administration procedure from start to finish* [recommended practice]. *The relevant medication is prepared and*

checked by two nurses, but if an infusion device is used, it tends to be programmed and commenced by just one nurse." (Sources C-19 and C-21)

"*The [surgeon] was not directly involved in the theatre checklist [WHO] process for this patient, as he was scrubbing for procedure in an adjacent area. This was not challenged by the nursing team as it had been standard practice within the service."* (Source E-05)

4.2.2.2.4 Patient factors

Patient factors were identified 33 times across 27 (21%) incidents. I explored three broad sub-themes. First, patients' non-compliance with recommended care was a particular challenge in some incidents. Sometimes non-compliance was the result of patients' impaired judgements due to concomitant conditions (such as mental health issues).

"The patient was showing signs of paranoia towards the ward team and would not consent to all observations or investigations being performed." (Source E-37)

"Whilst it was agreed that the fact that the patient was intoxicated made him at a higher risk there was nothing else that made him high risk and there was no evidence that the patient had attempted to get off the trolley or climb over the bed rails prior to his fall." (Source D-01)

Second, patients' disease complexity and severity contributed to error-prone situations and were obvious from the investigation reports. Similarly, atypical presentations of certain conditions contributed to diagnostic errors being made. In such situations, investigators used evidence from subject experts to pass a judgement on whether such patient factors, if present in a different scenario, would lead to the same mistakes by a different practitioner.

"The patient had an atypical presentation of pulmonary tuberculosis Therefore the respiratory physician felt that a diagnosis of sarcoidosis was much more

likely. Laryngeal tuberculosis is extremely rare and so was not considered… It is thought that colleagues of similar experience would probably have taken the same actions." (Source E-08)

A final recurring theme among patient factors related to language barriers and how they contributed to episodes of miscommunication between members of staff and patient. Such episodes were present for different aspects of care, from communication of basic history to instructions relating to management. Interpreting services were available, though not always used, and at times not appropriate for the clinical context.

"There appear to have been particular difficulties in communicating the technique of pushing [during labour] and this will have had an impact on the perceived lack of maternal effort during both the active pushing stage and the attempted forceps delivery…Telephone interpreting is clearly not suitable for a woman in the 2nd stage of labour and it is not always possible to access a [female] face to face interpreter at short notice." (Source E-28)

4.2.2.2.5 Staff well-being and preparedness for work

Factors relating to the well-being of staff and how well-prepared they were in performing their tasks were identified in eleven instances across eight incidents. Investigators commented on self-reported levels of fatigue or stress of staff members at the sharp end, even if they were not deemed a direct contributory factor. When such factors were deemed contributory, investigations sometimes identified reasons for stress or fatigue linked to the work context, such as the operational workload and isolated work-related events.

"The ED was experiencing very high inflow during the evening…Additionally, a [member of staff] had been unexpectedly brought into the department in cardiac arrest… which inevitably adversely impacted on the psychological well-being of the ED staff in the department after this time." (Source D-47)

> *"RN1 [registered nurse 1] described how they were trying to deal with multiple demands such as phone calls from the [ITU] team trying to discharge additional patients, patients requiring assistance with their stoma bags, no linen delivery, another patient's [Patient Controlled Analgesia] had run out and needed changing. It appears that RN1 was subject to mental overload at the time of the incident… This led to the inadvertent erroneous connection of the epidural line to the central line."* (Source D-33)

Failure to maintain proficiency and competency through compliance with mandatory and essential training exercises was only rarely identified among the contributory factors (five references across four incidents). When identified, investigators commented on how widespread such non-conformity with training requirements were, though the reasons for such non-conformity were not identified in the reports.

> *"All clinical staff are required to complete [Mental Capacity Assessment] e-learning training. This is essential to job role training and is linked to performance objectives at appraisal. The investigation team identified that not all the ward team have completed this training and this forms part of the recommendations for this report."* (Source E-37)

4.2.2.3 Supervisory factors

Supervisory factors relate to those decisions and actions made by members of staff in positions of power at a departmental level, which adversely affect performance at the sharp end or the organisation and delivery of healthcare.[69, 70] These factors were found to overlap with other contributory factors, e.g. a senior consultant's failure to communicate changes in policies might also be classed as a communication issue. Of the five broad categories of contributory factors, supervisory factors had the lowest frequency (73 instances across 40 incidents). Unsafe supervision was deemed to be due to (1) inadequate level of oversight, (2) inappropriate planning, (3) supervisory violations and (4) failures to address known problems, as shown in figure 4.3.

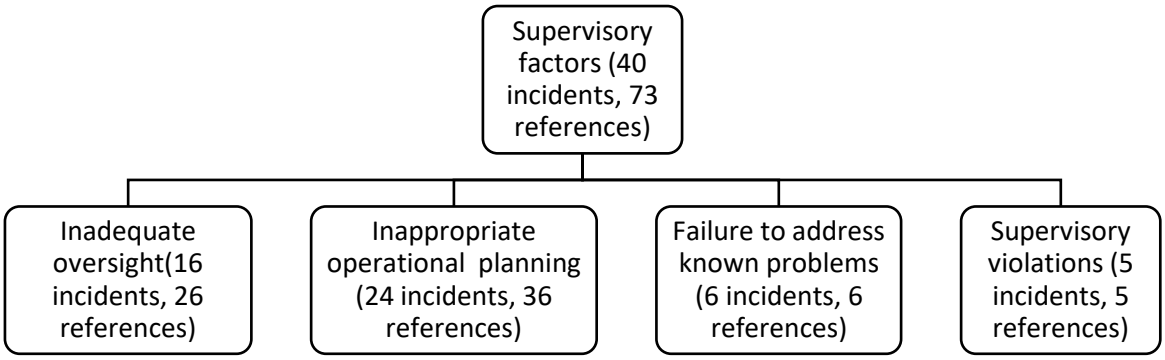

Figure 4.3 - Different types and frequencies of supervisory factors.

4.2.2.3.1 Inadequate oversight

I identified 26 references relating to inadequate oversight by staff in positions of leadership across 16 (13%) incidents. These instances were particularly an issue when members of staff with lesser experience, such as junior doctors, were left to their own devices to deal with problems requiring senior input, especially out of normal working hours. Investigation reports did not comment on whether in-person senior clinical reviews were sought by junior members of staff and declined by seniors. Instead, the language in the reports used implied that senior staff members felt that advice would suffice.

> *"…the patient was transferred to the Surgical Assessment Care Unit …and started to deteriorate… Her review was undertaken by a junior doctor, who did inform a senior colleague… However, given the severity of the patient's deterioration, it was considered that the junior should have been supported further by a senior clinical review."* (Source E-14)

> *"During the night, SpR A contacted Consultant (4) on 5 occasions with concerns regarding Mrs X, her pain, the fall in her haemoglobin, the development of*

(Disseminated Intravascular Coagulopathy) *and the activation of the Major Haemorrhage protocol and yet Consultant (4) did not come into the hospital until 09.00hrs when Mrs X was already in Theatre…"* (Source E-35)

Other examples relating to poor oversight centred on inadequate training or induction. Baseline assessments of skills and training needs of staff were not always done, in particular when local management had to deal with other pressures, such as staff shortages and high workloads.

> *"… the locum registrar…was shown briefly round the department and told the basics about how to use patient flow system. His recollection was that this brief induction lasted for only a short period at the start of a very busy night shift."* (Source C-09)

> *"There was no documentary evidence of the member of staff having been assessed as competent to carry out scans independently…It was highlighted to the investigation team that on the second week of joining the Trust, the Sonographer was put in a situation whereby he was scanning independently, without supervision, due to shortage of Sonographers because of sickness level within the department."* (Source E-43)

4.2.2.3.2 Inappropriate operational planning

Inappropriate operational planning by local management or those in charge of a team or department was identified as a contributory factor in 36 instances across 24 (19%) incidents. Lack of or poor planning led to staff on the front-line being overloaded with work and created unbalanced teams, ultimately leading to hazard-prone situations arising, sometimes despite warnings from front-line staff at the receiving end.

> *"…Nurse B was supporting two other members of staff. The baby being cared for by the nurse who was being supervised by Nurse B, was ventilated….and required a lot of additional interventions from Nurse B. At the time of being allocated to support the nurse in supernumerary period and the nurse who was undergoing*

additional training, Nurse B challenged the decision making but the shift leader felt the allocation was appropriate." (Source D-33)

Investigation reports also highlighted instances where planning failed due to problems with written policies and guidelines which fell or should have fallen under the remit of local management. Such documents were inexistent, imprecise or not communicated to staff on the front-line.

> *"Without the lactate being known the other symptoms would have met the criteria to trigger the interim ED specific guidance, which was not in place at the time, but is now in place. If the guidance had been triggered, she would have received fluids, intravenous antibiotics, observations (early warning score) monitored every 15 minutes within the first hour of the sepsis being identified and discussion with an ED Consultant or senior middle grade doctor."* (Source D-09)

> *"Following a review of [the policy on swabs, needles and instruments in the operating rooms], it was apparent that the wording was not explicit in respect of the surgeon and scrub practitioner pausing and double checking to ensure they have the correct implant, prosthesis, plate or screw."* (Source C-04)

Another form of poor planning included wrong decisions about where care could best be delivered for certain patients. Different clinical areas in Trust A were equipped to provide varying levels and types of care across three main sites, each of which provided different specialty services, though some specialties (such as inpatient mental health) were not provided by the organisation. Thus, it was of crucial importance that patients be admitted to the correct clinical area to ensure timely delivery of care. Such decisions regarding admissions were often made by a senior doctor or a senior member of the nursing staff.

> *"The patient was admitted to Ward XX at 15.00hrs at which point a bed was not available. At 17.20hrs the patient was transferred to Ward AB as this was*

where a bed was then available. Ward AB is a short stay ward and although familiar with consent…and the Safer Surgery checklist, they do not usually take patients undergoing [Coronary Arterial Bypass Graft] procedures." (Source E-48)

"When the ambulance service called [Crisis Response Team] they were directed to take Mr X to [the Emergency Department]. It is suggested by the Investigation team that the correct advice [from the senior nurse] with the history available should have been to take him to the Hospital J [specialist mental health unit] for [mental health] assessment, as this would have ensured that he was located in the appropriate speciality from the outset." (Source E-51)

4.2.2.3.3 Supervisory violations

Based on the findings of the investigation reports, I rarely identified reports of intentional departures from expected practice by staff members in positions of power in the investigation reports (five references across five (4%) incidents). This finding is explored in more details in the discussion section below as I believe it is a result of shallow investigations by investigators as opposed to accurately reflecting their true frequencies.

When such occurrences were recognised, they appeared to be routine (instances when rules were bent) rather than exceptional violations (one-off departures from accepted practice). Examples include failures to comply with established policies, and represented decisions made because of competing priorities (such as the busy nature of the job as the head of service for a department), thereby acting as workarounds.

"The [head of service] had reviewed and approved the locum Consultant's CV as part of the recruitment process, however had not met and discussed the locum Consultant's competency or experience in person since he had commenced employment in the Trust. This was considered to be a root cause of the investigation, and a serious service delivery failure." (Source E-14)

4.2.2.3.4 Failure to address known problems

Another rarely identified (six references across six (5%) incidents), yet hazardous issue was the failure by departmental managers and senior members of staff with supervisory responsibilities to address previously identified problems. As with many other identified hazards, the investigation reports were silent on the reasons why remedies were not put in place when these problems were first detected. Instead, reports took a more forward-looking line by stating that actions were being put in place to prevent recurrence.

> *"Within Ophthalmology, there are historical issues regarding the oversubscription of patients to the availability of appointments. Measures are in place to deal with these and improvements are underway with significant progress."* (Source E-13)

> *"Prior to this incident, another patient had attempted to harm themselves by hanging in the same toilet, this attempt was unsuccessful, and patient came to no harm, but the incident was a missed opportunity to recognise the risks posed by that environment and to prevent this incident."* (Source C-32)

4.2.2.4 Organisational factors

Organisational factors are actions and decisions at the blunt end of the organisation.[70, 208] Such factors may directly or indirectly affect operational choices made by local management within individual departments and impact on performance of front-line staff at the sharp end.[69, 70] In this study, I identified organisational influences 115 times across 59(47%) incidents. They were further distinguished into three broad causes, pertaining to issues secondary to: (1) resource management, (2) operational processes and (3) organisational culture, as shown in figure 4.4.

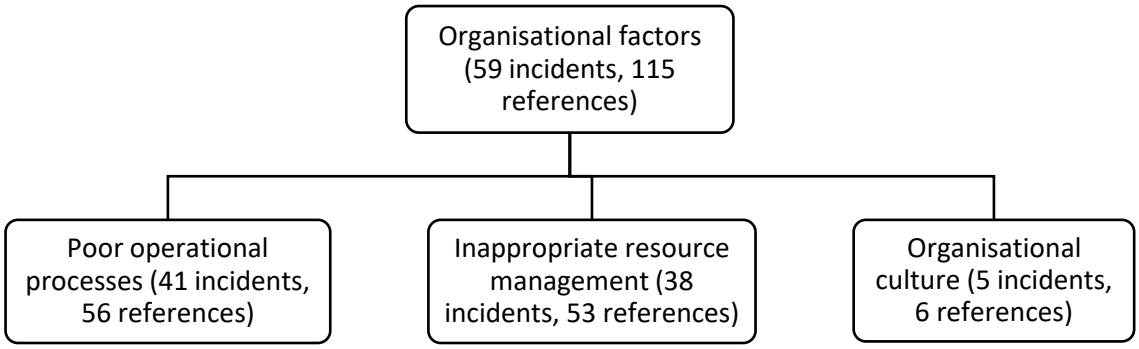

Figure 4.4 - Different types and frequencies of organisational factors

4.2.2.4.1 Poor operational processes

Numerous instances (33% of investigation reports) were identified where decisions, rules and assumptions ultimately undermined how the organisation functioned and frustrated its ability to deliver on goals on the front-line (56 references, 41 incidents). Issues relating to poor operational processes were not always made explicit in the investigation reports but were alluded to indirectly.

Investigators pointed to the lack of guidelines and standard operating practices within the trust to cover certain routine scenarios and emergency situations. Such written procedures were deemed necessary by investigators to formalise how care was meant to be organised and delivered.

> *"There is not a clear policy to assist staff in their decision making to advise diversion to ED or to make their way to* (Obstetric Assessment Unit) *in periods of high activity although it is worth highlighting at this point that additional chairs for early assessment have now been made available..."* (Source D-08)

> *"There is no current process in place for the time critical transfer of sick adults, with such standard operating procedures (SOP) only in place for children under*

16 years of age (though this is still in early implementation). The investigation team concurred that consideration should be given to the implementation of a similar policy for adults." (Source E-50)

In certain cases, policies or procedures were available but some components were found to be unclear and impractical to operationalise, generating confusion and tension among staff at the sharp end.

"There was a general awareness of the RTT (referral to treatment) *Policy but the policy was described 'too difficult to follow' and did not give clear guidance on the management of the planned waiting list…To some extent, the difficulties between colleagues appeared to be generated by 'system' problems within the team including that of staff having unclear standards and not having defined responsibilities…complicated technical guidance as well as lack of general support"* (Source E-49)

Some organisational rules and practices had been in operation for a long time despite their perceived lack of effectiveness, and at times, deficient logic. Failures at this level resulted in lack of patient follow-up and poor continuity of care. In one case, due to the lack of a robust organisational system in place to ensure follow-up of patients, the onus was placed on patients themselves to ensure continuity of care.

"On further review, there appears to be some inconsistency amongst clinicians including the nurses about who retains clinical responsibility for a patient in ED whilst they are waiting for a transfer to a ward, especially at times of high activity and limited bed capacity." (Source E-40)

"The current system relies on active engagement from the patient to make contact via the telephone and there is no evidence that the patient did this in order to book the test…At the time of the incident there were no procedures in place to follow up patients that do not make contact with the administrative

team and once removed from the waiting list there is no further contact with the patient unless they contact the team or are re-referred in." (Source E-01)

4.2.2.4.2 Resource management

At the organisational level, I identified issues relating to resource management 53 times across 38 incidents, making up 30% of all contributory factors identified at the organisational level. These contributory factors related to factors concerning the inappropriate management of organisational assets, such as human, technological and structural resources. Issues recognised at the organisational resource management level overlapped directly with environmental preconditions for unsafe acts. The examples below demonstrate how decisions made at the blunt end could create unsafe working conditions.

I identified issues pertaining to human resources across multiple incidents (39 references, 30 incidents). While there were occasions of short-term staffing problems due to sickness or annual leave, inadequate staffing was mostly seen by investigators as a long-term problem that was known to the organisation. As a result, numerous recurring patient safety concerns ensued, such as lack of continuity of care, absence of overall responsibility for patient's care, unsafe workarounds, reduced supervision of junior staff, and high caseloads.

"Due to staff shortages, the standard for checking patients' drugs should take place at the bedside where patients' medicines are stored in a locked cupboard; however, as a result of a shortage of pharmacists, discharge medication is checked in the satellite/main pharmacy." (Source E-21)

"Due to changes of clinicians and reduced number of clinicians within the Rheumatology Department, the patient was being seen by different doctors at some outpatient attendances. This resulted in lack of continuity of care and probably lack of ownership of this patient's care." (Source E-02)

Emergency areas were particularly affected by suboptimal capacity. The lack of bed space for unwell patients during times of increased demands (such as in the winter), due to cost-cutting executive decisions, led to delays in patients receiving appropriate management.

> *"It was discussed during the investigation that there are no dedicated Level one beds within the General Surgical unit at [site A]. There previously was a six bedded Surgical Acute Care Unit which acted as a step-down unit for patients being discharged from ITU but also transferred in sicker patients from the wards for increased monitoring. Various trust restructures meant these six beds were reduced to three and amalgamated into another ward area."* (Source E-33)

Some of the identified contributory factors were intrinsic to the structure of the organisation, and how it was built over time. In particular, the division of the organisation into three geographically separated sites and multiple satellite units (some over 50 miles away from the main hospital site) was found to be contributory to adverse events across incidents. The geographical separation led to heterogeneity in practices of similar activities, delays, and at times lack of clinical reviews by staff covering multiple sites.

> *"As the team is based across 3 sites there was a lack of senior oversight and junior staff were therefore making decisions about removal of patients without a senior overview or involvement of clinicians."* (Source E-01)

> *"Patients from Trust A are dialysed in local dialysis centres across the network…These units are nurse led on a daily basis, with all patients having a named consultant from Trust A who regularly reviews their treatment in a dialysis clinic. If urgent clinical problems occur, staff can contact an on call renal registrar at Trust A for telephone advice or make arrangements for the patient to attend site A for a review. The distance from dialysis centre S to Trust A is a 140mile round trip making attendance for a review less convenient..."* (Source E-41)

4.2.2.4.3 Organisational culture

Factors relating to organisational culture included those referring to the shared ways of thinking, feeling, and behaving within Trust A.[209] These norms, rules and habits were not restricted to individual departments but were identified across the wider organisation. Based on the investigation reports, I identified these factors as being contributory to incidents six times across five incidents (4%). Such culturally engrained practices were tolerated or accepted as the norm, even when they created hierarchical barriers, inhibited the voice of front-line staff, or posed as hazards during the delivery of healthcare.

> *"…the [specialist nurse on duty that day] did not consider making the referral [to the vascular team] herself. It is now known that it was at that time acceptable for direct referrals to be made via the on call vascular administration registrar by nurses when required, but this did not happen… historically, referrals are only made by doctors."* (Source E-39)

> *"… it is common practice at [site G] for requests for echos to be Consultant to Consultant on a verbal basis. As a result, there are often no completed request forms for which the clinician undertaking the echo can refer to directly to ensure any questions are specifically addressed by the procedure…"* (Source C-10)

> *"In spite of RN 1 expressing her concerns that the staff would 'struggle massively' to manage the patient group with the remaining skill mix of staff, they were said to be overridden by bleep holder (1) [senior member of nursing team who decides on relocation of staff from one department to the other]. RN 1 stated that on this and other occasions, despite her experience and confidence, she often felt intimidated when instructed by bleep holders that staff had to be moved elsewhere."* (Source D-46)

4.2.2.5 Extra-organisational factors

Some factors were identified which lay beyond the remit of Trust A. Previous derivatives of the HFACS framework have not highlighted these factors, since the

highest tier of contributory factors it describes are those at the organisational level. There were eight instances where I deemed extra-organisational factors to be contributory to incidents across seven (5%) incidents. They included lack of availability of resources and limitations of national guidance.

> *"Due to the national shortage of radiologists the department uses locum staff. There are known difficulties in recruiting into vacancies. This is due to the specialisation of radiologists and recruiting into those specialties. There are currently three vacancies out to advert which have not been filled as there has been only one applicant to one of the specialist posts."* (Source E-44)

> *"The PEWS [Paediatric Early Warning Score] chart is currently under review within the Children's Hospital. It has been identified that the current PEWS chart, which is based on national guidance, does not currently include oxygen saturation levels or pyrexia or identify the severity of any abnormal observations."* (Source D-37)

4.3 Discussion

To my knowledge, this is the first time a framework based on HFACS was applied to serious incident investigation reports across different specialties to provide a high-level overview of contributory factors identified during incident investigations in a UK setting. Previous studies that have analysed incident reports as source data[80, 208] have involved their prospective use during the conduct of investigations[70] or have focused only on never events.[78] My work suggests that analysis of aggregated investigation reports using a human factors lens such as a HFACS based framework provides a robust method to capture common contributory factors, and identify priority areas for improvement.

The findings of this study suggest that most contributory factors identified in incident investigation reports arise from errors made at the sharp end of healthcare: *unsafe actions or errors* were detected in 79% of incidents and made up 40% of all contributory factors. I found errors occurring at the sharp end of care to be mostly

(63%) related to inadequate decision-making due to cognitive biases, poor judgement and poor understanding of logistics within the trust. Similar findings have been demonstrated in studies using malpractice claims data[210] and incident reports.[80]

Such findings are particularly concerning given that incidents relating to poor clinical decision-making are associated with serious patient harm.[211] The high frequency of errors identified at the sharp end also presents opportunities for targeted interventions to improve decision-making. But it is important to look beyond the apparent failures of specific individuals to the broader context and how it structures decisions and behaviours. Neuhaus et al. argue that the predominance of cognitive errors in stressful and dynamic clinical settings may be partly explained by the lack of specific training targeted at reducing cognitive biases and clinical reasoning in medical education.[80] While a wide variety of such interventions have been described in the literature, for example simulation,[212] clinical-decision support systems[213, 214] and the use of focused and timely feedback, their evaluations have often been limited to artificial settings.[215]

The high frequencies of factors detected at the sharp end may also be an artefact of the way investigations are conducted at present. Investigators may be more susceptible to identifying more easily visible and identifiable slips, lapses, mistakes and violations. Such an approach may have two unfortunate implications. First, it may promote the existence of a blame culture[216] which may manifest itself through the arbitrary nature with which tools such as the incident decision tree were being used, as shown in this study. Second, the focus on factors at the sharp end may come at the expense of the identification of organisationally engrained factors at the blunt end of care.[70] In a number of instances as described in the results section above, the rationales for actions of practitioners at the sharp end, such as the influence of managerial decisions were rarely explored. For instance, supervisory factors only made up 10% of all contributory factors (see Table 4.5).

Previous studies, using data from either completed incident investigations or staff-generated incident reports (which had not been formally investigated), also highlight

the low frequencies of contributory factors identified at the organisational (4-6%) and supervisory levels (1-8%).[70, 78, 208] Diller et al. suggest that such low frequencies represent a limitation of the use of the HFACS framework to the retrospective analysis of incident reports.[70] On the other hand, I identified organisational factors more frequently (20% of all contributory factors, present in 47% of all incident investigation reports), highlighting that a framework based on HFACS can be used to identify organisational factors retrospectively from incident investigation reports. The involvement of members of staff from different backgrounds (see Table 4.4), including those from a dedicated patient safety team whose focus was to improve quality and safety within the wider organisation, may partially explain the higher frequency of organisational factors identified in this study.

Previous studies using frameworks based on HFACS have also shown that supervisory factors remain under-reported.[70, 208] This finding was reproduced in this study, with supervisory factors identified in relatively low frequencies (27% of all incidents). The lack of involvement of human factors experts (only present in 2% of investigations, as shown in Table 4.4) and the fact that investigation panels routinely included senior members of staff who usually operate in the department where the incident occurred, could be potential explanations. Prospective use of a contributory factors framework such as the HFACS when investigating and analysing incidents may prompt investigators to look for and identify more supervisory and organisational factors.

More than a third of incidents in my analysis included instances where staff were found to perform routine violations, such as poor documentation and non-compliance with written policies and guidelines. Barach et al. argued that such violations occur when trade-offs need to be made because of competing priorities, which are often related to production goals (such as not documenting a medical plan due to time constraints secondary to high workload).[217] This gradual process, where poor practices and standards become accepted by the wider community within a profession or within an organisation was originally described by Diane Vaughan when reviewing the Challenger disaster.[218]

Initially, such deviant practices may be without any associated significant harm, accounting for their normalisation.[218] Eventually, normalised deviance contributes to incidents by slowly nudging the healthcare system towards a state of higher risk, where eventually an adverse outcome ensues.[219] These findings are not unique to the organisation studied in this research. Similar findings were described in the Mid-Staffordshire and the Morecambe Bay investigation reports.[20, 116] To address such routine violations and further understand normalisation of deviance, Barach et al. argued that effective change needs to emerge from within local healthcare systems, as opposed to being dictated by regulators.[217] In the context of incident investigations, such changes can be achieved by engaging with front-line operators during investigations and when devising risk controls. The fact that junior doctors and nurses in non-management roles were involved in only 2% of investigations highlights the challenges ahead.

My study also suggests that particular attention should be paid to the role of environmental factors, identified in 44% of cases, as contributory to incidents. The environment within which medical staff operates is increasingly complex with multiple sub-specialties working together to provide care, a rising workload associated with the demands on a finite workforce, resources and capacity. I identified further environmental hurdles complicating the safe provision of care, such as the lack of integration between different electronic systems, missing information (e.g. paper records), poor user interface of electronic systems and equipment.

In order to understand such potential sources for error better, systems theory has much to offer. It suggests that safety can only be appreciated when all the interactions between different components of a system are studied together.[84, 153] As discussed earlier (see section 2.2.3), Leveson, a proponent of systems theory, argued that each component of a system maintains its stable state through feedback loops or constraints and adverse events results as a consequence of the loss of control of these constraints. Use of approaches based on systems theory, when investigating incidents,

such as the systems-theoretic accident model and processes[153] may allow a better understanding of the role of environmental factors in contributing to incidents.

An important finding of my study is the ongoing problem of poor communication as preconditions for unsafe acts or errors across different grades of staff, and at all organisational levels (micro, meso and macro). A common assumption is that the use of tools to facilitate communication, such as communication standardisation techniques (e.g. SBAR, Situation-Background-Assessment-Recommendation), electronic handover systems or checklists will automatically lead to improvements in communication. I identified recurring poor communication even when such tools were deployed: they do not necessarily lead to improvements in practice and outcomes without the presence of concomitant facilitators at the organisational and supervisory levels, such as role modelling, reminders and constructive feedback.[220, 221] Such tools are only effective if adequate usability testing have been conducted and staff adequately trained before implementation.[222]

Application of the original HFACS framework devised by Diller et al. to the investigation reports in this study enabled me to enrich the framework further with new potential contributory factors to incidents. An important group of factors, not previously identified in previous adaptations of the HFACS framework applied to healthcare data,[70, 78, 80, 208] is the influence of extra-organisational factors, such as national shortages of particular groups of professionals and equipment design, as contributory to incidents. These factors lie outside the remit of the organisation where the incident(s) occurred. Identified in only 5% of incidents, low frequency of extra-organisational factors may reflect the fact that such factors were not actively sought by investigators during investigations, as opposed to not being present as contributory factors.

This study has some limitations. First, the results of the study may not represent a complete overview of all the contributory factors to serious incidents, and their relative incidence. This is because the study involved the retrospective application of a HFACS based framework to incidents which had already been investigated using other

techniques such as the “five whys “and Vincent’s Organisational Accident Model (see section 2.2.2.2).[68] Consequently, some factors may not have been explored, leading to some silences, in particular those at the supervisory, organisational and extra-organisational levels. Diller et al. thus argue that frameworks based on HFACS may offer a more accurate representation of the contributory factors involved in incidents when applied prospectively during the conducts of investigations.[70]

Second, the dataset involved investigation reports from a single organisation. Such a sample frame may limit the generalisability of the results when compared to other studies which used similar frameworks. Nonetheless, the commonality in findings across these studies and the present one, such as the burden of communication and environmental factors, suggest reproducibility of similar findings in other organisations.

Third, only 20% of the data set included incident investigation reports which resulted in no harm, highlighting a potential under-representation of not only adverse events which did not cause harm to patients, but also near misses. As much as this figure may highlight a limitation of the findings in this study, it may also be the case that it highlights a bigger problem: the weakness in the reporting culture within the organisation and potentially other secondary healthcare organisations. Close calls or near misses comprise events which did not reach patients because of active recovery from potential harm by staff acting as the last line of defence or by chance alone.[223] Analysis of such events provides insight into the level of resilience of an organisation and provides a more transparent space for discussion of how an event unfolded and identification of contributory factors, given that staff do not have to deal with the trauma of patient harm. Numerous reasons have been purported in the literature to explain why such events may go unreported or are not prioritised for investigation, including poor understanding of what constitutes a reportable event, perceived lack of effectiveness of the incident reporting system and conflicting priorities.[223-225]

4.4 Conclusions and next steps

In this chapter, I explored the different categories of contributory factors reported across multiple incidents investigated over a three-year period from different specialties in a single organisation using a modified HFACS framework. Such a classification system may allow organisations to collect and analyse recurring contributory factors across different types of incidents. The findings of this study demonstrate that most contributory factors identified in reports were at the sharp end, such as unsafe actions or errors, relating to issues such as poor decision-making. This may to some extent be an artefact of how investigations are conducted or reported. Preconditions of the occurrence of unsafe actions or errors identified in the reports included miscommunication and the pernicious role of environmental factors within the complex and often non-integrated system healthcare workers were expected to operate.

An important contribution of the systematic use of a framework such as HFACS when conducting aggregated analyses of incidents or investigation reports is that it enables identification of priority areas for patient safety interventions, many of which may otherwise remain unidentified when incidents are analysed individually. In the next chapter, I describe the categories of solutions proposed by investigation teams following the conduct of serious incident investigations and explore the link between categories of contributory factors and solutions proposed.

5 What are the risk controls generated following serious incident investigations in a large acute NHS trust? Content and thematic analysis of action plans following serious incident investigations in a large acute NHS trust between 2013 and 2015.

5.1 Introduction

The serious incident investigation process aims to identify contributory factors to incidents, as described in Chapters 2 and 4. It is also intended to identify robust risk controls to prevent the recurrence of similar incidents. As discussed in Chapter 1, in the context of this thesis, a risk control is defined as an action proposed to address one or more factors contributing to a serious incident following a structured investigation. An example of a risk control could be, for instance, buying new equipment or retraining staff. However, as described in section 2.5.2, previous research has reported that the risk control process following incident investigations

remains weak and often does not lead to sustainable improvement. This chapter specifically aims to answer the following two research objectives:

1. To identify the range of risk controls generated following root cause analysis of serious incidents in healthcare.

2. To identify the types of risk controls formulated by investigating teams to address particular categories of contributory factors.

As discussed in section 3.2.4.3, I conducted two types of qualitative analysis on the action plans from serious incident investigations. First, I performed a content analysis of action plans from serious incident investigations conducted in Trust A between 2013 and 2015. I did this by applying a modified version of Veteran Affairs' hierarchy[10] (see Appendix E) to categorise recurring types of risk controls across multiple serious incidents according to presumed effectiveness. Versions of this framework have been used previously by researchers to categorise risk controls.[9, 151] In order to identify the types of risk controls formulated by investigating teams to address particular categories of contributory factors, I used the "matrix coding" function on NVIVO to code each risk control against a category of contributory factor which the risk control was aiming to address.

Second, I conducted a thematic analysis[183] of the action plans to identify recurring themes across identified risk controls. As described in section 3.2.4.2, each theme was inductively derived and sought to describe a family of risk controls aimed at operating in a similar manner to address hazards identified from the serious incident investigation reports. For example, I labelled a theme including the following risk controls: training, reflection, assessments and feedback as "improving individual or team performance". Based on the thematic analysis, I made inferences on the suitability of the proposed risk controls in addressing identified contributory factors.

5.2 Results

5.2.1 Content analysis of risk controls from action plans

Using content analysis, I identified 822 risk controls that had been proposed by investigating teams across the 126 incidents in my dataset, with a median of six risk controls (Q1-Q3: 3-9) per incident report. As shown in Table 5.1, the four most common types of risk controls proposed were training (168 (20%) references, across 62 (49%) incidents); audits or further investigations (148 (18%) references across 75 (60%) incidents); reminders (136 (16%) references across 63 (50%) incidents); and policy changes (77 (9%) references across 55 (44%) incidents).

Main types of risk controls	**Number of action plan (% of action plans where particular risk control proposed)**	**Number of references across all action plans (% of all risk controls)**
Training	62 (49%)	168 (20%)
Auditing/ further investigations	75 (60%)	148 (18%)
Reminders	63 (50%)	136 (17%)
Policy changes	55 (44%)	77 (9%)
Reflections	43 (37%)	69 (8%)
Enhanced documentation	31 (25%)	40 (5%)
Process changes	30 (24%)	38 (5%)
Staffing improvement	19 (15%)	33 (4%)
Checklists/ cognitive aids	23 (18%)	28 (3%)
Software enhancements	20 (16%)	20 (2%)

New devices	9 (7%)	9 (1%)
Disciplinary actions	9 (7%)	9 (1%)
Architectural or physical changes	8 (6%)	8 (1%)
No risk control	52 (41%) *	106**

Table 5.1 - Frequencies and percentages of the most common types of risk controls proposed by investigating teams across all incidents.

** 41% (52 incident reports) represents the number of incident reports which included at least one contributory factor without a corresponding risk control.*

*** The percentage of references of "No risk control" is not included as the overall denominator used when calculating the percentages of other risk controls only involves instances when a risk control was proposed.*

Using the modified VA hierarchy (see Appendix E), which classifies risk controls according to their presumed degree of effectiveness, most risk controls proposed by investigators in my dataset (611 references- 74% of all risk controls) would be classed as "weak". Risk controls of presumed "intermediate" effectiveness based on the hierarchy, were proposed 153 (19%) times. Finally, "strong" actions were the least frequent (62 references (7%)). These results are summarised in Table 5.2.

Risk controls ranked according to presumed effectiveness based on VA hierarchy of effectiveness	Number of incident reports (% of incident reports where particular category of risk controls proposed)	Number of references across all action plans (%)
Stronger risk controls (e.g. process changes, architectural changes, new devices)	45 (36%)	58 (7%)
Intermediate risk controls (e.g. enhanced documentation, software enhancements, checklists, staffing improvements)	77 (61%)	153 (19%)
Weaker risk controls (e.g. staff training, auditing, policy changes, reminders)	117 (93%)	611 (74%)

Table 5.2 - Frequencies of risk controls of different presumed "strength" according to the Veteran Affairs hierarchy of effectiveness.

Table 5.3 shows the main risk controls recommended by investigating teams to address each level and sub-level of contributory factors identified from Chapter 4. Risk controls recommended to address extra-organisational factors were policy level changes (50% of instances) and further auditing or investigations (38% of instances). No changes were recommended for 20% of identified organisational factors. When organisational factors (issues with operational process, resource management and organisational culture) were identified, 20% were not followed by any recommended risk control. When risk controls were recommended by investigating teams for organisational factors, the most common ones were policy changes (15%), staffing improvement (15%) and process changes (10%). The most common risk controls recommended to address supervisory factors were policy changes (22%), staff training (21%) and audits and further investigations (14%).

For 24% of factors which I classed as “preconditions for unsafe acts” (such as the environmental conditions, poor communication, staff well-being, patient-related and poor team dynamics), no risk controls were recommended by the investigation team. Risk controls recommended to address preconditions for unsafe acts included auditing or further investigations (17%), reminders (12%) and staff training (10%). When errors (decision-based, skill-based or perceptual) were detected by the investigating team, the three most common risk controls recommended were staff training (30%), reminders (22%) and reflective practices (21%). Finally, when contributory factors relating to poor compliance were identified, the three most common risk controls recommended were staff training (29%), reminders (28%) and auditing or further investigations (14%).

HFACS contributory factors (n)	Main risk controls	N (% of contributory factors)*	HFACS contributory factors (sub-levels)	Main risk control	n, % of sub-level contributory factors
Extra-organisational factors (8)	Policy changes	4 (50%)			
	Auditing or further investigations	3 (38%)			
Organisational factors (115)	None	20 (17%)	Operational process (56)	Auditing	15 (27%)
	Policy changes	17 (15%)		Policy changes	13 (23%)
	Staffing improvement	17 (15%)		Staff training	5 (9%)
	Process changes	11 (10%)		None	5 (9%)
	Staff training	9 (8%)	Resource management (53)	Staffing improvement	14 (26%)
				Auditing/ further investigations	13 (25%)
				None	13 (25%)
			Organisational culture (6)	Reminders	3 (50%)
				None	2 (33%)

Supervisory factors (73)	Policy changes	16 (22%)	Inappropriate planning (36)	Policy changes	9 (25%)
	Staff training	15 (21%)		None	7 (20%)
	Auditing/ further investigations	10 (14%)		Process changes	5 (14%)
	Process changes	9 (12%)	Inadequate oversight (26)	Staff training	10 (38%)
	None	9 (12%)		Policy changes	5 (19%)
				Auditing/ further investigations	5 (19%)
			Failure to address a known problem (6)	Process changes	1 (17%)
				Policy changes	1 (17%)
			Supervisory violations (5)	Staff training	2 (40%)
Preconditions for unsafe acts (223)	None	53 (24%)	Environmental (92)	Auditing/ further investigations	24 (26%)

	Auditing/ further investigations	39 (17%)		None	17 (18%)
				Reminders	11 (12%)
	Reminders	27 (12%)	Communication (80)	None	24 (30%)
				Reminders	12 (15%)
	Staff training	22 (10%)		Staff training	11 (14%)
	Improved documentation	14 (6%)	Patient factors (33)	None	10 (30%)
				Staff training	3 (9%)
			Staff wellbeing (10)	Staff training	5 (50%)
				None	2 (20%)
			Team dynamics (8)	Audit	3 (38%)
				Reminder	2 (25%)
Errors (162)	Staff training	49 (30%)	Decision-based errors (117)	Staff training	42 (36%)
	Reminders	36 (22%)		Reminders	25 (21%)
	Reflection	34 (21%)		Reflection	22 (19%)

	Auditing/ further investigations None	30 (19%) 16 (10%)	Skill-based errors (36)	Reminders Auditing Reflection	12 (33%) 10 (28%) 9 (25%)
			Perceptual (9)	Reflection Staff training	5 (56%) 3 (33%)
Poor compliance (120)	Staff training Reminders	35 (29%) 34 (28%)	Failure to comply with policy (47)	Reminders Staff training Auditing	17 (36%) 12 (26%) 10 (21%)

	Auditing/ further investigations	17 (14%)	Inadequate documentation (29)	Staff training Reminder	8 (28%) 6 (21%)
	Policy changes None	15 (13%) 11 (9%)	Failure to carry out critical responsibilities (27)	Staff training Policy changes	12 (44%) 5 (19%)
			Failure to take appropriate precautions (8)	Reminders Staff training	5 (63%) 3 (37%)

Table 5.3 - Main risk controls recommended by investigation teams to address each category of contributory factor.

* total percentage did not amount to 100% as some contributory factors had multiple risk controls and some risk controls were recommended to address multiple contributory factors.

In the next section, I broaden the analysis by performing a thematic analysis[183] of the action plans to identify recurring themes across risk control, with a view of identifying "families" of risk controls.

5.2.2 Thematic analysis of risk controls from action plans

Across all the action plans, I generated seven themes, each describing a group or family of risk controls. As discussed above, each theme comprised a group of risk controls recommended by incident investigators and sharing similar characteristics, based on how they aimed to address identified hazards. The seven themes are shown, with examples, along with their relative frequencies and percentages in Table 5.4.

Themes	**Examples of risk controls**	**Number of action plans (%)**	**Number of references across all action plans (%)**
Improving individual or team performance	Training, reflection, assessments, feedback	82 (65)	246 (30)
Defining, standardising or reinforcing expected practice	New policies, checklists, reminders of policies	95 (76)	232 (28)
Further investigations	Audits, decision for risk controls deferred to other meetings	75 (60)	148 (18)
Improving working environment	Improve staffing, new devices, software enhancement	45 (36)	74 (9)

Improving communication	Standardised communication tools, software enhancements, improved documentation	42 (32)	63 (8)
Process improvements and redundancies	Simplify processes, double checks, forcing functions	36 (29)	50 (6)
Punitive risk controls	Cessation of duties, increased supervision, referral to regulatory body	9 (7)	9 (1)

Table 5.4 - Seven themes, each describing a group of risk controls, operating similarly to address identified hazards.

5.2.2.1 Improving individual and team performance

The most commonly occurring theme described risk controls aiming to improve individual and team performance (246 (30%) references across 82 (65%) incidents). These risk controls targeted deficiencies in how individuals or teams performed with a view to improving how they worked individually or collectively.

Risk controls featuring under this theme comprised primarily educational interventions (identified 168 (20%) times across 62 (49%) incidents). They typically consisted of training sessions targeted at both individuals who were involved in the serious incidents and occasionally groups of professionals who might benefit from the learning. Group-based training interventions were recommended, such as lecture or seminar-based sessions on pre-organised study days.

> Incident: A patient suffered from major haemorrhage and sepsis after evacuation of retained products of conception following a normal birth. There was a delay in recognising the signs of deterioration by the clinical team.

Action: *"Anonymised case to be presented at …study days for the education of the multidisciplinary team."* (Action plan E-35)

Training interventions focusing on individuals who had been involved in incidents took a variety of formats, dependent on the seniority of staff. Junior doctors and nurses were, for example, asked to complete e-learning packages or to have supervisory meetings with their seniors. Such focus on retraining and further supervision was primarily targeted at junior members of staff. When similar mistakes were made by senior members of staff, training interventions proposed took a more informal configuration, comprising feedback on performance from another senior member of staff such as the heads of service.

Incident: A junior doctor wrote "6u" when prescribing six units of insulin to the patient. The nurse interpreted the "u" as a "4" and administered 64 units of insulin to the patient who subsequently had an episode of hypoglycaemia. Guidance on insulin prescription clearly states that no abbreviation should be used.
Action: *"The clinician involved completes safer insulin e-learning package and electronic prescribing training as soon as possible."* (Action plan E-18)

Incident: A patient was seen by a junior doctor on admission and multiple senior doctors during his admission. They all failed to identify that the patient might have had a pulmonary embolus and instead focused their management of the treatment of sepsis.
Action: *"A decision was reached that it was safe to allow the clinician* (junior doctor) *to continue to work and that he should receive further training and consideration should be given to increased supervision."* (Action plan E-07)

Incident: A consultant allowed a registrar to perform an unsupervised evacuation of retained products of conception on a patient. The patient's consultant had not reviewed the patient's notes, thereby not realising that this could be a complicated procedure, requiring supervision (which would have

been obvious had he reviewed the notes).
Risk control: *"Individual feedback (on need for review of patient notes before deciding on management plan) to Consultant."* (Action plan E-35)

More novel and immersive educational methods, focusing on the development of technical alongside non-technical skills, such as human factors training, and simulation were rarely proposed as risk controls in the action plans (five recommendations across five incidents).

Incident: A newly appointed locum Urology consultant used an unconventional technique to insert a suprapubic catheter in a patient who eventually developed sepsis. Theatre staff recognised that the consultant was struggling but did not immediately raised their concerns.
Action: *"A working party to pilot interventions and an escalation process in urology theatres utilising human factors and key phrases* [to encourage speaking up]*."* (Action plan E-14)

Incident: A premature baby was delivered in a poor clinical condition and required resuscitation. There were issues with identifying the appropriately sized equipment for the baby during the resuscitation.
Action: *"Neonatal resuscitation simulation workshops focussing on the resuscitation and stabilisation of preterm infants to be increased."* (Action plan E-12)

As shown in Table 5.3, training-based interventions were used to address issues across four out of five levels of contributory factors (organisational, supervisory, preconditions for unsafe acts and errors/ compliance), though were primarily recommended to address hazards identified at the sharp end. *Unsafe actions or errors* that were commonly addressed using educational interventions were *decision-based errors* (36% of such errors resulted in a training-based action), such as inadequate monitoring of patients, poor clinical assessment and management or issues with *compliance* such as sub-standard record-keeping.

When training was recommended on its own to address latent factors (including those higher in the modified HFACS hierarchy, such as *organisational influences* or *supervisory factors*), it was not always clear how training would address the underlying contributory factors, other than acting as a mere reminder. In these cases, training might not address the underlying structural issues that had given rise to the incident.

> Issue: A patient was discharged back to a mental health unit from the Emergency Department, without a thorough assessment. The investigating team concluded that the fact that the patient was almost going to breach the four-hour wait target may have contributed to hasty decisions being taken by the medical team.
> Action: *"A few cases to be presented at Emergency Department Quality and Safety meeting of issues relating to patients who had been discharged close to the four-hour target."* (Action plan E-47).

Another means of improving individual performance proposed as a risk control involved reflective exercises. They were recommended in action plans 69 times (8% of all recommended risk controls) across 43 (37%) incidents. As shown in Table 5.3, they were more commonly recommended when unsafe actions or errors were identified. They typically comprised two inter-related parts: a supervision meeting with a senior or line manager, where the role of the member of staff in the incident was discussed and feedback given, and a written reflective piece on the individual's involvement in the incident which was logged in the staff's portfolio.

> Incident: A junior doctor failed to recognise a patient might have had a venous thromboembolic event and instead focused on treating the patient for sepsis. The patient was not prescribed further thrombo-prophylaxis before being discharged home (despite having recently had orthopaedic surgery and being at high risk of a thromboembolic event). This was not spotted by the discharging pharmacist.
> Action: *"The junior doctor who clerked the patient on admission, the*

pharmacist who carried medication reconciliation and the discharging consultant should formally reflect on their omission." (Action plan E-07)

Incident: A patient had a CT scan which picked up an incidental finding of a small lung lesion. He was reviewed by two surgeons for unrelated reasons; they both reviewed the CT scan results but failed to act on it.
Action: *"Consultant Surgeon B and Consultant Surgeon D to complete a reflective learning from this incident [with Head of service]."* (Action plan D-14)

Assessments, such as testing of staff members' practical skills, were rarely (four instances across four incidents) recommended as risk controls to improve individual's performance. When used, they were primarily targeted at members of the nursing staff to assess some of their core skills such as drug preparation and administration.

Incident: Nurse did not independently check the dose of Levetiracetam prescribed.
Action: "*Staff to be reassessed in drug preparation and administration."* (Action plan D-31)

5.2.2.2 Defining, standardising or reinforcing expected practice

This theme included risk controls that provide guidance on what the standards of care should be if they had not previously been defined or reinforcing expected practice if standards already existed. This strategy was identified 241 (29%) times across 96 (76%) incidents. As described by Vincent and Amalberti,[226] the essence of such a strategy is that safety depends on implementing standardised, evidence-based practices. The theme comprised interventions which aimed to remind staff of expected practice (reminders), changes to existing policies or the creation of new local policy documents (policy related changes) and checklists to operationalise reminders and policy related changes.

5.2.2.2.1 Reminders

On occasions, investigation teams identified that expected practice had already been defined and needed reinforcing through reminders (136 (16%) references across 63 (50%) incidents). Reminders of procedures, policies and expected or best practices were delivered through emails and at pre-organised meetings such as mortality and morbidity, governance and handover meetings. Email reminders (>90% of all reminders) were far commoner than face-to-face reminders.

> Issue: A patient was operated on the wrong toe. It was noted that the operating staff did not adhere to the safer surgery checklist during the operation.
> Action: *"Policy to be emailed to each relevant staff member within the department"* (Action plan E-05)

> Issue: An infant suffered an eye injury due to instrumental delivery. It was found that there had been communication issues during the delivery of the infant. Due to language barrier, the mother did not understand how and when to push during the delivery. No interpreting services were secured during labour.
> Action: "(Email) *communication to be sent to all midwives and clinicians reminding them of the appropriate use of interpreting services."* (Action plan E-28)

Reminders were used to communicate two distinct types of messages. First, as discussed above, they served the purpose of reinforcing local policies and procedures already in place. For example, basic expected standards, such as the requirement to keep contemporaneous and accurate documentation, were highlighted using reminders. However, the content of the circulated reminders was sometimes much less succinct and targeted, relying on staff to tease out whether it was relevant to them and what the lessons were.

> Incident: There was a power failure in one of the hospitals, leading to limited functioning of radiology equipment in the cardiac catheter laboratory. It was found that staff members did not know the contingency plan to instigate in such a situation.
> Action: *"Internal Incident plan to be widely circulated within department"* (Action plan E-27)
>
> Issue: A patient spent more than 12 hours in ED and there was incomplete documentation of the medical reviews that occurred during those 12 hours.
> Action: *"All medical staff to be reminded of the importance of documenting all patient reviews in the ED, in particular for those patients who are waiting for long periods in the department for inpatient beds."* (Action plan D-06)

Second, reminders were used to create staff awareness of errors and particularly high-risk practices that had come to light through individual investigations. Reminders were also used to inform staff of potential solutions, where available, to identified areas of risk.

> Issue: There was a delay in administering intravenous potassium replacement to a patient. Staff thought they could only administer potassium through an electronic rate-controlled infusion device.
> Action: "(Newsletters for) *raising profile of safe methods of administration of potassium to nursing and medical staff across our hospitals"* (Action plan D-12)

Despite the frequency of reminders, their effectiveness was questionable, as evidenced by the recurrence of the same contributory factors across incidents even when reminders had been issued following previous similar incidents. One example was that of recurring concerns regarding how promptly laboratory or radiology results were acted upon. In each case, investigation teams repeated the suggestion that staff be reminded of the "acting on results" policy.

Incident: A patient was found to have a shadow in the lung on a CT scan. The results were not followed up. The shadow turned out to be a cancerous lesion when the patient represented.
Action: *"Remind all clinicians of their responsibility in relation to the acting on results policy."* (Action plan E-36)

Issue: A senior doctor did not review the blood results of a patient in the Emergency Department. Only a junior doctor signed it off.
Action: *"All medical staff in the ED to be reminded of the local process/policy for the review of blood results in the ED"* (Action plan D-06)

5.2.2.2.2 Policy related changes

I identified changes to existing policies or the creation of new protocols and policies as risk controls 77 times (9% of all references) across 55 incidents (44%). Such actions were intended to standardise clinical management of particular clinical conditions or procedures (such as patient transfers, consenting).

Changes to existing policies or the creation of new policies were among the top two most common risk controls (Table 5.3) proposed to address hazards identified with operational processes (i.e. how things were done in Trust A) and were aimed at defining expected practice.

Issue: A patient who was referred for endoscopic investigations and did not respond to initial contact was removed from the waiting list by the administrative team without further attempts made to contact the patient and without informing the referring team, leading to a delay in follow-up.
Action: "*Standard operating procedure to be developed to provide consistency across all sites."* (Action plan E-01)

Policy changes or new policies were also recommended by investigating teams following the identification of unsafe acts or errors by healthcare practitioners, in particular when there was a risk of recurrence of such errors by other practitioners.

> Issue: A clinician (non-cardiologist) failed to advise a GP to refer a patient to a cardiologist following identification of the patient's cardiac murmur at an outpatient appointment. The patient developed heart failure a few years later and died.
> Action: *"Discuss the development of local clinic [outpatient letter] standards at the next board meeting."* (Action plan D-07)

In at least five instances, national guidance was already available, and the investigation team recommended tailoring the guidance to the specifics of the local context.

> Issue: A patient was admitted with signs of sepsis but did not receive timely treatment in the hospital.
> Action: *"Current trust sepsis guidance is being redesigned"* (Action plan D-09)

5.2.2.2.3 Checklists

Checklists were also used (19 times across 17 incidents) as a means of operationalising new and existing guidelines and policies. In so doing, checklists became "mini" guidelines and policies, intended to act as cognitive prompts to ensure staff delivered evidence-based care.

> Issue: A patient who was meant to have constant one-to-one supervision was left unattended by a healthcare assistant for a short while. During the investigation interview, it became clear that the healthcare assistant's definition of what "one to one" meant was flawed.
> Action: *"A Standard Operating Procedure is developed for provision of 1:1 care. A pocket card/tag is designed and distributed to all wards that details the roles responsibilities of 1:1 care provider."* (Action plan E-09)

5.2.2.3 Further investigations

In certain instances (148 (18%) references across 75(60%) of incidents), investigation teams concluded that further reviews were needed before any risk control was recommended. Such reviews primarily took the form of audits of current practices. A

review of current practice before finalising risk controls might well be an entirely reasonable and legitimate modus operandi in order to further establish whether problems identified through the investigation were one-offs or were reflective of a wider endemic issue. What was not clear from the action plans was whether any changes were enacted following these further investigations.

Audits or further investigations were proposed as risk controls by investigating teams for two different types of problems. First, there were the easily auditable issues (e.g. adherence to particular guidelines), where data was readily accessible through patient records or electronic result systems. Such audits were used as measures of compliance with already accepted practices.

> Issue: A patient with a past medical history of tuberculosis was admitted with an abnormal lesion on his chest x-ray for further evaluation. He was initially treated for a chest infection on an open ward though further investigations revealed that the patient had tuberculosis. The team had not documented that the patient had tuberculosis in the past, thus this diagnosis was not considered, and the patient was not isolated before confirmation of the diagnosis.
> Action: *"Documentation to continue to be audited through the monthly nursing metrics and following this incident investigation regular spot checks will also be carried out by the Matron and Charge Nurse."* (Action plan E-08)

Second, investigation teams recommended audits or further investigations when they identified systemic issues, such as problems with operational processes, staffing or technological issues. These reviews were recommended to establish the extent of the problem, and further validate the need for future risk controls given the significant resources which might need to be mobilised, and the extent of reorganisation that might be necessary to address such problems, as outlined below. However, the risk controls generated after these audits or further enquiries did not seem to be subject to the scrutiny of the investigating team.

Issue: The local ambulance service had recently decreased the number of paramedic crew and increased the number of non-paramedic crew for hospital transfers. A patient was admitted to the emergency department and required transfer to a cardiac centre. Since a non-paramedic ambulance crew attended for the transfer, a nursing escort was requested but there was a significant delay in getting one. The patient ended up waiting more than twelve hours on a trolley in the Emergency Department before being safely transferred.
Action: *"Issues relating to cross site ambulance transfers from the Emergency Department to be monitored and report to be produced to demonstrate current issues relating to changes in the local ambulance service provision".* (Action plan D-06)

5.2.2.4 Improving the working environment

Risk controls aimed at improving working conditions were identified 74 (9%) times across 45 (36%) action plans. These risk controls aimed to address factors at the latent end which did not always directly contribute to adverse events but were nonetheless regarded as unsafe by investigating teams. This theme comprised actions aimed at improving staffing levels, technological and physical infrastructure. Each of those three subthemes are explored below, with examples.

5.2.2.4.1 Improvement in staffing levels and workforce balance

The most common risk control proposed to improve working conditions was improvement in staffing levels and workforce balance. It was recommended 33 (4%) times across 19 (15%) of incidents by the investigating teams. Improvement in staffing numbers was aimed at addressing factors where the number and skills mix of staff was found to be deficient, with the rationale that such changes would decrease workload and prevent staff from committing errors. Recruitment of permanent staff was recommended where possible by investigators, but they recognised that there might be instances where temporary staff through locum banks or agencies would be required.

> Issue: A patient who was at risk of falls, sustained a fall at night on a ward. It was found that this ward was short-staffed, despite funding available for recruitment of nurses.
> Action: *"Staffing levels to be increased to two registered and one healthcare assistant, supplemented with bank/agency staff as necessary.*" (Action plan D-16)

Investigators acknowledged that improvement in staffing numbers was not an easy risk control to implement. For example, evidence from incident reports and action plans suggested that the problem of poor staffing had been recognised prior to the occurrence of incidents yet could not be solved.

> *"Within Ophthalmology there are historical issues regarding the oversubscription of patients to the availability of appointments. Measures* [i.e. recruitment of ophthalmologists] *are in place to deal with these and improvements are underway with significant progress.*" (Action plan E-13)

In such circumstances, when simply increasing the number of staff in a department was not deemed feasible or enough to solve issues regarding workload, investigators recommended risk controls which were not necessarily their first choice such as the outsourcing of care to private suppliers.

> Issue: A patient was started on topical eye steroids. She had multiple follow-up appointments cancelled by the organisation due to lack of staffing. When she was seen 10 months down the line, it was noted that she had suffered from drug-induced eyesight damages.
> Action: *"Further outsourcing of a large number of patients to an independent provider … who have been instructed to see all patients on the follow-up waiting [list]."* (Action plan E-13)

5.2.2.4.2 Improved technological solutions

Another means that investigating teams recommended for improvement to working conditions was better and easier access to technology. Investment in new devices were recommended as risk controls in nine (1%) instances across nine (7%) incidents. Given the costly nature of some technological solutions, decisions regarding their funding had to go through bureaucratic hurdles, such as reviews by other layers of management.

> Issue: A sonographer took incorrect measurements of a foetus' nuchal translucency thereby underestimating the foetus' risk of Down's syndrome. The ultrasound machine used by the sonographer was an old one which was due for replacement. Newer machines allow more accurate measurements to be made.
> Action: *"Business case made for machine [ultrasound] replacement at high specification, needs agreement by [department] who are responsible for funding."* (Action plan E-16)

There was evidence that such "red tape" and consequent delays frustrated the organisation's ability to address identified risks in a timely fashion, leading to the recurrence of similar incidents. Three months after the incident described above, a similar one recurred.

> Issue: A [different] sonographer performed the wrong nuchal translucency and crown rump length readings on multiple patients, leading to miscalculations in the risks of Down's syndrome. All the old ultrasound machines from the example above were due to be replaced by month X but were not. As a result, there were two different types of Ultrasound equipment within the department. The Sonographer was trained on the newer model but had been allocated the old machine for use which incorporates a different process for magnifying images.
> Action: *"The Trust is already aware of this issue and is in the process of replacing the older model of ultrasound equipment for consistency of*

equipment usage. Therefore, no further action is required on this factor." (Action plan E-43)

5.2.2.4.3 Physical infrastructural improvements

Risk controls aimed at improving working conditions also included investment in more expensive improvements in infrastructure. These largely physical and structural changes comprised interventions aimed at improving the built environment where staff worked, or care was delivered. Such risk controls were recommended by the investigating teams eight times (1% of all risk controls across all action plans) in eight action plans (6% of all action plans). When proposed, they were aimed at *organisational influences*, such as issues with resource management and capacity. Additionally, such types of recommendations did not seem to have resulted directly from the incident investigations but had been planned from before the incidents.

> Issue: A patient had a fall in the resus area of the Emergency department. It was found that the patient was in an area that was not visible from the nursing desk.
> Action: *"All cubicles will be visible in resus in new emergency floor."* (Action plan D-01)

5.2.2.5 Improving communication

I identified risk controls aiming to improve communication 63 (8%) times across 42 (32%) incidents. Improving written documentation was the most common risk control in this strategy, used 44 (5%) times across 33 (26%) incidents. Improved documentation was recommended to address issues relating to human error, most commonly *inadequate documentation* itself. Thus, the purpose of proposed improvements to written documentation practices was to enhance communication between staff and between departments to develop a shared understanding of patient's progress.

> Issue: A baby was transferred to a tertiary centre for ongoing management of sepsis and for an echocardiogram to be performed. The receiving team did not

> request for the echocardiogram to be performed after the baby was transferred. It was found that the receiving team did not have a standardised way of recording referrals received.
> Action: "*Document to be developed* [to record referrals from other centres]" (Action plan D-05)

Such actions sometimes took the form of improvements to forms used in clinical practice to make them more user friendly.

> Issue: A patient had the wrong optical intraocular inserted during a cataract operation. The wrong strength of lens was documented on the biometry chart.
> Action: *"Revision of the biometry forms to minimise the risk of selecting the wrong lens"* (Action plan E-52)

How staff were meant to improve their documentation practices was, however, not always clear. For instance, on occasions, action plans were inconclusive in terms of which action to take to improve record keeping and simply recommended a "review" of current documentations in place. As discussed above, the outcomes of such reviews fell outside the remit of the serious incident investigation process.

> Issue: A patient was brought to the seating area in the Emergency Decisions Unit to wait for a mental health assessment. There were numerous delays for the assessment and the patient walked off the unit and later that day committed suicide. It was found that there was limited nursing documentation for the duration of his stay.
> Action: *"nursing documentation to be reviewed to ensure that it is appropriate for patient needs and meets required standards."* (Action plan E-51)

Solutions to improve communication were sometimes already known in the trust but were not being used or were not used consistently. For example, the use of standardised communication tools such as SBAR (Situation-Background-Assessment-

Recommendation) was proposed as a risk control in one clinical area but had already been introduced previously.

> *"Re-launch of the SBAR tool at site L"* [Action plan E-12]

Investigation teams also proposed the use of technological solutions to improve communication between individuals, departments and organisations. Examples included electronic requesting of investigations, electronic note record systems, electronic rostering and electronic handovers. Such software improvements were often large scale, affecting multiple departments and requiring significant investments. Similar to physical infrastructural improvements discussed above, technological solutions were not recommended solely based on the incidents reviewed but had been planned for implementation since before the occurrence of the incidents.

> Incident: Several patients waited beyond their "guaranteed test date" for their investigations to be carried out. It was found that the manual scheduling system was particularly hard to navigate for staff members, leading to difficulties in staff knowing whether other staff members had already listed patients or not.
> Action: *"Endoscopy to continue working with [software manufacturer] to secure electronic scheduling within the service."* (Action plan E-49)

> Incident: A patient was due to have a repeat scan, which the consultant requested on a paper form, but the radiology department never received the form.
> Action: "*Roll out electronic system in outpatient departments within the trust for requesting tests and investigations electronically."* (Action plan D-14)

5.2.2.6 Process improvements

Process changes aimed to improve the safety of current working practices which had been found to be unsafe during investigations. Though they were often accompanied with policy related changes, actions falling under this strategy also included specific

and tangible changes to how work was carried out within the organisation, as opposed to simply making amendments or writing a new policy. I identified such changes 50 (6%) times across 36 (29%) incidents. Process changes took two different approaches. The first approach was aimed at simplifying current working practices, such as removing unnecessary steps in clinical or administrative workflows, standardising practices or centralising departments.

> Incident: Current policy gives responsibility to the perfusionist to check if a tube is negatively pressured during cardiac surgery and confirm with the surgeon. This is technically difficult as the tube is placed on the other side of the table to the perfusionist.
> Action: *"Change in practice to ensure it is the surgeon that makes a final tubing 'wet test' of the (cardiopulmonary bypass machine) just prior to connecting it to the vent."* (Action plan D-13)

The second approach espoused the principle of "defences in depth"[62] and aimed at improving safety by adding an extra barrier in work processes. Typically, it took the form of an additional step in how work was carried out. Notably, this extra layer of defence served differing purposes depending on the nature of the risk it was trying to address. There were occasions where the intervention chosen aimed at developing a shared mental model of evolving clinical and administrative situations. In others, the intervention sought to act as "forcing function" by engineering a layer of defence into electronic systems which could not be bypassed.

> Issue: The oncology assessment unit had difficulties in meeting capacity demand. In one particular case, a patient was asked to wait at home for longer than she should have due to the lack of beds within the unit. The patient's clinical condition started deteriorating at home before arriving in hospital.
> Action: *"Implementation of 2.30pm daily board round to identify discharges for the following day to ensure that [discharge scripts] and transport are in place for early discharge are ready."* (Action plan D-08)

5.2.2.7 Punitive actions

In the investigation reports, recommendations were rarely made for staff to undergo disciplinary actions. Such actions were recommended only nine times (1%) across nine (7%) incidents in instances when the investigating teams identified poor compliance with basic safety rules or where they deemed the standard of care delivered by individual members of staff to have been particularly poor. The nature of the disciplinary actions varied considerably, from reduced level of independent practice to referrals to disciplinary or regulatory institutions.

> Incident: A health care assistant failed to comply with instructions provided to them by the ward sister and did not provide 1:1 care to a patient who was deemed to be at high risk of falls. The patient subsequently had a fall resulting in a hip fracture.
> Action: *"The member of staff should be referred to disciplinary panel."* (Action plan E-09)

Disciplinary actions appeared to be recommended in a relatively arbitrary manner with apparently similar errors resulting in completely different actions. For instance, in two separate instances, two staff members missed the diagnosis of an ischaemic limb on different patients. In one instance, the investigating team recommended retraining, while in the other, they recommended referral to regulatory bodies.

> Incident: A patient presented with an acutely painful limb. The locum registrar who saw the patient thought it was due to nerve damage due to stretching exercises. A day later, the pain worsened and the patient was this time diagnosed of an ischaemic limb by the surgical team. The delay in diagnosis led to the patient losing his limb.
> Action: *"SpR to complete reflective account and share with Educational Supervisor or Appraiser…and undergo corrective training."* (Action plan D-20)

> Incident: A patient presented with an acutely painful limb. The ED consultant who saw the patient did not diagnose the patient with an ischaemic limb in a

timely fashion, resulting in the patient losing his leg. Instead he attributed the pain that the patient presented with to being due to a deep vein thrombosis. Action: *"The General Medical Council and recruiting agency will be informed regarding the actions of the Consultant in order for them to take action as appropriate."* (Action plan D-27)

5.2.2.8 No risk controls

The investigation team did not recommend any risk control for 106 identified contributory factors (15% of all contributory factors). Across the different categories of contributory factors, 24% of preconditions for unsafe acts, 17% of organisational influences, 13% of extra-organisational factors, 12% of supervisory factors and 9% of unsafe actions had no corresponding risk control. Table 5.5 below shows the distribution of all contributory factors with no risk controls. The Table is divided into the five broad HFACS contributory factors and sorted in terms of percentage of contributory factors with no corresponding risk control summarises these findings.

Modified HFACS contributory factors with no risk controls	N	% of contributory factors with no risk controls
Preconditions for unsafe acts	53	24
Communication factors	24	
Environmental factors	17	
Patient factors	10	
Staff well-being	2	
Organisational influences	20	17
Extra organisational factors	1	13
Supervisory factors	9	12
Unsafe actions	26	9

Table 5.5 - Contributory factors with no risk controls.

I identified two reasons why solutions did not seem to be proposed, depending on the type of problem identified. First, many challenges were large-scale complex problems, with no easy solution, such as lack of beds, overworked staff and increasing frailty and complexity of patients, as being particularly challenging factors to address. I did not code these factors as "extra-organisational" as they were considered by investigators in the investigation reports to be problems within the remit of the trust to solve, though I could not find a specific solution to these problems in the action plans.

> *"This is higher than average occupancy and longer than average waiting time indicating that the area was busy on that day. This may have impacted on the staff's ability to document repeated interactions with the patient."* (Source E-20)

> *"Mr XX had significant co-existing limited mobility and health conditions, increasing his vulnerability to clinical/physical deterioration."* (Source E-21)

> *"Due to the national shortage of radiologists the department uses locum staff. There are known difficulties in recruiting into vacancies."* (Source E-44)

Second, some of the problems required coordination with multiple departments, sites or organisations in order to identify potentially workable solutions. For example, investigators identified concerns with communication at the macro and meso levels, in between different department or organisations. Issues with technological infrastructure also required coordination with multiple actors such as other healthcare organisations or external agencies such as regulatory bodies, pharmaceutical and hardware companies.

> *"The investigation team identified the difficulty of obtaining the MRI images from another hospital due to non-compatible IT systems."* (Source D-05)

> *"On examination of the handover patient record transfers, [the patient's] information was present on a handover sheet on [date xx]. However, this was declined and returned back to [organisation AB] …This referral should have returned the following week, but this did not happen."* (Source E-31)

Conversely, contributory factors identified at the sharp end (unsafe actions) rarely (9%) had no recommended risk controls, suggesting that investigators saw them as more straightforward targets for intervention.

5.3 Discussion

In this chapter, I examined the different risk controls proposed by investigating teams in an NHS trust following serious incident investigations and their frequencies. A total of 822 risk controls were recommended in action plans following root cause analysis of 126 serious incidents (median: six per serious incident). I grouped the different categories of risk controls according to their presumed effectiveness based on the

modified hierarchy of risk control (Appendix E). Based on shared characteristics across interventions, I identified seven themes, each describing a family of risk controls. I explored which risk controls were proposed to address particular categories of contributory factors. The analysis offered several related insights into the quality of risk controls formulated following serious incident investigations in healthcare.

First, according to the modified hierarchy of risk controls, most (74%) of the risk controls recommended would be classed as weak, since they rely mostly on human agency to be effective. Overall, the most common risk controls proposed were training (20%), auditing or further investigations (18%) and reminders (17%). The two most common themes (improving individual and team performance and defining, standardising and reinforcing expected practice) targeted the sharp end of care as opposed to improving systems.

These findings mirror those of other reviews of incident reports and action plans from healthcare institutions in the US[17, 149] and Australia.[9] Hibbert et al. suggest that one of the reasons for the high frequencies of risk controls focusing on factors at the sharp end of healthcare is that incident investigators failed to identify pre-existing latent factors during their analysis,[9] suggesting that the weak risk controls recommended reflect the lack of depth of analysis during investigations. Combining with the results of Chapter 4, my findings would suggest that this may only be partially true. Investigators were able to identify certain latent factors (such as environmental factors) more commonly than others (concerns with organisational or departmental culture). Yet, the most common risk controls proposed in my study were still those aimed at correcting slips, lapses and mistakes. This finding suggests that there might be other constraints, beyond the quality of investigations, affecting the decisions of investigators when recommending risk controls. Based on a qualitative study of investigators from a range of high risk industries, Lundberg et al. labelled this problem as "what you find is not always what you fix".[36] Constraints such as cost benefit of implementing risk controls, the existence of cheap, temporary and potentially unsustainable solutions and managerial decisions were illustrative of this problem.[36]

Second, I identified an inherent tension in the action plans for investigators to get as close as possible to what they deemed to be ultimate "root cause" of incidents and a pragmatic need to recommend risk controls that they considered feasible and that could be presented to the trust's executive board and the local CCG. The unintended consequence was that risk management following serious incidents was at risk of being reduced to a "sticking plaster" exercise, which often resulted in easily achievable risk controls such as rewriting a policy or delivering a training exercise being recommended to address organisational problems. Such solutions may have merit in some instances. However, particularly when not well-designed or when an operational plan for implementation is lacking, they risk introducing further hazards. For instance, a previous study by Carthey et al. identified that the multiplicity of inaccessible and complex guidelines in existence in an acute trust contributed to further non-compliance amongst staff and created new areas of risk.[227]

Third, the action plans reviewed in this study highlighted the problem that, in response to serious incidents, Trust A was left to its own devices in generating solutions. The risk controls identified from this analysis consisted of local interventions situated within the remit and responsibility of either the department where the incident happened or the organisation itself. This approach might be adequate when trying to finetune processes that are already in place but may be less appropriate when trying to address large, complex and recurring problems faced by different healthcare organisations.[228] Problems such as lack of particular skills at a national level, lack of capacity in emergency departments, lack of interoperability of software, rising frailty and acuity of patients may require whole-sector coordination and action.[57] Unsurprisingly, I identified that when complex organisational, environmental and patient-related factors were identified, investigators often failed to identify any suitable risk control (see Table 5.5). Additionally, when they did propose recommendations, they were often non-committal and suggested further auditing and investigations. Based on the action plans reviewed, there was no evidence to suggest that the outcome of these further enquiries was necessarily fed back to the investigating teams. Such findings

question the ability of incident investigations to lead to significant organisational improvement.

Fourth, investigators consistently failed to explain how they expected proposed risk controls to address identified contributory factors. Successful interventions require understanding of the content of the intervention alongside a recognition of the enabling factors to successful implementation within a specific context.[229] Yet investigators did not generally offer a rigorous explanation of the theory-of-change behind the proposed risk controls nor a robust implementation plan when devising action plans. As a result, risk controls that did not address the underlying contributory factors (such as local training exercises to address sector-wide problems like breaches in the four-hour waits in the Emergency Departments) were formulated.

Action plans were generally richer in detail when describing the content of interventions and comparatively more lacking in information regarding the supportive and facilitating factors required for successful implementation of risk controls, such as the engagement of influencers like senior clinicians on the frontlines or managerial sponsorships. Consequently, action plans tended to be muted on the issue of sustainability of risk controls. The serious incident management process failed to integrate a robust risk control monitoring process to identify which risk controls were, over time, successful in reducing risk and which ones were not, leading to the same failing recommendations being generated across incidents (such as reminders about acting on results).

Fifth, risk controls aiming to discipline staff were particularly rare (1% of all risk controls), perhaps indicating that the focus of incident investigations at Trust A was primarily not to apportion blame, liability or punishment. The presence of disciplinary actions as risk control following incident investigations can be perceived by some to be a weakness. Multiple commentators and researchers on healthcare quality and safety have spoken about the importance of a “just culture” which considers broader systemic concerns when adverse events happen and describes a climate of trust where staff feel empowered to escalate safety related concerns and are clear about the

difference between acceptable and unacceptable behaviour.[60, 230-233] Such an approach has to be systematic, robust and reproducible. The findings in this present study would suggest that these criteria may not be met, as decisions regarding escalations to disciplinary proceedings were made inconsistently. As shown in section 4.2.2.1.2, even tools operationalising a "just culture" principle such as the incident decision tree (a tool providing an algorithmic method to determine whether incidents were due to a system issue or a human error) were deployed arbitrarily, and perhaps not in ways that account for the messiness of systems in which unsafe acts, including deviations from expected practices, occur.[216]

This study has some limitations. I retrospectively applied a framework to action plans from serious incident investigation reports to identify risk controls. This strategy may not have captured all the risk controls deployed in the aftermath of serious incidents as some may not be explicitly worded as such in action plans. An example, for instance is "leadership involvement", which is a risk control deemed as "strong" as per the Veteran Affairs hierarchy.[10] Though many risk controls would necessitate a degree of involvement from leaders for successful implementation, they were not explicitly worded in this way in the action plans. Future research could aim to use ethnography and interviews to study the full range of risk controls deployed in the aftermath of incident investigations. Second, similar to Chapter 4, I restricted my sample frame to a single organisation, which may limit the generalisability of these results.

5.4 Conclusion

In this chapter, I have identified that the most frequent risk controls formulated by incident investigators following serious incident investigations were training-based exercises, reminders, policy changes and further investigations. I have identified seven broad themes, each describing a group of risk controls which share similar characteristics based on their nature and how they aim to address particular areas of risk. When addressing risk, there was rarely an integrated coordinated and inclusive approach to risk management, resulting in a "sticking plaster" approach involving the formulation of risk controls to address mostly factors at the sharp end of care, within

the remit of the healthcare organisation. These findings raise important considerations regarding the importance of identifying factors influencing the formulation and implementation of risk controls following serious incident investigations. In Chapters 6 and 7, I aim to identify these features influencing strong risk control by first conducting a narrative review of the safety critical industries' literature (including healthcare) and, second by exploring the views of multiple stakeholders in the risk management process following incident investigations from safety critical industries (including healthcare).

6 Improving risk controls following incident investigations in healthcare: A narrative review of practices from safety critical industries

6.1 Introduction

In Chapter 2, I outlined how problems that arise when formulating and implementing risk controls following investigations of safety incidents are not unique to healthcare. Given these commonalities, it makes sense to review the literature developed from studies within other high-risk industries to explore approaches used to address the problem of developing and implementing strong risk controls. Thus, in this chapter, I present a narrative review[192, 234] that synthesises the literature from healthcare and other safety critical industries, with the aim of exploring practices and approaches that may be used to improve the formulation and implementation of risk controls following incident investigations in healthcare. The findings of the narrative review are used as sensitising constructs for subsequent analyses in chapter 7.

I have described the methods used to conduct the narrative review in section 3.3. In summary, I developed a search strategy (see section 3.3.1) to identify peer reviewed academic literature discussing approaches used in high risk industries, including healthcare, to:

1. Generate risk controls following incident investigations.
2. Maximise the implementation of risk controls following incident investigations.

Figure 3.2 summarises the search results. Using both primary database search and secondary manual searches, 49 articles were included for analysis in the final review. Using the principles of thematic analysis,[183] I identified nine important approaches used when formulating or implementing risk controls following incident investigations and grouped them into three broad themes. The themes (as described below) emerged inductively in an iterative manner, following a process of reading and re-reading.

6.2 Results

Of the 49 articles analysed, 23 were exclusively from healthcare, and 26 were from other safety critical industries, including some which discussed practices from multiple industries which may also include healthcare. Forty were empirical studies, eight were reviews or commentaries and one was a book reporting the empirical findings of an extensive observational study in aviation risk management. Appendix L provides a summary of the included literature. In this section, I expand on three themes, each outlining a group of approaches with potential to improve the generation and implementation of risk controls in healthcare following incident investigations, as identified in the included articles.

The first broad theme describes factors improving the inputs into the design of risk control, both during and after investigations: a systems-based approach to investigations, accounting for the voices of relevant stakeholders, the empowerment of investigators and use of clearer language by investigators when recommendations are made to departments or organisations. The second theme deals with the wider need to recognise risk control formulation as a distinct step in the risk management process, requiring time, space and specific methodologies to design defences in depth. The third theme expands on approaches which occur after risk controls have been generated: feedback to relevant stakeholders and evaluation of implemented risk controls.

6.2.1 Improving the inputs into the design of risk controls

First, to improve the quality of risk controls designed following investigations, multiple studies highlight the need to recognise the importance of practices which occur before risk controls are designed and their influence on the latter. Four practices are described below: using incidents as a window into systems, maximising the input of relevant stakeholders, empowering investigators, and ensuring the clarity of language between stakeholders.

6.2.1.1 Using incidents as a window into systems and processes

The generation of strong risk controls necessitates an understanding of a systems-wide view of incidents, with a particular focus on improving the understanding of how numerous sub-systems interact with each other.[153, 235, 236] A basic premise of the systems approach (introduced in section 2.2.3), as described in the included studies, is that accidents result from flawed interactions between components of a system, not just failures in individual components.[153] Thus, in these studies, components of a system, or sub-systems were not analysed separately. Instead, incidents were used to capture a 'bird's eye view' of how different components of a system operate together to ensure safe functioning of the system.

Use of systems-based approaches has roots in the non-healthcare literature with researchers such as Rasmussen and Leveson describing some of the first used models. Rasmussen's hierarchical risk management framework (see section 2.2.3) and its related accident analysis model, Accimap[83] (see figure 6.1), were some of the first developments in the field mapping the effect of decisions made at the management and regulatory level on the front-line, and thereby identifying areas of risk across an entire system.

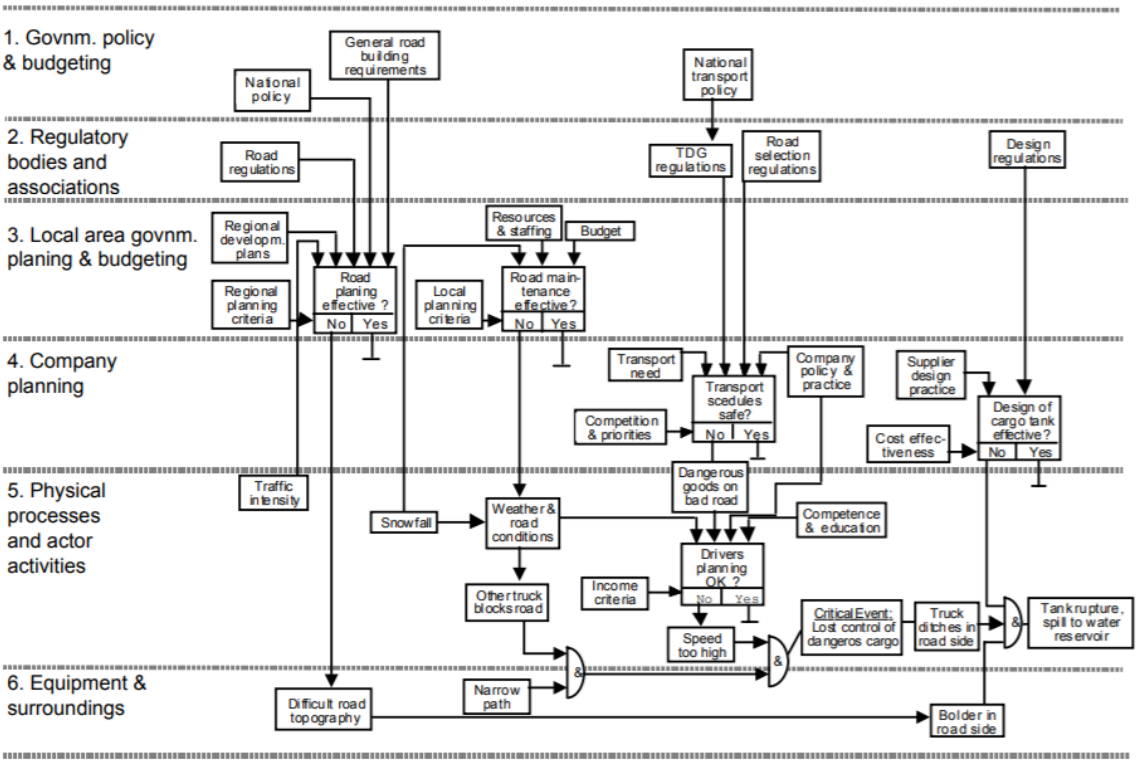

Figure 6.1 - An Accimap model of a traffic accident involving an oil spill to a drinking water supply (from Rasmussen et al. Safety Science. 1997)[83]

Leveson et al. termed such a model a "safety control structure" (see figure 6.2), arguing that, when compared to other traditional incident investigation approaches based on complex models (see section 2.2.2), the use of systems-based approaches allows the identification of weaknesses in risk controls already in place, their influence on staff's actions or inactions, and how the risk controls could be improved or changed.[153] In so doing, Leveson et al. argue that the emphasis of a system-based approach is identifying latent factors influencing actions and behaviours on the front-line. Leveson's system-based model (Systems Theoretic Accident Modelling and Processes) was one of the first applied to a healthcare accident. Using real adverse events in cardiac surgery, the authors showed how accidents developed due to suboptimal implementation of important safety elements on the behaviour of the sub-systems and the overall system.[153] For such safety elements to be implemented successfully, they should have adequate risk controls in place. For instance, an

example of a safety element for patients having cardiac surgery was that "*pre-emptive immunosuppression must be administered to patients before receiving a heart transplant".* A corresponding facilitator or control might be a checklist or removal of mistake-prone steps in the delivery of the safety element.[153]

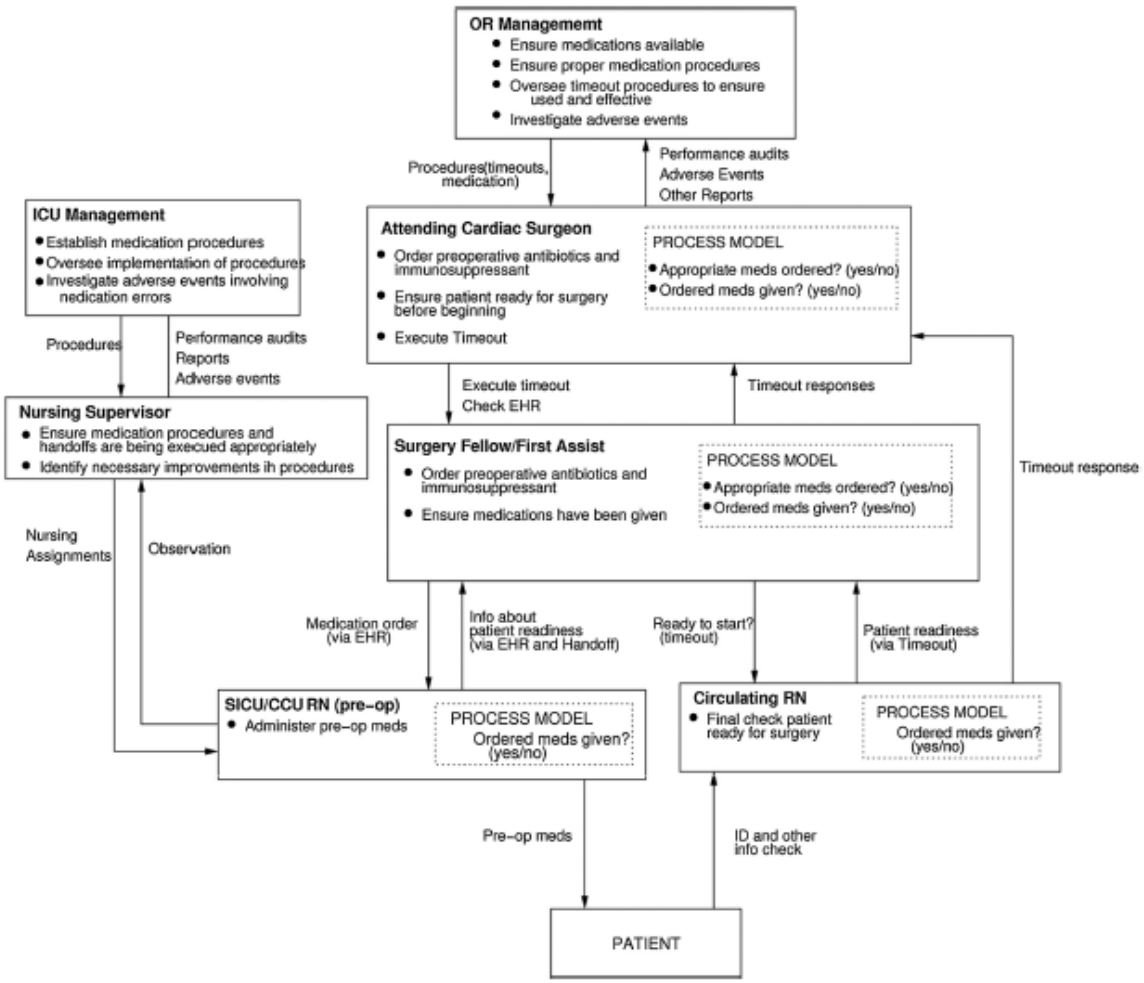

Figure 6.2 - The safety control structure to protect against preoperative medical errors (From Leveson et al. Journal of Patient Safety 2016)[153]

A systems approach has also been used to guide aggregated analyses of multiple similar incidents relating to infection outbreaks, leading to more effective recommendations with significantly longer intervals between outbreaks.[235] Comparing the outputs of traditional root cause analysis techniques with the Systems Theoretic Accident Modelling and Processes technique on the same medication error incident in

a mock setting, Canham et al. demonstrated that the STAMP analysis allowed more consideration to be given to systemic issues such as service development and change management.[237] Goode et al. extrapolated the principles of systemic models (such as Rasmussen's risk management framework and Accimap[83]) to develop a method to identify networks of risk controls (termed Preventimaps), instead of unconnected standalone risk controls, following investigation of incidents in led-outdoor activities (such as kayaking, rock climbing).[238] Importantly, this method allowed investigators to identify risk controls at higher levels of the risk management hierarchy (such as policy or management – see section 2.2.3) to support the implementation of risk controls at the operational level.[238]

6.2.1.2 Valuing stakeholders' input

Some studies, particularly those from healthcare, emphasised the importance of a participatory approach when formulating risk controls so that the voices of stakeholders across the whole system are heard and accounted for.[239-241] A participatory approach maximises the understanding of how numerous sub-systems function and interact with each other, such as the interface between primary and secondary care in healthcare, thereby adding to approaches that seek to gain a system-wide view. As described by Williams et al. and Li et al., an innovative strategy to promote a participatory approach in healthcare is "swarm intelligence," which entails the involvement of a heterogeneous group of professionals in the analysis of an adverse event and formulation of risk controls *immediately* after the event had happened, with the prime aim of maximising involvement of front-line staff.[240, 241] The authors suggested that this approach demonstrates an organisation's commitment to safety in two ways. First, it democratises access into how investigations are conducted by widening participation and minimises confirmation bias which can occur when investigations are carried out by homogeneous groups of healthcare professionals.[240, 241]

Second, involvement of staff at the blunt end (managerial and executive) of the organisation was also found in some studies from healthcare to facilitate the allocation

of resources required to ensure the successful implementation of recommended risk controls.[24, 152, 163] For example, Mills et al. reported that leadership and middle management support were associated with increased likelihood of implementation of risk controls following incidents relating to adverse drug reactions[163] and suicides.[152] Another key enabler to implementation was management continuity, as identified by Wrigstad et al. in the context of the Swedish healthcare system.[154] A participatory approach, with involvement of management, was seen in some healthcare studies as a means of ensuring risk controls were *owned* by a particular individual with a position to effect change, thereby maximising implementation rates.[26, 242] In that light, Gandhi et al. suggested that *"Hospital leaders, not just the members of the patient safety team, must own these changes or improvements. It is critical to emphasize that safety is part of everyone's job, and not just the job of the safety team."*[242]

6.2.1.3 Empowering investigators

Based on practices in aviation, Pham et al. advocated separation between core members of the investigation and the implementation teams, in part to ensure clear lines of accountability.[159] Such separation was also present when investigations were carried out by external bodies such as a national accident investigation branch (e.g. the AAIB).[63] Such distinction between investigating and implementing teams may, on the face of it, seem contradictory to the concept of a participatory approach but this need not be the case. As shown in qualitative studies involving investigators from numerous non-healthcare settings,[243, 244] a clear line of communication between investigators and implementers throughout investigation and implementation facilitates the creation of shared understandings on the nature of recommended actions.

Separation of the investigation and implementation teams may also facilitate the independence of investigators. Macrae highlighted the value of such independence in ensuring investigators' legitimacy and authority in the context of safety investigation practices in aviation.[63] Reviewed literature which described the operations of national investigating bodies, in aviation and many other safety critical industries, further

demonstrated the wider practice of independent investigators operating as part of safety authorities or investigation branches.[63, 245, 246] As shown in a qualitative study of railway investigators by Cedergren et al., the independence of investigators allowed them to keep a distance from individual organisations, thereby also empowering them to give a critical external view of operations and provided recommendations to organisations without undue influence from organisational management.[245] In aviation, such independent agencies (like the AAIB), tasked with the sole purpose of investigating incidents, were even separated from regulatory bodies. This independence allowed them to give recommendations to organisations at all levels (from regulatory bodies to airlines) without risking conflicts of interest.[63]

Stronger risk controls can also be achieved through a better understanding of human factors, as shown in the context of healthcare by Canham et al.[237] The authors highlighted the importance of having human factors expertise when using systems-based methods of incident analysis and when formulating risk controls following investigations.[237] They found that investigations using system-based methods, as described in section 6.2.1.1 and facilitated by human factors specialists, resulted in the formulation of more risk controls at the system level when compared with traditional root cause analysis led by those without the required expertise.

6.2.1.4 Clarity of language

When investigators are independent and separated from industry, they may not have holistic insider knowledge of how daily operations are carried out. Thus, for investigators, the task of being very specific when formulating solutions following investigations can be problematic and may lead to bottlenecks when implementing those solutions.[245] In the context of transport and engineering accidents, Macrae and Cedergren et al. showed that investigators operating separately from industry as part of national bodies, provided general recommendations for improvement based on the findings of their investigations, which also included views of staff receiving the recommendations, as opposed to providing detailed specific risk control.[63, 245] It was then up to staff in the organisations concerned, armed with knowledge of how daily

operations were carried out, to generate specific risk controls, based on the recommendations provided to them.

A few studies from non-healthcare industries highlighted the importance of clearly understandable recommendations in maximising the chances that they were turned into actions and implemented, in particular in the context of investigations carried out by external or national investigators.[244, 245] Cedergren et al. showed that clear recommendations were not always the norm even in sectors with excellent safety standards such as the rail industry, with one in five recommendations from investigation branches not acted upon.[245] More broadly, an interview study of Swedish investigators from different sectors found that clarity of language resulted in appropriate interpretation of recommendations by receiving organisations, and their successful implementation.[244]

In healthcare, there is evidence that organisational leaders tasked with signing off recommendations might not do so if recommendations were not clear.[24] Cedergren et al. further suggested that a richer understanding of the nature and purpose of recommendations could be achieved by clearly delineating the link between the historical account obtained during the analysis phase (what happened) and the normative account (what should be done).[245]

A strategy used to ensure clarity of recommendations and maximise likelihood of implementation is for organisations to formulate SMART (Specific, Measurable, Actionable, Relevant and Time-bound) risk controls.[36] When not followed, resulting risk controls could be perceived as being too vague and possibly futile, as revealed in an interview study of investigators and implementers in a Scandinavian gas and oil refinery.[247] In healthcare, specific, relevant and actionable risk controls have been found to lead to more rapid implementation.[248] Though clearly a helpful technique on the face of it, none of the included studies compared the effectiveness of implementation with and without a SMART approach.[249]

6.2.2 Recognising problem-solving as a distinct step

Research from multiple safety critical industries, including healthcare, has shown that the process of problem-solving and formulation of risk controls following analysis is generally not given enough attention in the aftermath of investigations, with organisations spending more time identifying causes than coming up with solutions.[87, 166] In that light, some studies included in this review report on ways to improve the problem-solving phase. Three broad approaches are identified.

6.2.2.1 Giving time and space to problem-solving

First, the value of allocating dedicated time and space to the problem-solving phase in the aftermath of incident analysis is highlighted.[165, 250] Reporting in the context of local investigations in the Swedish nuclear industry, Rollenhagen et al. demonstrated that a separate recommendation meeting after identification of causes was feasible and generally welcome by staff.[165] Similar findings were reported in the context of software companies. One study found that the introduction of a dedicated meeting focusing on the formulation of risk controls increased the quality, feasibility and effectiveness of risk controls, as perceived by staff.[250]

6.2.2.2 Use of tools to structure problem-solving

Second, some studies explored the use of particular tools to facilitate the generation of risk controls.[146, 159, 251-253] One such tool, with origins in occupational safety, is the hierarchy of risk controls (see section 2.5.1.1).[146, 251, 252] As previously discussed, this tool is based on the principle that "hazard elimination" is the most effective means of reducing risk in a system, and that controls which act independently of human action (such as forcing functions) are more effective than those that do not.[146, 251, 252] To explore the usefulness of the hierarchy of risk controls in the context of healthcare, Card et al.[146] reported on the combined findings of two studies[26, 163] exploring the results of aggregated RCAs. Based on a total of 1738 risk controls, those focusing on training and education (administrative controls) alone correlated negatively with improved outcomes.[146] On the other hand, those aiming to improve processes and environmental conditions were associated with improved outcomes. When studied

prospectively in simulated conditions, the hierarchy of controls has also been found to be a useful brainstorming tool, maximising the quality, quantity and variety of risk controls generated by investigators.[252]

Another toolkit, the "model of sustainability and effectiveness in RCA solutions" (see figure 6.3), based on similar principles as the hierarchy of risk controls, was described by Hettinger et al.[149] The design of this model was informed by a qualitative analysis of healthcare related incidents and interview with front-line healthcare staff.[149] A different tool, grounded in data from healthcare, was devised by Vacher et al and consisted of a framework with seven categories (patient, actors, procedures, organization, consumables, equipment and premises). The tool also accounted for the resources needed for successful implementation of each risk control proposed and their cost to the organisation.[254] Use of this framework was found to lead to more actions generated by risk managers when compared with use of no framework, though the authors did not comment on the potential strength of risk controls.[254]

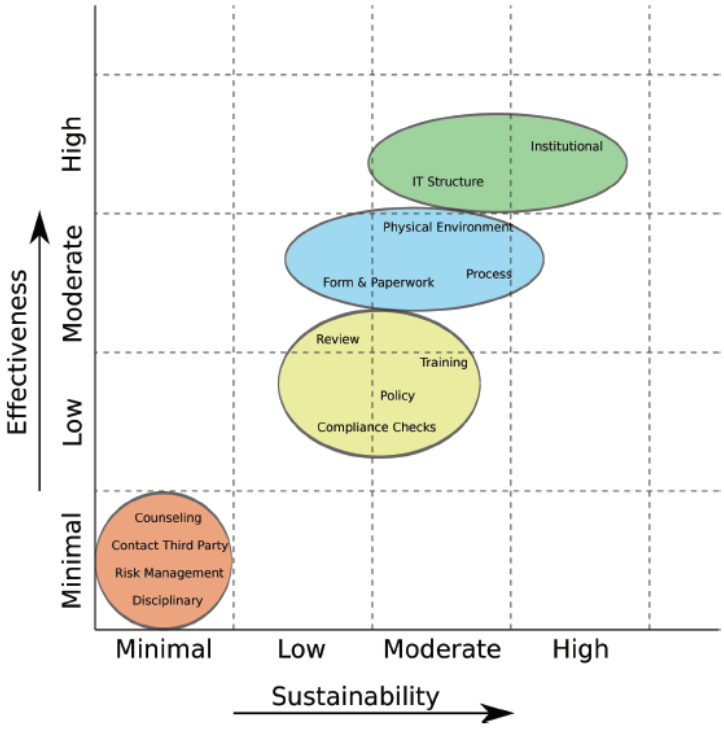

Figure 6.3 - Model of sustainability and effectiveness in RCA solutions (from Hettinger et al Journal of Healthcare Risk Management 2013[149])

Other tools used to assist in the formulation of risk controls from both healthcare and non-healthcare industries focus on prioritising risk controls based on the causal factors they aim to address and their relative contribution to the incident.[159, 253] For instance, Pham et al. adapted a method from commercial aviation for use in healthcare. The authors described how determination of causal factors was performed by first assigning a numerical value to their relative importance in causing an incident, and another numerical value to their relevance to future adverse events. A priority score was then determined as the product of these two values. A similar prioritisation score was given to interventions being considered for implementation based on the degree to which the intervention mitigates the identified causal factor(s) and the likelihood of implementation of the intervention.[159]

6.2.2.3 Designing defences in depth

Third, one of the aims of using systems-based methods to investigate incidents and structured tools in the generation of risk controls is to be able to construct multiple barriers in a system to guard against individual control failures. This concept, known as "defence in depth," aims to increase a system's overall functioning reliability[238] and was described in some of the non-healthcare literature reviewed.[164, 255, 256] Its underlying philosophy is that one layer of barrier, even if deemed strong, is not enough to prevent an adverse event from occurring. Instead, multiple barriers are required to account for the random and systematic nature of failure.[256] Saleh et al., in a review of system safety in high risk industries, expanded on the notion of defence in depth and argued that barriers may serve three different purposes.[255] First, barriers could be placed at the source of hazards to prevent them from leading to an initiating event. Second, barriers were useful at stopping the initiating events resulting from the hazards from escalating, should the first barriers fail. Finally, barriers could be placed to contain the consequences of incidents should the first or second set of barriers fail.[255]

James Reason's Swiss Cheese Model (see section 2.2.2.1) and Charles Vincent's Organisational Accident causation model (see section 2.2.2.2), which are widely used

in healthcare, are clearly rooted in the defence in depth concept. Both models describe numerous potential layers of errors which may contribute to an incident, ranging from latent factors at the blunt end of an organisation to active failures at the sharp end,[60] all of which may also represent potential areas for improvement using a defence in depth strategy. The principles underlying a defence in depth approach were alluded to in a few of the healthcare articles reviewed.[239, 251, 252, 254] For instance, some studies identified the *quantity* of actions formulated as a strength of the tool used to identify risk controls.[251, 254] To exemplify the importance of having multiple defences, Branton et al. used a case study in infection control to describe a defence in depth approach across the entire healthcare ecology to reduce MRSA-related infections amongst patients with diabetic foot ulcers.[239]

The number of risk controls on its own isn't necessarily an adequate measure of the strength of a defence in depth approach. For instance, many risk controls addressing the same hazards, and ignoring others will not be maximally effective at reducing risk. Chuang et al. addressed this issue in their study describing how they combined a systems approach with the principles of defence in depth to address the problem of repeated scabies outbreak in a ward. The authors underline the importance of first understanding the relationships between numerous sub-systems involved in the care of a patient and their relative priorities in terms of their contributions to potential adverse events. Risk controls were then placed across the whole system, with those sub-systems with greater influence over potential outcomes prioritised.[235]

6.2.3 Feedback and Evaluation

The third theme identified in this narrative review expands on practices which are key in developing an understanding of the effectiveness of proposed and implemented risk controls.

6.2.3.1 Timely two-way feedback

Some studies investigating practices from both healthcare and non-healthcare settings explored the importance of providing feedback to staff involved in incidents and those in the wider organisation.[26, 163, 242, 257, 258] The term "feedback" was broadly used to

describe the process of communicating the findings of investigations and the steps taken to address the areas of risk identified.[242] This was regarded by authors as a means of maximising implementation rates and ensuring organisational learning. For example, Wu et al. argued that compliance with newly implemented actions in a radiotherapy department was maximised through feedback via appropriate channels of communication, though the authors did not provide guidance on the strength of particular channels over others.[257]

Feedback should not simply be a one-way process from the safety or investigating team to staff but also needs to account for the response of staff to the information passed on to them. For instance, Li et al. found that even when risk controls were communicated effectively (as measured by rates of staff awareness) in a radiation therapy department, compliance with them remained low, particularly when they were not deemed useful or practical by staff.[257] In an interview study of safety staff from multiple secondary care institutions, Mills et al. showed that a key enabler to successful implementation of risk controls following investigations of inpatient falls was to account for the responses of staff after they were provided with feedback from investigations but before risk controls were implemented.[26] Similar findings were also seen in the context of incident investigation of adverse drug reactions: higher rates of implementation of risk controls correlated positively with asking feedback from staff *before* implementation.[163]

6.2.3.2 Routine monitoring and evaluation of risk controls

The included articles identified the evaluation of implementation and effectiveness of risk controls as neglected aspects of risk management.[259, 260] When such evaluations were performed, Mills et al. found that they correlated positively with implementation rates and reports of improved clinical outcomes.[152] Based on the articles included, evaluation seems to serve three purposes.

First, at the most basic level, its purpose is to assess whether risk controls had been implemented. Even organisations with presumed high safety standards, across both healthcare and non-healthcare settings, demonstrated low implementation rates of

risk controls (as low as 12-13%). These findings only came to light when risk controls were appropriately monitored for implementation.[154, 245, 261] One method to capture and improve implementation rates, as reported by Leong et al. in the context of a multi-national oil and gas organisation, is structured action review meetings involving those responsible for implementation and senior management.[262] Such oversight offered a platform where risk controls were tracked and reasons for non-implementation identified, thereby facilitating the mobilisation of resources for successful implementation.[262] Technical measures to track actions included database software[263] and automated notification systems with triggers for escalation if actions were not implemented.[264] Eshareturi et al. showed that some healthcare organisations already had such databases available but staff were also not comfortable with the notion of having separate databases to record investigation findings, track risk controls and disseminate lessons from past events.[265]

Second, the follow-up phase was useful to assess the effectiveness of implemented risk controls.[159, 259, 266] To do so, Lundberg et al. report that risk controls need to have a "measurable" component.[36] In the context of the oil and gas industry, such measurements or performance indicators were obtained from multiple sources such as audits, incident reports, and direct observations.[267] In both healthcare and non-healthcare settings, the measurement of the effect of risk controls on safety was far from straightforward, as some adverse events were particularly rare, and thus hard to capture through such sources.[36, 159] In that light, Pham et al. suggested that measurement of effectiveness should be limited to more common factors known to contribute significantly to the occurrence of adverse events.[159] To encourage organisations to monitor effectiveness, incentives may be useful. For example, Bagian et al. demonstrated that more than 90% of organisations who signed up to a non-monetary recognition programme highlighting good RCA practices were monitoring their risk controls for both implementation and effectiveness after joining the programme.[266]

The third purpose of a monitoring system, as identified in some of the included studies, relates to the assessment of degradation in performance of implemented risk controls over time.[255, 268] The implementation of multiple risk controls following an incident may lead to a complex and tightly coupled network of defences and sub-systems, which could inadvertently obscure the operating status of individual risk controls. Thus, weaknesses in a system might paradoxically persist undetected as a result of a highly functioning defence in depth mechanism. To address this issue, Bakolas et al. proposed that implemented risk controls should have measurable properties allowing for monitoring of degradation.[268] These "leading indicators" could be considered as warning signs, used to detect potential functional breakdowns in defences which might eventually lead to an incident. Importantly, these indicators need to be built into systems at the design stage.[268] In light of these findings, systemic models of accident causation, as discussed in sections 2.2.3 and 6.2.1.1, may offer particular value when thinking about engineering such leading indicators into systems.

6.3 Discussion

This narrative review of 49 articles from safety critical industries, including both healthcare and non-healthcare literature, was performed to identify approaches and practices used to improve risk control formulation and implementation following incident investigations in healthcare. The articles consistently highlighted the challenges that have plagued the formulation and implementation of risk controls following incident investigations, and highlights that improvements are required. Three broad themes, outlining nine approaches spanning the investigative phase to the monitoring of implemented risk controls, were identified across the literature.

Table 6.1 below summarises these themes and lists relevant examples of practices described in the literature which have potential to be used to improve the formulation and implementation of risk controls following incident investigations in healthcare.

Theme 1: Improving the inputs into the design of risk controls	
Approaches	**Example of practices**
a. Using incidents as a window into systems and processes.	Use of systemic tools to analyse incidents (such as Accimap, STAMP). Identify networks of risk controls working in synchrony (such as policies supporting implementation of changes on the front-line).
b. Valuing stakeholders' input.	Involvement of staff at front-line and blunt end of an organisation is accounted for during investigation. Ownership of risk controls by management and front-line staff. Identification of resources for implementation Checking with staff before implementation of risk controls.
c. Empowering investigators.	Setting up of national independent investigation bodies. Use of human factors specialists in investigating and formulating risk control. Separation of investigation and implementation teams, while maintaining dialogue.
d. Clarity of language	Clear link between risk control and causal factor addressed. SMART risk controls.

Theme 2: Recognising problem-solving as a distinct step	
Approaches	**Examples of practices**
a. Giving time and space to problem-solving	Separate recommendation meeting. Prioritise interventions with potential for maximal risk mitigation.
b. Using tools to structure problem-solving	Use of tools (e.g. the hierarchy of controls) to brainstorm risk control options, and formulate f risk controls with a sound theory of change.
c. Designing defences in depth	Placing risk controls at numerous steps of a system
Theme 3: Feedback and evaluation	
Approaches	**Examples of practices**
a. Timely two-way feedback	Timing of feedback – before full implementation of risk controls. Include a consultation period with relevant stakeholders before finalising recommendations. Have an appropriate dissemination strategy of finalised risk controls to relevant stakeholders.
b. Routine monitoring and evaluation of risk controls	Upgrading local incident databases to ensure accurate tracking of implementation is made possible and better sharing of solutions. Upgrade national incident databases to ensure better sharing of lessons across organisations. Identification of auditable performance indicators to assess effectiveness of risk controls.

Table 6.1 – Themes from narrative review with relevant examples of how to improve risk control formulation and implementation.

Systemic accident models (discussed in section 6.2.1.1)[153, 237, 269] may help in developing a more holistic understanding of accident causation and areas for improvement. In mapping relationships between sub-systems, such approaches may also gear investigators towards understanding how work is carried out on a day-to-day basis, as opposed to simply creating a snapshot of how work happened on the day of the incident. Systemic analyses allow investigators to understand the impact of context on individual actions, as shown by both Leveson et al. and Chuang et al.[153, 235] Vincent et al. further suggest that incident investigations and targets for improvement should not be limited to the boundaries of the organisation where the ultimate harm occurred or was detected. Instead, analyses and targets for interventions need to be considered across the entire patient journey, which may require cross-organisational efforts.[270]

The second approach which merits further exploration is the democratisation of the process of formulating risk controls by encouraging the involvement of multiple stakeholders, in particular front-line staff, when designing risk controls. Such an approach allows the design of new processes to meet the needs of relevant stakeholders, and usability issues to be identified and addressed before implementation.[271-273] Involving front-line staff in investigation produces valuable information on risk, and their involvement in planning interventions may lead to an increased ownership of local risk controls. Feedback to staff on the front-line on the effectiveness of risk controls supports wider learning by staff and shows that they are being listened to.[274] Empowering front-line staff in decision-making relating to the improvement of healthcare services has been found to lead to higher levels of organisational trust, which consequently creates higher levels of commitment amongst staff, and more responsive and efficient services.[275, 276] In so doing, local personnel can be used both as a resource and as a *"route to regulate local safety practices."*[274]

My review also found that the job of an investigator goes beyond the application of problem-solving and risk management skills. Investigators also require facilitation,

management and leadership skills. The application of systemic methods of accident investigation, analysis and risk control formulation necessitates skills in human factors, systems thinking and cognitive interviewing, amongst others.[13]

Another enabler to effective risk control identified in this review is for independence of national investigators. In that light, the setting up of the Healthcare Safety Investigation Branch in the UK is a step in the right direction.[118] First, independence makes it possible for the body to investigate all constituents of a healthcare system without any conflict of interest. Second, independence from regulatory bodies allows the investigation body to serve its purpose of producing recommendations for learning, and not be conflated with a body responsible for performance management. Independence ensures that information is shared with the investigation body without fear of blame or retribution. Finally, independence from individual healthcare organisations allows the national investigation body to focus on providing objective recommendations for change based on the findings of its investigations, without being responsible for the formulation and implementation of specific risk controls. This separation of broad recommendation from specific risk control means that that the latter can be designed by staff (across both the sharp and blunt end) who understand their own working systems, context and processes better in individual organisations.[277]

Clearly, however, national investigative bodies will not have the capacity to investigate all reported patient safety incidents, nor should it be their role to do so. Much organisational learning can happen through internal investigations, case note reviews, mortality reviews conducted by departmental staff or others from within the organisation. Even in other high-risk industries, such as nuclear power, much of the investigative work is performed by "in-house" professionally trained investigators, who maintain a close working knowledge of organisational operations and function separately from human resource and implementing teams. Such an approach focusing on the development of local investigative expertise (elaborated in more details in section 8.1.3) may address apparent tensions between ensuring a participatory

approach accounting for the views of those close to operations and the separation between investigating and implementing teams.

Results of this review suggest that staff value databases of incidents, but are understandably reluctant to engage with multiple databases[265] and the associated complexity.[278, 279] In the UK, the planned improvement to a central and more user-friendly National Reporting and Learning System database is thus a welcome initiative.[280] Once live, it aims to allow organisations to receive more purposeful feedback which can be shared with staff and importantly also allow dissemination of improvement work following incidents across organisations.[280]

This review has some limitations. First, most practices and approaches identified in the review have not been evaluated prospectively in healthcare settings to determine their effectiveness in reducing similar types of adverse events. Evaluations have mostly consisted of staff perception of the usefulness of particular practices, have been retrospective in nature, or have been performed in simulated settings. An example of such a practice, evaluated in limited settings, is the use of the hierarchy of controls in the context of healthcare risk management. While its use as a brainstorming technique may add structure to the risk control planning stage in healthcare, deciding on risk controls solely based on the presumption of a hierarchy may be misleading. For example, the hierarchy categorises all training interventions as weak (under the administrative category). Yet, training can exist in multiple forms, with some more successful than others when formally evaluated.[281, 282] In that light, in a research paper I co-authored, we suggest that a sound theoretical explanation of the mechanisms through which risk controls address specific areas of risk (a theory of change) is also required when formulating risk controls (discussed in more details in section 8.2).[151] Such a strategy may also maximise implementation by describing the link between causal factors and risk controls proposed. Second, the reviewed articles did not highlight guidance on how to involve patients and relatives in the process of risk control. This absence may be due to limitations in the search terms used in the review. Third, this narrative review did not provide any data on the relative effectiveness of

the above described themes in improving risk controls. Thus, based on the results of this narrative review, it is not possible to identify which, if any, of above described approaches is more effective at improving risk control formulation or implementation over another. Finally, the narrative review did not assess the methodological rigour of the included papers as it did not set out to do so.

6.4 Conclusion

This narrative review of the literature from healthcare and other safety critical industries has identified a number of approaches that could be used to improve the generation and implementation of risk controls following investigation of incidents in healthcare. It was, however, not always clear how straightforward or challenging the implementation of these approaches, some of which were imported from other safety critical industries, would be in the context of healthcare. It is also evident that the available literature fails to comprehensively capture the views of the multiple stakeholders involved in investigating incidents and those coordinating the response following incidents or implementing risk controls. This gap is addressed in the next chapter.

7 How can the risk control process be improved following serious incident investigations in healthcare? Results of a semi-structured interview study with multiple stakeholders in post-incident management.

7.1 Introduction

So far in this thesis, I have reported a content analysis of serious incident investigation reports and action plans in one NHS trust to identify contributory factors leading to serious incidents in healthcare and the risk control strategies used to prevent recurrence. I have also identified some potential lessons relevant to formulating and implementing risk controls in healthcare following incident investigations, based on a narrative review of the literature from safety critical industries. In this chapter, I seek to deepen the understanding and broaden the range of perspectives on incident investigation and the processes of generating and implementing risk controls by directly capturing the views of the multiple stakeholders.

The methods used in this part of the research project were described in section 3.4. In summary, I undertook an in-depth semi-structured interview study with serious incident investigators from healthcare, accident investigators from other safety critical industries, academics in patient safety, implementers of serious incident investigation

action plans, and clinical commissioners responsible for reviewing serious incident investigation reports and action plans. I used the principles of framework analysis to analyse the data. The analysis was divided into five stages as outlined in Table 3.4, with the analysis from the narrative review (Chapter 6) used as a set of sensitising constructs[189] to help in the initial structuring of the data from the interviews. The aim was to explore features of high quality generation and implementation of risk controls (termed collectively as "the risk control process") in healthcare following serious incident investigations and how they could be made more robust in healthcare based on practices from both healthcare and other safety critical industries.

7.2 Results

I contacted 87 potential participants. Of these, 52 (60%) consented for the study and were interviewed. As shown in Table 7.1 below, nineteen participants were serious incident investigators in healthcare organisations, ten were accident investigators from other safety critical industries, eight were academics who conducted research on the topic of healthcare incident investigation, eight were commissioners of healthcare with responsibility for reviewing serious incident investigation reports they received from different UK healthcare trusts, and seven were senior medical or nursing members of staff with responsibility for implementing risk controls following incident investigations (referred to as *healthcare implementer* in the transcripts below). Participants who could be classed into two or more stakeholder groups were asked to choose that group most closely defined their responsibilities in the incident investigation process or in which they had most experience. Forty-two participants were based in the UK, six in the USA, three in Canada and one in Ireland.

Participant role and industry	Number of participants
Healthcare serious incident investigators	19
Investigators from non-healthcare safety critical industries	10
Aviation/ Air traffic control	3
Energy (Chemical, Energy)	3
Rail	1
High risk sports	1
Military	1
Cybersecurity	1
Academics	8
Commissioners	8
Healthcare implementers	7

Table 7.1 - Professional role and industries of interviewed participants.

Participants across all roles and industries recognised the value of serious incident investigations in improving patient safety. Analysis of the interview data showed that, while there were opportunities for healthcare to learn from other industries, some similar challenges were faced across all industries. Participants across all sectors raised concerns regarding how findings of investigations could be translated into both effective risk controls to prevent the occurrence of similar incidents, and wider learning in practice. My analysis identified seven key features to improving risk control formulation and implementation:

1. Using a participatory approach and valuing voice from the front-line.
2. Prioritising the deployment of skilled and independent investigators.
3. Formulating a sustainable set of risk controls with a sound theory of change.

4. A collaborative approach to quality assurance of risk controls
5. Effective knowledge management and brokerage within and across organisations.
6. Purposeful tracking of implementation of risk controls.
7. Accounting for patients' and carers' voice.

Some of those features of high quality risk controls (using a participatory approach and valuing voice from the front-line, the deployment of skilled and independent investigators, purposeful tracking of implementation of risk controls) were already identified in the narrative review. The interview study allowed me to explore reasons why these approaches were hard to implement in healthcare and understand how they could be facilitated. I identified four additional features to improving risk control formulation and implementation in the interview study: formulating a sustainable set of risk controls with a sound theory of change, a collaborative approach to quality assurance, effective knowledge management and brokerage within and across organisations, and accounting for patients' and carers' voice.

7.2.1 Using a participatory approach and valuing voice from the front-line

Participants from both healthcare and non-healthcare sectors agreed on the importance of involving staff from the front-line in formulating and implementing risk controls. While healthcare investigators had access to departmental and organisational policies outlining expected procedures, they did not always know why they were not followed. On the other hand, such information was routinely discussed among front-line staff. Staff at the sharp end of healthcare were thus considered to possess vital information enabling a better understanding of operational logics and the feasibility of possible risk controls.

> *"Well their (front-line staff) contribution … is pivotal because they're the ones that were involved in the incidents, they're the ones that were there on the ground, they're the ones that make the decisions, so it's about understanding, their rationale for decisions made or actions taken, and these are the guys that do the job day in, day out…"* [Healthcare investigator 9].

"But you also need the cooperation and the collaboration of those who are within the organisation, to actually say whether the actions are …possible to implement, or understand what else has been going on in the organisation so you don't get actions cancelling each other out, or getting in the way of performance." [Academic 8]

Attractive though it was in principle, participants reported that a participatory approach was not used in practice. Healthcare participants, in particular investigators and implementers, expressed concerns that, on the ground, those asked to implement risk controls simply received recommendations from investigation panels and managers, rather than actively contributing to those recommendations themselves. For instance, senior clinicians, managers with responsibility for implementation of risk controls and investigators who had previously spent time working at the sharp end reported frustrations with the non-involvement of staff responsible for implementation of risk controls. The consequence was a lack of engagement of frontline staff with the outcomes of investigations, and variable implementation of risk controls.

"I can think of a particular [action plan] that still winds me up several years after the event…involving a patient around anticoagulation… the [investigating] team…said that all patients should have some sort of risk stratification of their need for anticoagulation to be documented in the notes. And they wanted me to ensure that. Now, I was never asked about that. I don't think any of us would dispute there is a role for risk stratification… [but] the practicalities of getting that documented across an entire trust…was …almost impossible." [Healthcare implementer 1]

"So they [front-line staff]…got no engagement in the process… they just get given this action plan, and of course they're not interested in it and think it's all rubbish so they're not going to do it, they do it half-heartedly, they say they've done it but there's no evidence that they've done it…" [Healthcare investigator 8]

The reasons for the lack of a participatory approach, despite wide acknowledgement of its value, related to the wider context within which serious incident investigations took place. First, regulatory requirements, in particular strict timelines for the production of an investigation report with an action plan, were viewed by healthcare investigators as a hindrance, limiting the quality of investigations and risk controls.

> *"And there's certain reasons why that [involving front-line staff] isn't done. One, because of timeframes for the RCA, they're very very tight… places that do investigations very very much better than we do, i.e. rail and oil and aircraft ….take months and months and months to do a really good investigation, whereas we have to complete it within 60 days. So, your ability to really get up and under and test is this the right action, or would that be a better action? We don't have the luxury of time to do that."* [Healthcare investigator 5]

Second, staff responsible for implementation in healthcare were not always able to attend meetings with investigators to discuss the way forward following investigations. Competing clinical and managerial priorities often took precedence.

> *"They [staff responsible for implementation] don't always all attend … sometimes because of you know pressures etc., people who perhaps it would be useful to have at the meeting to review the reports can't always attend… because of their work pressures they don't always prioritise it or respond."* [Healthcare investigator 12]

Third, though healthcare investigators and commissioners believed that it was important to involve front-line staff in risk control formulation, they also had some reservations about relying too heavily on opinions from the sharp end when formulating risk controls. They questioned the ability of staff operating at the sharp end to generate strong enough systemic risk controls, for example because they perceived them to lack a holistic view of operations.

> *"My problem is that …they [front-line staff] tend to concentrate on the things that are within their sphere of influence."* [Commissioner 1]

Investigators from non-healthcare industries reported that, in contrast to their counterparts in healthcare, they usually had the advantage of being able to carry out investigations in less strict timeframes. They also sought to proactively create opportunities for staff from the front-line to influence the formulation of risk controls. Non-healthcare investigators recognised that engagement with staff at the sharp end would improve implementation rates and utilised strategies to ensure staff were consulted before finalising risk controls.

> *"That [safety recommendation] would go out as a draft copy to all those whose reputations may be affected by what we'd written. We would receive their comments, and it would be our call as to whether we change the report as a result of those comments. Usually we would do."* [Industry investigator 3]

Such strategies, for example the production of draft recommendations for comments by implementers before implementation or co-producing risk controls following independent investigations, were reported by some healthcare investigators but did not seem as widespread.

> *"The draft investigation report goes to the people who are managing the service … and that includes the draft recommendations. So, at that point there would be an opportunity for them to engage in the formulation of the recommendations, or to say they don't think it's sensible, or…they think it could make the situation worse."* [Healthcare investigator 2]

In non-healthcare industries, the formulation of recommendations was described by participants as an iterative process, with feedback from the organisation or department receiving the information used to inform the final recommendations. When these recommendations were then made to individual organisations (such as airline companies or airplane manufacturers), the latter were then responsible for

coming up with specific risk controls to cover these recommendations. Non-healthcare investigators acknowledged that their own expertise was in the identification of the causes of incidents and demonstrated respect for the operational know-how of front-line staff in the organisation receiving recommendations.

> *"…the habit here is to be specific in identifying the problem, and not at all prescriptive in identifying the solution. Because we're not qualified to, apart from anything else… we're not aircraft operators, we're not manufacturers, we're not designers."* [Industry investigator 2]

> *"So, the safety recommendation was very much about identifying a deficiency... We don't see ourselves as the expert in anything apart from the process of investigation. We would always go and fire these things to the people who were experts in fixing that particular problem."* [Industry investigator 3]

7.2.2 Prioritising the development of skilled and independent investigators

The quality of risk controls was considered by participants to be, at least in part, a function of the quality of investigation: weak investigations were reported to produce weak risk controls. Previous studies have shown that numerous variables determined the strength of an investigation: good investigative methodology, a sound understanding of how humans and systems interacted, a just approach (which accounts for the effect of the system on human mistakes) to allocating responsibility and accountability fairly and equitably,[270, 277] and the conduct of investigations by *skilled* investigators operating *independently* of the department or organisation where the incident occurred.

Healthcare investigations were often seen to be lacking in these attributes by participants in my study. They reported that lack of appropriate investigative skills was likely to lead to investigations focusing on actions of individuals, ignoring systemic causes of incidents.[277]

> *"people [investigators] don't have those skills set at all, they don't understand …that it's a systems-based analysis. What's been happening here is it's been a very blame-focused, person-blamed focus in the investigations, and not looking at the wider issues, very superficial analysis of reports."* [Healthcare investigator 8]

Two academics who had researched the topic of incident investigations in healthcare commented on the perceived lack of objectivity by healthcare investigators. Truly independent investigations were reported to be rare in healthcare, as investigative panels often included members of staff from the same department where incidents occurred.

> *"There's no truly external eyes. We ...have blind spots, biases…things that are untouchable…everybody knows what the real problem is. but nobody's going to go there."* [Academic 2]

Among the sample of participants interviewed, healthcare practitioners who conducted incident investigations tended to come from two distinct but related clinical backgrounds. The first group comprised practitioners mostly from nursing backgrounds, who usually operated as part of a corporate patient safety team under the supervision of senior risk managers, such as directors of safety or risk. They typically performed the groundwork of investigations, conducting interviews, summarising findings of investigations and pulling investigation reports together. They were reported to have basic knowledge in safety science and investigative methodologies, but there were concerns among certain healthcare investigators and academics on how well-equipped and well trained this group of investigators were in performing accurate investigations and identifying strong risk controls, and whether they were positioned optimally in their organisations to make the kinds of recommendations that would be most effective in reducing risk.

"it's a day training…it's not the greatest thing to be fair… they're [the investigators] always bombarded with information, quite often then when they speak to me, they're in a blind panic." [Healthcare investigator 12]

"We've trained all the investigators and done some training for the chairs, but that's to a greater or lesser extent. And frankly, the RCA investigators are usually band sevens [senior nurses]*, and sometimes there are issues with insight, with judgment, with clinical wisdom, with knowledge."* [Healthcare investigator 5]

"RCAs are carried out by people at kind of middle managerial level, and when they start thinking about recommendations and action plans, they are to some extent cognitively inevitably going to be thinking about recommendations for action plans which can be actioned by people at their level or below. Because that's what their organisational vision is, you know, they kind of see it from where they stand and what they can get done." [Academic 3]

The second group comprised hybrid practitioners who balanced managerial and clinical duties (unlike the first group who, by and large, worked full-time with the patient safety team) and often led investigation meetings or provided expert clinical opinions. They were usually senior clinicians who were expected to participate in incident investigations by virtue of their seniority or managerial positions, such as heads of service or matrons. Two academics and a healthcare investigator who had studied the process of incident investigation in healthcare reported that despite this group's seniority and influence, they were often not well versed in the tools used to investigate incidents, particularly newer system-based models. As a result, the quality of risk controls from investigations led by these individuals was poor.

"…we have people [healthcare investigators]… who doesn't understand investigation, who doesn't understand systematic approaches, who do not understand the system are then writing things like [person A] should be nicer to

her colleagues, communication is a big problem, everyone should take a communication course, oh such rubbish." [Academic 1]

"…they are senior clinical members of staff who are leading serious incident investigations. With the best will in the world, they are not expert investigators, and some are better than others. Some are…downright poor." [Healthcare investigator 15]

Another inherent adverse consequence of investigations led by senior staff without adequate objectivity and expertise was a perception by certain healthcare commissioners that senior members of staff involved in incidents, in particular, colleagues of those leading investigations, were not always held accountable.

"We [commissioners] did some theming of a series of reports in mental health, and never did the investigations identify poor supervision as an issue. However, when you looked at who the investigators were, they were at that supervisory level." [Commissioner 1]

Certain healthcare investigators recognised the value of expertise in human factors when investigating incidents and formulating risk controls. Few in healthcare, however had access to such expertise for investigations due to resource constraints. Only one healthcare investigator interviewed (US-based) reported having access to human factors expertise routinely during investigations and commented on the eye-opening and impactful insight they brought to both investigations and the formulation of risk controls.

"But unless you have a human factors expert, you won't always get to some of the things that I think we could get to. So again, that's a capacity and capability issue that we need to address within the team or call in experts." [Healthcare investigator 5]

"So, he [the human factor specialist] focused very much on…recommendations… beyond [the hospital], they should be about packaging

> *of prostheses.... You know, I wouldn't have paid attention to things like that... we wouldn't have asked questions, so has this packaging been tested in the environment with the users? What is the font size and at what distance can you see that at realistically?"* [Healthcare investigator 16]

In section 6.2.1.1, I identified how structured tools may be used to strengthen the generation of risk controls following incident investigations. In this interview study, healthcare investigators were often not familiar with using such tools. Academics observed that healthcare investigators did not always have a sound understanding of how proposed risk controls would work to effectively mitigate risk, and instead tended to focus their efforts on producing recommendations that were easy to implement and not resource intensive.

> *"They [investigators] don't really seem to focus a great deal on the nature of the solution to that problem… they launch into the first thing that comes to their mind that addresses that problem, very often training or a new policy, or training about a policy, or a policy about training, and all those things that are their go-to solutions for any problem…it's about the ease of getting it [the action] off the plate, so that people can move on to the next problem, is the main thing that I have seen."* [Academic 5]

In non-healthcare industries, participants referred to the conduct of both internal and external investigations following incidents. External investigations were generally performed by national organisations which served the prime purpose of investigating incidents with the highest risk of harm or those which did lead to harm. Both internal and, in particular, external investigations were generally conducted by professional investigators. Many simultaneously maintained knowledge of operations by also working in the field (e.g. an investigator in aviation who also worked as a pilot), though their prime role was as investigators, where they felt their expertise lay.

> *"And the other thing is, a lot of our staff at the AAIB were still working. I was still flying as a current pilot until a few months ago, and so we would be on the*

other end of those anyway, so we would see the effect that that was having on the industry." [Industry investigator 3]

These investigators focused on producing recommendations backed with evidence based on previous similar incidents or from a detailed analysis of causation of the current incident under investigation. A solid understanding of how such recommendations were meant to improve safety was considered by these investigators to be essential to effective risk management following incidents.

"I would come up with suggested recommendations and examples of how those recommendations might be implemented or examples of similar things that have occurred in other companies or in other parts of the world to provide a bit more substance or guidance as to how, you know, well first of all an explanation behind the recommendations, if that's needed, but also how those recommendations can be embedded within the organisation…" [Industry investigator 6]

Additionally, industry investigators were able to access human factors specialists with expertise in the interactions between humans and other components of the system and how such interactions contributed to errors. Identification of such factors were considered by industry investigators to offer distinct advantages: the detection of previously unknown contributory factors which had remained latent in systems, the promotion of a blame-free approach to risk management by understanding *how* errors occurred instead of simply stating *that* they occurred, and importantly the formulation of recommendations focusing on the design of safer systems.

"…in fact, we have a department in my own organisation [Energy sector] that deals exclusively with human factors in the design and operation of high hazard chemical facilities. So the human factors is something that pervades a lot of what we look at…what we're trying to do is… not to blame individuals, that's the first aspect, but secondly it is a management responsibility to ensure that

the impact or the likelihood of human factors is minimised." [Industry investigator 6]

7.2.3 Formulating sustainable defences mapped to identified problems

A common concern among participants with experience in healthcare investigations was that most recommendations coming out of investigations focused on risk controls which were, on paper, easier to implement: rewriting policies, re-educating staff and reinforcing existing practices. Healthcare participants consistently expressed their frustrations with how such risk controls only addressed superficial factors or symptoms of the problem without addressing wider systemic issues. Such risk controls were aimed at addressing active failures, rather than latent conditions.

> *"I think they [risk controls] are for the most part, likely to be futile. I don't think they go far enough, deep enough into the organisation…They are more likely to produce a temporary improvement."* [Healthcare investigator 7]

> *"There is retrain, there's change in policy. But in general, those are considered less firm, less quality interventions."* [Industry investigator 5, discussing her experience of reviewing healthcare incident reports]

Two main reasons were proposed by academics who had researched the practice of healthcare incident investigation to explain the lack of effective and sustainable risk controls following incident investigations in healthcare. First, two academic participants reported that risk controls did not always address the identified hazards. Risk controls in healthcare were rarely supported by a sound link between the identified hazards and the proposed controls describing how the latter were meant to prevent the former.

> *"They [investigators] don't really seem to focus a great deal on the nature of the solution to that problem…they launch into the first thing that comes to their mind…very often training or a new policy."* [Academic 5]

Second, the production of investigation reports and action plans was viewed by healthcare investigators as a target-driven exercise focused on getting reports signed off by the different layers of quality assurance from within (local governance boards) and from those outside (commissioners) the organisation. Key determinants for sign-off were cost of implementing controls and the feasibility of implementation within a specific time frame. These determinants took precedence over the strength and perceived effectiveness of risk controls in the process of formulating risk controls. Consequently, risk controls proposed by healthcare incident investigators were typically those within the scope of control of their department or organisation. The need to be seen to do something in the aftermath of an adverse event, as a display of compliance with externally mandated rules,[283, 284] led to a piecemeal approach to improvement as opposed to developing wider and more coherent strategies for safety.

> *"They [investigators] put simple things on [the action plan] …things that they can sign off that they've done…and move on."* [Commissioner 1]

> *"Things that do not involve purchases are more apt to be done quickly. It's about the ease of getting it off the plate, so that people can move on to the next problem."* [Academic 5]

> *"You make action plans that can be achieved…because of resources, money et cetera…because your commissioners who you're sending your SI reports want to know it's happened, and usually in ridiculous timescales."* [Healthcare investigator 16]

I believe that part of the solution to poor quality risk controls may well be the development of a well-founded "theory of change", which would produce a holistic understanding of the relationship between risk controls and causal factors[285] and the mechanisms through which interventions would lead to improved outcomes. As discussed above, the lack of skilled investigators in healthcare may, in part, explain the poor quality of recommendations coming out of investigations. In contrast, an air accident investigator discussed the significance the aviation industry ascribed to the

evidence behind their findings and how risk controls were meant to address shortcomings identified during investigations.

> *"I think the key thing is that they [risk controls] are all evidence-led, and the evidence should clearly point to a deficiency in a particular area, and if that happens to be training, then that's fine for the fix to take place in that area."* [Industry investigator 3]

Participants from an industry background also paid attention to the resilience of their defence strategy. A single layer of defence was viewed to be unsustainable. Prevention of incidents necessitated the presence of multiple barriers, or defences in depth, as discussed in section 6.2.2.3.

> *"What prevents that incident from occurring …[is]…more than one layer of protection."* [Industry investigator 6]

Participants across all industries recognised that humans were prone to mistakes, and an effective risk control strategy would need to account for human fallibility. Controls that required less human intervention were viewed as stronger, in line with the hierarchy of risk control (see sections 2.5.1.1 and 6.2.1.1). Such interventions have been described in the literature as more effective and sustainable,[9] though also harder to implement.[154]

> *"They [risk controls] shouldn't rely entirely on people being perfect. Indeed, they should rely as little as possible on people doing the right thing every single time."* [Academic 5]

> *"A good action plan…it's one that engineers the problem out. So, [a good risk control] doesn't rely on the individual, doesn't rely on…training, policies, vigilance."* [Healthcare investigator 16]

One promising approach proposed by certain healthcare participants in senior leadership position to address the tendency to adopt short-term or shallow solutions

was the use of aggregated analyses of multiple incidents to generate more intelligence around areas of risk across departments and organisations.

> *"I've had a look at the human factors classification system, if that's used consistently, it produces a themed report which will show you where you need to take your action. So, you might not, based on one incident, completely change your computer system. But if it's contributed to a series, that's where that needs escalating."* [Commissioner 1]

7.2.4 A collaborative approach to quality assurance of investigations and risk controls

All healthcare participants reported some degree of oversight into the outputs of their investigations by managers and regulators not involved in investigations to ensure that they were of an adequate standard. By and large, quality assurance of incident investigations and action plans in healthcare comprised two levels of oversight. First, an internal level where a senior manager or clinical manager (internal quality assurer), not involved in the investigation nor the incident, would review the incident reports and action plans and provide comments to the investigating team. Second, in England (though not consistently in other parts of the UK), external oversight was provided by a group of healthcare professionals (usually made up of General Practitioners and senior nurses) from the local Clinical Commissioning Group (external quality assurer). They reviewed the revised incident report and action plans after internal scrutiny and provided comments. Incident investigations and action plans were not signed off until they were satisfied. The principle of assuring the quality of investigations and risk controls was valued by participants.

> *"I think it [external oversight of investigations] is very useful…you get to the salient points"* [Commissioner 3]

Despite the widespread acknowledgement of its importance, participants expressed multiple frustrations with how the quality assurance processes operated in practice, in particular, external oversight from CCGs in England. Healthcare incident investigators

felt that clinical commissioners were less equipped than senior management within the organisation to sign off investigation reports and the proposed risk controls, since they possessed less operational knowledge of the inner workings of a department or organisation, and did not always possess the skills in safety science to dissect reports.

> *"one was an RCA investigation chaired by the medical director, who has a good understanding… of human factors and. the RCA, and really really was engaged in this process and really took it home and took it apart. That was signed off by him, and it came back [from the CCG] with two pages of things saying we're not signing it off because you haven't put this point in here, or you haven't put an action about that. Which was quite frankly nonsense."* [Healthcare investigator 5]

> *"And they* [commissioners] *don't have the expertise ... to know whether they're looking at a good report or not."* [Healthcare investigator 8]

The perceived lack of competence among commissioners in effectively and productively analysing incident reports and action plans, and the consequent poor quality of feedback they provided, contributed to a tense relationship between healthcare investigators and commissioners. At the same time, commissioners felt that their feedback was not taken seriously enough by investigators. In certain circumstances, such tensions could lead to a breakdown in trust between investigators and commissioners, undermining the quality assurance process and creating unproductive power struggles.

> *"I've sent it back to the CCG saying whether you sign this off or not is up to you, but we're not changing the report. They've come back and said you have to change it if we say so, and I say unless you're standing in the coroner's court, no we don't. If it's my name on it, and I'm standing in the coroner's court, it's my report. If you want to put your name on it and stand in the coroner's court, be my guest…the comments, most of the comments back from commissioners are*

unhelpful, lack of insight, people who don't understand the process, and I think often have personal interests." [Healthcare investigator 5]

"I wish…relationships are better. I wish that people considered the CCG as part of the process, as some fresh eyes, people that have experience of looking across a lot of investigations, and they saw our input as helpful rather than punitive if you like." [Commissioner 1]

Such tensions and negotiations between investigators and commissioners, along with the resulting feedback from commissioners, remained out of sight of staff within the organisation, including implementers and internal quality assurers, since the only tangible output of any investigation was the investigation report and the action plan. These stakeholders were unaware of the discussions and outcomes of the external quality assurance processes which shaped the incident reports and action plans. Such opacity in the feedback loop further eroded trust in the quality assurance process.

"I believe they send out to the CCGs; I've never seen what feedback comes back. I'm often asked to sign off SI reports as well…in my sort of capacity as deputy clinical director. So, I'll sign it off and it's that signed version which will go... to the CCG, but then nothing ever seems to come back to me." [Healthcare implementer 1]

In the few instances (three) where participants did report a productive relationship between commissioners and healthcare investigators, two common factors were a collaborative approach to quality assurance of risk controls through transparent channels of communication, and an understanding of the principles of safety science by commissioners. Collaborative approaches to quality assurance manifested in the form of commissioners attending internal incident quality assurance meetings and investigators attending commissioner assurance meetings. This allowed the co-construction of risk controls by supporting the development of learning communities where investigators benefited from commissioners' experience of reviewing multiple organisations' incident reports and action plans, and commissioners maintained a

greater sensitivity to operations and understanding of context within individual hospitals.

> *"It's having that open relationship. So, when I work within the CCG, you know, it was* [about] *having regular contact meetings with the patient safety team. We invited them to our review meetings… They* [investigators] *could come to our meeting to actually see …what our questions were, what our discussion was about the SI, and …the reason behind our questions back to them."* [Commissioner 2]

> *"I think it's very useful… Because it's quite difficult to represent the conversation in a letter. When you're identifying gaps, what you get is the key salient points. The providers themselves have said it's been very helpful to have someone in the room to have heard the dialogue."* [Commissioner 3]

In contrast, quality assurance of incident investigations and recommendations in other safety critical industries was provided through rigorous internal processes, within independent bodies. Expectations and standards were further raised through high quality investigations and recommendations from national investigation bodies such as the National Transport Safety Board in the US, Rail Accident Investigation Branch and Air Accident Investigation Branch in the UK. These national investigation bodies promoted transparent investigations and allowed conclusions of investigation reports to be scrutinised by all stakeholders before finalising them.

> *"when we did make safety recommendations, we went through a very rigorous in-house series of meetings where I and the senior management team would very strongly challenge the investigation team with their recommendation."* [Industry investigator 3]

> *"That* [sharing investigation reports with stakeholders prior to publishing] *was the UK law…it gave people [stakeholders] a chance just to check our facts that we'd put in the report, and generally more widely they would give us responses*

on why they agreed or disagreed with some of our conclusions." [Industry investigator 3]

7.2.5 Effective knowledge management and brokerage within and across organisations

Daft and Weick[286] describe organisational knowledge as an organisation's internal representation of the world, serving the key purpose of driving organisational performance.[92, 287, 288] Such knowledge, which can be generated from incident investigations, is helpful if harnessed and mobilised to improve safety and performance. Learning from incidents is a distinct process from the analysis of incidents.[289] Learning entails the changes in functioning and behaviour that result from the effective sharing of results of event analyses. Such exchange of information allows recipients of learning activities to reflect on the content being shared and contextualise them to their own reality.[289]

In this interview study, participants across all groups considered the effective dissemination of information to be an integral part of ensuring risk controls were sustainable and thereby reducing the risk of future incidents. Healthcare participants however expressed frustrations with the fact that different healthcare departments and different healthcare organisations faced similar problems, yet also practised post-incident improvement work and learning in isolation.

> *"I've been reading reports from the three large hospitals here in [location 4] …there's nothing different happening. But they're not sharing them."* [Commissioner 1]

> *"…we are all busy in every Trust…reinventing the wheel to put these [safety standards for procedures] in place locally, when at national level… specialties could have come out with templates… Learning in the NHS …isn't as good as it should be."* [Healthcare implementer 2]

Healthcare participants identified multiple reasons for this kind of silo working and lack of effective learning following incident analyses. First, they reported that current means to disseminate information in healthcare organisations did not always take into consideration the complex divisional structures of healthcare organisations. The latter are divided according to many criteria such as specialty, geographical location and management structure.

> *"if something went disastrously wrong on [Ward X], I'm not sure that there is a mechanism in place to share the learning to all staff."* [Healthcare implementer 1]

> *"organisations don't join up, and I don't think they even talk among divisions sometimes if you like."* [Commissioner 1]

Healthcare participants also recognised that, despite complex divisional boundaries, numerous channels were used to share information generated from healthcare incident investigations by management to employees, but they were not always effective. Those not involving face to face contact (such as emails, newsletters), were seen as especially problematic. While emails and newsletters provided a relatively quick and passive means of sharing information, their non-specific and untargeted nature could result in information overload. They were not considered by participants to contribute to effective post-incident information dissemination and were a concern to participants, who struggled to separate important and relevant safety signals from noise.

> *"In patient safety…I think there is probably information overload throughout the organisation. I delete 250 e-mails a week... There is information fatigue."* [Healthcare implementer 4]

> *"there's so much going on. It may be that [that particular issue] isn't high on your trust's agenda at that time…it's about how you can select…and look to others to get that information."* [Healthcare investigator 3]

Existing face-to-face channels for dissemination of lessons from investigations included, most prominently, clinical governance and mortality and morbidity meetings. Healthcare participants reported frustrations with such forums, as the audience comprised mostly senior members of medical, nursing and managerial staff, with under-representation from more junior members of staff. Thus, important learning from investigations often stagnated at the higher levels of the hospital hierarchy, without making their way down to staff on the front-line.

> *"…if I had resources…I would have many more people…attend the M&M [mortality and morbidity meetings], the junior doctors, physios, OTs [occupational therapists]"* [Healthcare implementer 4]

Healthcare participants felt that they lacked guidance on how to effectively maximise and disseminate information generated from incident investigations and the effectiveness of risk controls following incidents. They believed that different agents in healthcare, in particular national bodies with responsibility of providing guidance to improve safety had, over time, developed a myopic focus on investigation rather than risk control. As a result, less time was spent on developing guidance on how healthcare organisations could develop robust means to sustain both intra and inter organisational learning following investigations. The consequence was inadvertent goal displacement in healthcare organisations, with the reports of investigations being seen as the end product as opposed to the beginning of the learning cycle.[12, 13] Commissioners also observed the relative lack of attention investigators provided to the production of actions when compared to the investigations.

> *"I think there is far more inputs from NHS Improvement and NHS England on the doing the investigation, rather than on help us share the learning."* [Healthcare investigator 5]

> *"so much effort and time is put into an investigation report…getting the investigation report right…then there is a real tail-off of enthusiasm at the other end of it."* [Commissioner 1]

Participants often shared frustrations about the timeliness of the implementation of risk controls and the durability of the learning generated from past incidents. The longer it took for information relevant to past incidents to be shared, the less impactful the learning was considered to be by participants. Regulatory requirements have focused on the need to conduct timely investigations (such as the need to complete investigations within 60 days of it being notified to the CCG in England), but such time frames are not imposed on the implementation of risk controls.

> *"maintaining that level of learning is quite difficult…so if you go for three or four years and nothing happens, then the sort of organisational memory fades."* [Healthcare implementer 7]

> *"it's just the time that things take before they get to fruition…this happened [three years ago] and we still haven't got the learning package down."* [Healthcare implementer 5]

Inter-organisational learning was regarded by participants from healthcare as a further challenge. They reported that national structures tasked with spreading learning from incidents, such as the NRLS, were inefficient in sharing safety concerns which stemmed from single organisation investigations. The fact that healthcare organisations are expected to submit their investigation reports online to the NRLS, with no reciprocal acknowledgement, created a distant relationship between them.

> *"we sent some [incident reports] where the labels for the sedative and the muscle relaxant, one was red and one was orange…on the same tray… and …twice in the same organisation, we saw the muscle relaxant being given instead of the sedative, with one fatal consequence…we escalated that up to the NRLS. I haven't seen any response to that…"* [Commissioner 1]

There was widespread recognition among participants from healthcare that current means of disseminating lessons learnt following incidents were not working, as

described above. Healthcare participants saw post-incident organisational learning as an issue which had to be solved.[290]

> *"I think we really struggle with this [dissemination of safety lessons]. And I think one of the useful things would be to have…a group that looks at what's happening intelligently…at the moment we don't have a group that looks at this thing overall and tries to triangulate it with what else is going on."* [Healthcare investigator 8]

A number of the solutions proposed to improve intra and inter-organisational learning came from healthcare participants. They had numerous ideas on how post-incident learning could be improved and, in some instances, had already implemented them. Senior leaders tasked with disseminating lessons found that using forums or sessions which already existed for other training purposes, to raise awareness of particular safety issues identified from investigations, was a potential solution to the problem of non-targeted and ineffective organisational learning. For instance, participants described using junior doctors' mandatory teaching sessions, nursing handovers and medical grand rounds to discuss specialty-specific safety concerns raised from incidents and improve intra-organisational learning. By contrast, the sustainability of new forums dedicated to learning from incidents were hampered by poor attendance by staff from different disciplines who had to create time out of their busy schedule to attend such forums.

> *"So they could do that [share lessons learnt] at M&M meetings, they could do that at ward and departmental meetings, they can do it as part of handover, they can do it as part of a handover, you know…They could have it as part of a poster presentation, they could have it as part of journal club. So those sorts of things about sharing the learning in a practical way to get it down to troops on the ground."* [Healthcare investigator 5]

Participants from across both healthcare and other industries valued having an identifiable and tangible agent who could facilitate knowledge brokerage across

healthcare organisations. Such knowledge-brokers, which might be individuals or organisations, were considered capacity-builders, enabling the spread of innovations, linking like-minded individuals and facilitating exchange of information. Knowledge brokers described by non-healthcare participants, such as in aviation or chemical industries included organisations made up of individuals who came together with the purpose of sharing information across organisations.

> *"There were meetings of people like there was a flight safety committee, so every flight safety officer from every airline would meet regularly, and they would discuss safety problems that they had had, and what they'd done about it, and so there was a lot of exchange of information."* [Industry investigator 3]

> *"…the organisation…the company involved will usually be a member of some kind of industry association. I mentioned a few of them, The Energy Institute for example, The Chemical Industries Association is another one. There are various, they call them clusters I think, regional clusters, so there is one in the midlands, there's one in the north west, there's one in the north east, industry kind of collaborative forums that are available to share, they meet regularly anyway to discuss a whole range of issues…Usually it's in the context of, well either we've had this incident, we think other people would benefit from knowing about it, or we've had this incident and we've got the regulator involved has anybody else experienced this and, you know, how best to deal with the regulator."* [Industry investigator 6]

Similarly, knowledge brokers in healthcare took various forms, including patient safety collaboratives or learning networks, organised around specialties, particular clinical groups or geographical areas.

> *"we share our learning between ambulance trusts both as a reporting mechanism and then we get together and we have like a two-day bench-marking every 6 months, where we will also go through what has happened, go through our serious incidents and our patient safety incidents to determine if*

there's something that other organisations need to pick up and we might do a national piece of work then." [Healthcare investigator 11]

Though the relationship between commissioners and healthcare organisations in the UK was not always without tensions (see section 7.2.4), commissioners felt they held a unique position as scanners of risk across multiple organisations. Such a unique position implied a potential role of CCGs as knowledge brokers within the region they operate, perhaps alongside newer structures such as accountable care systems which aim to bring together healthcare providers, commissioners and local authorities to work in partnership in improving health and care in a particular geographic area.[291] In other industries, such as aviation, there was evidence of bespoke structures to facilitate learning, such as meetings involving flight safety officers across multiple airlines.

"CCGs have a broader view I suppose…they could see…if there was a theme emerging…but you'd have to have a good working relationship with the providers." [Commissioner 2]

An investigator with experience of both healthcare and aviation pointed out that a significant challenge with inter-organisational learning in healthcare was the scale of the industry, which made learning difficult to coordinate and disseminate through central channels, especially given that investigations into serious incidents were conducted by local teams unlike other industries such as aviation, where investigations into incidents with high risk of harm were investigated by national bodies which could disseminate information to all organisations concerned.

…the way that healthcare is structured perhaps doesn't make it ideal…In aviation, certainly, it's a smaller scale, so anything obviously that we reported would go to all the airlines, and so they would be able to learn from… [Industry investigator 3]

7.2.6 Purposeful implementation and tracking of risk controls

Implementation of risk controls was deemed by participants from both healthcare and other safety critical industries to depend on the clarity of the role and accountability of those tasked with implementation. These individuals were expected to hold a sense of ownership and commitment to the risk controls to be implemented (thereby also highlighting the importance of engaging them during risk control formulation as discussed in section 7.2.1), along with a sense of agency when implementing them. In reality however, participants from healthcare expressed concerns that those responsible for implementing risk controls were already overburdened with other clinical and managerial commitments, which took precedence.

> *"So, having somebody who really does own the action [leads to higher implementation rates], rather than having it assigned to them."* [Commissioner 8]

> *"…the portfolios of the frontline managers have expanded and expanded, and to really be, you know, a commitment-based leader and not just a compliance-based leader. You know, like anybody can force someone to go run around and do an audit, but to have a manager who's really a coach, who really helps people understand why these safety behaviours are needed, and really understand the risk of not adhering to the safety behaviours, they need time and mental energy, and if they're running around dealing with access issues 24/7, and a huge number of staff, they, they do not have time for that."* [Academic 2]

Participants from healthcare expressed concerns about the lack of a clear line of accountability when risk controls were not implemented, which could be perpetuated by the absence of robust mechanisms to track risk controls. On occasions (reported by three participants with backgrounds in healthcare), lack of accountability was an issue affecting risk controls intended to be implemented in the organisation where an incident had occurred.

"At the moment no single person is held to account for an action plan, and the oversight at governance forums is really inconsistent." [Healthcare investigator 8]

"I think it is about responsibility and accountability… I do think we don't hold people to account in terms of so who is responsible for this action" [Healthcare investigator 13]

Two academics thought that lack of accountability was even more acute when the locus of responsibility for implementation of particular risk controls lay outside the remit of the healthcare organisation where the incident happened: individual healthcare organisations inappropriately reabsorbed the responsibility to solve problems. Such unfair redistribution of accountability was often due to non-engagement by third parties who held greater powers to effect change, such as equipment companies.

"I do believe one of the problems in the NHS…is it is very easy to put the problems all in the hands of the hospital" [Academic 7]

"we see imperfect design…where we then have to train people around the pitfalls of the technology. In some cases, we might go back to the vendor. They always say we're the only people who've noticed it [a particular problem]." [Academic 2]

Once risk controls were implemented in healthcare organisations, they were not always followed-up. Many participants from healthcare expressed frustrations with the lack of formal infrastructure in place to track the implementation of risk controls. The lack of resources to establish and maintain such structures was highlighted among participants from healthcare.

"there was no tracking process in place, so they [healthcare managers] didn't realise until…months after the fact, that they had never even implemented the

action plans that they'd spent probably hundreds of person-hours coming up with." [Academic 5]

On the other hand, participants from other safety critical sectors, such as the military, provided accounts of how resources were allocated by organisations where the incidents occurred to ensure risk controls were implemented, tracked and monitored.

"For military, it's relatively easy...there is time, resource, money allocation to ensure that the loop is closed." [Industry investigator 9]

In certain non-healthcare safety critical industries, like the military, risk control monitoring was facilitated by the use of bespoke databases which allowed the detection of previously identified uncorrected hazards.

"In the military, there's a clear chain of command…If for whatever reason, things are not followed through correctly or the solution is not implemented or we see that the problem is recurrent, the database will flag that situation for further analysis, closer attention [is given to] why the solutions weren't effective or why…it was broken down." [Industry investigator 5]

When such formal structures were in place in healthcare, participants valued the use of tracking software allowing different stakeholders responsible for the implementation of individual risk controls to provide updates. Such systems relied on a level of trust between those responsible for implementation and those monitoring implementations. Perhaps the biggest advantage of such electronic solutions to risk control tracking was the fact that they facilitated an organisation-wide approach to monitoring implementation, allowing tracking of risk controls generated from multiple incidents alongside those generated from other sources such as CQC inspections or local improvement plans, all in one place.

"…software [Q] has got a very good reputation within the organisation…We've used it successfully, because we can track plans from incidents…audits, CQC

inspections, etc…we can monitor [every action] through to closure…our general managers can see all their actions." [Healthcare investigator 5]

Internal oversight from different layers of governance provided an additional drive to successful implementation according to certain healthcare participants. Such oversight was provided by a team of senior managers, clinicians and hybrid clinical managers who came together at regular intervals to track the implementation of risk controls and review why some were not being implemented. Such hierarchical risk monitoring structures were considered by healthcare participants to be useful if they had both a supportive and critical function, allowing reasons for non-implementation of risk controls to be explored and simultaneously questioning whether those risk controls implemented were the right ones.

"…we're increasingly trying to make…our Patient Safety Evaluation Team track actions until they're completely done… and question the strength of [implemented] actions." [Healthcare investigator 17]

In safety critical industries, external oversight from regulatory authorities, distinct to the investigative bodies, provided a layer of monitoring to the implementation of risk controls generated by national investigative bodies and was an additional motivation to implementation by individual organisations.

"*Civil Aviation Authority [CAA], would follow up all the recommendations we made to the airlines or the airports or whoever…they would take it on as their duty to check that they had done what they said they had done, and they wouldn't actually close off the associated CAA kind of file on this event, whatever initiated it, until they were completely satisfied that everything had been completed. So that would often stay open for years whilst they waited for all the tasks to be done."* [Industry investigator 3]

> *"the [regulator's] board will look at the action plan and what was done, and they would make a judgment that this recommendation was done, or this recommendation is still open, it's not done."* [Industry investigator 10]

7.2.7 Accounting for patients' and carers' voice

There was acknowledgement amongst healthcare participants that the healthcare sector had gotten better in demonstrating candour (being honest and transparent to patients and carers) following occurrences of adverse events. Nonetheless, participants from healthcare recognised that the process of involving families in investigations and action planning remained challenging. It required skills from staff such as emotional intelligence, empathy, and advanced levels of communications, alongside organisational maturity.

> *"I think it [involvement of families] does make it [processes of investigating incidents and coming up with actions with family members present] difficult... it takes skills to work with a family and…bring the different parties together, reconciliation, all those things, that takes an awful lot of time."* [Healthcare investigator 17]

Healthcare participants were divided on the role of patients in risk control formulation. Some healthcare participants found it hard to fathom how risk controls could be formulated without accounting for the opinions of those who are at the receiving end of care while others felt they were not equipped with the knowledge to be involved. Those who did advocate for the involvement of patients and carers in risk control formulation highlighted their readiness to tackle difficult issues for the greater good, in the hope of preventing others from suffering from the consequences of similar adverse events. For instance, one participant reported that patients were able to offer a creative and impactful solution to organisational learning through storytelling.

> *"The action plan must involve patients…for staff..., it's sometimes possible to duck when it gets tough and patients don't duck when it's tough"* [Healthcare investigator 18]

> *"one of the patients…who suffered as a result of a serious incident, they* [the organisation where the incident occurred] *made a video of her story. She was more than happy to share her story."* [Commissioner 8]

Healthcare participants who were less convinced of the usefulness of patient involvement in the formulation of risk controls highlighted the complex nature of the decision-making process involved when deciding on risk controls, requiring knowledge of individual specialties or an understanding of logistics within organisations. On occasions, healthcare investigators and commissioners were concerned by the emotional and biased responses families and patients might have if involved in the action plans, leading to a fear of retribution from them.

> *"…I don't want to come across as paternalistic, but ultimately…the things that we're involved with are fairly complex…I'm not sure they would understand it or, be the right people to make those decisions."* [Healthcare implementer 1]

> *"I don't know that the patient would understand human factors either…quite often the public are still wanting people sacked…when they've made errors."* [Commissioner 1]

Participants from non-healthcare industries held similar views. They highlighted the importance of candour and ensuring that victims and their families were kept abreast of investigation findings but felt risk control formulation was a process which required specific professional skills from investigators and an understanding of context which staff within an organisation possessed (see section 7.2.1) but not families and carers.

> *"I would hope that if I were a patient, and some harm came my way, I would be standing back and letting the professionals work together to find a solution….I think a minimal degree of involvement in the investigation and the solution, but*

absolute understanding of the fact that a process is going on to try to achieve a better result for others in the future." [Industry investigator 2]

7.3 Discussion

In the previous chapter (6), I identified multiple features influencing the successful formulation and implementation of risk controls based on a narrative review of the literature of multiple safety critical industries, including healthcare. I have extended the analysis by interviewing multiple stakeholders responsible for investigating incidents, reviewing the quality of investigation reports and action plans, and implementing recommended changes, as well as researchers investigating the subject and expert accident investigators from other safety critical industries. The 52 participants, between them, had experience in the investigation and risk control processes in healthcare and other safety critical industries. Using the results of the narrative review from Chapter 6 as guiding framework of sensitising constructs combined with an inductive approach, I analysed the interview data.

This led to identification of seven key features important to improving risk control formulation and implementation: (1) accounting for voice of staff on the front-line whilst recognising the limits of their input, (2) the need for skilled and independent investigators, (3) the creation of sustainable layers of risk controls, (4) establishing a collaborative approach to quality assurance of investigations and risk controls, (5) better intra and inter-organisational learning, (6) improved structures for ensuring implementation of risk controls and (7) accounting for the opinions of patients and carers. These features can be clustered into three broad considerations when thinking about improving the formulation and implementation of risk controls: those relating to the improvement of individual skills of those conducting investigations and framing recommendations, those aiming at establishing or enhancing organisational structures to improve risk controls and the learning process and those factors aiming to address extra-organisational constraints outside the remit of the organisation within which the incident occurred.

7.3.1 Better expertise when investigating incidents and formulating risk controls

Participants reported that lack of skills in safety science and human factors among staff working in healthcare contributed to challenges at numerous levels: from investigating incidents to formulating better risk controls and improving the quality assurance of investigations. Investigation of safety incidents, the design of appropriate risk controls and assuring the quality of these processes were challenging processes which required specialist skills, often lacking in healthcare.[277] Vincent et al. reported that healthcare incident investigators are mostly clinicians with an interest in safety, with the bulk of their expertise being in clinical and nursing domains, not safety investigation. This is in contrast to the expertise and experience of safety investigators in other high risk industries such as aviation.[63] To be able to dissect incidents, identify the appropriate areas of risk, understand those areas amenable to risk controls, and balance the risk and benefits of certain types of risk controls over others, I propose that incident investigators in healthcare should be experts in safety investigation while maintaining a working knowledge of healthcare systems.[277] This combination of the right expertise with experience of the context within which risk controls are to be implemented may result in the formulation of risk controls which are not just fantasies, but which are robust, oriented at improving systems and likely to be implemented successfully.

National healthcare safety investigative bodies such as the Healthcare Safety Investigation Branch in the UK have a particularly important role to play in expanding the investigative capacity of local trusts and quality assurance capability of CCGs. This can be achieved by providing secondments, continuous professional development opportunities and guidance to staff conducting or reviewing local incident analyses in order to gain, maintain and update technical skills in safety investigations. Technical skills alone are not enough for an individual to conduct thorough incident analyses in a sensitive sector such as healthcare. Previous research has shown that healthcare investigators struggle to manage the emotional component of dealing with patients and families when investigating incidents.[292]

An additional challenge I identified was uncertainty among investigators from both healthcare and other safety critical industries regarding the usefulness of patients' and their representatives' contributions to the formulation of risk controls. Current evidence proposes that patients play a key role as informants to the investigative process or "problem- sensors".[284] O'Hara et al. identified that patients were able to identify leading indicators of wider safety concerns which might in turn be targets for risk controls devised by investigators and front-line staff before the occurrence of an adverse event.[293] Thus, while probably not equipped with the technical knowledge of how to design effective safety interventions within a healthcare context, patients and their representatives hold valuable information which investigators need to learn to harness and translate into effective recommendations. Research looking at the level of involvement of patients in risk control formulation and how best to engage them is nonetheless lacking.

7.3.2 Establishing or enhancing organisational structures aiming to improve the risk control and learning processes

Numerous enablers for strong risk control fall within the responsibility of individual healthcare organisations. The findings from this interview study suggest that these organisations need to create conditions which empower staff investigating incidents to do so robustly, develop stronger processes to track the implementation and effectiveness of risk controls, and disseminate the lessons learnt from investigations. Local healthcare safety investigators, who are also conducting clinical duties, need to have dedicated time in their job plans to conduct robust investigations and be supported to develop the skills required to do so. Importantly, healthcare organisations need to also develop local leaders with responsibility to oversee the quality of local investigations, providing strong internal quality assurance. The development of clinicians with expertise in safety science alone will not be enough to improve an organisation's capacity in investigating incidents and develop strong risk controls. Such activities also require the inputs of human factors specialists who are as, I previously reported (see section 4.2) currently rarely involved in healthcare.

Participants from healthcare reported frustrations with systems in place to track implementation of risk controls. Similar findings were identified in studies looking at implementation of risk controls following incidents in the Swedish healthcare system.[294, 295] Such findings may highlight a lack of technical infrastructure to track implementation, and an improvement at this level may well be the next logical step in the improvement of safety given that, in the last twenty years, healthcare, as a sector, had primarily focused its attention on building infrastructure for incident reporting and analysis.[104]

Improvement in technical infrastructure alone may not be enough though in bridging the gap between recommendation and implementation. Wrigstad et al. attributed this "lack of dialogue" between implementers and investigators to be due to the absence of a strong "social infrastructure" which promotes improvement.[295] Findings from section 7.2 would suggest that the divisional structure within healthcare organisations often promoted silo working and silo learning. Studying the Challenger Space Shuttle disaster, Vaughan et al. termed the compartmentalisation of knowledge resulting from division of labour in complex organisations as "structural secrecy".[218, 296] Healthcare organisations need to develop means to use incident investigations as a medium to bring together investigators and implementers to discuss areas of risk, identify solutions for improvement and discuss means to transparently monitor improvement. Waring et al. suggest that staff in hybrid roles such as clinical-managers, may play an important role in knowledge sharing and learning, in part due to their reach and influence spanning across departmental and hierarchical boundaries and their "legitimacy" in being part of multiple communities.[297]

7.3.3 Improvements at a sectoral level

Where improvements in the risk control process are concerned, changes at the individual level (better trained investigators for instance) and organisational level (such as better methods to track implementation) cannot happen without enablers at a sectoral level. The establishment of independent national investigation bodies such as the Healthcare Safety Investigation Branch in the UK and the National Investigation

Board for the Health and Care Services in Norway provide examples of possible platforms for the development of such enablers.[298] Along with improving investigative capacity of healthcare systems, one of their other key attributes, akin to investigative bodies in other safety critical industries, is their potential ability to target recommendations at multiple organisations and bodies beyond those where the incident occurred, including pharmaceutical industries, regulatory and educational bodies. In this way, they may be able to better place accountability to those agents with an ability to produce change.

At a technological level, to improve knowledge management across organisations, better infrastructure to curate relevant learning from incidents happening in different organisations is required. In the UK, a previous evaluation of the performance of the NRLS found deficiencies in its ability to effectively capture and disseminate lessons from incidents.[105] Areas for improvement identified included the need for more user-friendly interfaces, more explicit incident classification systems and technologies to improve local analytics, staff and patient feedback.[105] Resolving these constraints will result in improvements in participative engagement of the multiple stakeholders in the investigation and risk control processes, including front-line staff and patients. Macrae argues that for true improvement to result from incident reporting and investigation, feedback to staff should be more purposeful and inclusive through the development of spaces to *"encourage open conversation, participative investigation and collective improvement of safety."*[104]

Prioritising psychological safety[299] and minimising regulatory constraints are two essential requirements for staff from the front-line to engage in incident reporting and investigation, for investigators to feel they can freely articulate areas of risk they identify from investigations and for organisations to feel that they can share their lessons learnt from past incidents. Using the principles of systems theory, it can be argued that the first step towards promoting psychological safety within organisations and departments needs to come from outside organisations, at a regulatory level. The provision of a "safe space" for healthcare incident investigation, comparable to similar

legal arrangements in many other safety critical industries, as recently recommended by the UK government's response to the draft health service safety investigation branch bill[300] is a step in the right direction. Such a safe space might increase the engagement of staff in investigative processes by ensuring that information provided to the Healthcare Safety Investigation Branch during their investigations could only be disclosed in very limited circumstances or by measure of a court's order. It could be argued that similar arrangements should be in place to encourage healthcare organisations to share their lessons learnt from investigations. Bodies such as NHS England have an important role to play at a sectoral level by removing rigid constraints, such as the requirement to produce investigation reports within 60 days in the England and 45 days in the US which, as demonstrated above, hamper the depth of investigations and in turn, the quality of risk controls. A promising recent development in England is the adoption of a more flexible investigation timeframe by NHS England for a few trusts as a trial in order to improve the quality of investigations. If successful, such changes are expected to be implemented more widely from Spring 2022.[301]

7.3.4 Limitations

This study has some limitations. First, while I recruited participants from multiple countries, the majority were from the UK, and their views were more prominently represented in the analysis. Thus, while many of the principles and approaches discussed may be applicable to other healthcare settings, some were specific to the UK. Second, the method used in this study was in-depth semi-structured interviews. It could be argued that a more holistic approach to answering the research questions could be obtained through ethnographic observations of incident investigation and the risk control process in healthcare and other safety critical industries. However, the limited time available during the doctoral study made semi-structured interviews more feasible. Finally, I did not recruit patients or patient representatives into the interview study. This was because I felt that the patients' views required more in-depth attention through a separate study, which was beyond the time frame of the PhD.

7.4 Conclusion

In this interview study, I aimed to explore features of high quality generation and implementation of risk controls in healthcare following serious incident investigations. Based on the views of relevant stakeholders from both healthcare and other safety critical industries, I identified seven features influencing the formulation and implementation of strong risk controls following serious incident investigations in healthcare. Many of these findings reinforced and enriched the findings of the narrative review in Chapter 6. Improvements at the individual and organisational levels alone are not enough in improving the risk control process. At a sectoral level, capacity-building exercises to develop networks of professionals able to conduct better investigations and identify stronger risk controls need to be supported with the establishment of adequate technical and social infrastructure that harbours participative learning.

8 Discussion

In this thesis, using the findings from a combination of analysis of serious incident reports and action plans, narrative review, and interviews with experts, I aimed to build detailed insights into how risk controls are formulated and implemented following incident investigations in healthcare to inform an understanding of "what good looks like" for the risk control process following serious incident investigations in healthcare.

Workpackage 1, reported in Chapters 4 and 5, was a qualitative analysis of serious incident investigation reports and corresponding action plans from a large acute NHS trust. In Chapter 4, using a modified HFACS framework, I identified categories of contributory factors leading to serious incidents, ranging from factors at the sharp end of care to latent factors which were less prominent in investigation reports. In Chapter 5, I identified that the more commonly recommended risk controls were also the ones which would be deemed those less likely to improve safety according to the hierarchy of risk control. I found a typically uncoordinated and shallow approach to investigating and managing risk, focusing on addressing problems at the sharp end of care, which would be easier to implement.

In workpackage 2, I undertook a narrative review of literature from healthcare and other safety critical industries with the aim of understanding approaches and practices which could be applied more widely in healthcare to improve the formulation and implementation of risk controls following incident investigations. I reported the findings in Chapter 6, identifying three themes describing a set of approaches which might improve the risk control process:

1. Improving the inputs into the design of risk controls (using incidents as a window into systems and processes, valuing stakeholders' input, empowering investigators, clarity of language).

2. Recognising problem-solving as a distinct step (giving time and space to problem-solving, using tools to structure problem-solving, designing defences in depth).
3. Feedback and evaluation (timely two-way feedback, routine monitoring and evaluation of risk controls).

Workpackage 3, reported in Chapter 7, comprised semi-structured interviews with 52 stakeholders from healthcare and other safety critical industries who had expertise or experience in incident investigations and risk controls. My aim was to develop a deeper and wider understanding of influences on risk control formulation and implementation by directly capturing the views of multiple relevant stakeholders. Using a combination of both inductive (based on data emerging from the transcripts themselves) and deductive approaches (using sensitising constructs derived from the results of the earlier narrative review and the wider literature), I identified seven features contributing to strong risk control formulation and implementation in healthcare settings:

1. Using a participatory approach and valuing voice from the front-line.
2. Prioritising the development of skilled and independent investigators.
3. Formulating sustainable defences mapped to identified problems.
4. Developing a collaborative approach to quality assurance of risk controls.
5. Developing effective knowledge management and brokerage within and across organisations.
6. Ensuring more purposeful implementation and tracking of risk controls.
7. Accounting for patients' and carers' voice.

Some features developed in Chapter 7 were not identified in the narrative review, such as the importance of a collaborative approach to quality assurance, the need for effective intra and inter-organisational learning, and the role of patients and carers during the processes of investigating incidents and coming up with risk controls. Alongside these new features, I also identified numerous challenges frustrating the implementation of these approaches and potential solutions to address these challenges.

Combining the findings of the chapters above, I have identified eleven features which I propose are necessary for formulating strong risk controls and implementing them. Table 8.1 outlines these features, organised into the three broad themes identified from chapter 6 (i.e. improving inputs into the design of risk controls, recognising problem-solving as a distinct step and feedback and evaluation). Table 8.1 also includes the numerous challenges to implementation of these approaches and potential solutions to address these challenges based on the findings from previous chapters – many of them requiring organisational and institutional (supra-organisational) support to implement.

What does good risk control formulation and implementation look like?	Challenges and consequences of current challenges	Proposed solutions
Improving the inputs into the design of risk controls		
Using incidents as a window into systems and processes.	Lack of familiarity with tools drawing on systems theory. Investigations are conducted in isolation, each requiring an action plan resulting in stop-gap solutions.	Involvement of experts in safety science and human factors when producing risk controls. Training in the use of systemic tools to analyse incidents (e.g. Accimap, STAMP). Performing aggregated analysis of incidents to identify significant areas of risk where current risk controls are failing. Identify networks of risk control working in synchrony (such as policies supporting implementation of changes on the front-line).

Skilled and independent investigators	Common practice is to have investigators local to the department or organisation where incident occurred. Local investigators are often clinicians or members of the nursing staff who do not possess skills in investigation methods, safety science.	Setting up of national independent investigation bodies. Separation of investigation and implementation teams. Development of skilled investigators, through national investigation bodies Using human factors' expertise to conduct investigations and generate risk controls.
Clear and shared language	Poorly written recommendations may not be turned into actionable risk controls.	Agreed and explicit language used consistently. Clear link between risk control and contributory factors. Creation of SMART risk controls.

Accounting for the patients' and carers' voice	Lack of consensus in healthcare regarding level of involvement of service users (patients and carers) in investigation and the risk control process.	Need for staff responsible to coordinate patient involvement to have good emotional intelligence and empathy.
Recognising problem-solving as a distinct step		
Use of tools to structure problem-solving	Lack of familiarity with tools to improve risk control formulation.	Use of tools such as the hierarchy of controls to brainstorm risk control options. Prioritise interventions with potential for maximal risk mitigation. Better training in risk management tools for investigators and those formulating risk controls. Involvement of experts in safety science and human factors when producing risk controls.

Giving time and space to problem-solving	Strict timelines to produce incident reports and action plans.	Separate recommendation meeting. Flexible timelines for investigations.
Formulating sustainable defences mapped to identified problems.	Risk controls are not often evidence based. Risk controls proposed only address superficial factors contributing to incidents.	Identification of a theory of change for proposed interventions (i.e. outlining how risk controls will eliminate/ mitigate the risk identified). Using tools such as the hierarchy of risk control when brainstorming during risk control formulation. Performing aggregated analysis to identify multiple layers of defence.

Feedback and Evaluation		
Purposeful implementation and better tracking of risk controls	Current databases are not fit for tracking implementation of risk controls. Lack of accountability of agents outside the organisation where the incident occurred.	Upgrading local incident databases to ensure accurate tracking of implementation and better sharing of solutions. Upgrade national incident databases to facilitate cross-organisational sharing of lessons. Internal quality assurance serving both a supportive and critical function. Identification of auditable performance indicators to assess effectiveness of risk controls. Setting up of national investigation bodies able to serve recommendations to agents outside the remit of the organisation where the incident(s) happened.

Collaborative approach to quality assurance of risk controls	Poor sensitivity to operations by external assurers (commissioners). Lack of skills in safety science by assurers.	Attendance by commissioners to internal investigation or assurance meetings. Creating draft investigation findings and recommendations which can be reviewed by all stakeholders concerned before finalising. Better training of assurers in safety science principles.
Effective knowledge management and brokerage within and across organisations	Complex divisional structures within organisation promoting silo working and learning.	Sharing draft recommendations before finalising them.

	Multiple platforms used to share post-incident lessons learnt in an untargeted and hap-hazard fashion. Risk controls implemented late leading to erosion of lessons learnt following past incidents.	Have an appropriate and timely dissemination strategy of finalised risk controls to relevant stakeholders using existing well-attended face to face forums. Lessons learnt from common themes to be coordinated and disseminated centrally through networks of professionals such as the Royal Colleges and organisations such as accountable healthcare organisations.

Table 8.1 – Eleven features of strong risk control formulation and implementation following incident investigations, potential challenges and solutions.

Based on these identified features of strong risk control formulation and implementation, I have organised the content of this discussion chapter around three broad considerations.

First, in section 8.1, I propose the need for independent experts to lead and conduct safety investigations and to operate within a favourable legislative and cultural context. Second, in section 8.2, I discuss why robust risk control requires recognition of how healthcare systems can be made more resilient. Finally, in section 8.3, I expand on how learning follows on from analysis of incidents, situate the findings of Chapters 4 to 7 in a broad body of literature on organisational learning and discuss the need for healthcare to maintain the sociocultural and technological infrastructure vital for organisational learning following serious incident investigations.

8.1 Enabling better investigations

In this section, I argue that strong risk controls start with quality investigations. I discuss the importance of recognising safety investigations in healthcare as a professional activity. For safety investigations to lead to coordinated improvement on a national scale, I argue there is a need to build capacity for national investigative bodies. Finally, I recognise that local investigations will continue and discuss important cultural and logistical enablers to keep such investigations free of bias. In the UK, these factors are recognised in the newly published Patient Safety Incident Response Framework which aims to guide NHS organisations on how to build the cultures, systems and behaviours essential to responding effectively to patient safety incidents.[301]

8.1.1 Towards the professionalisation of safety investigations in healthcare

In Chapters 5, 6 and 7, I demonstrated that the processes of effectively formulating and implementing risk controls are invariably tied to the quality of incident investigations. I have shown that stakeholders in incident investigation and risk control recognise the importance of developing a body of professionals proficient in investigations (see section 7.2.2). This is a challenge for healthcare because in contrast

with other safety critical industries, where investigation has been professionalised, healthcare investigation remains mostly conducted by a hybrid of clinicians and managers (see Table 4.4) who lead investigations and make decisions on solutions by virtue of their seniority or availability rather than professional qualification or experience in investigation.[12, 13]

Investigating incidents, formulating and implementing risk controls requires knowledge of multiple related sciences and disciplines, ranging from safety science to human factors, alongside the development of distinct skills such as expert facilitation with multiple stakeholders, including front-line staff, management and patients. However, the training of healthcare safety investigators has been deemed deficient in the UK and Australia: training programmes are brief, mainly varying between one (as identified in section 7.2.2) and three days in length.[18, 139] As shown in Chapters 5 and 7, the process of risk control was often constrained by lack of depth of investigations, the limited repertoire of investigative methodology, and difficulties in knowing when and how to engage with relevant stakeholders such as front-line staff, patients and their representatives. These are complex processes, requiring time and expertise, which many healthcare safety investigators currently lack (see section 7.2.2) since they often have to juggle clinical and managerial commitments with safety work. The complexity, specificity and importance of the work conducted by healthcare safety investigators suggests that the status quo, whereby healthcare investigators are not fully equipped to conduct consistently rigorous investigations is not sustainable.

The creation of a dedicated "patient safety specialist" role in the UK is an important step proposed by NHS England in the wider quest towards the professionalisation of safety roles in healthcare.[302] These professionals are to be identified from both NHS trusts and CCGs, and hold a leadership role in patient safety in their respective organisation. The expectation is that they will aim to support the development of a patient safety culture, and promote better investigations.[302] Given the specific and complex set of skills required of such individuals, making the right appointment is key. Guidance documents from NHS Improvement[302] seem to suggest that NHS trusts may

seek to appoint individuals to this role from within their own organisations. I believe such a situation may contribute to more risks such as concerns relating to lack of independence and preservation of partisan interests (akin to those seen when healthcare investigators are too closely linked to individual departments as discussed in chapter 7). Such an important appointment may require fresh perspectives, including those held by safety experts from outside healthcare organisations.

More specifically, professionalisation of healthcare safety investigators is also needed. The parliamentary review into clinical incidents in the UK recommended the development of professional courses specific to the needs of healthcare investigation, with formal examinations and qualifications.[18] The aim is to build a cadre of professional safety investigators competent at conducting system-wide investigations both locally and nationally.[277] Such a goal may require both national investigators who are full-time, trained and operate within a national independent investigative body and local investigators who work as clinicians or managers and operate part-time but with dedicated time and resources for investigations. Similar skills are required by those assuring the quality of investigations, both in internal quality assurance processes and external ones – including CCGs.

The recruitment and training of midwives and obstetricians as maternity investigators, who are spending a year's secondment with the national Healthcare Safety Investigation Branch in the UK before returning to their own organisation, is a welcome signal of the growing recognition for high quality skills in investigation.[303] The training of such professionals could benefit, as discussed by Waring et al.,[304] from the growing corpus of scientific theories and applied methodologies, which are constantly enriched by an accompanying and expanding body of research. New courses at postgraduate levels in patient safety, quality improvement and clinical human factors are now offered to healthcare professionals through universities, facilitating the development of a body of professionals with skills in safety science.[305, 306] Another welcome initiative in the UK is the creation of a national interdisciplinary patient

safety syllabus, intended to outline the core knowledge in patient safety expected of all healthcare staff working in the NHS.[307]

8.1.2 Towards the independence of national safety investigations

A move towards professionalisation of healthcare safety investigators may also be further facilitated by the development of national *independent* professional bodies of investigators. Many other safety critical industries have a tradition of conducting independent investigations through national investigative bodies. They include the Air Accident Investigation Branch in the UK, who over time have developed skills and expertise to lead, manage and conduct investigations, and translate their findings into practical, actionable recommendations.[63] Alongside their role in setting investigation standards, such bodies also have the important attribute of being independent and the perspective that such an external position brings, uninfluenced by partisan interests which may bias investigation findings. They also operate separately from regulatory organisations which may even be the recipient of their recommendations (see section 7.3.3).

In a review I co-authored on current issues facing contemporary healthcare investigation practices, my co-authors and I argued that the identification and resolution of extra-organisational problems are constrained by the "problem of many hands".[13, 57] This problem describes a situation where multiple actors contribute to performance, yet when things go wrong, it remains hard to assign responsibility to any of one them. It is particularly challenging when the locus of responsibility lies outside the organisation where the incident happened.[57] Resolution of such issues requires a wider understanding of the factors, external to the organisation, contributing to decisions being made within the organisation, through involvement of patients, manufacturers, regulators and primary care physicians.[308, 309]

The ability to perform cross-organisational investigations and develop a high-level view of factors contributing to incidents places national investigative bodies in a unique position to address system-based issues which lie beyond the remit of individual organisations. As shown in Chapter 4, local investigators showed

weaknesses in seeking and identifying extra-organisational factors. Local investigations accordingly may not provide a sufficiently deep understanding of the patient's journey through healthcare nor an adequate understanding of the influence of external factors on patient outcomes. National investigative bodies may be better placed to address these problems. For instance, the HSIB in the UK investigated the problem of incorrect lens insertions during cataract surgery in 2018, and made three recommendations, all aimed at the extra-organisational level: to the Medicines and Healthcare products Regulatory Agency, the Department of Health and Social Care and the Royal College of Ophthalmologists.[310] In contrast, the incident investigation reports and action plans I reviewed in Chapters 4 and 5 included two cases of wrong lens insertions and in neither case were concerns identified at the supra-organisational level. Consequently, the organisation reabsorbed the responsibility of solving the problem of wrong lens insertion without liaising with external agents.

As it currently stands, HSIB does not meet the requirements for independence that my findings seem to call for. Among the institutions that recommendations from investigative bodies may at times be directed to are regulatory bodies such as NHS England or the General Medical Council. Such a situation highlights the need for the investigation body to be completely independent of any regulators to negate any potential perception of conflict of interest.[311] However, HSIB exists as an NHS quango (semi-public administrative body outside the civil service), hosted by a regulatory body (NHS Improvement),[312] and accordingly is not fully independent.

As Dempsey has suggested, *"change… can be socially and economically difficult. These difficulties can be more easily overcome if the institution advocating change is perceived as competent, objective, and credible*."[311] For national investigation bodies to have credibility with the public and healthcare professionals, and be able to consistently provide impartial recommendations across all levels of the healthcare system (from regulators to front-line staff), primary legislation is required to establish it as a completely independent institution.[119] In that light, legislation currently

proposed by the UK parliament to establish HSIB as an independent institution is a welcome advancement for patient safety.[313]

The aviation safety investigation model offers a template for how the Healthcare Safety Investigation Branch might be legislated as an independent body. For example, Annex 13 of the Chicago convention[314] (ratified by 190 countries, including the UK), which addresses aviation accident investigations, stipulates that *"the accident investigation authority shall have independence in the conduct of the investigation and have unrestricted authority over its conduct…"* and clearly separates any action relating to apportioning blame or liability from the activities of the investigation body whose prime aim is solely on identification of causal factors and recommendation of preventive measures to relevant organisations. In the UK, for instance, the Air Accident Investigation Branch operates independently of the Civil Aviation Authority and the head of the AAIB reports directly to the Secretary of State for Transport.

8.1.3 Ensuring capacity and expertise for local investigations

While the conduct of external investigations through national investigative bodies is a leap forward in healthcare improvement, the bulk of investigations conducted in healthcare, in particular in the UK setting, are set to remain local. Thus, strategies for improving the quality of investigations and, in turn, the quality of risk controls formulated following investigations, cannot only focus on building capacity and capability of national investigative bodies.

As discussed in section 7.3.1 and 8.1.1, local investigative capacity can be built through secondments to national investigative bodies and through dedicated postgraduate training programmes. Maintaining independence of local investigators is harder to achieve in healthcare organisations as the investigations are conducted by staff themselves. This situation may not entirely be a shortcoming though. Being close to operations within an organisation allows investigators to maintain knowledge of context, which is important when understanding areas of risk and deliverability of risk controls.

Understanding of context facilitates the process of sense-making for investigators by providing a "lens" through which investigation findings are interpreted before strategies for improvement are recommended.[226] Some authors also argue that learning happens best when healthcare organisations investigate themselves since investigation involves questioning, refining and restructuring of the reality of work in the organisation alongside an appreciation of the gap between work as imagined and work as done.[315]

To improve impartiality while simultaneously maximise learning, Dutch hospitals have recently started employing an external chair to lead incident investigations and work alongside local investigators, with promising results.[316] De Kam et al. report that such an arrangement facilitates inter-organisational learning since external chairs conduct investigations in multiple organisations, thereby effectively acting as a knowledge broker across organisations.[316] Additionally, external chairs are able to identify blind spots in locally conducted investigations by asking questions on "thorny" issues which internal investigators may stay away from and critically reviewing an organisation's culture. Such questions are particularly relevant and, as I demonstrated in Chapter 4, were consistently lacking with cultural factors not recognised as contributory to incidents by local investigators. For example, in only 4% of incident reports were issues with organisational culture identified (see section 4.2.2.4.3).

At policy level, the House of Commons Public Administration Select Committee's report into the investigation of clinical incidents in the NHS heard evidence that an open and transparent culture from ward to board level was essential to ensure good quality local investigations.[18] Such changes require radical cultural changes given that staff can be reluctant to share important information relevant to the conduct of thorough investigations, thereby thwarting important learning,[20, 116] which may partly be due to perceptions of not being treated fairly. Factors which may improve staff engagement include better feedback from investigations, better personal support through the investigative process, and a separation between incident investigations and human resources or fitness to practice referrals.[242, 278, 317] Some countries, such as

Denmark and Italy, have enacted laws, effectively creating a "safe space" for reporting and investigating incidents, thereby protecting any information provided by staff from being used for legal proceedings against them.[318, 319] In the UK, similar proposals (see section 7.3.3) are being discussed in parliament but will only apply to national investigations, not local ones.[320]

8.2 Resilient risk controls require a sound theory of change

The intrinsic ability of a high reliability system to restore its stable state in order to allow ongoing safe operations after a major mishap is defined as "resilience" by Hollnagel et al.[321] Based on this definition, resilient systems share three major characteristics: the ability to detect and understand reasons for deviations (i.e. incident reporting and investigations), the ability to adapt and improve (formulating and implementing risk controls), and the ability to learn (discussed in more details in section 8.3).[322] Improving the quality of investigations alone is not enough to improve the risk control process. In this section, I argue that resilient risk controls generated from incident investigations depend on sound understanding of how and why they are meant to work and outline how this can be achieved.

Across Chapters 5, 6 and 7, I identified that the science or rationale underpinning proposed risk controls was often missing or ambiguous: it was not always clear why a risk control was proposed or how it was meant to address identified hazards. As previously discussed, this could be because decisions around risk controls were heavily influenced by bureaucratic filters (see section 5.3), such as the need for endorsement by multiple layers of management who prioritised ease of deliverability of risk controls over the implementation of evidence-based ones. In fact, I found that investigators rarely justified their proposed controls on evidence from the literature. Thus, I propose that an essential aspect of a robust risk control process following incident investigations is a sound "theory of change". It would aim to describe a generic approach defining how and why a programme (which can be one or multiple risk

controls) supported by adequate resources, works to achieve a specific result.[323] Defining a theory of change involves specifying assumptions, the roles of different actors, the influence of context, the research base underpinning the theory and indicators of implementation and effect.[324] In some instances, application of a theory of change would mean that a well thought-through risk control which may seem "weak" according to the hierarchy of control, may be considered more relevant and impactful for implementation based on the hazard it is aiming to address.

A theory of change for a programme of interventions is developed alongside consultation with multiple stakeholders involved in its implementation or affected by it and allows a transparent understanding of the elements required for the risk controls to work. It can be illustrated using a driver diagram (see figure 8.1) which provides a visual means of illustrating the relationship between risk controls (referred to as "ideas for change" in figure 8.1) and the aim of the risk controls.

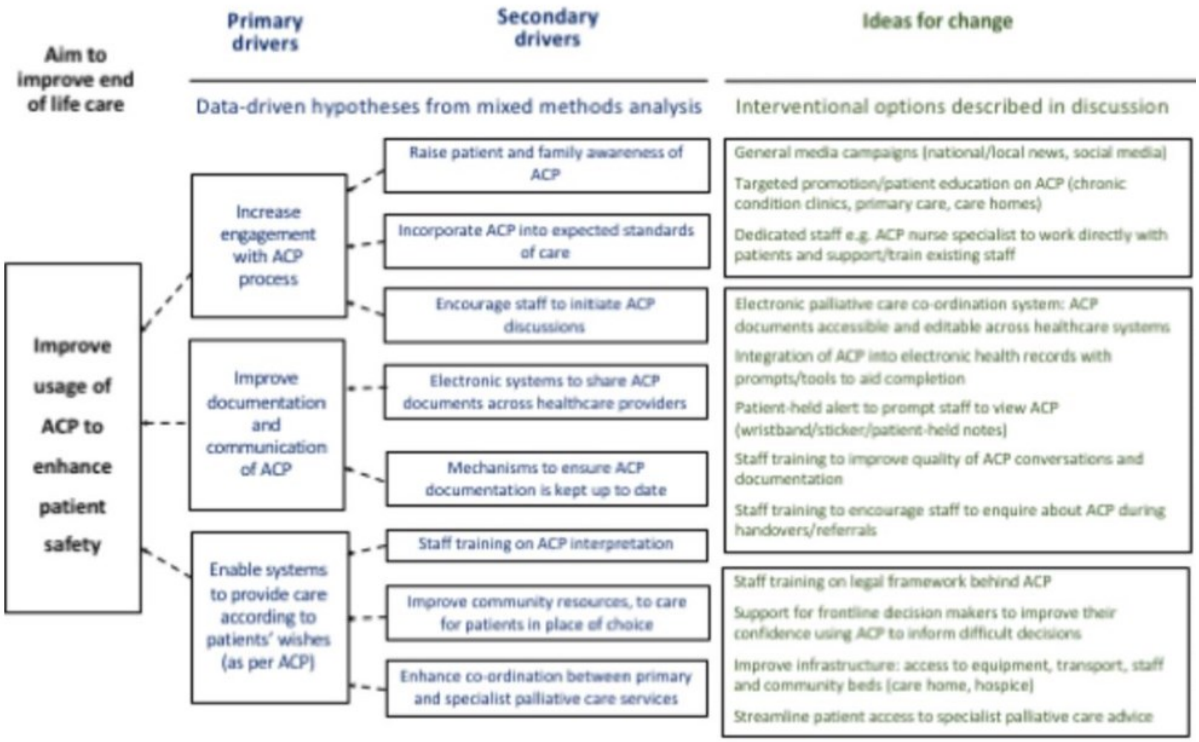

Figure 8.1- Driver diagram illustrating a theory of change to improve the safety of Advanced Care Planning (ACP) in patients at the end of life (from Dinnen et al. BMJ Supportive and Palliative Care 2019)[325]

I propose four key considerations for a sound theory of change when improving risk control formulation and implementation following incident investigations: an understanding of the roles of the multiple stakeholders involved in the implementation of risk controls, an appreciation of how risk controls will affect service users, a systems-based approach to identifying and controlling areas of risk, and a clearer understanding of normal day-to-day care.

8.2.1 Stakeholder involvement from across the continuum of care

A recurring theme across multiple chapters was the lack of stakeholder engagement in the formulation of risk controls (sections 6.2.1.2, 7.2.1 and 7.2.7). In this section, I postulate that a sound theory of change underpinning a risk control necessitates an understanding of the roles of individual stakeholders responsible for its implementation. Clearly, as shown in multiple studies, ensuring adequate

representation in the risk control process following investigations is challenging for multiple reasons.[12, 274, 326-329] Senior front-line staff have competing clinical and managerial priorities.[12] Risk control processes formulated and implemented solely by front-line staff without central oversight may create further problems,[328] in particular in organisations where staff turnover is high. For example, drawing on lessons from the nuclear industry, Woods and Shattuck describe how the adoption of a "kaizen" continuous improvement process, which encouraged workers to lead small improvements to local practices following identification of problems, led to the modification of complex work processes over time. These exclusively worker-led changes to working practices circumvented safety defences, eventually contributing to the death of two workers in preventable accidents.[274, 328]

A participatory approach to risk control formulation necessitates involvement of multiple stakeholders, ranging from those in control of resources, such as managers to those responsible for implementation on the front-line. Such a participatory approach requires supportive factors in place. Primarily, healthcare organisations need to ensure that relevant stakeholders such as managers or clinicians are released to attend both investigation meetings when invited and meetings where risk controls are formulated. As shown in section 7.2.1, this was not always the case. Similarly, flexibility in national governance requirements, such as the planned adoption of a more accommodating investigation timeframe by NHS England may allow more time for relevant stakeholders to be involved.[301]

To further facilitate the involvement of staff during meetings, trained facilitators in system-based approaches (see section 2.2.3), risk analysis and risk control generation may have a role to play. Jun et al. have shown that facilitator involvement can improve problem-solving by healthcare staff, allowing them to generate risk controls across multiple sub-systems.[326]

8.2.2 Service user involvement

Second, a sound theory of change requires an understanding of care from the end-user's perspective: that of patients and their families. As shown in Chapters 4 and 5,

risk controls were occasionally designed without an understanding of how they might affect patients or carers. For instance, there was one instance when patients were asked to chase their own follow-up appointment though doing so was not necessarily straightforward – see section 4.2.2.4.1. Studies have shown that patients and families have an important and valid role to play as part of the wider strategy in improving healthcare quality.[226, 330, 331] O'Hara et al. go so far as describing them as co-creators of resilience.[332] Patients and families have a unique view of their whole healthcare journey and are able to identify weak spots in quality and safety.[293] In many instances, they are also able to "scaffold" the quality of the care they receive by supporting those weak spots.[332] For instance, Fylan et al. demonstrated how patients could contribute to medication safety by facilitating post-discharge medication reconciliation.[330]

Involving patients and families who have been subjected to an adverse event in making decisions on the formulation of risk controls following investigations may nonetheless be challenging. Most available guidance focuses on how best to approach them when disclosing errors and analysing incidents,[329, 333] as opposed to the risk control process. Etchegaray et al. have demonstrated that patients and families were able to both identify contributory factors and propose possible risk controls following involvement in incidents.[334] It is unclear however, how robust or resilient such controls proposed by patients or carers, who may not have the professional understanding of safety nor the accountability of a healthcare worker or professional investigator, may be.

Future research may offer further clarity: a research project aiming to look at how best to involve patients and families in the investigative and risk control processes following incidents in healthcare has recently received funding from the National Institute of Health Research (NIHR) in the UK.[335] The professionalisation of safety investigators (see section 8.1.1) in healthcare may assist in this process by ensuring future investigators possess the facilitation skills to involve patients and relatives at such a vulnerable time. Potentially, an initial step could be to have public and patient representatives when investigating incidents and formulating risk controls. These

could be regular service users, not necessarily those directly involved in the incidents.[336]

8.2.3 A systems-based approach

Third, a sound theory of change necessitates a systems-based approach. Numerous studies broadly consider a systems approach to be one that accounts for how numerous sub-systems interact with each other and dictate the behaviour of an entire system.[153, 237, 255, 337] Each sub-system in turn comprises multiple elements: people, processes, information, organisations and services, as well as software, hardware and other systems that, when combined, have properties that are not present in any of the elements on their own.[338] A systems-based perspective takes a holistic approach to understanding this complexity that enables the delivery of intended outcomes based on how each sub-system's constituent part relates to each other and to the wider system.

As discussed in section 6.2.1.1, numerous established methods can be used to capture a holistic view of how different sub-systems interact when investigating incidents and formulating risk controls. Examples of systems approaches used when investigating causes of incidents include Leveson's safety control structure,[153, 337] Rasmussen's Accimap and hierarchical risk management (see section 6.2.1.1).[83, 339] Systems approaches based on similar principles can be used when devising risk controls, allowing the identification of risk controls at higher levels of the risk management hierarchy (such as policy or management) to support the implementation of risk controls at the operational level.[238]

Improving the understanding and implementation of systems approaches in healthcare may require an increased number of experts in human factors embedded in individual healthcare organisations. Such professionals are currently rarely involved in local investigations and in the risk control process, as shown in Appendix K and section 4.2.1. Pickup et al. report that even those healthcare professionals appointed to key safety roles within healthcare organisations, such as patient safety or governance leads, do not always have specific training in human factors engineering or safety

science.[340] As previously discussed, at a national level, however, the Healthcare Safety Investigation Branch in the UK has recognised this deficiency and is utilising human factors expertise when investigating incidents and making recommendations.[118]

8.2.4 Understanding everyday performance

Fourth, a sound theory of change when devising risk controls requires a better understanding of the complexities of real-world practice beyond that generated through traditional retrospective incident investigation methods. Such an understanding can be achieved in different ways, as outlined below, based on findings from the chapters above and the wider literature.

8.2.4.1 Simulation-based

Simulation is widely used in aviation for training and incident reconstruction.[341] As an educational tool, simulation facilitates the development and consolidation of technical skills through repetitive practice and softer non-technical skills, such as communication, leadership, situational awareness and team-working through targeted feedback, debriefing exercises, with the assistance of video replays where possible.[342]

In healthcare, its potential in improving patient safety has widely been recognised and it has mostly been deployed as a training exercise.[343] I propose that simulation could also be used to bring multi-disciplinary teams in healthcare together to re-enact incidents. Macrae suggested that this kind of use of simulation could allow different causation theories to be tested and uncover silent latent factors.[341] A previous study comparing conventional root cause analysis of incidents with the reproduction of incidents using simulation showed that the latter can identify more organisational factors.[344] Additionally, proposed interventions, such as the introduction of new drug packaging[345] and moving to new healthcare services [346] could be tested in simulated settings before implementation to identify their effectiveness and any unintended consequences. Simulation offers the opportunity to understand the influencing factors behind actions and behaviours through debriefing and video-playback.

Clearly, reproducing every single incident is not practical and healthcare organisations may need to prioritise those events where organisations may benefit most from based on their safety risk and learning potential. As shown in section 5.2.1, simulation-based exercises were rarely proposed as potential risk controls in the aftermath of serious incidents, perhaps because simulation centres are not readily accessible and come with an additional cost.[347] It may also be harder to integrate the complexities of real-day clinical life in a simulation-centre based training exercise where participants are taken away from their normal workplace. A solution could be in-situ simulation which has the advantage of being delivered in the clinical environment where healthcare staff usually work. Such an arrangement can be cost-saving and allow a "suspension of disbelief" by participants, allowing better immersion into the simulated exercise and increased fidelity in capturing "work as done".[348] In-situ simulation still requires buy in from management as such exercises requires clinical space but, unlike in-suite simulation, in-situ simulation can happen more regularly, in between work commitments, without the need to release staff for full training days.[347]

8.2.4.2 Proactive risk assessments

Use of proactive methods of risk assessments, such as failure mode and effect analysis (FMEA) and hierarchical task analysis (HTA),[349-352] during the design phase of healthcare processes offer ways of prospectively understanding the expected relationship between sub-systems and the effect of the wider context within which they operate. FMEA[353, 354] is a five-step process where a multi-disciplinary team uses tools such as flow diagrams, hazard scoring matrices and decision trees to identify weaknesses in a new process (e.g. an electronic healthcare record system[352]) before implementation. HTA is a methodology used to break down individual actions and cognitive processes involved in performing a particular task.[351, 355] When used appropriately in healthcare, HTA may allow clinicians and managers to deconstruct clinical processes, allowing a more transparent understanding of every team member's role in performing a task (see figure 8.2 for an example of a HTA for a handover in the Emergency Department).[351]

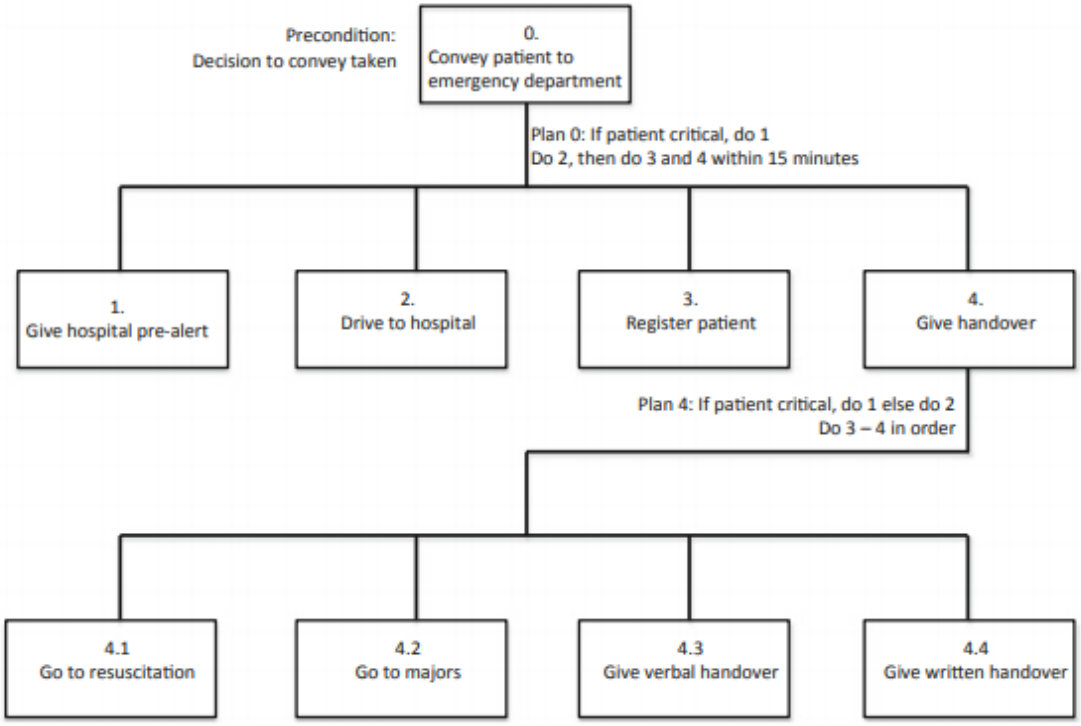

Figure 8.2-Hierarchical Task Analysis of Handover in an Emergency Department (From Spurgeon et al.Springer 2019)[351]

Such prospective risk assessments would be particularly useful given that I identified problems with operational processes in nearly a third of all incidents (see section 4.2.2.4). An example of its application could be during the integration of technological solutions into healthcare processes.

Simply introducing technological solutions does not translate into uptake nor does it necessarily result in improvement.[356, 357] Implementation of technological (such as electronic results or record systems) and technical (such as checklists) solutions necessitates adequate understanding of their systemic integration and prospective identification of cultural barriers to their widespread implementation.[358] For instance, Liberati et al. identified numerous factors affecting the uptake of computerised decision support systems (CDSS) ranging from staff attitudes, through the evidence accessible from the CDSS, to the effect of the legal framework within which the CDSS was being implemented.[356] Such evaluation should ideally occur before an incident,

yet none of the incident reports nor action plans I reviewed in Chapters 4 and 5, referred to prospective assessments having occurred.

8.2.4.3 The Safety II perspective

I believe healthcare needs to invest more effort into understanding why, often, despite its many deficiencies, the daily delivery of care does *not* result in adverse events. Retrospective safety investigations may be more influenced by the perception of work-as-imagined (what should happen under normal circumstances) and fails to fully account for work-as-done (what actually happens).[359] Work as done involves multiple interacting components and influences such as patient complexity, lack of resources, governance pressures, and so on.[360] To ensure a more resilient risk control process, I propose that healthcare investigators should understand why and how healthcare workers and institutions manage to keep their patients safe more often than not, by adapting their performance and compensating for systemically engrained weaknesses. This perspective, known as Safety II, has for instance, been used to identify risks during handovers[361] and other clinical practices in the Emergency Department.[362] The shift of focus from retrospectively dissecting and learning from events that have resulted in failures (Safety I) to prospectively observing how everyday clinical work is delivered safely also allows a better understanding of the role of frontline workers in preventing incidents and how their daily performance adjustments could be supported.

One example, for instance, could be how healthcare assistants from one ward routinely borrow electrocardiogram machines from other wards because the one on their own ward does not work. While this practice illustrates the resilience of healthcare assistants in getting the work done, it also reveals a risk which could be identified through a Safety II prospective analysis before an adverse event occurred (such as an event where a patient's diagnosis of myocardial infarction was delayed because the electrocardiogram machine on the neighbouring ward was also not working).

The two paradigms, Safety I and Safety II, need not be seen as being incompatible. I suggest that a Safety II approach should become embedded into routine incident investigation practices with investigators observing how daily care is delivered during their investigative work in order to understand the resilience of staff and systems, and the dynamic trade-offs routinely occurring in everyday clinical work.[363] In the UK, NHS improvement has recognised the importance of integrating a Safety II perspective in its wider patient safety strategy and has plans to incorporate learning from what goes well in the development of an updated version of the NRLS. In my opinion, this approach needs to go one step further by normalising the capture of everyday performance variability.[364]

8.3 Towards better organisational and institutional learning

In section 2.3, I argued that incident reporting and investigations have stemmed from a need to learn from past incidents. Such learning is best made evident through objective improvements in patient safety. As shown in Chapter 4, the recurrence of similar types of incidents and causal factors across incidents (see tables 4.1 and 4.5) would suggest that learning from incidents is not always happening either within organisations or institutionally – at the level of the healthcare sector.

Many risk controls proposed in the aftermath of incidents (such as reminders (present in 50% of all action plans), training (present in 49% of all action plans)) centre on dissemination of explicit knowledge (see Table 5.1). Such risk controls simply focus on "knowing", not "learning". As Lauder et al. states in his book on failures of public inquiries to improve risk governance, *"the question now becomes whether knowing that something might possibly happen is enough to ensure it will not happen?"*[365]

As identified in section 7.2, many challenges may prevent organisations from translating knowledge generated from past incidents into concrete learning. In sections 8.1 and 8.2, I have discussed some of these, located at the level of the investigative process (such as poor investigative skills or lack of independence), and at

the level of risk control formulation (such as a lack of a theory of change). Based on findings from Chapters 6 and 7, I also identified constraints located beyond these two levels which can prevent an organisation learning from past incidents. These constraints can be summarised into three main themes:

1. Not knowing which interventions have been implemented and why they have been implemented (see section 6.2.3 and 7.2.6).
2. Not knowing which implemented interventions have worked (see section 6.2.3).
3. Not knowing how other departments and organisations are dealing with the same risks (see section 7.2.5).

Insights from those findings can also lead to reflections on the modalities of learning following incidents. Based on my findings and evidence from the literature, I approach learning from incidents from two different but related perspectives: as a technical process and as a social process.

8.3.1 Learning from incidents as a technical process

First, learning from incidents can be considered a technical process, involving several steps. Based on expert opinion, Drupsteen et al. have conceptualised learning from incidents in a model,[366] made up of four interrelated stages: incident reporting and investigations, formulation, implementation of actions, followed by their evaluation (see figure 8.3). The quality of each preceding stage determines the strength of the outcome of the next stage, and ultimately influences the effectiveness of the learning from incidents process. Drupsteen et al. also include a feedback mechanism from each stage to preceding ones in their model, in particular if there is discordance between the intended and expected outcome of individual stages, such as if a particular action did not lead to improvement.[366]

Many of the findings from my thesis fit into this model. The four stages of the learning from incidents cycle are recognised in Chapters 6 and 7: investigation and analysis, risk control formulation (planning interventions), risk control implementation (intervening), risk control evaluation (evaluating interventions). Also, as discussed in

sections 7.2.2 and 8.1, I found that the quality of risk controls generated was related to the strength and depth of the investigations and analysis of causes. Similarly, multiple studies[152, 259, 260] from the narrative review identified an evaluation phase to be a positive influence in ensuring implementation of risk controls.

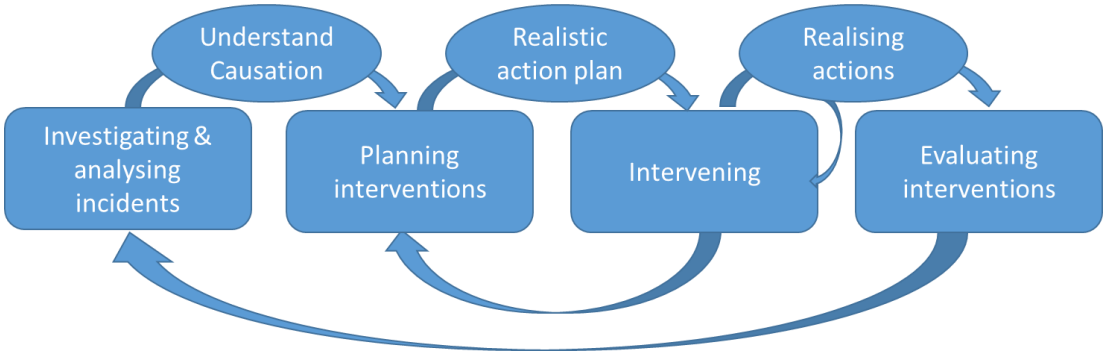

Figure 8.3 - Model of the learning from incidents process (Adapted from Drupsteen et al. JOSE 2013) [366]

Based on findings from Chapters 6 and 7, Drupsteen et al.'s model can be enriched further, as shown in figure 8.4. Drupsteen et al. considers "learning" to be occurring tacitly throughout the model via feedback mechanisms between each stage. For instance, investigators can "learn" more about the effectiveness of actions they have recommended through the results of evaluations.

This type of learning, though very important in enriching the process of learning from incidents, does not include the learning which happens through the more obvious discrete organisational activities that are designed to serve the sole purpose of sharing lessons learnt, such as strategies to disseminate lessons learnt to relevant stakeholders including staff, patient and other organisations. As discussed in section 7.2.5, participants stressed the importance of disseminating the *right amount* of information generated following both local and national investigations to a *targeted* audience through *effective* channels of dissemination. Such lessons may be from both investigation findings and from the evaluation of implemented risk controls.

Drupsteen et al.'s model also misses out on two stages identified through the body of research conducted for my thesis: the quality assurance process before finalising incident reports and risk controls, and a consultation period with relevant stakeholders before finalising risk controls. As discussed in section 7.2.4, I found that participants valued a strong quality assurance process, so long as it occurred collaboratively with investigators and implementers. Similarly, as discussed in section 6.2.3, multiple studies identified the importance of a distinct feedback stage between investigators and relevant members of staff who would be affected by changes occurring after implementation of risk controls.[26, 163, 242, 257, 258] This kind of consultation was found to occur best before risk controls were implemented (see section 6.2.3.1).[242, 257]

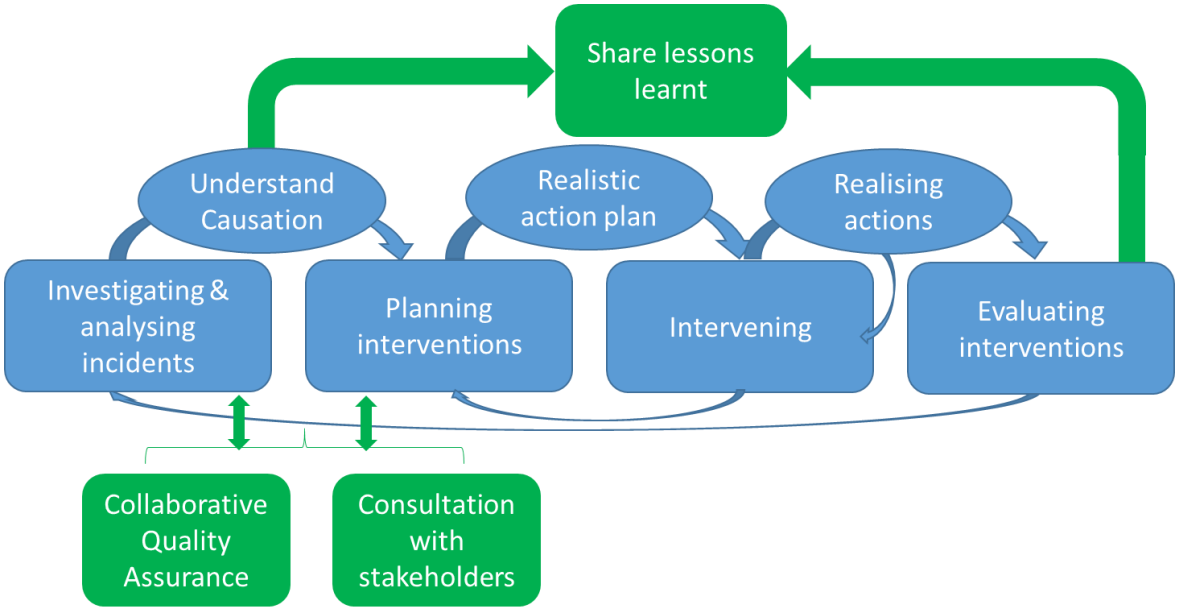

Figure 8.4 - Modified learning from incidents model, based on thesis findings

Both Drupsteen's model and the modified learning from incidents model align with Argyris and Shon's description of *double loop* organisational learning.[367] In the context of learning from incidents, I consider single loop learning to involve detecting and correcting errors incrementally as they arise through a superficial risk assessment where only the symptoms of a problem are addressed. Single loop learning does not involve organisations in questioning the way they carry out their investigations and

does not include an in-depth feedback mechanism between stages. On the other hand, double-loop learning involves in-depth investigations allowing underlying organisational factors to be addressed. Risk controls are followed-up to ensure both implementation and effectiveness, and importantly, the very values underpinning each of the stages of the learning from incidents model is questioned, to ensure that the process of learning from incidents is continuously improving.[368]

The findings in Chapters 4, 5 and 7 would suggest that the investigation of incidents as performed by Trust A and the wider healthcare sector were mainly characterised by single loop learning, evidenced by findings pertaining to results of investigations, proposed actions and concerns of interview participants regarding implementation of actions. In Chapter 4, I identified a predominance of contributory factors identified at the sharp end of care (see section 4.2.2.1), potentially suggesting that investigations were not deep enough. In Chapter 5, I identified the high frequency of risk controls relying on human interventions, highlighting their potential lack of sustainability. Single loop learning following incidents is not a problem unique to Trust A. In Chapter 7, I reported the frustrations of interview participants with the lack of robust structures for following up risk controls. Aggregated analyses of incidents have also shown that individual types of never event, such as retained foreign objects during surgery[17] and wrong intraocular lens implants,[369, 370] often recur despite local investigations.

8.3.2 Learning from incidents as a social process

Second, learning from incidents can be considered from a social perspective. As opposed to focusing on the stages involved in the process, the social perspective considers the *actors* involved in the process of learning from incidents, how they make sense of their experiences and how they interact with each other.[371, 372] More importantly, learning as a social process facilitates the understanding of context within which knowledge is shared following incidents (be it through training exercises, reminders or policy changes).[373]

Learning from a social perspective considers the tacit component of knowledge, which is harder to communicate. Currie et al. argue that unlike explicit knowledge, tacit knowledge is *"difficult to articulate and even more difficult to codify into a report about clinical error."*[373] Viewed from this angle, learning from incidents cannot simply be expected to happen after incident investigation reports and action plans shared between relevant agents.

The social perspective on learning from incidents accounts for the diffusion of knowledge from the individual to the group and the wider organisation or sector as part of the learning process.[374] Knowledge is thus achieved, constructed, processed, analysed, developed into new routines and behaviours, and at times rejected through interactions and collective reflections.[372] Importantly, knowledge acquired this way is also stored (e.g. in learning repositories or policy documents) and retrieved when required.[289] A social perspective on learning allows considerations to be made for the political and cultural determinants which may inhibit such learning from happening.[373] Based on findings from this thesis (in particular Chapter 7), table 8.2 summarises factors inhibiting learning from incidents when viewed from a social lens, with relevant examples from quotations in section 7.2.

Factors inhibiting learning from incidents when viewed from a social lens	**Examples**
1. Assumptions about what constituted knowledge worth sharing.	*See section 7.2.5 e.g. quotation: "I've been reading reports from the three large hospitals here in [location 4] …there's nothing different happening. But they're not sharing them."* [Commissioner 1]
2. Cultural deference to hierarchy over expertise.	*See section 7.2.2 e.g. quotation "…they are senior clinical members of staff who are leading serious incident investigations. With the best will in the world, they are not expert investigators, and some are better than others. Some are…downright poor."* [Healthcare investigator 15]
3. Ignoring the views of the learning agents (front-line staff).	*See section 7.2.1 e.g. quotation: "Well their (front-line staff) contribution … is pivotal because they're the ones that were involved in the incidents, they're the ones that were there on the ground, they're the ones that make the decisions, so it's about understanding, their rationale for decisions made or actions taken, and these are the guys that do the job day in, day out…"* [Healthcare investigator 9].

4. Lack of structures in place to disseminate learning.	*See section 7.2.5 e.g. quotation: "if something went disastrously wrong on [Ward X], I'm not sure that there is a mechanism in place to share the learning to all staff."* [Implementer 1] *"organisations don't join up, and I don't think they even talk among divisions sometimes if you like."* [Commissioner 1]
5. Information over-load and over-use of email as a channel	*See section 7.2.5, e.g. quotation: "In patient safety…I think there is probably information overload throughout the organisation. I delete 250 e-mails a week. There is information fatigue."* [Implementer 4]
6. Ineffectiveness of national efforts	*See section 7.2.5, e.g. quotation: "we sent some [incident reports] where the labels for the sedative and the muscle relaxant, one was red and one was orange…on the same tray… and …twice in the same organisation, we saw the muscle relaxant being given instead of the sedative, with one fatal consequence…we escalated that up to the NRLS. I haven't seen any response to that…" [Commissioner 1]*

Table 8.2 - Factors inhibiting learning from incidents when viewed from a social lens, with relevant examples from interview data.

Findings from Chapters 6 and 7 also allow insights to be drawn on potential factors which facilitate the learning process following incidents in healthcare, when considered from a social perspective: employee empowerment (section 6.2.1.2 and 7.2.1), open communication between quality assurers, investigators and staff affected by proposed actions (6.2.3.1 and 7.2.4), engagement with patients and families (7.2.7) and designing structures which facilitate knowledge management and dissemination (7.2.6). In the section below, I discuss potential mechanisms for learning from incidents which take these factors into account.

8.3.3 Mechanisms for learning following incidents

Learning from incidents, viewed from either the social or the technical lens, occurs through different mechanisms. I define a "learning mechanism" as the process that follows the identification of risk controls and is heavily influenced by the types of risk controls proposed. Each mechanism describes how knowledge generated from incidents is refined, disseminated and contextualised among individuals and groups or through organisational activities, either automatically or through deliberation. Three distinct but connected learning mechanisms emerged from the findings of my thesis: learning by doing, learning by reflecting and learning by sharing. These mechanisms for learning occurred through multiple activities, both formal and informal,[263, 375, 376] many of which are identified in section 5.2.2.

The methods used in this thesis mostly captured formal methods of learning i.e. those centrally coordinated and recommended by investigators and leadership within organisations as conduits to disseminate lessons learnt from incidents. Such formal practices are generally more structured in nature, aiming to integrate organisational knowledge into written routines and official instruments such as incident databases, mandatory training activities, policies and procedures.

Informal practices, on the other hand, are more unstructured and harder to control centrally, though generally more participative.[377] They focus on the development of knowledge by engaging recipients in tasks where learning was not necessarily a pre-defined objective. Examples identified in Chapter 5 included reflective practices and

non-mandatory training exercises but given that informal activities were generally not coordinated centrally, they were often not captured through action plans. Examples in the literature include mentoring and professional networks.[27, 63]

The distinction between formal and informal learning practices is not always clear. For example, informal sharing of lessons learnt between employees can follow on from many formal centrally coordinated learning activities.[378] The mechanisms through which learning occurs, along with a description of related formal and informal activities as identified in the wider literature and in this thesis are explored further below.

8.3.3.1 Learning by doing

Learning by doing or action-based learning broadly refers to the learning that happens from the direct execution of actions.[379] Argote et al. described this type of activity to be an essential source of developing and maintaining organisation knowledge and capabilities, leading to improved organisational performance.[380] In the context of learning from incidents, I consider learning by doing to include the different activities individuals and groups implement following incident investigations. Such activities may include those formally generated from incident investigations or those that individuals or groups choose to implement on their own after getting to know about previous adverse events.

The efficacy of learning by doing is tightly linked to the concept of single and double loop learning.[368] As discussed above, single loop learning involves the correction of superficial deviations without addressing the underlying latent conditions.[315, 381] Drawing on the work on organisational learning by Argyris and Shon,[368] Lukic et al. argued that single loop learning manifested as risk controls which were generally "quick fixes", displayed through the implementation of practices that were mostly dependent on human intervention, such as administrative changes, training exercises and punitive actions.[315] As shown in Table 5.1, most risk controls generated following incident investigations in Trust A fell within that category, suggesting that double-loop learning is limited.

Single loop learning may also take a very elementary form by mandating risk controls without ensuring staff understand the reasons for the changes. As shown in section 7.2.1, even when risk controls had been informed by investigation findings, those individuals responsible for implementation did not always know, understand or appreciate the rationale. In an interview study of staff members from the railway and marine industries, Størseth et al. warned that this type of superficial learning by doing could manifest itself as a *"pile up"* of procedures, which may not always be optimal.[382]

As identified in this thesis, single loop learning involves risk controls addressing only superficial hazards along with a lack of opportunity for stakeholders to question underlying assumptions and values of those risk controls. In this situation, single loop action-based learning may lead to a state where neither individuals nor organisations learn from failure since the underlying causes of failures are not addressed and individuals do not understand the rationale for implementation of actions.

Learning by doing can be enhanced through the process of double loop learning. In the context of this thesis, I propose that such learning involves the investigation and understanding of organisationally-engrained system failures and the critical examination of the values and assumptions underpinning implemented risk controls.[368] Double loop learning thereby allows an exploration of the link between the causes for failure and the actions aimed at improvement. In a study of learning practices in a Scandinavian refinery, Vastveit et al. argued that double loop learning should also allow employees to develop an understanding of the reasons for actions and apply their learning under different circumstances.[263] Such an understanding was valued by participants I interviewed, as reported in section 7.2.1.

Finally, learning by doing also includes the learning which occurs when a risk control has been evaluated. Simply implementing a risk control without knowing whether it has led to improvement is a form of single loop learning and should not be accepted in high risk industries such as healthcare, given the risk to life which may be involved.[383] In sections 6.2.3.2 and 7.2.6, I argued that a vital condition for investigations to lead to organisational learning was through the routine monitoring and evaluation of risk

controls for implementation, improvement and degradation over time. To develop this process further, I suggest that risk controls implemented following incident investigations could be tested on a smaller scale and monitored closely as part of Plan-Do-Study-Act cycles, for example, before upscaling.[384] Such rapid small sample measurements may contribute to learning by doing by providing individuals and groups with prompt feedback on the efficacy of risk controls while simultaneously assisting organisations in making decisions regarding whether or not to disseminate actions more widely.

Evaluations of certain risk controls for improvements can also happen in dry runs. Examples include the use of simulation and virtual reality, which as discussed in section 8.2, have been used to test the effectiveness of particular risk controls in the context of healthcare such as the introduction of new drug packaging.[385] Such exercises delivered within a safe space, away from the risk of causing harm to patient, provide the opportunity for organisations to test the suitability of risk controls while simultaneously providing a platform for staff to learn experientially and from the mistakes of others.[343] As discussed in section 5.2 and 8.2.4, such simulation-based activities were rarely, if ever, used in the aftermath of incident investigations at Trust A.

8.3.3.2 Learning by reflecting

Closely linked to the process of learning by doing is that of learning through reflective practices. As discussed above, the process of learning by doing becomes more purposeful from both an individual and organisational perspective when assumptions and values underpinning the risk controls are reviewed and challenged by those doing them. This process embodies the core of reflection, which Woerkom described as *"a mental activity aimed at investigating one's own action in a certain situation and involving a review of the experience, an analysis of causes and effects, and the drawing of conclusions concerning future action."*[386]

A deeper form of reflection in the aftermath of past incidents is *critical* reflection, where due consideration is given to the context (social, political, cultural) within which

incidents happened, along with the effect of the countermeasures being implemented. Such considerations allow individuals to develop insight into their individualised interpretations of events and actions.[387] Critical reflective practice following investigations, occurring individually or in groups, is a valuable source of learning in safety critical industries and, at times of even greater value than the formal outputs of investigations (such as investigation reports or training).[247]

Critical reflection can be an activity performed by individuals involved in incidents, thereby facilitating the process of experiential learning.[388] Critical reflection can also be performed by other members of staff not involved in incidents but who may draw important lessons from incidents. The learning from such type of reflection is called vicarious learning.[389] From the analysis in Chapter 4, reflections were recommended as a risk control for staff involved in incidents, thereby promoting experiential learning. I did not capture it as an activity recommended for staff not involved in incidents, thereby highlighting a lost opportunity to enhance the learning from incidents process.

Previous research has shown that educational activities promoting vicarious learning through reflections based on past healthcare incidents are valued by learners, who also consider such activities to be useful in preventing future incidents.[37] Vicarious learning could still, however, be occurring through informal practices. Looking at learning practices following incidents in the process industries, Vastveit et al. showed that vicarious learning through critical reflection occurred on an informal basis as staff sought to individually contextualise knowledge generated from investigations and apply to their own work practices.[263] Though such types of reflections usually happen informally in staff's own time, formal outputs of investigations such as investigation reports and alerts[106, 378] may be used as conduits to channel the focus of reflective practices. For such activities to occur, organisations need to possess robust and accessible means of sharing lessons learnt from investigation reports. This modality of learning is discussed in more details in section 8.3.3.3.

One particularly noteworthy form of experiential learning is counterfactual learning. Morris and Moore, for example, discussed how the practices of airline pilots could be

improved by getting them to perform upward (thoughts about how the situation could have been improved) and self-directed reflections on specific near misses.[390] Findings from Chapter 4 would suggest that counterfactual learning remained an untapped mechanism of learning in healthcare since events which resulted in no harms or near misses were much less commonly reported (see section 4.3).

The type of reflection recommended in the action plans reviewed in Chapter 5 focused on reflection as an individual activity. Some of the most fundamental learning processes performed when reflecting also occur at the collective level. Examples may include sharing of knowledge and opinion, challenging groupthink and experimentation with new ideas. Another powerful tool for collective reflection is through storytelling. As discussed section 7.2.7, storytelling could be used as a means of accounting for the patient's voice in the risk control process. Described by Boje et al. as "the preferred sense-making currency of human relationships", storytelling is a vehicle of social cohesion within organisations.[391] Stories focusing on past failures can allow the development of new understandings by those reflecting on them, through the deep feelings generated from the narratives.[392] A previous study focusing on the railway industry has shown that such informal storytelling were more favoured by staff as a means of disseminating learning than formal tools such as incident reporting.[376]

The power of such narratives is particularly compelling in the context of an apprenticeship model of learning of the type that characterises healthcare.[63, 376] A story allows the capture of valuable information about background, complexity and organisational norms and its passage between members of staff across hierarchies and disciplines. In his study of risk management and learning practices among air accident investigators, Macrae described how stories are useful to share knowledge around risk and safety, in particular how seemingly routine sets of events and seemingly innocuous failures could combine and contrive to lead to unexpected outcomes.[63]

Collective reflective practice opens individual's opinions and values to scrutiny by peers and others across the workplace hierarchy. An important example is the use of After-Action Reviews (AARs), which was first described and used widely by the United

States Army. AARs follow a structured process giving space for groups to break away from action, often during simulations, to reflect on the purpose of the action(s), the current state of play and what can be learnt from the current situation and group performance.[393, 394] This type of learning does not necessarily need to happen only after an adverse event has occurred, but can also happen during an evolving event, allowing scope for readjustments in performance through reflection-in-action.[393] For learning to happen in the context of such collective reflective exercises, organisations require a reflective culture accepting of individuals' decisions, opinions, assumptions and values being questioned and challenged without fear of retaliation or marginalisation.[395]

8.3.3.3 Learning by sharing

Learning by sharing is an important part of organisational learning as it concerns how knowledge is passed on from an individual (e.g. a nurse) to the collective memory of a group (e.g. all nurses and healthcare assistants within a particular ward) to the organisation (e.g. a hospital) and eventually the wider healthcare sector. Thus, learning by sharing is a medium for both intra and inter organisational learning. Effective means of learning through sharing aims to break down "structural secrecy", or the compartmentalisation of knowledge in organisations – or even across organisations, at institutional level.[396] In Chapters 5, 6 and 7, I identified numerous formal mechanisms through which learning by sharing occurred: reminders disseminated across wider communities of practice through electronic media or face-to-face forums, training exercises which took different formats, safety alerts from national organisations and incident databases.

Though considered an important means of learning, as reported in Chapter 7 by interviewed participants, learning through sharing via such formal modalities was also viewed as not always straightforward. Concerns by participants included information overload from the large number of reminders, lessons learnt not being disseminated to front-line staff and stagnating in the upper hierarchies of healthcare organisations and the lack of effectiveness of national databases designed to share lessons learnt

across healthcare organisations (see section 7.2.5). Considering these challenges, this section looks at how learning by sharing can be made more robust by focusing on two modalities specifically: learning through networks of participation and more effective usage of incident databases.

The focus by organisations on using formal methods of learning is not a finding unique to this thesis. In a review of learning initiatives following incidents in safety critical industries, Lukic et al. reported that most initiatives on learning from incidents *"perceive learning as a formal, systematic process involving post-investigation information dissemination."*[315] Such modalities focusing on information *"broadcasting"* is not learner-focused and understate the role of employees within the learning process.[397] This limitation was identified by participants in the interview study, who found that formal means used to disseminate lessons from incidents, such as emails to be untargeted and ineffective.

So, for learning from incidents to be an effective process, the learning needs of learners must be central to any activity. One aspect of learning by sharing which places the need of learners at the centre of all activities is through participative strategies. An important social structure which facilitates learning by sharing following incidents by prioritising the need of the learners is the formation of networks of participation or communities of practice.[398-400] At their most fundamental level, such networks consist of individuals, often from different professional backgrounds, engaging in collective learning around risk identified through the incidents.[400] In the aftermath of incident investigations, such networks can be formed either organically (informally) or by design (formally).[63, 263] For example, Vastveit et al. showed how operators and managers in process industries used departmental meetings to come together to share incident reports and learn from them.[263] Participants in the interview study valued the use of existing forums such as junior doctor training days, to improve the dissemination of lessons learnt from past incidents.

Other educational activities which may be of value for sharing knowledge through a network of participation, include simulation exercises and storytelling mechanisms.

Paradoxically, forums which are traditionally designed to improve learning from past failures, such as mortality and morbidity meetings, were not always considered effective by participants I interviewed. As reported in Chapter 7, one problem was poor attendance by junior members of staff. Ways to improve attendance include incorporating such meetings into their educational programme,[401] empowering junior staff to lead these meetings under the supervision of more senior staff members[402] and example-setting by seniors by ensuring their own attendance.[403]

In the aviation industry, Macrae highlighted how learning by sharing through a participative approach could stretch beyond the boundaries of individual departments and organisations. For example, aviation accident investigators could steer the formation of networks of participation around risk by formally bringing together staff with different expertise to discuss safety concerns and share their experiences and knowledge with a view to correcting them and learning from them both during and after investigations.[63] Examples of these kinds of initiatives in healthcare, spanning across organisational boundaries include groups of professionals with similar safety interests via networks such as the Patient Safety Collaboratives in the UK[404] and the Children's Hospitals' Solutions for Patient Safety in the US.[405] While research supporting the efficacy of such networks in the context of sharing risk controls and lessons learnt following incident investigation is still limited, emerging evidence shows promise.[405, 406] For example, hospitals involved in the Children's Hospitals' Solutions for Patient Safety network have reported significant reductions in hospital-acquired conditions and serious safety events after sharing solutions based on past experience through electronic, virtual and in-person interactions.[405]

A potential means of achieving successful learning across such networks of participation is through the establishment and maintenance of effective partnerships across organisational and professional boundaries, where learners' perspectives meet, leading to new possibilities.[407] Importantly, such mechanisms of learning are tightly connected to the relationships between human agents of learning. These interactions may allow an understanding of context through dialogue and reflections, allowing

knowledge to be socially constructed and interpreted,[373] thereby facilitating learning which may not be possible through more digital means of sharing learning.

As shown in section 7.2.5, staff in healthcare valued platforms where they could meet others engaged in learning spanning different professions, and valued the presence of a "knowledge broker" who could coordinate learning by linking those with common interests or facing similar problems but questioned the effectiveness of digital means of sharing information, such as emails and dismissed them as causing *"information fatigue".*

Another digital instrument commonly used as a vehicle for learning by sharing in safety critical industries, including healthcare, is incident databases or repositories. They serve the purpose of storing lessons learnt from past incidents in an organisation's or a sector's corporate memory for future use.[408] As discussed in sections 2.3.4 and 7.2.5, in the UK, the NRLS is not viewed by those using it nor by those who have evaluated it formally as having realised its potential at improving patient safety.[105] Researchers and policy makers have expressed concerns about the risk of important signals from incident reports uploaded to the NRLS being diluted by much noise from the vast number of similar incidents reported, thereby constraining the potential of the NRLS to facilitate collective learning. Its approach has been criticised as being *"wide and shallow",* comprising many superficial reports of similar incidents, as opposed to detailed analysis of contributory factors, effective risk controls and lessons learnt.[105] Thus, while the NRLS' focus on quantity of incidents reported has translated into an improved ability at detecting reported trends of incidents, its potential at understanding causes of incidents and actions which work appears to remain under-realised.

For databases such as the NRLS to effectively facilitate learning through sharing, they need to be user-friendly, easy to interrogate, and allow better mechanisms for feedback and analysis.[105] As discussed in section 6.3, these concerns have already been identified by policy makers and planned improvements to the NRLS system are underway.[409] Additionally, I propose that improved interrogation abilities can be

achieved through the use of detailed classification systems of contributory factors and risk controls such as HFACS (see Chapter 4 and Appendix D) and the modified Veteran Affairs hierarchy of controls (see Chapter 5 and Appendix E), as evidenced by the methods used in Chapters 4 and 5.

By and large, the most important source of insight within any organisation, including hospitals, is the collective memory of members of staff. In the aftermath of an incident investigation, not all members of staff are aware of the incident's occurrence, its potential causes and resulting risk controls put in place. As shown in section 7.2.5, participants questioned whether structures currently in place were effective at disseminating lessons learnt from past incidents to relevant members of staff in healthcare organisations. A potential concern, as identified in Chapter 7, could relate to the understanding across organisations of what constitutes knowledge worth sharing. This is not a finding unique to this study. Currie et al., in their evaluation of the NRLS in the first few years of its introduction, identified the normalisation of certain hazards within organisations as contributing to a state where such hazards persisted and were not deemed significant enough to be raised as concerns.[373]

Incident repositories may be useful in storing information, but they cannot direct staff to which lesson is relevant to them. Perhaps, an important necessary innovation required in the development of such databases, is better searching facilities akin to those available to electronic scientific libraries such as PubMed. Such solutions cannot come from individual healthcare organisations but need to be centrally coordinated. As shown in section 7.2.5, participants expected NHS Improvement and NHS England to take the lead on improving mechanisms for sharing lessons learnt.

Additionally, there may be a tendency by management to be in denial about the weaknesses of their own department or organisation by demonstrating the problem of *"distancing through differencing"*, where they fail to appreciate similarities between incidents occurring in other departments or organisations and their own positions.[410] While I found no direct evidence of this problem from the interviews I conducted, the recurrence of similar types of incidents and that similar causes led to different types of

incidents in Trust A (Chapter 4) may suggest that distancing through differencing may, at least partially, be responsible for limiting organisational learning.

For organisations to build collective memory based on shared learning from incidents happening elsewhere, leaders need to embrace the concept of *isomorphic learning*[411] i.e. the recognition that some lessons are universally applicable across departments, organisations and event types. Leaders have a particularly important role to play in promoting isomorphic learning by making lessons learnt from different incidents more generic and explicit to their members of staff. Some mechanisms through which such learning can be achieved include targeted dissemination of patient safety alerts, simulation-based training and storytelling.

8.4 Limitations of this body of research

The research conducted for this thesis aimed to provide an overview of risk control formulation and implementation following serious incident investigations in healthcare. It does have limitations. I have discussed limitations within each of the findings in Chapters 4 to 7. Some of the main ones, influencing the more pertinent findings of this thesis are discussed here. First, in workpackage 1 (reported in Chapters 4 and 5), I limited my sample frame to a single organisation, which may affect the generalisability of results. I sought to offset this limitation by having a wider sample of participants from multiple backgrounds and organisations in workpackage 3.

Second, workpackage 1 comprised retrospective reviews of published documents, which may constitute a limitation given that these are secondary sources of data, constructed through the lens of others (investigators), and therefore potentially provided a biased view of the investigation. As discussed in section 2.5.2.4, numerous bureaucratic filters may influence the written findings of such reports. Nonetheless, since one of my key objectives was to capture both identified causes of incidents and risk controls proposed based on findings of investigations, I believe incident investigation reports and action plans remained valuable sources of data.

Third, I did not capture the views of patients and their representatives. While I have previously noted (see section 7.3.3) that this was because I felt the views of patients required a dedicated research stream, the lack of the patient's voice in my results remains a significant limitation given that a recurring theme across Chapters 6, 7 and 8 was the value they bring to the investigative process and the need for further clarity on their role in formulating and implementing certain risk controls. This will be an important focus for future work.

Fourth, due to time constraints, this body of research lacked an ethnographic component following the "life span" of an incident from investigation to implementation of risk controls and learning, which would have added value to my results. After interviewing a few participants, it became clear to me that some organisations held a dedicated meeting where progress made on the implementation of risk controls was reviewed. Since one of my goals was to assess how the implementation of risk controls could be improved, observing such a meeting would have been useful.

8.5 Conclusion

This thesis set out to answer the following research questions: (1) How well suited are currently proposed risk controls to address contributory factors identified through root cause analysis of serious incidents? (2) What influences the formulation and implementation of risk controls following serious incident investigations in healthcare? (3) How could the formulation and implementation of risk controls following root cause analysis of serious incidents in healthcare be improved?

The findings suggest that for incident investigations to lead to real improvements in patient safety, risk controls formulated and recommended following investigations need to be more robust. Current practices in healthcare when investigating incidents typically result in the identification of contributory factors focusing on the sharp end of care and on the proximal causes. Many risk controls are weak or focused on the "easy fixes". Thus, as currently deployed in healthcare, risk controls are not well placed to

control risk: they are ill-coordinated, non-systematic, poorly evidenced, and unlikely to produce large-scale improvements.

I identified eleven features describing what good risk control formulation and implementation looks like following serious incidents in healthcare: using systems-based approaches to investigating incidents; accounting for the voice of staff from the sharp and blunt ends of care; building an investigative workforce with the right expertise and the capacity to operate without external influence; developing clearly worded recommendations; more purposeful engagement with patients and carers; allocating time and space to risk control formulation; using tools to structure risk control formulation; formulating evidence-based long-lasting defences; creating better structures to implement risk controls and track them; nurturing a collaborative approach to the quality assurance of risk controls and improved inter and intra-organisational learning.

Getting close to achieving this vision of what good looks like in practice will not be straightforward. It will require national efforts to develop a body of skilled and independent investigators, a realisation that risk controls need to be backed with a sound theory of change and a more purposeful understanding and operationalisation of the process of learning in the aftermath of investigations.

8.6 Recommendations for future research

The findings from this thesis highlight multiple gaps for further research. I divide my recommendations into five main domains. First, I believe that there is scope for better understanding of the influence of incident analysis methodologies on the quality of risk controls generated following investigations. In particular, we need to better understand the relationship between the use of systems-based analyses and more effective risk controls. As discussed in Chapter 4, the traditional root cause analysis model used to analyse incidents may miss the identification of factors at the supervisory, organisational and extra-organisational levels. Systems-based approaches, as argued in the narrative review in Chapter 6, may allow investigators to

pay closer attention to these and other latent factors.[81, 237] Similarly, as shown in Chapter 5, risk controls addressing latent factors were lacking when incidents were analysed using linear models. A second and related issue is whether there exists a potential gap between the recommendation of risk controls aimed at the macro level and their implementation, and the factors influencing this gap, particularly in the context of a bureaucratised health system such as the NHS.

Second, I propose there is a need for the development of a taxonomy of risk controls which could be deployed when deciding on risk controls in healthcare. In Chapter 5, I used a modified version of the Veteran Affairs hierarchy[10] to identify numerous risk controls used in the aftermath of incident investigations in an acute secondary healthcare setting, and grouped those risk controls together into broad themes based on shared characteristics across risk controls. The analysis did not provide a complete overview of all the different types of risk controls deployed following investigations across the whole healthcare sector in different contexts (including both primary and secondary care). The next step would involve observing and evaluating which risk controls work best to address particular hazards. This gap has previously been identified by Vincent et al. as well.[226]

Third, there is a need for a wider body of research focussing on the role of patients in both the investigative and the risk control phases. While currently ongoing NIHR funded research aims to develop a better understanding of how best to involve patients in incident investigations, their role in the formulation and implementation of certain risk controls remains under-researched.

Fourth, given the recent developments of national healthcare independent investigative bodies, staffed by professional safety investigators, I suggest that such institutions' direct and indirect impact on patient safety need to be evaluated. This may require both quantitative studies, investigating improvements over time in safety outcomes following national investigations of recurring incidents and ethnographic studies investigating enablers and barriers to the acceptability of recommendations

made by external investigative bodies to healthcare organisations and resulting changes in behaviour within healthcare organisations and the wider sector.

Finally, future research needs to focus on mapping and studying the range of learning activities, both formal and informal which occur in the aftermath of incidents. Such research needs to shift the lens through which learning following incident investigation is studied from a process of simple "information acquisition" to that of *"collective sensemaking, reflection on, and change in, practice and continuous knowledge flow".*[289] Such a research agenda lends itself particularly well to ethnographic methods which could be used to develop a more holistic understanding of how individuals, groups of professionals and organisations navigate the process of learning following an investigation.

8.7 Recommendations for practice: Improving the risk control process following incident investigations in healthcare

The findings of this thesis enable me to draw up a list of recommendations on how to improve the risk control process, based on my own research as reported in this thesis and informed by approaches from the literature.

To structure my recommendations, I divide them into five domains informed by the wider findings of my thesis. Each domain describes a phase, based on the modified learning from incidents model generated in section 8.3.1, where the risk control process could be improved. These domains are:

1. Investigating incidents (Table 8.3)
2. Planning or formulating risk controls (Table 8.4)
3. Intervening or implementing risk controls (Table 8.5)
4. Evaluating risk controls (Table 8.6)

5. Sharing lessons learnt (Table 8.7)

I target these recommendations at different stakeholders involved in serious incident investigation, risk control formulation and implementation in healthcare:

- Healthcare incident investigators, both local and those from national investigative bodies.
- Receivers, implementers and evaluators of recommendations: These stakeholders include those staff senior members from hospital departments receiving recommended risk controls from investigation panels, those tasked with implementing risk controls and those evaluating implemented risk controls. Often, many of these roles overlap. As discussed in Chapter 8, occasionally, recipients of such recommendations may also be organisations other than individual NHS trusts, such as equipment manufacturers or regulators.
- Quality assurers. This group includes both internal quality assurers (such as directors of risk in NHS trusts) and external quality assurers (such as commissioners).
- Local organisational leadership, including trust executives and senior managers within healthcare organisations who set local policy.
- National policy makers, such as the Department of Health and Social Care in the UK and other organisations directly influencing policy, such as statutory bodies like NHS England and NHS Improvement in the UK.

8.7.1 Investigating incidents

Healthcare investigators	Receivers/ Implementers/ Evaluators	Quality assurers	Local organisational leadership	National policy makers and influencers
Improve knowledge of safety sciences (such as investigation methodologies e.g. systems-based models, human factors, risk management) through nationally recommended courses.	Receivers of recommended risk controls and implementers should not form part of the main investigative panel but should be consulted and given time to provide feedback to the findings of investigations.	Improve knowledge of safety sciences (including but not limited to investigation methodologies e.g. systems-based models, human factors, risk management) through nationally recommended courses.	Provide training in safety sciences for local healthcare investigators, implementers and quality assurers. Ensure that staff are empowered to report incidents without fear of intimidation or retribution.	Develop a skilled workforce of investigators at a national level, whose prime role and expertise are in healthcare safety investigations. Consider extending the concept of safe space to NHS organisations if successfully implemented.

Healthcare investigators	Receivers/ Implementers/ Evaluators	Quality assurers	Local organisational leadership	National policy makers and influencers
Ensure the voice of front-line staff is accounted for during investigations.		Attend incident investigation meetings as observers to understand complexities of investigations and decisions made.	Ensure local investigators and patient safety specialists are equipped with the right skills, within a supportive organisational culture to involve patients or their representatives when investigating incidents.	Ensure relevant staff (such as national investigators) are adequately equipped with the right skills to involve patients or their representatives when investigating incidents.
Ensure the voice of patients or their representatives is heard when investigating incidents.		Give NHS trusts/ healthcare organisations flexible timelines for the investigation of incidents.		Give NHS trusts/ healthcare organisations flexible timelines for the investigation of incidents.

Healthcare investigators	Receivers/ Implementers/ Evaluators	Quality assurers	Local organisational leadership	National policy makers and influencers
Ensure relevant expertise (e.g.clinical or human factors experts) is sought for investigations, when required.				Set up national investigative bodies, with independence set in legislation
Perform aggregated analyses of incidents in order to identify significant areas of risk.				
Understand how everyday clinical work is delivered normally (Safety II).				

Table 8.3 - Recommendations for improving risk controls when investigating and analysing incidents, addressed at different stakeholders.

8.7.2 Planning or formulating risk controls

Healthcare investigators	Receivers/ Implementers/ Evaluators	Local organisational leadership
Dedicate a separate, facilitated meeting for drafting recommendations for risk controls with adequate representations from all stakeholders.	Receivers of recommended risk controls to work with investigators to formulate specific, measurable, actionable, relevant and timely risk controls.	Ensure relevant staff are allocated time to attend meetings where risk controls are discussed.
Ensure draft recommended risk controls are circulated to all relevant stakeholders subject to the results of the investigations and recommended risk controls, with adequate time for feedback.	Receivers of recommended risk controls to work with investigators to devise a theory of change to describe how and why risk controls will address identified hazards (e.g. using driver diagrams).	
Use tools such as the hierarchy of risk controls to brainstorm risk control options.	Consider simulating certain risk controls before implementation.	
Prioritise interventions with potential for maximal risk mitigation.	Perform proactive risk assessments of risk controls before implementing them to understand their wider impact on systems.	

Healthcare investigators	**Receivers/ Implementers/ Evaluators**	**Local organisational leadership**
Work with human factors experts when generating risk controls where relevant.		
Identify networks of risk controls, working in synchrony and supporting each other (such as policies supporting implementation of new processes).		
Address recommended risk controls to those stakeholders with agency to effect change.		
Consider engaging patients or their representatives in the risk formulation step, especially when risk controls will necessitate a degree of actions from them.		

Table 8.4 - Recommendations when formulating risk controls, addressed at different stakeholders.

8.7.3 Implementing risk controls

Receivers/ Implementers/ Evaluators	Quality assurance	Local organisational leadership	National policy makers and influencers
Implementers to ensure they possess the required agency to effect change.	Ensure internal quality assurance serves both a critical and supportive function.	Develop better software solutions to track implementation of risk controls within organisations.	Support local organisations in developing and sharing better software solutions to track implementation of risk controls.

Table 8.5 - Recommendations when implementing risk controls, addressed at different stakeholders.

8.7.4 Evaluating risk controls

Receivers/ Implementers/ Evaluators	Local organisational leadership	National policy makers and influencers
Identification of auditable performance indicators to assess effectiveness of risk controls.	Ensure that departments are held to account for the evaluation of risk control and supported to reinforce strong risk controls and address risk controls not improving safety.	Ensure that departments are held to account for the evaluation of risk control and supported to reinforce strong risk controls and address risk controls not improving safety.

Table 8.6 - Recommendations when evaluating risk controls.

8.7.5 Improving learning following incident investigations

Investigators	Receivers/ Implementers/ Evaluators	Quality assurers	Local organisational leadership	National policy makers and influencers
Ensure findings of investigations and recommended risk controls are disseminated to all relevant stakeholders.	Receivers of risk controls with managerial or supervisory roles to foster critical reflection sessions amongst staff with lessons to be learnt from incidents.	Commissioners to consider their role as knowledge brokers, sharing lessons learnt across healthcare organisations within their regional commissioning group.	Local organisations to ensure optimal conditions for attendance at M&M meetings for staff at all levels. Such conditions could include ensuring dedicated time in rota for attendance.	Encourage the development of cross-organisational multi-professional networks for sharing lessons learnt from past incidents.
			Patient safety specialists in NHS organisations to act as knowledge brokers to promote safety learning across departments.	

Investigators	Receivers/ Implementers/ Evaluators	Quality assurers	Local organisational leadership	National policy makers and influencers
			Local organisations to review their methods of sharing lessons learnt from incidents to encourage participative, collaborative and targeted methods (e.g. dedicated face to face teaching sessions) and abandon the sole use of non-targeted means such as group emails to disseminate lessons learnt.	Creation of user-friendly national incident repositories with record of evaluated risk controls and robust search functions.

Table 8.7 - Recommendations for improving learning following incident

9 Appendices

9.1 Appendix A: What should be reported and investigated as a serious incident?

This appendix is an excerpt from pages 13 and 14 of the Serious Incident Framework published by NHS England, outlining the general principles of what constitutes a serious incident.[3]

Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death[8] of one or more people. This includes
        - suicide/self-inflicted death; and
        - homicide by a person in receipt of mental health care within the recent past[9] (see Appendix 1);
    - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
    - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:—
        - the death of the service user; or
        - serious harm;
    - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
        - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring[10]; or
        - where abuse occurred during the provision of NHS-funded care.

      This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident (see Part One; sections 1.3 and 1.5 for further information).
- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information;[11]
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

[8] Caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice.
[9] This includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually - it may be appropriate to declare a serious incident for a homicide by a person discharged from mental health care more than 6 months previously.
[10] This may include failure to take a complete history, gather information from which to base care plan/treatment, assess mental capacity and/or seek consent to treatment, or fail to share information when to do so would be in the best interest of the client in an effort to prevent further abuse by a third party and/or to follow policy on safer recruitment.
[11] Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike. See the Never Events Policy and Framework available online at: http://www.england.nhs.uk/ourwork/patientsafety/never-events/

- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 2 for further information);
- Property damage;
- Security breach/concern;[12]
- Incidents in population-wide healthcare activities like screening[13] and immunisation programmes where the potential for harm may extend to a large population;
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
- Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services[14]); or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)[15]

- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation[16].

9.2 Appendix B: List of Never Events as per NHS England

The following is a list of never events, applicable after 1 April 2015.[111] This list has since been updated in 2018 to include the *"unintentional connection of a patient requiring oxygen to an air flowmeter"*.[412] Given that the incidents I analysed were between 2013 and 2015, I used the 2015 list of never events.

Surgical

1. Wrong side surgery
2. Wrong implant/ prosthesis
3. Retained foreign object post-procedure

Medication

4. Mis-selection of a strong potassium containing solution
5. Wrong route administration of some medications
6. Overdose of insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis-selection of high strength midazolam during conscious sedation

Mental Health

9. Failure to install functional collapsible shower or curtain rails

General

10. Falls from poorly restricted windows

11. Chest or next entrapment in bedrails

12. Transfusion or transplantation of ABO-incompatible blood components or organs

13. Misplaced naso-or oro-gastric tubes

14. Scalding of patients

9.3 Appendix C: NHS England serious incident framework guidelines on final investigation reports and action plan

This appendix includes guidelines from NHS England[3] on the content of the final investigation report and corresponding action plans produced by an internal investigating team following investigation of a serious incident in a trust .

4.4. Final report and action plan

Serious incident investigation reports must be shared with key interested bodies including patients, victims and their families. It is recommended that reports are drafted on the basis that they may become public, so issues concerning anonymity and consent for disclosure of personal information are important and should be considered at an early stage in the investigation process. Each NHS organisation has a Caldicott Guardian who is responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. Those investigating serious incidents can seek advice from the Caldicott Guardian if guidance is needed about the disclosure of patient identifiable information.

4.4.1. Final report

The investigation concludes with an investigation report and action plan. This needs to be written as soon as possible and in a way that is accessible and understandable to all readers.

The report should:

- Be simple and easy to read;
- Have an executive summary, index and contents page and clear headings;
- include the title of the document and state whether it is a draft or the final version;
- Include the version date, reference initials, document name, computer file path and page number in the footer;
- Disclose only relevant confidential personal information for which consent has been obtained, or if patient confidentiality should be overridden in the public interest. This should however be considered by the Caldicott Guardian and where required confirmed by legal advice[45];
- Include evidence and details of the methodology used for an investigation (for example timelines/cause and effect charts, brainstorming/brain writing, nominal group technique, use of a contributory factor Framework and fishbone diagrams, five whys and barrier analysis);
- Identify root causes and recommendations;
- Ensure that conclusions are evidenced and reasoned, and that recommendations are implementable (see section 4.4.2. below);
- Include a description of how patients/victims and families have been engaged in the process;
- Include a description of the support provided to patients/victims/families and staff following the incident.

NHS England recommends use of national reporting templates, available online: http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/ . National templates should be used unless agreed adaptions are required[46].

4.4.2. Action plan

NHS England recommends use of the NPSA Action Plan template available online: http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

The minimum requirements for an action plan include the following:

- Action plans must be formulated by those who have responsibility for implementation, delivery and financial aspects of any actions (not an investigator who has nothing to do with the service although clearly their recommendations must inform the action plan);
- Every recommendation must have a clearly articulated action that follows logically from the findings of the investigation;
- Actions should be designed and targeted to significantly reduce the risk of recurrence of the incident. It must target the weaknesses in the system (i.e. the 'root causes' /most significant influencing factors) which resulted in the lapses/acts/omissions in care and treatment identified as causing or contributing towards the incident;
- A responsible person (job title only) must be identified for implementation of each action point;
- There are clear deadlines for completion of actions;
- There must be a description of the form of evidence that will be available to confirm completion and also to demonstrate the impact implementation has had on reducing the risk of recurrence;

A SMART approach to action planning is essential. That is, the actions should be: Specific, Measurable, Attainable, Relevant and Time-bound. To ensure that the most effective actions/solutions are taken forward, it is recommended that an option appraisal of the potential actions/solutions is undertaken before the final action plan is developed and agreed [viii].

9.4 Appendix D: The modified HFACS framework applied to serious incident reports

The Table below includes description of the main categories of contributory factors at each tier of the modified HFACS framework. Column 2 outlines the differences from the HFACS framework devised by Diller et al.[70]

Contributory factors within each tier of the modified HFACS framework	**Changes compared to HFACS framework by Diller et al**[70]
Unsafe Actions or Errors **Errors** - **Decision-based errors**: Actions of staff proceeded from intention but were subsequently found not to have been appropriate for the situation. Examples include inadequate assessment, inadequate management plan, cognitive bias. - **Skill (action)-based errors:** Unintentional slips and lapses made during the execution of seemingly familiar tasks. Examples include miscalculation of early warning scores, omitted steps in procedure, documentation errors.	No changes

- **Perceptual errors:** Errors which occur when sensory input is degraded. Examples include misreading information, observational errors. **Violations** - **Routine violations:** Practices that had become routinised as workarounds (bending the rules) and seemed to be acceptable or done by peers in the same environment. Examples include not following policies, poor documentation practices. - **Exceptional violations**: One-off departures from accepted practice, which would generally not be acceptable by peers and seniors. Examples include failures to carry out critical job responsibilities, take necessary safety precautions.	No changes

Preconditions for unsafe acts - **Communication factors:** Issues with communication related to problems with the *content* of the information exchanged, not involving the right individuals or if the outcome of the exchange of information was not achieved. - **Team dynamics:** How a team worked together and provided support to each other, under the guise of appropriate leadership - **Environmental factors:** Three different factors relating to the environment within which staff operated are identified: physical (characteristics of the setting where care is delivered), technological and local cultural environment. - **Patient factors:** Factors relating to the patient's case (such as complexity, communication barriers) - **Staff well-being and preparedness for work:** Situations where the	Diller et al. divides preconditions for unsafe acts into three categories (personnel, environmental, condition of operator). Personnel factors include issues relating to communication, coordination and planning and problems relating to the readiness of staff to carry out their duties. Local (departmental) cultural factors are not present at this level in Diller et al.'s model. Equipment design falls under "organisational influences" in Diller et al.'s model. Patient factors are not present in Diller et al.'s model.

operator is incapable to perform the task required due to adverse mental or physical health. This category also includes how ready staff is to work (fitness for duty)	Fitness for duty falls under “personnel factors” in Diller et al.’s model.
Supervisory factors - **Inadequate oversight:** Not providing adequate training to juniors or the right level of professional guidance. - **Inadequate planning:** inadequacy of how the delivery of care was routinely organised, including the creation, enforcement and communication of local policies. - **Supervisory violations:** Intentional departures from expected practice - **Failure to address a known problem:** Hazard previously identified has not been addressed by local leadership team.	No changes Diller et al.’s framework does not include creation of local policies at this level. No changes. No changes
Organisational influences - **Poor operational processes**: These are issues with how things are meant	Diller et al. does not include issues with organisational policies here.

to happen within an organisation. They include inadequate *operations* (structured systems in place to deliver care), *inadequate procedures* (such as standard operating procedures) and the *oversight* of safety within an organisation. - **Resource management:** Factors relating to human and financial resources and hardware availability for adequate functioning of an organisation. - **Organisational culture:** The unspoken rules and habits governing how things get done within an organisation	No changes. Diller et al. label this factor as "organisational climate" and it covers both organisational culture and policies in place.
Extra-organisational issues - Issues identified at this level correspond to problems which are beyond the remit of the organisation investigating the incident. Some may have been identified as "preconditions for unsafe acts". Examples include issues with product	Not identified in Diller et al.

design, financial constraints from local commissioning bodies	

Table 9.1 - Description of each category of contributory factors in the modified HFACS framework used in this study and comparison with the HFACS framework devised by Diller et al.[70]

9.5 Appendix E: Modified hierarchy of risk controls

Stronger actions	New devices with usability testing/ improved functionality Engineering controls (forcing functions) Architectural/ Physical changes Simplify process or process changes Leadership involvement Stewardships and champions
Intermediate actions	Redundancy Eliminate/ reduce distractions Education using simulation based training or human factors training Checklist or cognitive aids Eliminate look and sound-alikes Standardised communication tools Increase staffing/ decreasing workload Software enhancements or modifications Enhanced documentation/ communication Increased senior or specialist input

	Improve multidisciplinary work Assessment of practice
Weaker actions	Checks and double checks Warnings Training/ Education Policy-related changes Disciplinary actions/ Reduced independence Auditing or further investigation Reflection or discussion with supervisor Reminders
No actions	

Table 9.2 - Modified hierarchy of risk controls.

9.6 Appendix F: Interview study poster, email invitation, participant information sheet and consent form

Poster

UNIVERSITY OF LEICESTER

The Health Foundation

An Interview study: Improving actions following root cause analysis of serious incidents

Development of a framework for robust action plans following root cause analysis of serious incidents in healthcare

We would like to hear from:

- Expert accident investigators from safety critical industries (such as aviation, rail, defence, maritime, nuclear, etc).
- Healthcare professionals who conduct serious incident investigations.
- NHS frontline staff involved in the implementation of action plans of serious incident investigations.
- Individuals in Clinical Commissioning Groups with responsibility for reviewing serious incident reports.
- Academics who have published on patient safety and/or accident investigation.

If you are interested in taking part in a short telephone interview, please contact:

Dr M Farhad Peerally
SAPPHIRE, Department of Health Sciences,
University of Leicester, UK
E: mfp6@le.ac.uk
T: +44 (0)116 252 5429
W: http://www2.le.ac.uk/departments/health-sciences/research/soc-sci/research-projects-1/do-you-conduct-supervise-review-or-research-accident-investigations-in-a-safety-critical-industry

SI Action Plans - Gov - Project documents - poster -mfp- 011116-v2d1

Invitation Email

Dear Sir/ Madam,

My name is Dr Mohammad Farhad Peerally and I am a Clinical Research Fellow with the SAPPHIRE group in the Department of Health Sciences at the University of Leicester. I am conducting a one hour telephone interview study looking at how actions following root cause analysis of serious incidents in healthcare can be made more robust (see link: http://www2.le.ac.uk/departments/health-sciences/research/soc-sci/research-projects-1/do-you-conduct-supervise-review-or-research-accident-investigations-in-a-safety-critical-industry).

As part of the study, I would like to hear from:

- Expert accident investigators from safety critical industries (such as aviation, rail, defence, maritime, nuclear, etc).
- Healthcare professionals who conduct serious incident investigations.
- Individuals in clinical commissioning groups (or equivalent organisations) with responsibility for reviewing serious incident reports.
- Academics who have previously published on accident investigation in safety critical industries and/or patient safety.
- Frontline staff involved in the implementation of action plans following serious incident investigations.

If you might be interested in taking part in a short telephone interview, please get in touch by emailing me at mfp6@le.ac.uk. I have attached a participant information sheet to this email.

Many thanks

Regards

Farhad Peerally

Dr Mohammad Farhad Peerally

Clinical Research Fellow/ SpR Gastroenterology

SAPPHIRE

Department of Health Sciences,
College of Medicine, Biological Sciences and Psychology,
University of Leicester, Centre for Medicine, University Road, Leicester, LE1 7RH, UK

t: +44 (0)116 252 5429
e: mfp6@le.ac.uk

Follow us on Twitter or visit our Facebook page

Participant information sheet

UNIVERSITY OF LEICESTER

The Health Foundation

Development of a framework for robust action plans following root cause analysis of serious incidents in healthcare

Participant Information leaflet

This study aims to establish a framework for "what good looks like" for action plans following root cause analysis of serious incidents in healthcare.

This leaflet outlines an interview study in which you may be interested to participate. **If you would like more information after reading the leaflet, please get in touch with Farhad Peerally.**

e: mfp6@le.ac.uk tel: +44(0)116 252 5429

What is the purpose of this study?

Root cause analysis (RCA) is a common incident investigation tool used in the aftermath of adverse events in safety critical industries. It has shown potential in risk identification but concerns have been raised about its effectiveness in producing robust action plans following identification of causal factors in healthcare.

This interview study is being conducted by researchers from the University of Leicester and is seeking answers to the following questions:

1. How are action plans formulated following root cause analysis in healthcare?
2. How are action plans formulated following accident investigation in other safety critical industries?
3. How can the generation and implementation of action plans following root cause analysis in healthcare be made more robust?

Who would we like to interview?

We would like to interview you if your professional role includes one of the following:

1. **Expert accident investigators from other safety critical industries (such as aviation, rail, defence, maritime, nuclear, etc).**
2. **Healthcare professionals who conduct serious incident investigations.**
3. **Individuals in clinical commissioning groups with responsibility for reviewing serious incident reports.**
4. **Academics who have published on patient safety and/or accident investigation.**
5. **Frontline NHS staff who implement action plans of serious incident investigations.**

What is involved?

This study will involve a telephone interview, focusing on the generation and implementation of action plans following root cause analysis of serious incidents. The interviewer will be in a private room and the interviews will be digitally recorded and encrypted. The interview data will be anonymised and transcribed word for word. With your consent, short quotations from the interview transcript may be used in an anonymised survey exercise in the future, as part of the same project. Participation is completely voluntary and if you do decide to take part, you can also withdraw at any time, without giving any reason.

What are the possible benefits of taking part?

The information collected from this study will help inform a framework for robust action plans following root cause analysis of serious incidents in healthcare. In this way, we hope to improve patient safety by improving our response to serious incidents.

What are the possible risks of taking part?

The interview will involve a small time commitment from your part. It will not involve any sensitive information.

If you would like to be involved in this study and/or you want to get more information, please contact Farhad Peerally

Email: mfp6@le.ac.uk

Tel: +44(0)116 252 5429

Confidentiality

All information collected will be kept confidential. Your details will be kept on a secured drive to which only Farhad Peerally and his supervisors will have access. Recording equipment will be encrypted and stored in a locked drawer in the University of Leicester's Centre for Medicine. Published data will be completely anonymised. Data may be accessed by the University of Leicester for monitoring or audit purposes.

What will happen to the results of this study?

The results of this research study will be used to write the PhD thesis of Farhad Peerally, conference presentations, peer and non-peer reviewed publications. None of these will enable participants to be identified.

What if I change my mind and want to withdraw from the study?

You can change your mind and withdraw from the study after the interview. If the data has not been published or the thesis has not been written, all attempts will be made to destroy the data from your interview.

What if there is a problem?

If you have any concerns, please get in touch. We will do our best to answer your question and address your concerns. If you remain unsatisfied and wish to make a formal complaint, you can do so through the University of Leicester complaints procedure.

Who is funding the study?

Farhad Peerally's PhD is funded by the Health Foundation.

Mary Dixon-Woods, who is supervising this study, is funded in part by the Wellcome Trust.

Who has reviewed the study?

This study has been approved by the University of Leicester Research Ethics Committee.

The Study Team

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RAND Professor of Health Services Research
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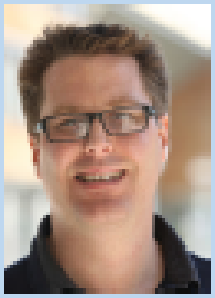

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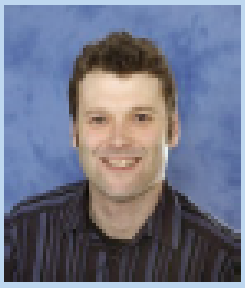


Professor Graham Martin
Professor of Health Organisation and Policy
(University of Leicester)
Graham.martin@le.ac.uk

If you would like to be involved in this study and/ or you want to get more information, please contact Farhad Peerally

Email: mfp6@le.ac.uk

Tel: +44(0)116 252 5429

Consent form for interview study

PARTICIPANT EMAIL CONSENT FORM FOR TELEPHONE INTERVIEWS

Version 2 01-Nov-2016

Once you have read the participant information sheet and had a chance to ask questions, please add your initials to each statement, add your name to the bottom of the form and date it. Send the e-mail back to mfp5@le.ac.uk from an email address operated by you personally.

Title of Project: Development of a framework for robust action plans following root cause analysis of serious incidents in healthcare

Name of Researcher: Dr Mohammad Farhad Peerally

Please initial

1. I confirm that I have read the information sheet dated 2016-11-01 v2d1 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.

3. I agree to the interview being digitally recorded for transcription and subsequent analysis.

4. I agree to anonymised word for word quotations being used in study reports and I understand that I will not be identified in any publications resulting from the study.

5. I agree to anonymised word for word quotations being used in a future phase of the study (which will consist of a survey to gather opinions of experts)

6. I understand that data collected during the study may be looked at by the study team at the University of Leicester Health Sciences Department, from regulatory authorities (such as ethics committees), representatives from the sponsor and/or NHS trusts accessing research data for monitoring and audit purposes..

7. I agree to take part in the above study.

_____ _____

Full name of participant Date

9.7 Appendix G: Interview topic guide

Domains	Details
How are risk controls/ APs generated, strength and problems with current & how can this process be improved?	**SI investigators/ Expert Accident Investigators:** Think of an example of an incident you either investigated or were responsible for part of the implementation of the actions. The incident can be memorable for whichever reason. Tell me how you went about investigating and coming up with actions - Anything that works particularly well? - Anything that you think could be improved? - Once you have identified causes, how do you go about identifying actions? - Do you try and identify solutions to each contributory factor, or do you try find a solution to the root cause or causes? - Are some actions considered and others rejected? Why? - Are some actions more important than others? Why? Do these actions get allocated more resources? - What would you list as the characteristics of a good action plan? - Specific: How hard is it to be specific about which action you want to take? - Measurable: How about measurement of the action? Does this happen on a routine basis? How hard is it to measure implementation and success? - Attainable: conflict between ideal action and action achievable

- Relevant: Are you always confident that actions are going to address problems?
- Time: What effect does the deadline have on the action?

Any decision-making tools used in the process of deciding which corrective action to use? Analytical hierarchy process/ brainstorming/ grey theory/ fuzzy / risk priority numbers

Example of incident where you were particularly pleased with the depth/ thoroughness of investigation and actions and why

Example of incident where you feel the team could have done a better job at investigation/ coming up with actions

Academics/ Implementors/ Commissioners:
From your experience/research, what are the processes in place to investigate incidents/ accidents in healthcare/ your industry?

From your experience, how are actions generated following an incident investigation?

What is your opinion on the strength of the processes in place to generate these actions?

To all except academics: tell me about your role wrt the action plans that are generated following RCAs?

All participants (except expert investigators):

What are the commoner risk controls that are proposed in healthcare?

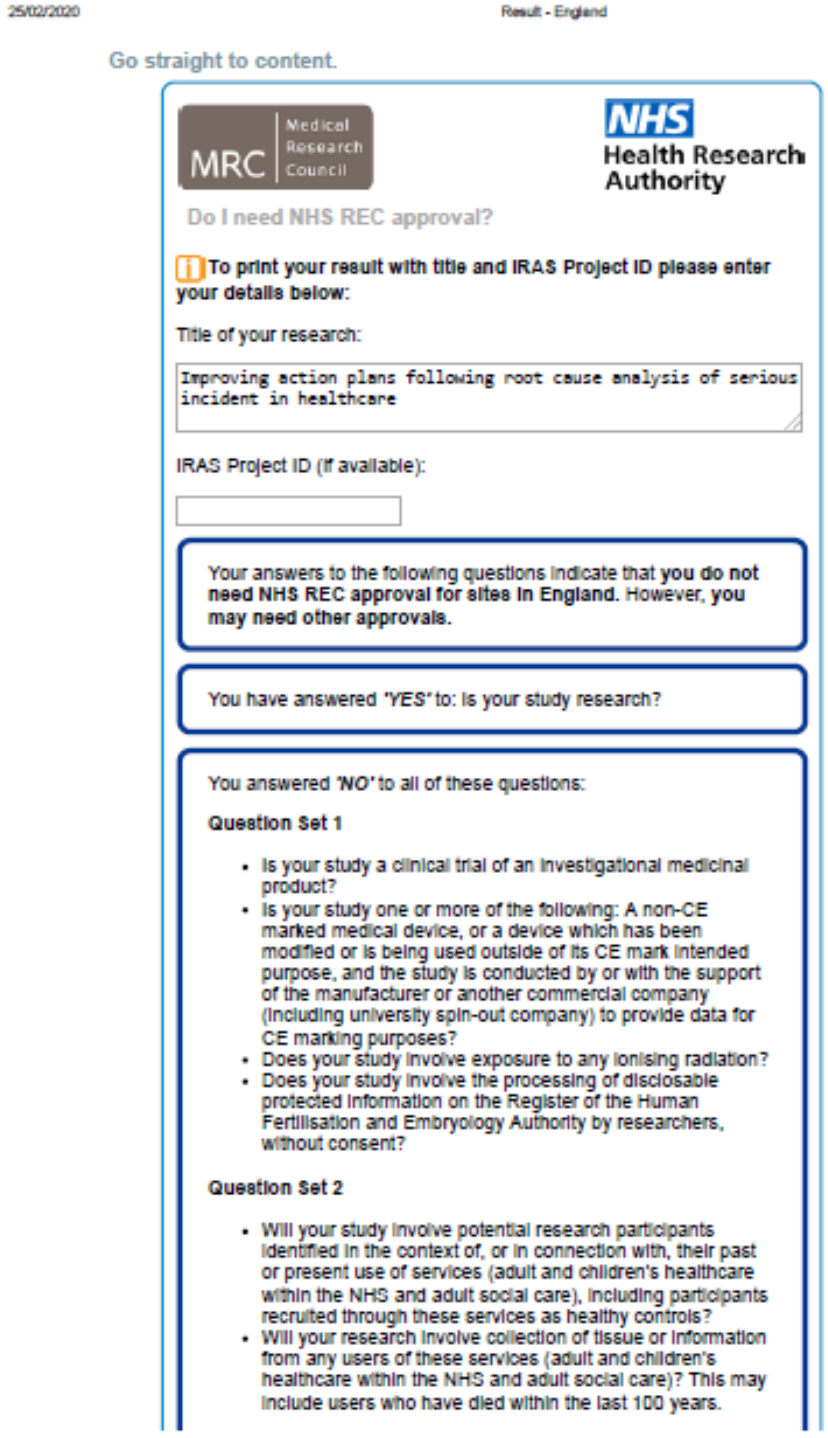
Quality of risk controls	General opinion on the quality of risk controls generated from RCAs in healthcare. What do they consider as weak and strong risk controls and why? Are human factors/ ergonomics considered when generating actions? If so – how? If not – why? There are times when an incident has been investigated and an action plan drawn up. Yet a few days/weeks/months/years down the line, the same event happens again. Why do you think that is? Value of aggregated RCA – recommendations.
Who generates?	**To all:** Who decides/ should decide on the choice of recommendations and the action plan? Why? What do you believe should be the role of the investigator in action planning in the aftermath of an investigation? What skills should those who design recommendations have? Intuitive or a hard process. How hard is it to come to the right action / AP? How can this process be facilitated? What ties do the investigators/ those who generate the risk controls have to the organisation/department where the incident happens?

Legislation	How important is legislation in facilitating/ disabling the process of incident investigation and action planning?
Finalising actions	**All (reword as required)** Numerous actions possible. How do you decide which one to go for? Do you ever give a priority list to the actions? If so, what determines one as being more important than another one **Commissioners:** What are the factors considered when approving risk controls? **To all:** How prescriptive should recommendations be? Are actions ever taken before the conclusion of an investigation? Can you give some examples? what are your feelings regarding these quick fixes?
Staff and service user involvement	How much involvement do front-line staff have in terms of the development of recommendations? How much should they have? What limits their involvement? How much involvement should patients have? How much involvement do they have? What limits their involvement?

Implementation & Follow up	**To commissioners:** How do trusts generally take the feedback you give them? **To trusts:** What's your opinion of the feedback you generally get from the CCGs? **To all:** How do you manage recommendations aimed at other organisations? Are actions generated outside the scope of the action plan in response to the SI? In your industry (industry you have investigated), Are risk controls followed up to ensure: Implementation. Improvement. If yes, what are the processes in place to ensure implementation and improvement? What are the factors that make recommendations likely to be implemented? What are the barriers to implementation of risk controls from action plans of serious incident investigations? What's the role of managers through the process to implementation? All participants: How can the implementation of risk controls be improved?

Learning	How do you ensure that the organisation is learning from past incidents? How can organisations learn from each other? How do we disseminate lessons learnt across organisations?
Any other comments from the participants on risk control choice, design and implementation.	

9.8 Appendix H: NHS HRA ethics decision outcome for interview study



25/02/2020 Result - England

Go straight to content.

MRC Medical Research Council

NHS Health Research Authority

Do I need NHS REC approval?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

Improving action plans following root cause analysis of serious incident in healthcare

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC approval for sites in England.** However, **you may need other approvals.**

You have answered *'YES'* to: Is your study research?

You answered *'NO'* to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study one or more of the following: A non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose, and the study is conducted by or with the support of the manufacturer or another commercial company (including university spin-out company) to provide data for CE marking purposes?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

Question Set 2

- Will your study involve potential research participants identified in the context of, or in connection with, their past or present use of services (adult and children's healthcare within the NHS and adult social care), including participants recruited through these services as healthy controls?
- Will your research involve collection of tissue or information from any users of these services (adult and children's healthcare within the NHS and adult social care)? This may include users who have died within the last 100 years.

- Will your research involve the use of previously collected tissue or information from which the research team could identify individual past or present users of these services (adult and children's healthcare within the NHS and adult social care), either directly from that tissue or information, or from its combination with other tissue or information likely to come into their possession?
- Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of these services (adult and children's healthcare within the NHS and adult social care)?

Question Set 3

- Will your research involve the storage of relevant material from the living or deceased on premises in the UK, but not Scotland, without an appropriate licence from the Human Tissue Authority (HTA)? This includes storage of imported material.
- Will your research involve storage or use of relevant material from the living, collected on or after 1st September 2006, and the research is not within the terms of consent from the donors, and the research does not come under another NHS REC approval?
- Will your research involve the analysis of DNA from bodily material, collected on or after 1st September 2006, and this analysis is not within the terms of consent for research from the donor? And/or: Will your research involve the analysis of DNA from materials that do not contain cells (for example: serum or processed bodily fluids such as plasma and semen) and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Will your research involve at any stage intrusive procedures with adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?
- Is your research health-related and involving prisoners?
- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health and Social Care (England)?

If your research extends beyond **England** find out if you need NHS REC approval by selecting the *'OTHER UK COUNTRIES'* button below.

OTHER UK COUNTRIES

If, after visiting all relevant UK countries, this decision tool suggests that you do not require NHS REC approval follow this link for final confirmation and further information.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

9.9 Appendix I: Types of serious incidents reviewed between 2013 and 2015

Type of incident	Number	Percentage
Fall	15	12%
Unexpected death	14	11%
Delay/ missed diagnosis of other condition	15	12%
10 times or more drug error	12	10%
Failure to recognise deteriorating patient	12	10%
Delay/ missed diagnosis of cancer	9	7%
Delay in following up patient/ not followed up	8	6%
Capacity issues (bed)	6	5%
Wrong Implant	5	4%
Inappropriate treatment	4	3%
Unnecessary surgery	3	2%
Bleeding from vascath/ AV fistula	3	2%
Surgical complications	3	2%
Technical problem	2	2%
Suicide of patient under care	2	2%

Retention of surgical products	2	2%
Failure to act on results	2	2%
Wrong side surgery/ procedure	2	2%
Loss of clinical data	1	1%
Loss of clinical specimen	1	1%
Injury from medical equipment	1	1%
Unexplained fracture	1	1%
Lack of consent	1	1%
Wrong line connection	1	1%
Accidental death of inpatient	1	1%

Table 9.3 - Types of serious incidents reviewed between 2013 and 2015.

9.10 Appendix J: Specialties where the serious incidents reviewed between 2013 and 2015 occurred

Specialties	Number	Percentage
Emergency Medicine	23	18%
Obstetrics and Gynaecology	19	15%
Radiology	11	9%
Paediatrics and neonates	11	9%
Ophthalmology	7	6%
Acute Medicine	6	5%
Upper Gastrointestinal surgery	6	5%
Orthopaedics	6	5%
Lower Gastrointestinal surgery	5	4%
Geriatrics and stroke	5	4%
Oncology	4	3%
Cardiothoracic	4	3%
Gastroenterology	3	2%
Cardiology	3	2%

Respiratory medicine	3	2%
Nephrology	3	2%
Urology	2	2%
Hepatobiliary	2	2%
Breast	2	2%
Infectious diseases	2	2%
Haematology	2	2%
Intensive care medicine	2	2%
Ear, Nose and Throat	2	2%
Whole trust	1	1%
Pathology	1	1%
Other theatres	1	1%
Renal transplant	1	1%
Podiatry	1	1%
Orthodontics	1	1%
Diabetes and endocrinology	1	1%
Rheumatology	1	1%
Neurology	1	1%

322

Rehabilitation medicine	1	1%

Table 9.4 - Specialties where the serious incidents reviewed between 2013 and 2015 occurred.

9.11 Appendix K: Professional roles of staff involved in serious incident investigations reviewed between 2013 and 2015

Professional roles of investigators	**Number of incidents**	**Percentage**
Patient safety team	115	91%
Clinical consultants	109	87%
Senior nurses and matrons	85	67%
Clinical managers	65	52%
Non-clinical managers	41	33%
Specialist nurses	16	13%
Midwives	14	11%
Radiographers	14	%
Human resources representatives	11	9%
Pharmacists	7	6%
Education team	6	5%
Safeguarding specialists	5	4%

External subject specialist (not employed by organisation)	5	4%
Administrative staff	5	4%
Health and Safety executive	4	3%
Nurses (not senior)	3	2%
Junior doctors	3	2%
Human Factors specialist	3	2%
Screening team	3	2%
Other theatre staff (e.g. operational department practitioners)	3	2%
Sonographer	3	2%
Therapists	3	2%
GP/ Primary care representative	2	2%
Perfusionists	1	1%
Radiation protection adviser	1	1%
Emergency planning officer	1	1%
Psychologist	1	1%

Laboratory manager	1	1%
Ambulance crew	1	1%
Embryologist	1	1%

Table 9.5 - Professional roles of staff involved in serious incident investigations reviewed between 2013 and 2015.

9.12 Appendix L: Table of included articles for narrative review

Author	Year	Sector	Design
Bagian et al.	2011	Healthcare	Quality improvement report
Bakolas et al.	2009	Multiple	Viewpoint
Boyd et al.	2015	Healthcare	Description of a new method
Branton et al.	2016	Healthcare	Descriptive case study
Canham et al.	2018	Healthcare	Comparison of two methods of incident analysis
Card et al.	2012	Healthcare	Systematic review
Card et al.	2014	Healthcare	Uncontrolled before and after study
Card et al.	2014	Healthcare	Randomised survey

Cedergren	2013	Railway	Mixed methods
Chuang	2015	Healthcare	Case study
Dechy et al	2012	Multiple	Qualitative analysis of working group discussions
Dodshon et al.	2017	Multiple	Survey
Drupsteen et al.	2014	Multiple	Focus group
Eshareturi et al.	2017	Healthcare	Documentary analysis and interviews
Gandhi et al.	2005	Healthcare	Viewpoint
Goh et al	2010	Waste Management	Case study
Goode et al.	2016	Led outdoor activities	Qualitative analysis of incident reports and application of a framework
Götmar et al.	2007	Multiple	Interview study

Hettinger et al.	2013	Healthcare	Qualitative- documentary analysis and interviews
Iedema et al.	2008	Healthcare	Interview study
Johansen et al.	2015	Oil and gas	Viewpoint
Lehtinen et al.	2011	IT	Mixed methods
Leong Fei et al.	2011	Oil industry	Descriptive case study
Leveson et al.	2016	Healthcare	Application of a new model to analyse incidents
Li et al.	2015	Healthcare	Descriptive Case study
Lundberg et al.	2010	Multiple	Interview study
Lundberg et al.	2009	Multiple	Document analysis
Lundberg et al.	2012	Multiple	Interview study
Macrae	2014	Aviation	Book - based on interviews and ethnographic studies

Mills et al.	2005	Healthcare	Evaluation of RCA and actions related to falls using results of RCA and interviews
Mills et al.	2008	Healthcare	Mixed methods. Documentary review and Interviews
Mills et al.	2006	Healthcare	Documentary analysis and interviews
Pham et al.	2010	Healthcare	Description of a new method to investigate incidents and draw up actions
Plett et al.	2010	Petroleum	Case study
Rasmussen	1997	Multiple	Review
Rollenhagen	2011	Nuclear	Viewpoint
Rollenhagen et al.	2010	Multiple	Questionnaire
Rollenhagel et al.	2017	Nuclear	Interview study
Russel Vastveit et al.	2014	Oil and gas	Ethnography and interviews

Saleh et al.	2010	Multiple	Review
Silva	2016	Chemical	Document analysis
Stackhouse et al.	2016	Oil and gas	Mixed methods
Stemn et al.	2018	Multiple	Review
Vacher et al.	2011	Healthcare	Randomised experimental design
Vastveit	2015	Oil and gas	Ethnography and interviews
Vrklevski et al.	2018	Healthcare	Mixed methods
Williams et al.	2015	Healthcare	Description of a new method
Wrigstad et al.	2014	Healthcare	Documentary analysis and interviews
Wu et al.	2014	Healthcare	Evaluation study with audit and questionnaire

Table 9.6 - Table of included articles for narrative review.

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