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**Improving Patient Safety by
Learning from Near Misses –
Insights from Safety-Critical
Industries**

Nicholas Woodier

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Abstract

Background

Patients are at risk of being harmed by the very processes meant to help them. To improve patient safety, healthcare organisations attempt to identify the factors that contribute to incidents and take action to optimise conditions to minimise repeats. However, improvements in patient safety have not matched those observed in other safety-critical industries.

One difference between healthcare and other safety-critical industries may be how they learn from near misses when seeking to make safety improvements. Near misses are incidents that almost happened, but for an interruption in the sequence of events. Management of near misses includes their identification, reporting and investigation, and the learning that results. Safety theory suggests that acting on near misses will lead to actions to help prevent incidents. However, evidence also suggests that healthcare has yet to embrace the learning potential that patient safety near misses offer.

The aims of this research, in support of this thesis, were to explore how best healthcare can learn from patient safety near misses to improve patient safety, and to identify what guidance non-healthcare safety-critical industries, which have implemented effective near-miss management systems, can offer healthcare. As this research progressed the aims were updated to include consideration of whether healthcare should seek to learn from patient safety near misses.

Methods

This research took a mixed-methods approach augmented by scoping reviews of the healthcare (study 1) and non-healthcare safety-critical industry (study 3) literature. A qualitative case study (study 2) was undertaken to explore the management of patient safety near misses in the English National Health Service. Seventeen interviews were

undertaken with patient safety leads across acute hospitals, ambulance trusts, mental health trusts, primary care, and national bodies. A questionnaire was also used to help access the views of frontline staff.

A grounded theory (study 4) was used to develop a set of principles, based on learning from non-healthcare safety-critical industries, around how best near misses can be managed. Thirty-five interviews were undertaken across aviation, maritime, and rail, with nuclear later added as per the theoretical sampling.

Results

The scoping reviews contributed 125 healthcare and 108 non-healthcare safety-critical industry academic articles, published internationally between 2000 and 2022, to the evidence gained from the qualitative case study and grounded theory. Safety cultures and maturity with safety management processes were found to vary in and across the different industries, and there was a reluctance for healthcare to learn about safety and near misses from other industries.

Healthcare has yet to establish effective processes to manage patient safety near misses. There is an absence of evidence that learning has led to improvements in patient safety. The definition of a patient safety near miss varies, and organisations focus their efforts on reporting and investigating incidents, with limited attention to patient safety near misses. In non-healthcare safety-critical industries, near-miss management is more established, but process maturity varies in and across industries. Near misses are often defined specifically for an industry, but there is limited evidence that learning from them has improved safety. Information about near misses are commonly aggregated and may contribute to company and industry safety management systems.

Exploration of the definition of a patient safety near miss led to the identification of the features of a near miss. The features have not been previously defined in the manner presented in this thesis. A patient

safety near miss is context-specific and complex, involves interruptions, highlights system vulnerabilities, and is delineated from an incident by whether events reach a patient.

Across healthcare and non-healthcare safety-critical industries the impact of learning from near misses is often assumed or extrapolated based on the common cause hypothesis. The hypothesis is regularly cited in safety literature and is used as the basis for justifying a focus on patient safety near misses. However, the validity of the hypothesis has been questioned and has not been validated for different patient safety near miss and incident types.

Conclusions

The research findings challenge long-held beliefs that learning from patient safety near misses will lead to improvements in patient safety. These beliefs are based on traditional safety theory that is unlikely to now be valid in the complexity of modern-day systems where incidents are the result of multiple factors and can emerge without apparent warning. Further research is required to understand the relationship between learning from patient safety near misses and patient safety, and whether the common cause hypothesis is valid for different types of healthcare safety event.

While there are questions about the value of learning directly from patient safety near misses, the contribution of near misses to safety management systems in non-healthcare safety-critical industries looks to be beneficial for safety improvement. Safety management systems have yet to be implemented in the National Health Service and future research should look to understand how best this may be achieved and their value. In the meantime, patient safety near misses may help healthcare's understanding of systems and their optimisation to create barriers to incidents and build resilience. This research offers an evidence-based definition of a patient safety near miss and describes principles to support identification, reporting, prioritisation, investigation, aggregation, learning, and action to help improve patient safety.

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I also want to thank three other individuals for the support they provided to me during the research for and writing of this thesis: Mrs Carol Appleby for her transcribing skills without which this thesis certainly would have taken a lot longer; Mr Graham Morton for challenging my thinking with an expert eye; and my wife Kate for, as always, being wonderful and there for me.

I have dedicated this thesis to my friend and previous work colleague, Mr Owen Bennett. Owen introduced me to the world of patient safety at a time when I was moving away from working in clinical medicine. Without his endless guidance and support, I would not be where I am today. Thank you and cheers.

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Declaration of interest

The author commenced this thesis while employed as Patient Safety Lead at Nottingham University Hospitals NHS Trust. Later during the period of study the author became employed as an investigator with the Healthcare Safety Investigation Branch (HSIB). This thesis is unaffiliated with either organisation, but reference is made to work undertaken by HSIB. During the period of research for this thesis, the author was not involved in any work at HSIB pertaining to safety management systems.

About the author and period of study

I commenced this thesis in 2015, three years after a career change that saw me move from being a medical doctor to completing a MSc in Human Factors and taking up a role in patient safety. My career change led me to develop an interest in incident investigation, ultimately resulting in me achieving employment with England's independent safety investigatory body as a senior safety investigator.

During my early patient safety career I became aware of 1) the challenges to effective learning from incidents, and 2) the exhortations for organisations to better learn from incidents, including near misses. Following initial exploration, I understood there to be value in learning from near misses but found no guidance to help with the development of processes for learning. That initial exploration subsequently led to the focus of study for this thesis.

The period of study for this thesis took longer than expected. It was undertaken alongside full-time employment and spanned a period that included the COVID-19 pandemic. The timeline was:

- 2015 – initial proposal and research questions defined.
- 2016 – 2018 – studies 1 and 3 (scoping reviews). A voluntary interruption in study was agreed due to work pressures.
- 2019 – 2020 – study 2 (qualitative case study). A further voluntary interruption was agreed due to redeployment during the pandemic.
- 2020 – 2021 – study 4 (grounded theory).
- 2022 – 2023 – thesis pending with submission in May 2023. Viva in October 2023 with minor corrections submitted shortly after.

If you are reading this thesis, thank you, and I hope it is informative and supportive of any organisation or industry considering their management of near misses and safety more widely. I genuinely enjoyed this period of my life, and am proud of the outputs.

About this thesis

This thesis is written across 14 chapters with associated references and appendices. Chapters one to three provide relevant background with introductions to the concept of safety, safety in different industrial contexts, and near misses themselves. Chapters four and five describe the research aims and questions, and the methodologies respectively.

This thesis involved four studies. Chapter six describes the protocol for and the findings of a scoping review of the healthcare literature in relation to near-miss management (study 1). Chapter seven then describes the protocol for and the findings of a qualitative case study used to explore near-miss management in different healthcare contexts (study 2). Following consideration of near misses in healthcare, this thesis progressed to consider their management in safety-critical industries. Chapter eight describes the findings of a scoping review of the safety-critical industry literature (study 3) and chapter nine describes the protocol for and the findings of a grounded theory to explore the principles of near-miss management in safety-critical industries.

The remaining chapters provide a synthesis of the findings from the four studies to answer the research questions, with conclusions drawn in chapter 14. Chapter 10 describes updates to the original research questions, with chapters 11 and 12 seeking to clarify the definition of a patient safety near miss and the value of learning from near misses respectively. Chapter 13 draws all the findings together to provide a summary of the potential elements of future safety and near-miss management systems for healthcare.

When reading this thesis

For those who may be less familiar with some of the topics included in this thesis, signposting is provided. Sample quotes are also provided, with consent from their sources, to exemplify areas of discussion. For quotes, double quotation marks have been used to represent dialogue

or speech (e.g. from interviews), and single quotation marks represent quotes from text (e.g. questionnaire responses) or to set apart a word/phrase. Reporting of statistics is in line with the American Psychological Association (2022) 7th edition.

Common abbreviations used

GT	Grounded Theory
HRO	High-Reliability Organisation/Organising
IRS	Incident Reporting System
LFPSE	Learning From Patient Safety Events
NHS	National Health Service
NRLS	National Reporting and Learning System
PSI	Patient Safety Incident
PSIRF	Patient Safety Incident Response Framework
PSNM	Patient Safety Near Miss
PSNMMS	Patient Safety Near Miss Management System
QCS	Qualitative Case Study
RCA	Root Cause Analysis
SCI	Safety-Critical Industry
SMS	Safety Management System

Supplementary materials

The nature of the research approaches used in this thesis is that they collect large amounts of data. Due to the word limit of this thesis:

- **Qualitative research** – limited quotes have been provided with further available on request from the thesis author.
- **Scoping reviews** – example citations have been provided where there are multiple available. All required information is available as supplementary materials via the link below.

LINK – Supplementary materials (Woodier, 2023)

Publications and presentations

Book

Woodier, N. (Ed) (2024) **Learning from near misses: cross-industry lessons for safety management**. Taylor and Francis, CRC Press. *In development*.

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1 The Science of Safety

1.1 Introduction

The aim of this thesis is to support improvements in patient safety in healthcare through a better understanding of the role of 'near misses.' This first chapter introduces the concept of safety, provides an overview of terms and definitions, and describes how safety has evolved from a focus on individuals, to systems.

1.2 Introducing 'safety'

A 'safe' situation is one where there is no danger or likelihood of harm (Cambridge English Dictionary, 2021). An unsafe situation is therefore where there is a potential for someone (staff or service user) or something (the industry itself or environment) to be harmed. Harms can be physical, psychological, financial, or reputational depending on the situation.

The interpretation of something being safe is bound to the context within which it exists or operates. This thesis will consider safety in several industrial contexts, the activities of which have the potential to cause significant harm.

1.2.1 Safety vocabulary

This thesis will refer to safety terms which may have different definitions depending on their industrial context. These differences will be acknowledged throughout this thesis. In an attempt to provide consistency and to support readability, the thesis will use the following generic terms and definitions unless otherwise stated:

- **Incident** – event leading to an outcome which may be harmful.
- **Harm** – negative effects from an event.
- **Risk** – likelihood of something occurring and its potential severity.

1.3 Safety science

Safety science is the 'interdisciplinary study' of incidents and their prevention (Dekker, 2019). The understanding of safety has evolved over the decades from beliefs that humans cause incidents, to appreciating the role of systems¹. The following sections provide an overview of dominant safety theories and models².

1.3.1 Incidents as linear sequences (1930s)

One of the earliest safety theories describes incidents as linear sequences, represented by toppling dominoes (Heinrich, Petersen and Roos, 1980). Unsafe acts (or conditions), resulting from ancestry and social environments, can lead to injury and incidents. Prevention of incidents therefore requires an interruption of the sequence.

The 'domino model' is now considered outdated and too simplistic for the complexity of modern systems. Its focus on cause and effect is insufficient to explain how or why most incidents occur (Hollnagel and Goteman, 2004).

1.3.2 Normal accidents and reliability (1980s)

'Normal Accident Theory' theorises that incidents are inevitable and normal, particularly in tightly-coupled systems with high complexity (Perrow, 1999). Certain industries, such as human space flight, are inherently risky and incidents may not be predictable. Normal Accident Theory has been described as 'pessimistic' (Hopkins, 2001), but many high-risk industries maintain safety because of their reliability (Perrow, 1999).

In the late 1980's reliability became an increasingly recognised component of safety. Certain industries are now labelled as High-

¹ System – 'a set of interdependent elements that interact to achieve a common aim. These may be human, process or procedures, technology, equipment, or policy and regulatory requirements' (Clinical Human Factors Group, 2018).

² Model – a communicable description of a system to a certain level of detail (Oberquelle, 1984).

Reliability Organisations (HROs) because of their ability to anticipate and avoid incidents and manage fluctuations in performance (resilience) (Rochlin, La Porte and Roberts, 1987). HROs will be considered further in 2.2.1.

1.3.3 Barriers to prevent harm (1990s)

In the 1990's James Reason published one of the most well-known models of incident causation which later became known as the 'Swiss Cheese Model' (Reason, 1997). The Swiss Cheese Model describes how hazards exist and errors happen, but barriers can prevent harm. However, barriers can fail due to unsafe actions (further errors) and latent factors (dormant issues).

The Swiss Cheese Model is now considered old and has been criticised for not accounting for the complexity of modern systems (Larouzee and Le Coze, 2020). Several authors have developed the Swiss Cheese Model into further models such as the Human Factors Analysis and Classification System (HFACS) (Wiegmann and Shappell, 2001). HFACS uses a taxonomy³ to categorise contributory factors to incidents (Woodier, Whiting and Bennett, 2022).

1.3.3.1 Barriers and controls

The role of controls, barriers, and safeguards in harm prevention is the focus of several risk and incident analysis approaches. Definitions include (Chartered Institute of Ergonomics & Human Factors, 2016):

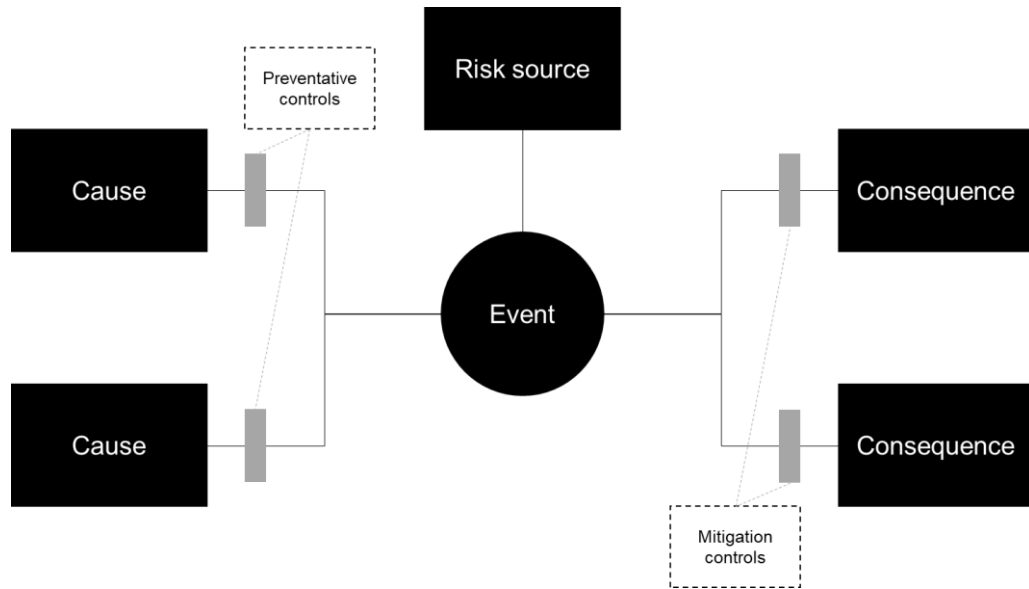
- **Controls** – measures to prevent incidents from occurring.
- **Barriers** – controls that are robust and reliable to prevent incidents.
- **Safeguards** – controls that contribute to the prevention of incidents but are not enough alone to prevent them.

'Barrier-Based Approaches' to risk and incident analysis include examples such as the Bowtie method. The Bowtie provides a representation of the threats to and consequences of a risky situation,

³ Taxonomy – a list of terms used to classify something, often organised in a hierarchical way.

and the controls in place (Figure 1) (Chartered Institute of Ergonomics & Human Factors, 2016).

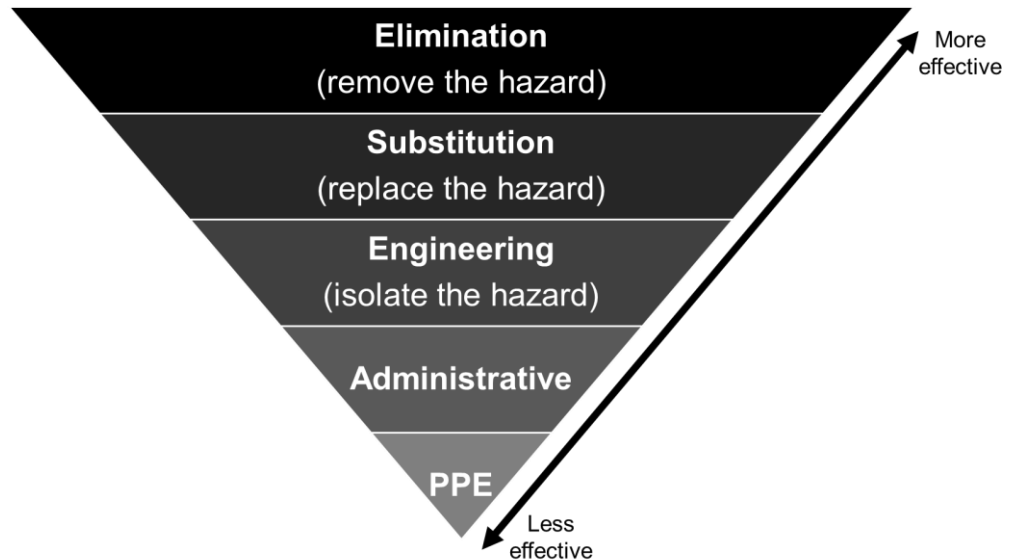
Figure 1. Simplified 'Bowtie' adapted from the Chartered Institute of Ergonomics & Human Factors (2016)



Theoretical hierarchies have been developed to help consider the potential effectiveness of various controls. Examples include the Hierarchy of Controls (Figure 2) (National Institute for Occupational Safety and Health, 2022), which originated in occupational health and safety (Gojdics, 2019), and the healthcare-focussed Action Hierarchy Tool (appendix 1A) (National Patient Safety Foundation, 2015). More effective controls, which may meet the definition of a barrier, are those that remove reliance on humans to act.

Figure 2. Hierarchy of Controls adapted from the National Institute for Occupational Safety and Health (2022)

Administrative controls include policies/checklists; PPE is personal protective equipment



1.3.4 Ergonomics, human factors, and systems

As theories surrounding safety evolved, interest increased around how humans interact with the systems around them. The science of ‘human factors,’ also referred to as ergonomics, was formalised as a science ‘... concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimise human well-being and overall system performance’ (International Ergonomics Association, 2021). Human factors practitioners use tools and models to help understand systems and their various elements.

1.3.5 Safety II and resilience engineering

During the period of research for this thesis there has been increasing attention on ‘resilience engineering’ with respect to safety. Resilience engineering is ‘the intrinsic ability of an organisation (system) to maintain or regain a dynamically stable state, which allows it to continue operations after a major mishap and/or in the presence of a continuous stress’ (Woods, Leveson and Hollnagel, 2017).

Resilience engineering is sometimes referred to as Safety II. In contrast, Safety I is the traditional, retrospective, and reactionary approach to incidents aimed at learning to prevent recurrence. Safety II is a reorientation of the safety lens towards resilience (Hollnagel, 2014) and 'identifying and then enhancing the positive capabilities of people and organisations that allow them to adapt effectively and safely under varying circumstances' (Dekker, 2019). The Functional Resonance Analysis Method is one method to help explore resilience (Hollnagel, 2012).

1.3.5.1 Work as done versus work as imagined

Safety II and other system-focussed approaches (e.g. Leveson, 2011) seek to understand how humans perform in the real world and how that performance can vary from what is expected of them (Verhagen, Vos, Sujana et al., 2022). Shorrock (2016) describes this as the differences between how work is imagined to be done, how work is prescribed (written down in policy) to be done, and how work is actually done in the real world.

1.4 Safety culture

The culture of an industry/organisation/company is often referred to when considering its safety. There is no agreed definition of 'safety culture' (Henriqson, Schuler, van Winsen et al., 2014) and it is not clear whether it is something an organisation 'does' or 'has' (Waring and Glendon, 2001). However, safety culture has come to commonly relate to the values, norms, and beliefs of an organisation and how these determine a commitment to safety. Reason (1997) describes how a safety culture has five elements:

- **Informed** – active dissemination of learning.
- **Reporting** – an atmosphere where staff feel able to speak up.
- **Learning** – from mistakes and making changes.
- **Just** – individual action only where acts were reckless/deliberate.
- **Flexible** – adaptation to changing demands.

1.4.1 Just culture

Reason (1997) defines a just culture as ‘an atmosphere of trust in which people are encouraged (even rewarded) for providing essential safety-related information, but in which they are also clear about where the line must be drawn between acceptable and unacceptable behaviour.’ A just culture should encourage individuals to report incidents, but not absolve individuals of their normal responsibilities (Macrae, 2014).

A just culture is a balance between safety and accountability. On paper it is easy to define, but in reality, it can be difficult to identify ‘where is the line’ between unintentional actions and recklessness (Dekker, 2012). The line may be specific to an industry, organisation/company, or individual.

1.5 Evaluation of safety

A safe industry is one that can demonstrate it poses no or a very low risk of harm. However, evaluation of safety is notoriously challenging because it is a ‘constantly moving target’ (Vincent and Amalberti, 2016). As systems become more complex, it becomes more difficult to predict what might happen (Hollnagel, 2012; Leveson, 2011). There is no single metric that can prove an industry is safe.

Traditional approaches to safety evaluation have used reactive metrics (lagging) such as incident rates and levels of harm. These may be appropriate when all incidents are known about, but there is often under-reporting and inaccurate grading of harm (Vincent, Burnett and Carthey, 2014). A further challenge for industries such as aviation and nuclear is that, if incident rates have been reduced to low levels, they need to identify other metrics to evaluate safety.

To evaluate the safety of an organisation or industry, evidence needs to be triangulated to provide assurance of safety. Vincent et al. (2014) developed a framework for safety measurement and monitoring aimed at healthcare organisations. The framework measures safety through

the dimensions of past harms, reliability, sensitivity to operations, anticipation and preparedness, and learning.

1.5.1 Measuring safety culture

Evaluation of safety cultures is important to help understand the safety of an industry/organisation/company (Vincent et al., 2014). Various tools are available to evaluate cultures, often through the perspectives of staff. Hudson (2007) describes a five-level model for safety culture which is now widely used (e.g. National Patient Safety Agency, 2006). A culture can be (Hudson, 2007) pathological (least trust, least informed), reactive, calculative/bureaucratic, proactive, or generative (most trust, most informed).

Hudson's (2007) five-level model also describes how cultures evolve and degrade because of factors such as leadership. It is assumed that an improving culture means a safer industry (e.g. Dekker, 2019; Guldenmund, 2000).

1.6 Summary

To be safe is to be free from risk of current and future harm, and safety science describes how systems can positively or negatively contribute to safety. The complexity and contribution of systems to safety varies depending on the industry and the next chapter will contextualise safety to different industries.

2 An Introduction to Industrial Safety

2.1 Introduction

This thesis aims to better understand the role of ‘near misses’ in patient safety improvement in healthcare, through learning from non-healthcare industries. This chapter describes how industrial safety is classified and introduces safety in the healthcare, aviation, and nuclear industries for context.

2.2 Classification of industrial safety

The literature refers to the safety of industries in relation to the characteristics of reliability, adaptability, and criticality. Vincent and Amalberti (2016) describe three contrasting approaches to industrial safety in that industries can be:

- **Ultra-adaptive** – industries embrace risk and rely on personal resilience, expertise, and technology; e.g. deep-sea fishing.
- **High-reliability** – risk is inherent, and industries rely on procedures, training for routine, hazard management, and being able to adapt; e.g. chemical processing and firefighting.
- **Ultra-safe** – industries avoid and prevent risk with significant use of supervision and regulation; e.g. civil aviation and nuclear power.

2.2.1 High reliability

High-Reliability Organisations (HROs) were introduced in 1.3.2. The HRO paradigm developed from studies of aircraft carriers, air traffic control (commercial aviation), and nuclear power; these were the first defined and now reference HROs (Roberts, 1990; Rochlin et al., 1987; Weick, 1987). HROs are a ‘subset of hazardous organisations that have enjoyed a high-record of safety over long periods...’ (Roberts, 1990). They operate in unforgiving environments, their technologies are risky, and they have complex processes (Roberts, 1990).

HROs have two complementary approaches to achieve reliable performance (Schulman, 2004) – they anticipate and identify events to avoid (prevention), and manage fluctuations in performance (resilience). They also exhibit certain characteristics such as preoccupation with failure, rich reporting of actual and near failures (misses), and a deference to expertise (Weick et al., 1999).

2.2.2 Safety criticality

Criticality refers to where safety is of primary importance to an industry because of the potential safety risks. Industries termed ‘Safety-Critical Industries’ (SCIs) have complex sociotechnical systems⁴ within which people undertake multiple roles, and where there is a risk of significant harm from failure (Wears, 2012). Many industries may be considered SCIs, including healthcare.

2.3 Industries in this thesis

This thesis will seek learning from non-healthcare industries to translate to healthcare. Appropriate non-healthcare industries to learn from are likely those that have achieved good safety records despite operating in complex and hazardous contexts. The characteristics in 2.2 can help with the selection of industries but are limited by inconsistencies in how different authors classify industries. For example, Vincent and Amalberti (2016) classify commercial aviation as ultra-safe and not high-reliability, while others classify it as high-reliability (Christianson, Sutcliffe, Miller et al., 2011).

To select appropriate industries, a pragmatic approach is required. Safer industries will exhibit a combination of the characteristics in 2.2, and will be safety critical, adaptive, and reliable. Examples often referred to as the ‘safest’ industries and used as exemplars for healthcare include (The Health Foundation, 2011):

⁴ Sociotechnical systems – systems that involve complex interactions between people, equipment, and the environment (Emery, Trist, Churchman et al., 1960).

- **Transport** – aviation, air traffic control, maritime, and rail.
- **Energy/processing** – nuclear, coal, oil and gas, and chemical.
- **Emergency responders** – disaster response and firefighting.
- **Other** – military and human space flight.

For consistency, this thesis will refer to the above non-healthcare industries as SCIs. Healthcare may also be considered a SCI (Wears, 2012), but to ensure clarity for readers, healthcare will not be referred to as a SCI in this thesis.

2.4 Safety in non-healthcare industries

This thesis will consider safety in multiple SCIs. To introduce each SCI is not possible and so a brief introduction is provided here for two SCIs. Aviation and nuclear have been selected as examples of ultra-safe industries (Vincent and Amalberti, 2016)

2.4.1 Commercial aviation and air traffic control

Aviation in the United Kingdom (UK) includes commercial, air traffic control, aerial work (such as photography), general (private and recreational), military, and unmanned (drones). Scheduled passenger aviation and air traffic control are SCIs (Wears, 2012), ultra-safe (Vincent and Amalberti, 2016), and high-reliability (Christianson et al., 2011; O'Neil, 2011).

The Civil Aviation Authority (CAA) is responsible for the regulation of aviation safety in the UK. They determine policy and are informed by the International Civil Aviation Organisation (ICAO). ICAO collaborates with member states to reach consensus on International Standards and Recommended Practices (SARPs). Annex 13 of the SARPs covers incident investigation and reporting (International Civil Aviation Organisation, 2016). It also defines safety terms such as aviation 'accidents' and 'serious incidents.'

2.4.1.1 Occurrence reporting and investigation

Occurrence reporting⁵ in the UK, and Europe, is (at the time of writing) governed by European Regulation (Regulation (EU) 376/2014). The regulation describes occurrences that must be reported which include ‘collisions,’ ‘near collisions,’ and ‘potential for collisions.’ The regulation also mandates establishment of voluntary reporting systems; in the UK, the Confidential Human Factors Incident Reporting Programme (CHIRP) provides this function.

The UK has an independent body for the investigation of aviation accidents and serious incidents, the Air Accidents Investigation Branch (AAIB). Similar bodies exist in other countries, and in rail and maritime. AAIB aims to improve aviation safety through investigation of accidents and serious incidents (The Civil Aviation Regulations, 2018).

2.4.1.2 Aviation safety culture

The safety culture in aviation is referred to as an exemplar because it supports reporting and learning without blame (Hudson, 2003). Aviation has a commitment to safety culture (The Civil Aviation Regulations, 2018), and the CAA inspects safety cultures.

Across aviation there are publications describing how best to develop just cultures. For example, Baines-Simmons, an aviation safety consultancy, provides a culture development process (Creber, Drew and Simmons, 2019) and toolkit (Baines Simmons, 2022).

2.4.2 UK nuclear operations

The UK has several licensed nuclear sites, including operational power stations, decommissioned power stations, reprocessing, and defence (submarines and weapons). The Office of Nuclear Regulation (ONR) is responsible for regulation of the UK’s nuclear safety and security. A site cannot have a nuclear plant unless granted a licence by ONR (Office of

⁵ Occurrence reporting – the reporting of ‘any occurrence that you feel could have an impact on aviation safety’ (Civil Aviation Authority, 2016). The CAA defines mandatory and voluntary occurrence reporting requirements for the UK.

Nuclear Regulation, 2017). Nuclear is considered an ultra-safe industry (Vincent and Amalberti, 2016).

The UK is a member state of the International Atomic Energy Agency (IAEA). The IAEA provides definitions for safety events which include 'criticality accidents,' 'nuclear accidents,' and 'incidents' (International Atomic Energy Agency, 2019). The severity of nuclear events are graded against the International Nuclear and Radiological Event Scale (INES) (International Atomic Energy Agency, 2013). INES helps communicate events to the public on a scale of 0 (no safety significance) to 7 (major accident). The meltdowns at Chernobyl and Fukushima power plants were INES 7.

2.4.2.1 Event reporting and investigation

Learning to improve safety in the nuclear industry is supported by 'operating experience.' This is the collection of information in a systematic way to improve safety and reliability (International Atomic Energy Agency, 2010). ONR dictates that sites must collect information on incidents and events through their operating experience processes (Office of Nuclear Regulation, 2017).

Investigation of events is expected by ONR (Office of Nuclear Regulation, 2017). The UK Operating Experience and Learning Group (OELG) (Nuclear Institute, 2015) describes that all events and near misses should receive some form of investigation appropriate to their actual or potential significance.

2.4.2.2 Nuclear safety culture

Safety culture is seen as a key factor in determining nuclear safety performance and is described as 'the unwritten rules that dictate behaviours' (Office of Nuclear Regulation, 2019). The IAEA requires regulators to consider safety culture when inspecting sites (International Atomic Energy Agency, 2016) and the ONR describes characteristics of a positive culture (Office of Nuclear Regulation, 2019).

2.4.2.3 Defence in depth

Nuclear safety is orientated around the concept of 'defence in depth.' This 'comprises a series of independent physical and/or non-physical barriers (inherent features, equipment, and procedures) aimed at preventing faults in the first instance and ensuring appropriate protection or mitigation of accidents if prevention fails' (Office of Nuclear Regulation, 2021). It includes layers of controls to prevent events and aims to keep incidents As Low As Reasonably Practicable (ALARP).

2.5 Patient safety in healthcare

Free at the point of care healthcare in the UK is delivered by the National Health Service (NHS) and is regulated by the Care Quality Commission (CQC). The World Health Organization (WHO) defines patient safety as the '...absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care...' (World Health Organization, 2019).

Patient safety has its own vocabulary, and the WHO (2010) has developed a framework to harmonise concepts. The framework includes definitions for terms such as 'patient safety incident' which is '...an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.' The term 'accident' is not used in the framework due to variation in its definition. In this thesis, the term Patient Safety Incident (PSI) will be used for healthcare.

2.5.1 Levels of patient harm

Levels of safety in healthcare vary. Vincent and Amalberti (2016) refer to parts of healthcare being ultra-adaptive (roadside trauma management), high-reliability (elective, routine surgery), and ultra-safe (blood transfusion). In 1999 the Institute of Medicine (IOM) published a report describing estimates that between 44,000 and 98,000 hospitalised patients die annually in the United States of America due to medical error (Kohn, Corrigan and Donaldson et al., 2000). In 2002 the

UK [former] Department of Health published its own report describing that 10% of inpatient episodes lead to a harmful ‘adverse event,’ around half of which are preventable (Vincent, Neale and Woloshynowych, 2001). The 10% adverse-event rate has persisted in subsequent years (de Vries, Ramrattan, Smorenburg et al., 2008). In response to the levels of harm, various reports have called for a fundamental rethink about the way the NHS learns from PSIs (e.g. Department of Health, 2002).

In England, PSI data is available through NHS England’s ‘Learning From Patient Safety Events’ (LFPSE) system (NHS England, 2021a), previously called the National Reporting and Learning System (NRLS) (National Patient Safety Agency, n.d.). Data since 2003 shows an upward trend in reported PSIs with the majority being no/low harm. PSIs are more commonly reported from acute/general hospitals, mental health, and community-based services (NHS England, 2021b). General practice and some community settings are underrepresented in LFPSE and there are concerns about the reporting of PSIs in general practice (NHS England, 2021c).

2.5.2 Incident reporting

The reporting of PSIs commonly relies on staff entering details into systems, often electronic. Incident Reporting Systems (IRSs) have long been established in healthcare organisations, taking inspiration from aviation and nuclear (Vincent, 2010). IRSs may be available at local (within an organisation) and national (across a country, such as the aforementioned LFPSE) levels (Cheng, Sun, Zhang et al., 2011).

PSI reports are a main source of intelligence for improving patient safety (Vincent, 2004). However, there is under-reporting of PSIs with some estimates suggesting that only 5% are actually reported (Sari et al., 2007). In response, attempts have been made to improve reporting and the literature is saturated with research and commentary exploring barriers to reporting (Table 1). For example, Archer, Hull, Soukup et al. (2017) identified 748 barriers to and 372 facilitators for PSI reporting

with their top two barriers being fear of the consequences and inadequate processes/systems.

Table 1. Examples of barriers to incident reporting

Barrier		Source (e.g.)
Events	Are not clearly defined	Tamuz et al., 2004
	Are not perceived to be important	Mitchell et al., 2016
Processes/ systems	Do not support reporting	Asghari et al., 2010
	Do not provide feedback	Macht et al., 2015
Context	Workload prevents reporting	Boyle et al., 2011
Organisation	Professional cultures affect reporting	Mitchell et al., 2016
	Staff fear blame	Vincent et al., 1998
	Unclear roles and responsibilities	Evans et al., 2012

The literature refers to facilitating and incentivising reporting of PSIs. Pfeiffer, Manser and Wehner (2010) found various factors that need to be considered when attempting to improve the willingness of staff to report. These include role identity, psychological safety, the subjective norm, characteristics of PSIs, and perceptions of reporting systems.

Incentives to report include recognition, financial, and anonymity (Milch, Salem, Pauker et al., 2006; Shaw, Drever, Hughes et al., 2005; Scott, Weimer, English et al., 2011). A well-designed, functional, and usable IRS is also known to support reporting. Boyle, Mahaffey, Mackinnon et al. (2011) describe several desirable features of an IRS including a modern interface, periodic updates, optional anonymity, easy speedy completion, and integration into normal work.

2.5.3 Incident investigation

The reporting of PSIs does not offer much unless reports are analysed by someone with expertise (Vincent, 2004). For over 20 years PSI

investigations have followed a Root Cause Analysis (RCA) approach, having adopted the practice from SCIs (Peerally, Carr, Waring et al., 2017). RCA explores the how and why of a PSI (Taylor-Adams and Vincent, 2004), but is often criticised for failing to produce learning (Peerally et al., 2017).

The Swiss Cheese Model (1.3.3) is the most well-known model of incident causation in healthcare (Taylor-Adams and Vincent, 2004) and commonly underpins approaches to investigation. In recent years, the SCM has become less popular following greater awareness of human factors and the need to account for the complexity of systems. For example, the Healthcare Safety Investigation Branch (HSIB), the independent investigator of PSIs in the NHS, now uses a variety of system-based approaches including the 'Systems Engineering Initiative for Patient Safety' (SEIPS) (Healthcare Safety Investigation Branch, 2021; Holden and Carayon, 2021).

2.5.4 Safety culture in healthcare

The safety culture in the NHS is often under scrutiny, particularly since the events at Mid-Staffordshire NHS Foundation Trust (Francis, 2013). The then Secretary of State for Health described widespread concerns about safety cultures in the NHS (Hunt, 2015). Plans were developed to improve safety cultures with increased transparency, inspections, and support for staff to speak up.

In 2019 NHS England published their NHS Patient Safety Strategy which focuses, in part, on safer cultures. The strategy describes that 'just culture' in the NHS is often 'thwarted by fear and blame' (NHS England, 2021c). In support, NHS England (2018; 2023a) has published guides which aim to support conversations and actions for the improvement of safety cultures.

2.6 A need to improve patient safety

There are repeatedly stated concerns about the quality and safety of healthcare services. During the time taken to produce this thesis, several national inquiries have focussed on safety in the NHS (e.g. Kirkup, Ridley and Sutton, 2022). PSIs continue to occur in the NHS and, while many are no/low harm, they highlight system vulnerabilities that can result in significant harm to patients (e.g. Healthcare Safety Investigation Branch, 2021).

The challenge of ensuring patients are safe is an international issue. The WHO has developed a global action plan to eliminate avoidable harm in healthcare (World Health Organization, 2021), and NHS England's Patient Safety Strategy sets out the need for the NHS to improve patient safety (NHS England, 2021c). To bring about improvements both the NHS and WHO strategies refer to the need for healthcare to learn from others and think innovatively.

Exhortations for healthcare to learn from other industries is nothing new. The IOM and Department of Health reports in 2.5.1 both refer to aviation successes in safety that could be translated to healthcare. Various academics have made similar exhortations (e.g. Denham, Sullenberger, Quaid et al, 2012), and 'deference to expertise' is a recognised characteristic of an HRO (Weick et al., 1999).

Thinking innovatively includes considering how safety management in SCIs can be translated to healthcare to support improvements in patient safety. Healthcare's reactive approach to learning from harm has not seen the improvements in safety hoped for (Peerally et al., 2017). There may therefore be benefit in looking at patient safety from different perspectives. HROs seek to learn from 'actual and near failures [misses]' (Weick et al., 1999), but it is suggested that healthcare has yet to harness the benefits of learning from near misses (Feng, Zhang, Tan, et al., 2022a).

2.7 Summary

Learning from ultra-safe and high-reliability industries around how they manage safety may support patient safety improvements in healthcare. SCIs are known to learn from near misses in their pursuits of safety improvement, but healthcare may have not yet harnessed the value of these events. The next chapter will introduce near misses.

3 Introducing the Near Miss

3.1 Introduction

This thesis aims to support improvements in patient safety in healthcare through learning from near misses. This chapter introduces near misses and the underlying safety theory that exemplifies their potential value in improving safety.

3.2 The ‘near miss’

A near miss is something that nearly happened. While the term does not make literal sense, it is used in everyday language. Table 2 provides examples of situations described as near misses.

Table 2. Example near misses from a range of industries

Industry	Example near miss	Source
Aviation	A pilot reported descending when they saw a drone at a similar altitude. The drone was within 50 metres of the aircraft.	UK Airprox Board, 2022
Disaster	The hotel was under a tornado warning. No tornadoes were reported near the hotel, but a tornado did strike two miles away and destroyed houses.	Dillon et al., 2014
Healthcare	A child required ventilation. Prior to anaesthesia I picked up a syringe of clear fluid, connected it to the cannula when a colleague noticed I had picked up the wrong syringe.	Thesis author
Maritime	An officer took urgent action to avoid a submarine. The submarine had underestimated the ferry’s speed and overestimated its range.	Marine Accident Investigation Branch, 2020

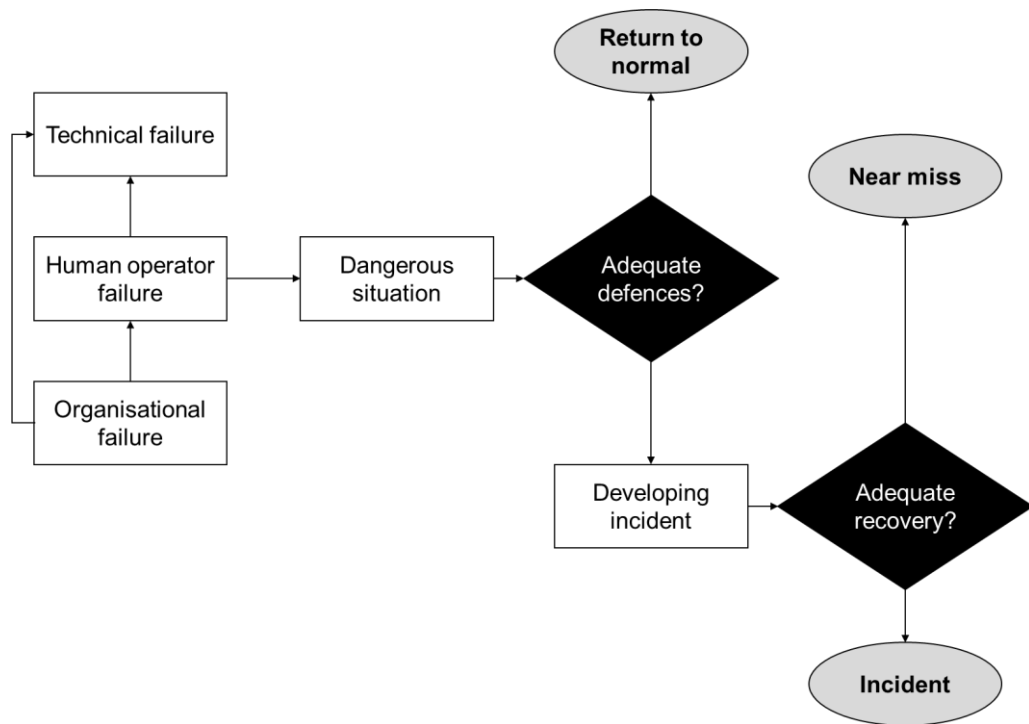
Rail	A jogger was five seconds from being hit by a train at a level crossing. The jogger was wearing headphones and did not hear the train.	Network Rail, 2021
Space	Seven space shuttles returned to earth with damage to their heat tiles from foam debris. Each time no bad outcome occurred.	NASA, 2009

3.3 Safety science and near misses

In 1989 a three-day meeting in Eindhoven (Netherlands) brought together knowledge from process and transportation industries to discuss the management of near misses. The meeting led to the publication 'Near miss reporting as a safety tool' (van der Schaaf, Lucas and Hale, 1991) which describes a framework for near-miss management and has informed much of the thinking around near misses in subsequent years.

van der Schaaf, an attendee at the meeting in Eindhoven, wrote his thesis on near-miss reporting in the chemical industry and developed a simple model of near-miss causation, nicknamed the 'Eindhoven Model' (Figure 3) (van der Schaaf, 1992). The Model demonstrates how defences in systems may not always be adequate and that sometimes the difference between a near miss and an incident is a human recovery.

Figure 3. The ‘Eindhoven Model’ of near misses adapted from van der Schaaf (1992)

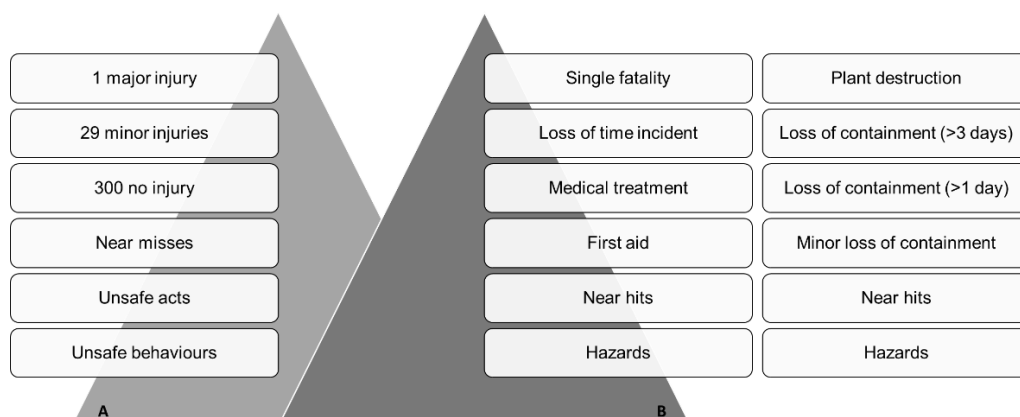


3.3.1 Relationship between near misses and incidents

The literature around near misses references triangles, pyramids, and icebergs. These models stem from the same theoretical origin and infer that incidents and harms are visible, but near misses, unsafe actions, and unsafe behaviours are plentiful and often unseen.

A regularly cited model is the ‘accident [safety] pyramid’ which originated from a study of workplace injuries at an insurance company (Heinrich, 1931). That original pyramid describes a ratio of 300 no-harm injuries, to 29 minor injuries, to 1 major-injury incident (Heinrich, 1931). This became known as ‘Heinrich’s Ratio’ and was expanded by others, such as Bird and Loftus (1976), to create various pyramids with the additions of near misses/hits and unsafe acts/behaviours across different industries (Figure 4).

Figure 4. A) Original accident [safety] pyramid adapted from Heinrich (1931), and B) example from the Energy Institute (2022)



3.3.1.1 Common cause hypothesis

Heinrich (1931) describes the moral of his pyramid (Figure 4) as ‘prevent the incidents and the injuries will take care of themselves.’ He further hypothesises about a ‘common cause’ between major injuries and minor injuries or near misses (Heinrich, 1980). This ‘common cause hypothesis’ is repeatedly stated in academic and policy literature in healthcare (e.g. Aspden, Corrigan and Wolcott, 2004; Feng et al., 2022a) and SCIs (e.g. Georgoulis and Nikitakos 2019; Bhattacharya, 2020), with statements that if one addresses the causes of a near miss, then major incidents will be prevented. However, not all are convinced that Heinrich’s Ratio or the common cause hypothesis are valid across different industries and contexts (Manuele, 2003; 2011).

3.4 The impact of near misses

The literature describes several ways in which near misses can influence quality, safety, and behaviours. As near misses generally do not result in harm they are described as ‘free lessons’ (Barach and Small, 2000a) and can be used to gain qualitative insights into how ‘failures or errors’ develop, and quantitative insights into factors that lead to incidents (van der Schaaf et al., 1991). The literature also describes how learning from near misses can improve safety cultures

(e.g. Greenham, Manley, Turnbull et al., 2018) and processes (e.g. Loh, Korne, Chee et al., 2017).

However, a near miss may not always have a positive effect. The psychology literature describes how near misses can negatively influence behaviours. Dillon and Tinsley (2008) describe a 'near-miss bias' and found that people who have survived a hurricane may be less willing to evacuate in the future. They have related the bias to disasters such as with the space shuttles Challenger and Columbia (see example in Table 2), where prior near misses were seen as successes and resulted in risky decisions (Tinsley and Dillon-Merrill, 2005). The 'near-miss effect' is also seen in gambling where a near-miss win increases the desire to play (Clark, Lawrence and Astley-Jones et al., 2009).

3.5 Healthcare near misses

A search of the healthcare academic literature for near misses (April 2022 MedlineOVID® using MeSH 'near miss, healthcare,' 286 hits) demonstrates that three types of near misses are referred to – maternal and neonatal (n=173), patient safety (n=111), and health and safety (n=2).

Maternal near misses are events where a pregnant person has come close to death but has survived. The World Health Organization (WHO) provides a standardised approach to the evaluation of maternal near misses (World Health Organization, 2011). Neonatal near misses are similar (Santos, Pileggi-Castro, Camelo et al., 2015).

Health and safety near misses are defined by the UK Health and Safety Executive as events '...not causing harm, but [having] the potential to cause injury or ill health...' (Health and Safety Executive, 2021). They relate to the health of workers/staff (e.g. Macaluso et al., 2018).

3.5.1 Patient safety near misses

This thesis is concerned with Patient Safety Near Misses (PSNMs). 'Near miss' is the common term used in healthcare (Castro, 2014), but

these events may also be termed 'close calls' (Coyle, 2005) or 'good catches' (Lozito, Whiteman, Swanson-Biearman et al., 2018).

To define a PSNM is challenging because there is a 'multiplicity' of terms and definitions. Yu, Nation and Dooley (2005) identified 12 different definitions for a PSNM with different functional meanings depending on whether events reach patients. Two PSNM definitions provided by national/international bodies are:

- '...an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as the result of compensating action, thus preventing injury to a patient' (Department of Health, 2002).
- '...incident[s] which did not reach the patient' (World Health Organization, 2010).

3.5.1.1 Reporting of patient safety near misses

National documents from regulatory and policy bodies describe the need to report and learn from PSNMs (e.g. Care Quality Commission, 2016). In response, healthcare organisations include PSNMs in their incident reporting policies.

Despite policies stating the need to report PSNMs, there is evidence of under-reporting (Feng et al., 2022a). This has been found by several studies with differences between the number of PSNMs observed in clinical practice and the number reported in incident reporting systems (Hamilton, Pham, Minzenmayer et al., 2018; Yan, Wang and Al-Hakim, 2021). It may be the intention of staff to report, but they do not (Noureldin and Noureldin, 2021; Toren, Dokhi and Dekeyser, 2021; Yan et al., 2021).

Various barriers have been described that limit the reporting of Patient Safety Incidents (PSIs) (2.5.2). There are additional barriers specific to PSNMs that further disincentivise their reporting. These include: confusion because of variation in terminology and definitions (Kundu, Jung, Valle et al., 2021; Yan et al., 2021); perceived limited value of their reporting (Evans et al., 2012), particularly because there is no

harm (Kang, Park, Oh et al., 2017); and because they are forgotten following correction (Colldén Benneck and Bremer, 2019), termed 'fixing and forgetting' (Hewitt and Chreim, 2015).

Incentives and motivators for the reporting of PSNMs have also been identified. These include anonymity, positive teamworking, managers promoting safety, and where the risk of harm is higher (Crane, Sloane, Elder et al., 2015; Noureldin and Noureldin, 2021; Toren et al., 2021). Reporting is also facilitated by supportive safety cultures (Toren et al., 2021) and feedback to reporters (Sudan et al., 2019).

Much like with PSIs, professional backgrounds influence reporting of PSNMs. Non-medical staff are more likely to report PSNMs (Baig, Wang, Elnahal et al., 2018; Barnard, Dumkee, Baines et al., 2006; Traynor, 2015). For pharmacists this may be because it is seen as part of their routine work (Traynor, 2015) and clear procedures exist for them (Patterson and Pace, 2016).

3.5.1.2 Rates of patient safety near misses

The thesis author was unable to find public data quantifying the number of PSNMs reported in the English National Health Service (NHS). This data is not available at an accessible, national level. While PSNMs are reported into the NHS Learning From Patient Safety Events system for England, it does not quantify PSNMs and no-harm PSIs separately.

PSNM rates are sometimes referred to in the academic and policy literature. It is common to see statements such as PSNMs 'occur 7 to 100 times more frequently' than PSIs (e.g. Aspden et al., 2004). The Serious Hazards of Transfusion (SHOT) (2020) include near-miss rates in their annual reports and define a near miss as '...any error which if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before the transfusion took place.' In 2020, PSNMs accounted for the largest proportion of reports to SHOT (35.2%).

The academic literature provides some data on PSNM rates in different settings. These include medication (Emerson, Shabo and Jones, 2019),

radiotherapy (Baig et al., 2018), intensive care (Lipshutz, Caldwell, Robinowitz et al., 2015), transfusion (Serious Hazards of Transfusion, 2020), primary care (Crane et al., 2015), and ambulatory settings (Pfoh, Engineer, Singh et al., 2021). In medication administration, for example, Speroni, Fisher, Dennis et al. (2013) found frequent near misses resulting from personal (e.g. not following policy) and institutional (e.g. distractions) factors.

3.5.2 Learning from patient safety near misses

PSNMs may be valuable sources of learning to support improvements in patient safety because they are high frequency, of low emotional impact, have low associated liability, and focus on controls (Barach and Small, 2000a, 2000b; Clinton and Getachew, 2003; Kaplan and Fastman, 2003).

In response to their potential value, the academic literature provides examples of where learning from PSNMs has been used to change processes, tasks, environments, and equipment. Crane et al. (2015), for example, initiated 32 quality improvement projects following reported PSNMs.

Learning from PSNMs may also offer other indirect safety benefits. The literature describes their use in education, such as in medication administration (Teal, Emory and Patto, 2019), and their influence on safety culture (Kusano, Nyflot, Zeng et al., 2015).

3.5.2.1 Calls for healthcare to better learn from near misses

As discussed in 2.6, healthcare's reactive approach to learning from harm has not seen the improvements in patient safety hoped for (Peerally et al., 2017). There may be benefit in shifting the healthcare safety-lens away from reacting to harm, to a focus on preparedness and resilience; this is common in SCIs (Woods et al., 2017). Learning from near misses is one part of this shift by looking at how they can help develop reliable systems (Weick et al., 1999). Some authors believe

learning from near misses is more important than from incidents (Battles and Shea, 2001; Shojania, Wald and Gross, 2002).

The need for healthcare to learn from PSNMs has long been stated (Leape, 1994; Leape, Berwick and Bates, 2002). In England, the [former] Department of Health (2002) described that 'No account is taken of near misses.' However, despite these calls, 20 years later there is little evidence that healthcare is effectively learning from PSNMs. Feng et al. (2022a) published a scoping review of PSNM research and, from a review of 67 articles, concluded that while there has been a focus on reporting, there remains significant gaps in PSNM management.

To support improvements in PSNM management there may be benefits from considering how SCIs have developed effective management systems for reporting and learning from near misses. Barach and Small (2000b) describe how complex non-medical industries have 'evolved incident reporting systems that focus on near misses...' and that '...focussing on data for near misses may add noticeably more value to quality improvement than a sole focus on adverse events.'

3.6 Summary

Near misses are common and have the potential to offer learning that can help improve safety. Despite calls for over 20 years for healthcare to learn from PSNMs, little progress has been made. There are opportunities for healthcare to learn from how SCIs have successfully implemented management and learning processes for near misses. The next chapter will describe the thesis and the aims and objectives of this research.

4 Thesis, Research Aims, and Questions

4.1 Introduction

This chapter outlines the thesis and associated research aims and questions. It also provides a rationale for the focus of this research, the proposed methodology to answer the research questions, and states working definitions.

4.2 Thesis

Healthcare has yet to implement effective management systems to learn from Patient Safety Near Misses (PSNMs) to improve patient safety. Safety-Critical Industries (SCIs), that effectively learn from near misses to improve safety, can offer guidance to healthcare about how best to implement systems to learn from PSNMs.

4.2.1 Research aims and questions

The aims of this research are to 1) explore what learning from PSNMs can offer healthcare to improve patient safety, and 2) identify what guidance SCIs, which have successfully implemented effective near-miss management systems, can offer healthcare.

This research will ask (see 4.3 for definitions of relevant terms):

1. how are PSNMs managed and learned from in healthcare, and what impact has that learning had on patient safety?
2. how are near misses managed and learned from in SCIs, and what impact has that learning had on safety?
3. how can findings from healthcare and SCIs contribute to implementation of PSNM management systems to improve patient safety?

4.2.2 Thesis scope

This thesis is concerned with PSNMs (3.5.1). This research will be undertaken in England through engagement with National Health Service (NHS) organisations and UK-based SCI companies/bodies.

The NHS is an appropriate focus as it is the primary healthcare provider in England with which the thesis author and their academic institution are linked. The English NHS has around 2 million Patient Safety Incidents (PSIs) reported per year to the national reporting system (NHS England, 2018b) which include PSNMs. UK-based SCIs have been selected based on pragmatism. Insights around near-miss management in wider healthcare and other SCIs will be gained from international academic and policy literature.

4.3 Working definitions

For clarity, this research will use the working definitions outlined in Table 3 unless otherwise stated.

Table 3. Working definitions in this research

Term	Working definition	Source
Harm	The negative effects to someone or something resulting from events.	Thesis author
Impact	'...fundamental intended or unintended change occurring... as a result of program activities.'	Kellogg, 2004
Learning	'...acquire, process, retain and recall knowledge...'	Gandhi and Mukherji, 2022
Management	Defining, identifying, reporting, analysing, and learning from near misses, and the evaluation of the impact of any actions.	Thesis author

Outcomes	'...changes in program participants' behaviour, knowledge, skills, status and level of functioning.'	Kellogg, 2004
Patient safety	'...absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care...'	World Health Organization, 2019
Patient safety incident	'...an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.'	World Health Organization, 2010
Patient safety near miss	'...an incident which did not reach the patient.'	World Health Organization, 2010
Quality	Delivery of a function that is '...effective, safe and provides as positive an experience as possible.'	National Quality Board, 2021
Safety	'...absence of preventable harm... and reduction of risk of unnecessary harm...'	World Health Organization, 2019

4.3.1 Answering the research questions

The research in this thesis will take a mixed-methods approach. The methodologies are outlined in chapter 5. The research will commence with scoping reviews of the healthcare and SCI literature (studies 1 and 3 respectively), and a qualitative case study (study 2) exploring the experiences and perceptions of those working to manage PSNMs in NHS organisations. Further research will then follow the most appropriate methodologies dependent on findings.

4.3.1.1 Further research (written retrospectively)

As the research progressed a grounded theory (study 4) methodology was included and undertaken to explore the management of near misses in SCIs. The methodology is outlined in chapter 5.

4.4 Rationale for this research

PSIs are a 'global public health challenge' (World Health Organization, 2021). In England, attempts to improve patient safety have had limited success with similar safety issues described in 2020/21 (NHS England, 2021c), as in the early 2000s (Department of Health, 2002). PSNMs offer alternative insights into why incidents occur, but to date have not been taken advantage of (Feng et al., 2022a). It is understood that SCIs have embraced learning from near misses and so have the potential to offer guidance to healthcare. That guidance has never been described. This research is therefore novel, appropriate, and justified.

4.5 Summary

This research will aim to understand how healthcare can best implement management processes to learn from PSNMs to improve patient safety. It will do this through mixed-methods research. The next chapter will describe the methodologies to be used in this research.

5 Methodologies and Methods in this Research

5.1 Introduction

This chapter introduces the methodologies and methods that will be used in this research. It is intended that the research will take a mixed-methods approach through scoping reviews, a qualitative case study, and a grounded theory.

5.2 Research approaches – an overview

5.2.1 Quantitative research

Quantitative research ‘seeks to discover new knowledge by simplifying complexities in settings that tend to be more contrived’ (O’Dwyer and Bernauer, 2014). It is deductive with evidence gathering and the use of numerical findings to support or refute a hypothesis (Salmons, 2019).

Positivism or post-positivism are the research paradigms (philosophical frameworks) traditionally underpinning quantitative research (O’Dwyer and Bernauer, 2014). The positivist epistemology⁶ considers that reality can be measured and understood objectively (Salmons, 2019). The epistemology helps define the methodologies⁷ and methods⁸ to be used. Quantitative methodologies may be experimental or non-experimental (Coolican, 2014), and methods include structured and validated data-collection instruments. Analysis of data is descriptive or inferential (Patel, 2009).

While quantitative research has been traditionally held as the ‘true’ scientific research approach, it is limited by its breadth and depth (Muijs, 2011). It may also require large sample sizes and controlled

⁶ Epistemology – ‘way of understanding... how we know what we know’ (Crotty, 1998).

⁷ Methodology – a strategy to answer research questions.

⁸ Methods – techniques for data collection and analysis.

conditions to help minimise the influence of different variables on the results.

5.2.2 Qualitative research

Qualitative research explores beliefs, values, and motives to explain behaviours (Castleberry and Nolen, 2018). It is useful for describing novel, poorly understood phenomena (Hurley, 1999) and provides rich descriptions to support hypothesis generation about phenomena (Miles, Huberman and Saldaña, 2020). It 'seeks to discover new knowledge by retaining complexities as they exist in natural setting' (O'Dwyer and Bernauer, 2014). It is commonly inductive and looks for patterns and associations (Salmons, 2019).

Constructivism is the paradigm that underpins qualitative research and claims that multiple realities exist and that they are socially constructed (Merriam and Tisdell, 2015). The constructivist epistemology considers that meaningful reality can be understood through the knowledge, experiences, and perceptions of the people who construct them (Crotty, 1998). The researcher is part of the social construct and may influence findings.

Within constructivism there are several theoretical perspectives around how reality is created. One perspective, pertinent to this research, is 'symbolic interactionism.' While difficult to define, its relevance is recognised in methodologies such as grounded theory (Chamberlain-Salaun, Mills and Usher, 2013) and relates to how humans 'interact with, interpret and understand symbols [things]' (Atkinson and Housley, 2003). This interaction influences how humans define reality, develop values and norms, and behave towards others and things (Müller, 2015).

There are several methodologies in qualitative research, each with their own approach, assumptions, sampling, and analyses (Nolen and Talbert, 2011). Common methodologies include phenomenology, grounded theory, and ethnography. The selection of a methodology requires an understanding of its purpose (Chapman, Hadfield and

Chapman, 2015) and how the data will be analysed (Thorne, 2000). Methods include interviews, focus groups, observations, and document review.

Qualitative research has faced criticism, particularly from fields where quantitative approaches are traditional. Criticisms relate to a potential lack of rigour (Rahman, 2016) because of difficulties appreciating contexts (Silverman, 2011), researcher bias (Gough, Thomas and Oliver, 2012), and complex analyses (Holloway and Galvin, 2017; Rahman, 2016). To help improve rigour, Morse, Barrett, Mayan et al. (2002) recommend participant verification (5.4.4), triangulation (5.4.2.2), and reflexivity (5.4.3.3).

5.2.3 Mixed-methods research

Mixed-methods research is an approach where ‘the investigator gathers both quantitative (close-ended) and qualitative (open-ended) data, integrates the two and then draws interpretations based on the combined strengths of both sets of data to understand the research problem’ (Cresswell, 2015). It is used for research that requires exploration, explanation, and confirmation, and brings in a divergent perspective (Tashakkori, Johnson and Teddlie, 2021).

Mixed-methods research aligns with the pragmatist paradigm (Brierley, 2017). Pragmatism considers that thoughts are linked to actions and that no two people will have identical experiences (Kaushik and Walsh, 2019). It is a ‘what works best’ approach to answer research questions (Tashakkori et al., 2021). Several types of mixed-methods design exist; quantitative and qualitative data may be collected simultaneously, or one after the other (Merriam and Tisdell, 2015).

Mixed-methods research is common (O'Dwyer and Bernauer, 2014). However, they are challenged by traditionalists who feel data types should be kept separate (Murphy, Dingwall, Greatbatch et al., 1998). Further challenges include the time and resource for data collection, difficulties integrating data, and difficulties presenting findings (Tariq and Woodman, 2013).

5.3 Mixed methods in this research

The choice of research approach is influenced by a researcher's philosophical stance (Salmons, 2019). The thesis author leans toward a constructivist epistemology, believing that to understand reality different perspectives need to be sought. Qualitative approaches align with the author's stance, but with recognition that mixed methods are appropriate in certain circumstances. The nature of this research's aims lend themselves to a mixed-methods approach, but with predominantly qualitative data.

This research will be a 'conversion' design (Tashakkori et al., 2021) commencing with qualitative data collection and then quantifying aspects of the data in a non-experimental way. The approaches and methodologies will be:

- **Qualitative** – healthcare Qualitative Case Study (QCS).
- **Qualitative** – Safety-Critical Industry (SCI) Grounded Theory (GT).
- **Quantitative** – analysis of certain aspects of the data (5.5.2).

5.3.1 Research and ethics approvals

Research and ethics approvals have been sought. For healthcare, the Health Research Authority's (HRA) Integrated Research Application System provided approval (ID 262065, protocol 19018) on 7 May 2019. An amendment was approved for additional healthcare sites on 10 December 2019.

HRA approval does not apply to non-NHS organisations. Therefore, relevant research departments of SCIs have been approached. Any company requirements for research approval have been met.

The University of Nottingham's Research Ethics Committee provided approval (264-1903) on 15 March 2019.

5.4 Methodologies in this research

5.4.1 Scoping review – an overview

A scoping review is ‘a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesising existing knowledge’ (Colquhoun, Levac, O’Brien et al., 2014). It determines the range of evidence available on a topic and describes it (Peters, Godfrey, Khalil et al., 2015), and is useful where there is a paucity of randomised control trials and research gaps need to be identified (Arksey and O’Malley, 2005; Pham, Rajić, Greig et al., 2014). A scoping review is not equivalent to a systematic review in its integrity (Daudt, van Mossel and Scott, 2013).

Historically there has been no standard approach for undertaking a scoping review which has been a criticism of the methodology (Pham et al., 2014). To address this Arksey and O’Malley (2005) developed an approach which has then undergone refinement over the years (e.g. Daudt et al., 2013; Levac, Colquhoun and O’Brien, 2010). The Joanna Briggs Institute (JBI) now describes an evidence-based approach considering the various refinements (Khalil, Peters, Godfrey et al., 2016). The scoping review protocol to be used in this research is presented in 6.2.

A scoping review can include any type of data and so the amount of evidence can be considerable (Arksey and O’Malley, 2005). This means completeness can be limited by time and resource (Grant and Booth, 2009). During a scoping review, no formal assessment of the quality of the literature is made (Moher, Stewart and Shekelle, 2015).

5.4.2 Qualitative case study – an overview

Merriam and Tisdell (2015) describe a QCS as ‘an in-depth description and analysis of a bounded system.’ QCS is widely used where the research focus is ‘how’ and ‘why,’ and where context is relevant

(Ebneyamini and Sadeghi Moghadam, 2018). Through stories and descriptions, participants provide a view of reality to build the understanding of the researcher (Lather, 1992).

There are several QCS approaches available (Harrison, Birks, Franklin et al., 2017), many of which overlap (Yazan, 2015). Ebneyamini and Sadeghi Moghadam (2019) describe an approach based on the work of Yin (2018) which makes specific reference to the importance of defining the case and propositions.

Defining the case (unit of analysis) includes identifying the case(s), the number, and their boundaries. QCS can be used with single or multiple cases (Ebneyamini and Sadeghi Moghadam, 2018), but multiple cases allow analysis across a range of settings (Baxter and Jack, 2010). The selection of the case is linked to the research question and can include individuals, small groups, organisations, or projects (Yin, 2018).

Bounding the case is done through limits, such as spatial or temporal.

5.4.2.1 Undertaking a qualitative case study

Data collection in QCS is similar to other qualitative approaches.

Purposive sampling is commonly used (5.4.2.3) (Patton, 2015) and multiple sources of evidence should be used for triangulation (5.4.2.2) (Yin, 2018).

Analysis in a QCS is often thematic. Thematic analysis is a method for 'identifying, analysing and reporting themes in data' (Braun and Clarke, 2006). It involves the researchers familiarising themselves with the data, coding the data into groups, creation of themes, and the drawing of conclusions. Yin (2018) suggested five techniques to support the analysis process including the use of logic models⁹ (5.4.2.4).

Various factors can undermine the rigour of a QCS including case selection, data volumes, case boundaries, anonymity, and confidentiality (Crowe, Cresswell, Robertson et al., 2011). Höst and Runeson (2007) have developed a checklist to support rigour in QCS

⁹ Logic models – visual ways of presenting an idea, whether that be a theory of change or a programme of work (Wyatt Knowlton and Phillips, 2012).

and various authors recommend the following (Baxter and Jack, 2010; Crowe et al., 2011, Miles and Huberman, 2009; Yin, 2018): developing a QCS protocol (7.2); stating propositions and using a conceptual framework (5.4.2.4); triangulation and the inclusion of multiple perspectives (5.4.2.2); analysis using pattern matching and explanation building; participant verification of findings (5.4.4); and transparency throughout the process, such as with journal notes (5.4.3.3).

5.4.2.2 Triangulation

Triangulation is used to establish validity in research by converging information from different sources (Carter, Bryant-Lukosius, Dicenson et al., 2014). Guion (2002) describes how triangulation can include multiple and different methods, investigators, professional participant perspectives, and sources of data.

5.4.2.3 Purposive sampling

Purposive sampling is widely used in qualitative research to identify information-rich data sources for a limited resource (Patton, 2015). Individuals or groups are identified who work in or are experienced in the area of interest. It is a form of non-probability sampling to provide a sample that can be logically assumed to represent the population (Lavrakas, 2008).

While purposive sampling is pragmatic, it has limitations. The sampling approach may not always account for variation in the population (Palinkas, Horwitz, Green et al., 2015). It also relies on an expert identifying the sample but cannot guarantee that a different expert would not have selected a different sample.

5.4.2.4 Logic models

Logic models are suggested in QCS to support the analysis process (Miles and Huberman, 2009; Yin, 2018). Logic models link underlying theoretical assumptions with processes and outcomes (Kellogg, 2004), and provide an approach to visualising how planning, implementation, and evaluation are interrelated (Hayes, Parchman and Howard, 2011).

They enable transparent and theory-based planning and evaluation (Langley, Gillespie, Lewis et al., 2021).

Logic models commonly include inputs, activities, outputs, outcomes, and impact (appendix 5A) (Kellogg, 2004). During planning for this research, no logic model for a near-miss management programme was found. However, van der Schaaf et al. (1991) have previously described a framework for a programme which has been used to develop a draft model to be used in this research (appendix 5B).

5.4.3 Grounded Theory – an overview

GT was developed as a systematic approach for collecting and analysing data to generate theory (Holloway and Galvin, 2017). It is 'emergent' (Charmaz, 2008) which makes it different to other qualitative methodologies (Corbin and Strauss, 1990). GT is appealing because it is inductive, doable, credible, rigorous, and lends itself to understanding processes from participant perspectives (Foley and Timonen, 2014).

The two leading approaches to GT are referred to as 'Glaserian' (Glaser, 1992) and 'Straussian' (Corbin and Strauss, 1990). The Glaserian approach is objectivist and positivist (5.2.1), believing that the research questions and later theory are grounded in the data, and that there should be no literature review prior to generating theory (Charmaz, 2008). The Straussian approach is more pragmatic, aligning with constructivism and symbolic interactionism (5.2.2), and acknowledges the role of literature to derive research questions and the role of the investigator in the research (Corbin and Strauss, 1990). Whichever approach is chosen, the core steps of a GT are similar with an example shown in appendix 5C from Chun Tie, Birks and Francis (2019).

Data in GT includes everything and anything, and is commonly elicited through interviews, focus groups, observations, field notes, memos, and documents (Holloway and Galvin, 2017; Merriam and Tisdell, 2015). Interviews guides are useful to help build consistency in data collection (Foley and Timonen, 2014).

The rigour with which GT is undertaken and the credibility of the theory generated can be affected by several factors, including a researcher's own prior knowledge that may lead to premature reasoning (Olsen and Rizk, n.d.). To support credibility and rigour, authors suggest (Corbin and Strauss, 1990; Glaser, 1978; Glaser and Strauss, 2017; Sikolia, Biros, Mason et al. 2013; Merriam and Tisdell, 2015; Willig, 2013): theoretical sampling and reaching theoretical saturation (5.4.3.2); the use of constant-comparative analysis and coding families or paradigms (5.4.3.1); triangulation (5.4.2.2); a clear protocol and audit trail (9.2); and the avoidance of preconceived ideas and acknowledgement of assumptions (5.4.3.3).

5.4.3.1 Data analysis in Grounded Theory

In the Straussian approach to GT, analysis occurs in three coding stages (Chun Tie et al., 2019) – open (descriptive categorisation into concepts), axial (exploring relationships between concepts), and selective/advanced (further categorisation and integration to create a theory). In support of analysis, sensitising questions (e.g. what, who, how, when, why, whereby, and for what?) (Vollstedt and Rezat, 2019), coding families (Glaser, 1978), and paradigms (Corbin and Strauss, 1990) help sensitise a researcher to theories and reduce the risk of bias (Vollstedt and Rezat, 2019).

'Constant comparison' should be used during analysis (Chamberlain-Salaun et al., 2013). This builds increasingly more abstract concepts and theories through an inductive process (Charmaz, 2012). It involves comparing data, integrating categories, delimiting the theory, and writing the theory (Glaser, 1965).

5.4.3.2 Theoretical sampling and saturation

Theoretical sampling is one way to improve validity in GT (Morse et al., 2002). This type of sampling involves interviewees identifying the next person, document, or case for the researcher to move on to. It is an evolving process that helps identify theoretically relevant aspects of a phenomena (Foley and Timonen, 2014).

Saturation can be data/theme (sampling until findings are repeated) or theoretical (sampling to develop theoretical categories and until no new concepts emerge) (Saunders, Sim, Kingstone et al., 2018). GT seeks to achieve theoretical saturation which is a point where theories can be identified from the data (Butler, Copnell and Hall, 2018). Determining sample size for theoretical saturation is difficult as it is determined by the emerging concepts, rather than being predetermined (Seidman, 2006). Some authors have tried to quantify sample sizes for GT, for example, Francis, Johnston, Robertson et al. (2010) suggest a minimum of 10 interviews, and then a further three when there are no new themes.

5.4.3.3 Reflexivity and memos

Reflexivity refers to making explicit the influence a researcher has on their own research by recognising and engaging in self-aware analysis of their role (Finlay, 2002). The Straussian approach to GT acknowledges that the researcher has a role in the research (Corbin and Strauss, 1990).

Researchers should engage in reflexivity (Finlay, 2002). Field notes, memos, diagrams, and reflections are encouraged, which should include acknowledging assumptions (Corbin and Strauss, 1990). A theoretical memo is a record of the researcher's ideas as research progresses, representing their thinking and links between codes in theory generation (Montgomery and Bailey, 2007).

5.4.4 Participant and expert verification

Participant verification supports rigour in qualitative research. Review of findings by research participants allows checking and confirming of results, addition of further information, and helps minimise researcher bias (Birt, Scott, Cavers et al., 2016).

5.4.4.1 Verification in this research

In this research, participant verification will occur following collation of findings from the QCS and GT. Further verification will occur following preliminary answering of the research questions with experts in safety.

The same approach to verification will be used for participants and experts. Using the structure suggested by Birt et al. (2016), participants/experts will be sent summarised findings. For the participants, a survey will ask: 'does this match your experience;' 'do you want to change anything;' and 'do you want to add anything?' For the experts, semi-structured interviews will explore the findings, with interviews audio recorded and transcribed. All responses/interviews will be thematically analysed.

5.5 Methods in this research

5.5.1 Interviews

Interviews allow a researcher to gain insights into a problem by asking questions of people who experience that problem, particularly when the problem cannot be observed. Interviews range from unstructured to fully structured and can be undertaken individually or in small groups. Semi-structured interviews allow some focus on a topic, but also free discussion (Merriam and Tisdell, 2015).

Interviews can be affected by intersubjectivity (Wengraf, 2011) and feelings of participant vulnerability (Roulston, 2010). Interviews may also not allow understanding of social contexts and may only focus on thoughts and perceptions (Kvale and Brinkmann, 2009).

5.5.1.1 Developing the interview guide

Semi-structured interviews will be used in this research for the QCS and GT. Semi-structured interviews will balance the need to obtain answers to the research questions, openness of discussion, and the limited time with participants. Semi-structured interviews require a guide for

consistency (Dikko, 2016; Yeong, Ismail, Ismail et al., 2018) which is provided in appendix 5D.

The limitations in 5.5.1 were considered when developing the interview guide. Questions have been developed in line with the aim and objectives of this research (Dikko, 2016), and align with the draft logic model (appendix 5B) to ensure all aspects of a near-miss programme will be explored. Questions also align with principles of good question design in that they are open, avoid leading, and are structured to support the comfort of participants (Merriam and Tisdell, 2015).

The interview questions have been refined through review and update. Nine professionals with experience of safety management in healthcare and SCIs reviewed the questions and provided feedback on whether they meet the research aims and objectives, are written appropriately, minimise bias, and are clear. Questions have been piloted with a head of patient safety and a lead for aviation safety. During future interviews, the interviewer (thesis author) will be conscious of the need to explore thoughts behind what participants say to ensure facts are not taken at face value.

5.5.2 Definition and culture questions

The background literature review for this research demonstrates that near-miss definitions (3.5.1) and the maturity of safety cultures (2.5.4) are important aspects to explore. Appropriate questions have therefore been developed.

5.5.2.1 Definition question

To help understand the variance in definitions of a near miss a 'scenario' has been developed, inspired by the work of Henneman and Gawlinski (2004) (appendix 5E). The scenario will be shown to participants during interviews with the ask that they label each outcome as an incident, near miss, non-event, or something else. They will be given time to consider answers and be asked to term them based on

the way their company/organisation would term them. Discussion will then allow exploration of the rationale behind the selected terms.

5.5.2.2 Culture question

To examine the maturity of safety cultures in each company/organisation, a question has been developed to support exploration and comparison. The five levels of safety culture provided by the Manchester Patient Safety Framework (MaPSaF, appendix 5F) (National Patient Safety Agency, 2006) will be shown to participants with the ask that they rank their company/organisation's safety cultures in general, and specifically in relation to near misses. The MaPSaF, while designed for healthcare, is based on culture terminology used across industries (1.5.1) (Hudson, 2007).

5.5.2.3 Analysis of question responses

Quantitative and qualitative analysis will be used for definition and culture question responses. Qualitative responses will be included in interview data. Quantitative analysis will be descriptive with inferential statistics for the definition question.

To quantify the degree of agreement between participants when allocating terms to the outcomes in the definition question, Fleiss' Kappa will be used. Fleiss' Kappa is a measure of agreement between many judges when using a nominal scale (Fleiss, 1971). Three requirements for the Kappa will be met – outcome variables are categorical, outcome variables are the same categories, and judges are independent (Data Nova, 2018). Fleiss' Kappa will be calculated using SPSS (IBM, 2022).

5.5.3 Questionnaires

Questionnaires collect quantitative and qualitative data. A questionnaire will be used to gain insights from harder to reach participants, such as those working in operational areas that are not easily accessible.

5.5.3.1 Developing the questionnaire

The questionnaire has been designed in line with the principles set out by Jenn (2006). These include development of a conceptual framework, which will again use the draft logic model (appendix 5B), and the minimising of satisficing¹⁰ and acquiescence¹¹.

Satisficing occurs where a respondent becomes disinterested as a questionnaire progresses. Satisficing is associated with task difficulty, respondent ability, and motivation (Krosnick and Presser, 2009).

Acquiescence is associated with satisficing, attention, and a willingness to be polite (van Sonderen, Sanderman and Coyne, 2013; Weijters and Baumgartner, 2012). To reduce satisficing and acquiescence, questions have been written in a simple way to support understanding, and were tested (Krosnick and Presser, 2009).

Question order and ranking have been considered. Simpler questions will be asked first (Siminski, 2008) and a five-point scale will be used as this balances reliability and ease of use (O'Muircheartaigh, Krosnick and Helic, 2000; Preston and Colman, 2000). Question reversing has also been considered, but there is no convincing argument for reversing questions (Baumgartner and Steenkamp, 2001).

The questionnaire has been piloted with individuals from healthcare (a nurse, a medical consultant, and a pharmacist) and responses have helped to refine the questionnaire. The final questionnaire is available in appendix 5G.

5.5.4 Observations and field notes

During data collection, the thesis author will have opportunities to visit companies/organisations. Observations will be made of industrial functions, operational meetings, and learning forums. Field notes will be made to collect contextual information, social interactions, and to show

¹⁰ Satisficing – where a person makes a choice that is satisfactory, but sub-optimal.

¹¹ Acquiescence – the tendency for a respondent to answer each question the same as the first.

the building of findings for trustworthiness (Phillippi and Lauderdale, 2018). To ensure confidentiality, field notes will be anonymised.

5.6 Summary

This research will take a mixed-methods approach as it aligns with the research questions and the author's philosophical leanings. The next chapters will detail the protocols for each element of the research with their associated findings, starting with a scoping review of the healthcare literature (study 1).

6 Study 1: Learning from Patient Safety Near Misses – a Scoping Review

6.1 Introduction

To gather a broad understanding of the management of near misses in healthcare and Safety-Critical Industries (SCIs), scoping reviews of the literature were conducted. Scoping reviews were appropriate because the literature around near misses had not been previously, comprehensively reviewed.

This chapter describes the protocol developed prior to conducting the scoping reviews and findings from review of the healthcare literature (study 1). Chapter 8 describes findings from the SCI literature (study 3).

6.2 Scoping review protocol

The scoping reviews will follow the methodology defined by The Joanna Briggs Institute (Peters, Godfrey, McInerney et al., 2020) which represents the most current version of the methodology (5.4.1).

Findings will be reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses – Scoping Review (PRISMA-ScR) checklist (Tricco, Lillie, Zarin et al., 2018).

6.2.1 Purpose of the scoping reviews

The purpose is to describe the literature surrounding near-miss management in healthcare and SCIs. Definitions of terms used in the review questions are provided in 4.3. The questions are:

- What is a near miss?
- How are near misses managed in healthcare and SCIs (how is reporting encouraged, how are they analysed and learned from, and what changes are made as a result)?

- What is the impact of learning from near misses to improve safety/quality in healthcare and SCIs?
- What can healthcare learn from the way SCIs manage near misses?

6.2.2 Protocol

The scoping review protocol has been prepared by the thesis author with review by their supervisors and has been registered with the Center for Open Science (Woodier, 2022). Updates to a protocol during a review are appropriate to allow exploration of emergent themes (Moher et al., 2015) and updates will be recorded (appendix 6A).

6.2.2.1 Eligibility criteria

To be included, literature will need to meet the following:

- **Population** – any healthcare setting or in scope SCI, and their workforce.
- **Concept** – any evidence in relation to defining, identifying, reporting, analysing, learning, and actioning changes (including evaluation of impact of actions) following learning from near misses.
- **Context** – international evidence from healthcare and SCIs, published in English since 2000 with full texts available. Where full texts are not available authors will be contacted.

In-scope SCIs will be those seen as safety-critical, high-reliability, and/or ultra-safe (list as per 2.3). Literature since 2000 has been chosen as after this year international reports started to highlight harm in healthcare and call for a focus on PSNMs (2.5.1).

The following are the exclusion criteria (appendix 6A for rationale):

- maternity, obstetric, and neonatal near misses
- health and safety near misses
- asteroid near misses with earth
- individual case studies without exploration
- healthcare where PSNMs are a secondary outcome.

6.2.2.2 Literature sources

All literature (academic articles and grey works) will be included. This 'open' approach will include all primary and secondary evidence as preliminary searches identified limited primary research. To identify literature the sources in Table 4 will be searched.

Table 4. Sources for the scoping reviews 2000 to 2018

Focus	Sources
Healthcare	Allied and Complementary Medicine Database (AMED), British Nursing Index (BNI), Cumulative Index to Nursing and Allied Health (CINAHL), Excerpta Medica Database (EMBASE), Health Business Elite (HBE), Health Management Information Consortium (HMIC), MedlineOVID®, APA PsycINFO, Cochrane Database, and Joanna Briggs Institute Database.
Non-healthcare	Ergonomics Abstracts, NASA Databases, ProQuest (Technology, Biological Science, Materials Science and Engineering, and Oceanic databases), Energy Citations, and Office of Scientific and Technical Information (OSTI).
General	Scopus and Web of Science.
Grey	British Library EthOS, Google, Grey Literature Report, Open AIRE, Open Gray, and Proquest (PhD).

The choice of sources is based on subject coverage, availability, pragmatism, and expert input. For selection of healthcare sources, advice was taken from the thesis supervisor and other academics. For wider sources covering SCIs, advice was taken from experts in safety science and human factors. During selection, the thesis author reflected as to whether the range of sources is excessive. However, the purpose of a scoping review is to extensively describe the literature (Pham et al., 2014) and so the range is justified.

6.2.2.3 Search strategy

A three-stage search strategy will be used. Stage one will use terms identified following initial review of the literature and a thesaurus. Two example databases will be searched – MedlineOVID® (predominantly healthcare) and Ergonomics Abstracts (predominantly SCI). Outputs from stage one will be reviewed to analyse terms in the titles, abstracts, and indexes. This will help define terms for stage two and identify MeSH terms.

Stage two will be undertaken across the sources in Table 4. Appendix 6B provides the final search strategy for MedlineOVID®. Stage three will review reference lists to provide additional literature via ‘snowballing’¹² (Horsley et al., 2011).

Grey works will be searched for using strings of terms such as ‘near miss AND nuclear.’ The intended search engine ranks results by relevance. A pragmatic approach will be to review the top 20 results for each search.

6.2.2.4 Selection of included literature

Search results will be downloaded into Citavi (version 6), and duplicates removed. The thesis author will undertake an initial screen of titles and abstracts to identify literature that meets the inclusion criteria. A second review will then identify whether literature meets any exclusion criteria. All relevant literature will have their full texts retrieved.

The thesis author and a second reviewer, with experience in literature reviews, will independently review the full texts and those excluded. This will ensure appropriate literature has been included. Any conflicts between reviewers will be resolved by the thesis supervisors.

6.2.2.5 Data charting, critical appraisal, and synthesis

A data extraction form has been prepared by the thesis author and agreed with supervisors. This determines the variables to extract from

¹² Snowballing – using reference lists and tracking other literature that have cited the publication to identify further texts to review.

the literature. Data will be extracted by the thesis author, checked by the second reviewer, and entered into the form.

Data charted will include characteristics related to the literature (e.g. country), industry of focus (e.g. healthcare specialism or SCI), and specific review questions. For care settings in healthcare the International Classification for Patient Safety will be used for charting (World Health Organization, 2010).

No systematic critical appraisal of the literature will be undertaken, but any limitations and quality issues will be noted. The objective of a scoping review is comprehensive coverage, rather than looking for standards of evidence (Moher et al., 2015).

6.2.3 Updating the literature (written retrospectively)

The original scoping reviews were undertaken in May 2018. The reviews were updated at intervals until completion of the research. The same search terms were used as per the original review protocol (6.2.2), but a more limited set of sources were searched (Table 5) to balance resource, time, and the benefits of any new literature.

Table 5. Sources for the updated scoping reviews 2018 to 2022

Focus	Databases
Healthcare	AMED, EMBASE, HMIC, MedlineOVID®, and APA PsycINFO.
Non-healthcare	Ergonomics Abstracts and ProQuest.
General	Scopus.
Grey	Google, Grey Literature Report, Open Gray, and Proquest.

6.3 Scoping review – healthcare findings

The appendix provides the PRISMA summaries (6C), frequency counts of academic article characteristics (6D) with a diagrammatic representation (6E), and a table of the final included healthcare scoping

review academic articles 2000 to 2022 (6F). Rejected articles are available via the supplementary materials link.

6.3.1 Summary of the literature – 2000 to May 2018

The scoping review included 102 academic articles. Of these, 79 pertained to PSNMs alone with the rest including other event types such as no-harm incidents. Stage-two searches identified 72 articles, with the rest from stage-three searches.

The articles included 68 original research, with the rest being opinion (n=21), reviews (n=9), and book chapters (n=4). Of the original research articles, 39 used quantitative methodologies and were predominantly non-experimental/descriptive (n=37). There was one quasi-experimental article (Ethchegaray, Thomas, Geraci et al., 2005) and one randomised control trial (Adelman, Kalkut, Schechter et al., 2013). There were 14 qualitative, 10 mixed-methods, and 5 quality improvement studies.

The majority of articles were published in the United States of America (USA) (n=64), with 50 articles published since 2010. Articles commonly considered the reporting of PSNMs, and then analysis/learning. The most common care setting was 'general hospital' (n=92) with no specific or multiple specialties (n=29). Other common specialties included surgery (n=15), medication/pharmacy (n=13), and radiotherapy (n=8).

The scoping review included 51 grey works. Of these, 36 were specific to PSNMs alone and 17 originated from the stage-two search. The works predominantly originated in the USA (n=31) and focussed on reporting. Fourteen provided overviews of or related to near-miss reporting systems, 13 were conference abstracts or presentations, and 12 were non-academic reports or articles. They mostly involved no specific specialty (n=21), with a small number focussed on specialties such as medication/pharmacy (n=8) and oncology (n=5).

6.3.2 Terminology and definitions of near misses

6.3.2.1 Terminology

'Near miss' was the commonest term used across the literature (in 74 articles) to refer to near-miss type events; Castro (2014) also found this. Other terms were 'close call' (Wu and Marks, 2013) and 'good catch' (Hewitt and Chreim, 2015). Less common terms included 'nearly event' (Rosenorn-Lanng and Michell, 2014), 'non-event' (Kaplan, 2005), and 'great save' (Jefferson, 2018).

Several authors described near misses, close calls, and good catches as synonymous (e.g. Keim, Ross and Smolinski, 2006; Marks, Kasda, Paine et al., 2013; Martin, Etchegaray, Simmons et al., 2005). Even if synonymous, terms may invoke different feelings which will influence reporting. Close call may be a more descriptive term (Castro, 2014; Institute for Safe Medication Practices, 2009), while near miss is vague (Siegenthaler, Schneider, Graves et al., 2005), confusing (Institute for Safe Medication Practices, 2009), blame orientated (Ginsburg, Shuang, Richardson et al., 2009), and subjective (Clinton and Getachew, 2003).

In the NHS, near miss is used as the term by bodies such as the General Medical Council (n.d.). However, the National Patient Safety Agency (NPSA) (2004) in the early 2000s called for the term to change to 'patient safety incident (prevented)' because of public perceptions. Near misses have continued to be referred to in the literature, including by the NPSA's successor (NHS England, 2015).

Good catches were increasingly referred to over the years, particularly in literature from the USA (e.g. American Data Network, 2017; Crandall, Almuhanha, Cady et al., 2018; Herzer, Mirrer, Xie et al., 2012). Good catch was found to be a more positive term than (Wallace et al., 2017), and preferential to, near miss (Aston and Young, 2009). The term was also found to imply vigilance, critical thinking, prompt action, and patient advocacy (Mahlmeister, 2006).

The literature demonstrated no support for one term over another. However, terminology is important as it may help or hinder reporting. A

person may feel blamed for reporting a PSNM (Ginsburg et al., 2009), but celebrated for a good catch (Tamuz, Thomas and Franchois, 2004).

6.3.2.2 Definitions

The literature provided a range of definitions for a PSNM (and its synonymous terms). Definitions were often provided with examples (Table 6), commonly involving medications.

Table 6. Examples of patient safety near misses

Focus	Example	Source
Medication	'... if a nurse while performing a medication double-check... realizes that it is the wrong dose prior to administering it to the patient, the event is a close call.'	Castro, 2014
Non-medication	'... transferring a patient into a bed with locked wheels when the bed moved, despite the wheels being locked.'	Wallace et al., 2017

Sixty-three 'broad' (not specific to a specialty or event type) definitions were found in the literature. These varied in how they described the following: the relationship of events to a patient (39 implied or stated that events could reach the patient, while others described stopping short); whether they included an intervention (48 mentioned an intervention); and whether harm could occur (6 suggested harm could still occur, but less severe than it could have been, e.g. Champion, Meglan and Shair, 2008).

The variation in definitions had also been identified by other authors. Marks et al. (2013) found four types of PSNM depending on whether events reach a patient and whether they cause no harm, minimal harm, or avoid death. Yu et al. (2005) found 12 definitions with three functionally different meanings depending on whether events reach a patient and whether harm occurs.

'Context-specific' definitions were also identified (Table 7) with some specialties calling for specific definitions to help with identification and reporting (Mandal, Adams and Fraser, 2005).

Table 7. Examples of context-specific definitions of patient safety near misses

Specialty	Specific near-miss example	Source
Pharmacy	Ordering and retracting a medicine order within 10 minutes	Adelman et al., 2013
Transfusion	Mislabeled tubes	Siegenthaler et al., 2005
Urology	Over four-week delay since referral for microscopic haematuria	Singh et al., 2003

Context-specific definitions also highlight differences in the interpretation of PSNMs across different specialties. Maternity and neonatal near misses (3.5.1) were excluded from this scoping review because they are defined differently to PSNMs (Madden and Milligan, 2004). In mental health, the contribution of vulnerabilities to a near miss means they are also different to a PSNM (Jeffs, Rose, Macrae et al., 2012a).

6.3.2.3 Agreeing a definition

The definition of a PSNM may be dependent on the local context (Tamuz and Thomas, 2006). The literature was unclear as to whether a PSNM is different to a Patient Safety Incident (PSI) (harmful or non-harmful), and whether an intervention must occur (intentional or unintentional), for events to be a PSNM. Language was also debated as to whether a PSNM is something that 'almost' happened or had the 'potential' to happen (Capucho, 2011), or was an 'avoided' (Ardenghi, Martinengo, Bocciardo et al., 2007) PSI.

A small number of definitions of a PSNM included the potential for harm to have occurred (e.g. Berry and Krizek, 2000; Jacobs, Benavidez,

Bacha et al., 2008; Nashef, 2003). The majority described a PSNM in association with events that had not reached a patient. An Institute for Safe Medication Practices (2009) poll, with 3,800 respondents, found that the majority of responders (88%) interpreted a PSNM as an event that had not reached a patient.

An intervention resulting in the avoidance of an incident was considered by some to be a key feature of a PSNM, separating it from a PSI (Kessels-Habraken, van der Schaaf, Jonge et al., 2010; Sheikhtaheri, 2014). However, several international databases and safety classification systems were seen to not separate PSNMs and no-harm PSIs where events reach a patient (Cooper, Williams, Hibbert et al., 2018; National Patient Safety Agency, n.d.). Seeing PSNMs and PSIs as the same event may make reporting easier, but may limit learning (Martin et al., 2005; Schildmeijer, Unbeck, Muren et al., 2013).

Definitions of a PSNM in the literature often included an intervention (e.g. Hurley, Rothschild, Moore et al., 2008; Jeffs, Lingard, Berta et al., 2012b; Parnes, Fernald, Quintela et al., 2007; Taylor, Brownstein, Klein et al., 2007). Various interventions were described and could be intended/planned, or unintended/by chance (Jacobs et al., 2008). Lopes-Soques, Garcia-Alvarez, Basil et al. (2015) defined different types of PSNMs depending on whether an intervention was planned (type 1) or by chance (type 2).

Interventions were also termed 'recoveries' by several authors (e.g. Habraken and van der Schaaf, 2010; Hurley et al., 2008). Henneman and Gawlinski (2004) used the Eindhoven Model (Figure 3) to help describe the role of unplanned nursing recoveries in PSNMs.

Recoveries were found to often be unplanned (Currie, Desjardins, Levine et al., 2009; Habraken and van der Schaaf, 2010), and defined as where humans intervene to terminate progression of events (Kaplan, 2005; Parnes et al., 2007).

While the role of interventions may be a key feature of a PSNM, they may be difficult to conceptualise because an intervention may be seen

as a routine behaviour (Clinton and Getachew, 2003). Authors also debated the point at which an intervention acts for events to be a PSNM. Several authors had developed typologies describing different types of PSNM depending on the point of intervention (e.g. Lopes-Soques et al., 2015; Nashef, 2003). Ginsburg et al. (2009) proposed major (caught close) and minor (caught further away) types of PSNMs, and Sheikhtaheri (2014) proposed the following four PSNMs:

1. does not reach the patient because of formal/planned interventions.
2. does not reach the patient because of chance/unplanned interventions.
3. does reach the patient but does not cause harm because of early detection, interventions, and treatment.
4. does reach the patient but does not cause harm because of chance.

Parnes et al. (2007) overcame the issue of definitions by encouraging reporting of 'any event you don't wish to have happen again that might represent a threat to patient safety.' In their approach they coded events as PSIs or PSNMs after reporting.

6.3.3 Reporting near misses

Reporting related to identification and recording of PSNMs. Recording was seen to often involve electronic Incident Reporting Systems (IRSs) with identification relying on staff 'spotting' a PSNM.

In addition to IRSs, there were observational approaches described in research to identify PSNMs. These included procedural video reviews (Bonrath, Gordon and Grantcharov, 2015) and live observations (e.g. Galvan, Bacha, Mohr et al., 2005; Putnam, Anderson, Diffley et al., 2016). These methods were effective, but time consuming. In one example Mandal et al. (2005) used nurses to observe deviations in cataract operations, spotting 25 PSNMs across 500 cases. In another example observations in operating theatres identified events that were not reported into the IRS (Hamilton et al., 2018).

Other methods for identifying PSNMs included retrospective record review (Schildmeijer et al., 2013), process mapping (Nithiya, Phoa, Chin et al., 2013), safety huddles (Institute of Healthcare Improvement, 2004), and proformas/checklists (Singh, Saleemi, Walsh et al., 2003); each was thought to be valuable. For example, Singh et al. (2003) developed a proforma comprising various aspects of the management of bladder cancer and if any criterion was not met, the episode was recorded as a PSNM; across 115 episodes they identified 57% had PSNMs.

6.3.3.1 Supporting reporting

The literature described under-reporting of PSNMs across healthcare (e.g. Etchegaray, Thomas, Geraci et al., 2005; Hamilton et al., 2018; Jimenez, 2005). Authors made suggestions to support reporting (Table 8).

Table 8. Suggested interventions to support reporting of patient safety near misses

Further citations available via the supplementary materials link

Intervention	Description	Source (e.g.)
Leadership support	Leaders at all levels to encourage reporting and support the right culture.	Crandall et al., 2018; Mick et al., 2007
Policy development	Policy and procedures to be clear for reporting.	Simmons et al., 2008; Wagner et al., 2006
Promotion and engagement	Seek champions for reporting, foster competition, and reward reporting. Provide education on reporting.	American Data Network, 2017; Herzer et al., 2012
Safety culture and protection	Remove fear of blame and provide opportunities for anonymous reporting.	Marella, 2007; Simmons et al., 2008

Clarifying definitions	Make definitions clear and change terminology to something positive.	Brecher, 2014; Traynor, 2015
Time for reporting	Have multiple routes for reporting, including end-of-shift reporting.	Crandall et al., 2018; Simmons et al., 2008
Provide feedback	Use scoreboards and examples. Provide feedback on the results of reports and action plans.	American Data Network, 2017; Zwart et al., 2011

Several of the examples in Table 8, when implemented, resulted in increased reporting of PSNMs. The absence of some of the interventions was also found to be detrimental. For example, the Medical Event Reporting System for Transfusion Medicine (MERS-TM) saw a 50% fall in reporting when no leadership support was available (Callum, Kaplan, Merkle et al., 2001).

Returning to definitions, several authors found improved reporting following changes to terminology, particularly to ‘good catch’ (e.g. Brecher, 2014; Herzer et al., 2012; Lozito et al., 2018). For example, Penne (2011) described how their close-call reporting system only received 175 reports in 3 years, but with a change to talking about good catches and incentives, they saw a 1500% increase. The American Data Network (2017) has published a ‘good-catch toolkit’ which has resulted in facilities reporting an average of 246 more PSNMs per month.

Regarding rewards and incentives for reporting, examples in the literature included financial rewards, free lunches, reduced antisocial shifts, and sports tickets. The Pennsylvania Patient Safety Reporting System was thought to be successful because of incentives (The Joint Commission, 2016; Wallace et al., 2017). Reporting targets were also found to incentivise reporting (Zwart et al., 2011), however, Dekker (2011) described targets as ‘useless.’

A small number of authors questioned whether all incidents and PSNMs need reporting. 100% reporting may not be needed, nor be desirable, as it may overwhelm IRSs (Hewitt and Chreim, 2015). System issues may be identified without needing to know about all safety events (Marella, 2007; Wu and Marks, 2013).

Anonymity versus confidentiality

The literature debated the benefits of anonymity when reporting PSNMs. There were several examples described of fully anonymous reporting systems (e.g. Dooley, Streater and Wilks, 2001; Guffey, Szolnoki, Caldwell et al., 2011; Kaplan, Callum, Rabin Fastman et al., 2002; Medmarx, 2009; Mick, Wood and Massey, 2007; Near Miss Project, 2009; Vrablik, Schneider, Todorov et al., 2012), optionally anonymous systems (e.g. Aston and Young, 2009; Graves, 2008; Watson, 2006), and confidential systems (Ferrolì, Caldirolì, Acerbi et al., 2012; Kanse, van der Schaaf, Vrijland et al., 2006). Taylor et al. (2007) described how an anonymous IRS saw a 'modest' increase in the number of reported incidents, but a 'significant' increase in reported PSNMs.

In practice very few IRSs are truly anonymous (Barach and Small, 2000b), and some authors felt anonymity limits information and sacrifices accountability (Barach and Small, 2000b; Dekker, 2011). Other authors advocated for anonymity (Martin et al., 2005), particularly early in the lifecycle of an IRS or safety culture programme (Barach and Small, 2000b; Martin et al., 2005). It may be important to give staff the option (Carthey, Leval and Reason et al., 2001; Wagner, Capezuti, Ouslander et al., 2006).

Voluntary versus mandatory

PSNM reporting was found to be mostly voluntary. However, Wu and Marks (2013) advocated for making it mandatory. Not all authors agreed and preferred voluntary reporting (Wagner et al., 2006). Dekker (2011) warned against making PSNM reporting mandatory because it may have a counter effect by reducing reporting if staff believe

mandates mean sanctions; staff may work to interpret an event as not requiring reporting.

Reporting culture

The need for the right safety culture to support reporting was regularly described in the literature and was felt to be 'key' (Kaplan and Fastman, 2003). Culture was referred to in relation to being just (Carthey et al., 2001; Crandall et al., 2018) and/or no-blame (e.g. Dekker, 2011; Deraniyagala, Liu, Mittauer et al., 2015; Dooley et al., 2001; Yoon, Alaia, Hutzler et al., 2015). There was no consensus amongst authors about whether a just or no-blame culture is most appropriate, but Carthey et al. (2001) described that a no-blame culture would not work because someone will always get disciplined.

Interventions solely focussed on improving cultures were thought unlikely to improve reporting of PSNMs as other issues also need addressing. For example, Dooley et al. (2001) saw consistent reporting of PSNMs when a system was implemented with a no-blame approach and training. Crandall et al. (2018) saw improvements following technological and infrastructure changes, work on reporting cultures and education, and leadership involvement. A quality improvement approach was found to be useful when implementing changes (Crandall et al., 2018; Illingworth, 2015; Wagner et al., 2006).

6.3.3.2 Incident reporting systems

Aspden et al. (2004) described three levels of complexity of near-miss IRSs: 1) basic, local, and one-domain systems; 2a) intermediate, hospital-wide systems; 2b) intermediate, domain-specific nationwide systems; and 3) upper, nationwide systems covering all domains. The availability, accessibility, and functionality of IRSs for PSIs and PSNMs were described as problematic by several authors.

Most type 1 or 2a IRSs seen in the literature supported reporting of PSIs and PSNMs in the same system (e.g. NHS Rushcliffe Clinical Commissioning Group, 2016). Several level 2b (e.g. Callum et al.,

2001) and a small number of level 3 IRSs were also seen (e.g. National Patient Safety Agency, n.d.), but were not specific to PSNMs.

Several of the IRSs described as 'near-miss reporting systems' included other events which may have caused harm (e.g. Kusano et al., 2015; Near Miss Project, 2009; Weiss, Scott, Demmel et al., 2017). At the time of the review it was not clear whether some IRSs were still in use. The thesis author contacted SafetyNet (Beyea, Killen and Knox, 2006), MedMarx (2009), and the New York State Near Miss Registry (Fried, 2011), but received no reply, nor found evidence of continued use.

Accessibility

Most IRSs seen in the literature were electronic and this is known to support reporting of PSNMs (Walters, 2011). Other routes seen for reporting included paper-based examples (Keim et al., 2006; Royal Pharmaceutical Society, 2015) and phone or email (Coyle, 2005). Keim et al. (2006) used brightly coloured good-catch cards in break rooms and medication areas for nurses to report PSNMs; they were anonymous, included rewards, and saw a 300% increase in reporting.

Functionality

There has been a proliferation of IRSs in healthcare over the years, with limited consistency in their design (Chang, Schyve, Croteau et al., 2005). Some IRSs were seen to include specific questions for PSNMs, although not widely. Examples of questions included 'critical points breached prior to catching' (Callum et al., 2001), and 'what were the controls and timing of those controls' (Callum et al., 2001; Clinton and Getachew, 2003; Currie et al., 2009). Several systems asked about causes and solutions (e.g. Aston and Young, 2009; Ferroli et al., 2012). Yen, Jian, Currie et al. (2009) developed a hazard and near-miss system which asked two questions – 'on shift today were there any dangerous situations that could cause a future event,' and 'on shift today were there any near misses?'

Chang et al. (2005) described the need for IRSs to have a standardised taxonomy to support reporting, analysis, and comparison. Several

taxonomies were found in the literature (e.g. Chang et al., 2005; Cure, Zayas-Castro and Fabri, 2011; D'Souza, Koller, Ng et al., 2004) and are considered further in 6.3.4.2.

6.3.4 Responding to reports of near misses

Responses related to immediate actions after a PSNM, prioritisation for investigation, the investigation itself, and sharing learning. There were three types of response described: a quick fix; the PSNM is reported but no feedback is given; the PSNM is reported and the factors causing it addressed (Jefferies, Berta, Lingard et al., 2012c).

6.3.4.1 Prioritisation

Authors recognised a need to prioritise PSNMs for investigation due to volume (Zwart, Steerneman, van Rensen et al., 2011). Prioritisation tools often considered potential severity, likelihood, controls overcome, and detection (e.g. Barnard et al., 2006; Kodama and Kanda, 2010; Novak, Nyflot, Ermoian et al., 2016; Nyflot, Zeng, Kusano et al., 2015; Thornton, Miransky, Killen et al., 2011). Tools ranged from simple (e.g. Mullen, Nyflot, Zeng et al., 2016) to complex matrices (Table 9).

Table 9. Patient safety near miss prioritisation tool adapted from Thornton et al. (2011)

Element	Less risk	Score			More risk
		2	3	4	
Worst potential outcome	1	2	3	4	5
	Minor				Death
Frequency	1	2			3
	Novel				Repeat
Mode of discovery	1				2
	Planned				
Number of barriers	1	2			3
	Many				None
Quality of barriers	1				2
	Strong				Weak

Risk prioritisation was found to not be straightforward, with difficulty predicting the severity of a PSNM which, by definition, is not visible (Thornton et al., 2011). To help with prioritisation a team approach was suggested (Ferroli et al., 2012). Putnam et al. (2016) reviewed good catches with a group of experts and grouped them to guide improvement efforts.

6.3.4.2 Investigation

Following reporting and prioritisation, the literature described various processes for identifying contributory factors to a PSNM for learning. Formal investigation was referred to, as was aggregating learning for identification of themes. Investment is needed in analytical expertise (Dekker, 2011).

Formal investigation

Where the literature described investigation of PSNMs, this was commonly via Root Cause Analysis (RCA) (Battles and Shea, 2001; Ferroli et al., 2012; Miller and Chaboyer, 2006). RCA is commonly referred to in NHS policies (e.g. East of England Ambulance Service, 2017). Some added approaches for intelligence gathering, including text mining (Sawaragi et al., 2009) and staff surveys (Raposo, 2016) were also described in the literature.

A small number of specific investigatory methods/tools were used in academic settings. Examples included the Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) RCA approach (Kanse et al., 2006; Nyst and van der Schaaf, 2005), the Human Factors Analysis and Classification System (HFACS) (Mosaly, Mazur, Miller et al., 2013), and SHEEP (systems, human, environment, equipment, and person) (Rosenorn-Lanng and Mitchell, 2014). Nyst and van der Schaaf (2005) found PRISMA useful for anaesthetic PSNMs. Rosenorn-Lanng and Mitchell (2014) described SHEEP as useful for 'nearly events,' but others challenged its rigour (McCaig, 2014).

Woloshynowych, Rogers, Taylor-Adams et al. (2005) undertook a review of analysis methods for healthcare incidents taking learning from high-risk industries. They found that most tools could be used for investigating PSNMs, but several were too resource intensive. They concluded that RCA and the Organisational Accident Causation Model (OACM)¹³ were appropriate.

Aggregation

A small number of authors described the benefits of aggregating PSNM data. For example, Carthey et al. (2001) described that both qualitative, such as RCA, and quantitative, such as categorisation against a taxonomy and aggregation, is needed. One PSNM by itself is not very meaningful, but a cluster identifying a similar issue are (Colwell, 2011).

Aggregation was felt to be beneficial because it allows identification of trends over time (Royal Pharmaceutical Society, 2015), provides opportunities to look for dangers in systems (Cure et al., 2011), allows tracking of the impact of safety actions (Callum et al., 2001), and confirms that mechanisms are in place to prevent incidents (Simmons, Mick, Graves et al., 2008).

Coding for aggregation was commonly manual using a taxonomy (Cure et al., 2011; D'Souza et al., 2004; Lipshutz et al., 2015). There may be future opportunities in the use of artificial intelligence for coding, but currently it has shown limited benefit because of difficulties coding nuanced data (Kaplan and Fastman, 2003).

Taxonomies

Taxonomies were referred to when discussing the reporting and analysis of PSNMs (e.g. Cure et al., 2011; Greenham et al., 2018; Lipshutz et al., 2015; Raposo, 2016; Traynor, 2015). A taxonomy is a classification system and may help standardisation of the recording of factors contributing to PSNMs.

¹³ Organisational Accident Causation Model (OACM) – Reason's (1997) model that was ultimately adapted to become the Swiss Cheese Model (1.3.3).

The literature demonstrated a breadth of taxonomies, many bespoke, and ranging from simple to complex. Examples included Furukawa and Okada (2009) as per Table 10, and MERS-TM which has event, latent, active, and causal codes (Callum et al., 2001).

Table 10. Simple example for classification of a patient safety near miss adapted from Furukawa and Okada (2009)

Category	Subcategory
Gestalt	Lack of skill
	Lack of knowledge
Affordance	Difficulty of confirmation
	Difficulty of distinction
	Imperfection of apparatus
	Lack of criterion for judgment
Preview	Difficulty of prediction
	Inappropriate of communication
	Unplanned work
Workload	Excess of information
	Complicated work
	Psychological burden
	Bad work environment
	Physical burden
	Distract attention

Taxonomies need to be suitable for the context within which they are applied, and allow for the identification of themes (Arnold, 2017; Chang et al., 2005). Chang et al. (2005) developed a standardised taxonomy on behalf of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Their JCAHO taxonomy was published and has been used by some authors (e.g. Cure et al., 2011; Greenham et al., 2018; Guffey et al., 2011; Lipshutz et al., 2015).

Not all authors were supportive of taxonomies because they may hinder analysis by forcing decisions, drawing lines, and removing context (Dekker, 2011). Others suggested that one single taxonomy may not be

enough because of the need to look at, in the case of PSNMs, causes and recoveries (Aspden et al., 2004; Carthey et al., 2001). Habraken and van der Schaaf (2010) developed an example recovery taxonomy for medication errors (Table 11), as did Kanse et al. (2006) (Table 12).

Table 11. Recovery opportunities adapted from Habraken and van der Schaaf (2010)

Category	Planned*	Unplanned
Failed	Formal barrier used, but failed	Person tries to correct, but fails
Missed	Formal barrier present, but not used	Person does not detect a problem that they should have
Absent	Formal barrier could not be used	Person should detect a problem, but is unable because of lack of resource or ability

* May involve organisational and technical controls

Table 12. Recovery processes adapted from Kanse et al. (2006), based on Nyst and van der Schaaf (2005)

Process	Description	Example
Detection	When a person first detects a deviation	the patient doubted the prescribed dose
Explanation	When the person looks for further information to draw conclusions about the deviation	the nurse consulted the doctor about the dose
Countermeasure	When the person plans and implements actions to return	the doctor corrected the dose

6.3.4.3 Sharing learning

Sharing learning referred to how PSNMs, their causes, and interventions/recoveries were summarised and disseminated to staff to increase awareness of risks. Learning from PSNMs is difficult because they often fall into a ‘black hole’ (Jefferis et al., 2012c). The literature included several ways by which learning is shared (Table 13). No evaluation of any sharing method was identified.

Table 13. Methods for sharing learning from patient safety near misses

Further citations available via the supplementary materials link

Learning method	Method	Source (e.g.)
Reading and watching	Reports/newsletters	Mick et al., 2007; NASA, 2002
	Alerting	Killen and Beyea, 2003
	Emails	The Joint Commission, 2016
	Procedural videos	Bonrath et al., 2015
Discussion and listening	Story telling	Beyea et al., 2006
	Discussion forums and reflection	Cohoon, 2003
	Morning huddles	Raposo, 2016
	Mandated briefings	Sorokin et al., 2002
Education	Just in time learning at reporting	Yen et al., 2009
	‘Offender’ course	Yoon et al., 2015

Methods for sharing learning commonly involve reading, watching, listening, and discussing. Discussion was felt to allow rich exploration and systems thinking (McCafferty and Polk, 2004). Where discussion was used, facilitation of the learning events was noted to be important,

and appreciative inquiry was found to increase awareness, morale, and allow a focus on good practice (Clinton and Getachew, 2003).

A small number of authors used PSNMs in education. Yen et al. (2009) developed 'just in time learning at the time of reporting,' meaning staff could refresh knowledge immediately after a PSNM. Yoon et al. (2015) developed an educational course for staff involved in wrong site surgery PSNMs. They referred to staff as 'offenders' and believed it had impact.

A further method described for sharing learning was feedback. Authors felt feedback was important to share learning and support further reporting (e.g. D'Souza et al., 2004; Herzer et al., 2012; Lozito et al., 2018). However, there is a lack of feedback resulting in lost learning (Jeffs et al., 2012c).

6.3.5 Actions following learning from near misses

The literature repeatedly stated how learning from PSNMs would improve patient safety (e.g. Barach and Small, 2000b; Jeffs, Affonso and Macmillan, 2008; Novak et al., 2016). Several authors stated how the causes of PSNMs and PSIs are the same (e.g. Barach and Small, 2000b; Chang et al., 2005; Lombardi et al., 2016).

PSNMs were thought to be particularly useful because they are high frequency, low in emotion, low in liability, and focus on interventions (Barach and Small, 2000b; Clinton and Getachew, 2003; Kaplan and Fastman, 2003). PSNMs allow systems to be understood and provide insights into vulnerabilities (Ginsburg et al., 2009).

The literature provided several examples of actions taken by organisations following learning from PSNMs. It was difficult to ascertain whether the actions were the result of PSNMs alone or were influenced by learning from other safety events. Examples of actions are described in Table 14, categorised against the Action Hierarchy Tool (appendix 1A). Actions were mixed, but mostly weak and intermediate.

Table 14. Strength of actions seen in the literature

Further citations available via the supplementary materials link

Strength	Focus	Source (e.g.)
Weak	Training	Lozito et al., 2018; Yoon et al., 2015
	Awareness building	Mick et al., 2007; Weiss et al., 2017
	Distractions	Penne, 2011; Weiss et al., 2017
Intermediate	Policy and guidance	Putnam et al., 2016; Weiss et al., 2017; Vanderford et al., 2014
	Checklists	Fargen et al., 2013; Lopes-Soques et al., 2015
Stronger	Equipment replacement or redesign*	Tseng et al., 2018; Wallace et al., 2017; Wu and Marks, 2013
	Process redesign	Loh et al., 2017
	Recall** and national change	Hamrick et al., 2011; Marella, 2007
	Environmental redesign	Nithiya et al., 2013; Wu and Marks, 2013
	Strategic***	Bedi et al., 2011; Kanse et al., 2006

*Redesign included medicine packaging (Barnard et al., 2006; Tseng et al., 2018), alerts (Lombardi et al., 2016), barcoding (Early et al., 2011), and software for electronic prescribing (Dooley et al., 2001; Hyman et al., 2012).

**National recall for look and sound alike medicines (Hamrick et al., 2011).

***Included building of workforce capacity and a new clinic (Singh et al., 2003).

The literature also referred to several non-specific quality improvement projects that had been the result of learning from PSNMs. There was limited detail about the actions in those projects and it was again difficult to ascertain whether PSNMs alone had influenced the actions (e.g. Bedi, Kaur and Basu et al., 2011; Deraniyagala et al., 2015; Novak et al., 2014).

6.3.5.1 Impact of actions

Impact in the context of PSNMs referred to whether learning and actions led to evidenced improvements in patient safety. The majority of actions were not supported by any evaluation of their impact (e.g. Crane et al., 2015; Lipshutz et al., 2015; Lopes-Soques et al., 2015; Wallace et al., 2017; Wu and Marks, 2013). Some authors stated that there had been impact, but provided no evidence (Ardenghi et al., 2007).

Where evidence was provided to substantiate claims of impact, it was generally descriptive (e.g. Davey, Britland and Naylor et al., 2008; Early, Rhia, Martin et al., 2011; Fargen, Velat, Lawson et al., 2013; Ford, Smith, Harris et al., 2012; Lombardi, Gaston-Kim, Perlstein et al., 2016; Tseng, Wen, Lee et al., 2018; Vanderford, Capezuti and Finley, 2014).

There was one experimental study providing evidence of impact. Adelman et al. (2013) evaluated actions aimed at preventing wrong-patient orders and found that, compared with control, an identification verification alert reduced the odds of retract-and-reorder events, and identification re-entry functionality had an even greater effect. The authors concluded that 2 events per 100,000 orders would have been life threatening.

Some other studies included measures of significance, for example:

- Chemotherapy errors reduced from 3.8 to 1.9 per 1,000 doses, with a decline in 'errors' after 16 months ($p < .001$) (Weiss et al., 2017).
- Dispensing errors due to drug-name confusion reduced from 66.3% to 55.0% ($p = .004$) (Tseng et al., 2018).
- Incorrectly booked surgical cases reduced from 0.75% to 0.41% ($p = 0.014$) and improperly performed time-out procedures reduced from 18.7% to 5.9% ($p < .001$) (Yoon et al., 2015).

In several studies, reductions in PSNM rates following actions were seen as positive improvements in safety (e.g. Ford et al., 2012; Tseng et al., 2018; Weiss et al., 2017). In contrast, other authors saw

increases in PSNM rates following actions (Davies, Piper, Ferguson et al., 2018; Nyflot et al., 2015). However, increasing rates were also seen as a positive sign of improved safety culture (Nyflot et al., 2015)

Assumptions of safety improvements were stated in the literature, often with reference to the common cause hypothesis (3.3.1.1). For example, Yoon et al. (2015) described that, by reducing incorrectly booked surgical procedures and improperly performed time-outs in operating theatres, they would have decreased wrong-site surgeries. Early et al. (2011) estimated an overall decreased length of stay of 1476.6 days and reduced costs by improving the use of bar-code medication administration.

In contrast to the positive findings above, there were also examples where learning had not been taken from PSNMs, and actions made as a result had not led to any improvements. Mahlmesiter (2006) described a situation where harm had occurred during medication administration; a previous, similar PSNM had not been learned from which may have prevented the situation. Callum et al. (2001) implemented education and changes to blood-bank forms to reduce transfusion errors but found no impact. The authors described the need for innovative interventions to address transfusion-related PSIs and PSNMs.

Evaluation of impact also considered other aspects of quality and safety including culture, team satisfaction, and productivity. Wallace et al. (2017) and Kusano et al. (2015) found improvements in safety culture measures and staff satisfaction following learning from PSNMs, and Fargan et al. (2012) found improvements in team communication. Loh et al. (2017) used learning from PSNMs to reduce transcription time when completing reservation slips for ocular implants.

6.4 Updating the scoping review

6.4.1 Additional literature – June 2018 to 2021

Fourteen academic articles and 9 grey works were added to the scoping review. Most articles considered PSNMs alone (n=12) and came from the USA (n=12). There were 12 original research articles, most commonly quantitative, non-experimental (n=9). There were two quality improvement projects, one mixed-methods studies, and two reviews. The articles most commonly considered reporting, analysis, and learning. They all came from the general hospital setting, across a range of specialties including emergency medicine and radiation oncology.

The grey works mostly considered PSNMs alone (n=8) and came from the USA (n=5), although there were examples from across the world. The works were either conference abstracts/presentations (n=6) or reports/non-academic articles (n=3). They commonly focused on reporting in the general hospital setting.

6.4.1.1 Terminology and definitions

'Near miss' continued to be the most common term (in 12 articles). 'Good catch' was seen in grey works, particularly from the USA. 'Close call' was also used (Goolsarran, Martinez and Garcia, 2019; The Joint Commission, 2018). Goolsarran et al. (2019) differentiated between PSNMs and close calls in MRI by describing a near miss as the process of improper MRI screening, and the close call as what happens to the patient. Other terms included 'unsafe conditions' which are what contributes to a PSNM or PSI (Grabinski, Babineau, Jamal et al., 2021). The literature again demonstrated differences in opinions about whether a PSNM could cause harm (Bonaccorsi-Riani, Daudre-Vignier and Ciccarelli, 2019; Moreno and Zuberi, 2019), or whether events could reach a patient (Cohen, Francis, Wiegmann et al., 2018).

To support understanding of definitions, categorisation of PSNMs into clinical types or by key features was used. Wilson, Bakun, Bertens et al.

(2020) used a Delphi approach with experts in liver surgery to identify categories of events that should be considered a PSNM; their aim was standardisation and comparison of events.

Kundu et al. (2019) described that, in radiation oncology, PSNMs did not cause harm, but they elicited different responses from staff that affected their recognition. They offered a categorisation of six types of event and gave staff scenarios with questions about whether they were successes or failures, and whether they would be willing to report them. 'Willingness-to report scores for "almost happened" events were greater than "could have happened" events' ($p < .001$).

6.4.1.2 Reporting of near misses

Other than IRSs, methods to identify PSNMs included reviews of alert logs in electronic infusion pumps (Aljaber and Waterson, 2021), medical record reviews (Bonaccorsi-Riani et al., 2019), and automated triggers (Hartvigson, Gensheimer, Spady et al., 2020).

Routes to report PSNMs commonly involved IRSs. Other routes included: an email inbox which received 244 events in one year (Chen, McCormack and Heher et al., 2018); specialty-specific reporting forms (Pfoh et al., 2021); hotlines, huddles, and line managers (American Data Network, 2019); and a survey-based tool (Rudolphi, Madiraca and Wheeler, 2019). The IRSs also included good-catch systems (American Data Network, 2019; Cuyuna Regional Medical Center, 2020; Tanz, 2018; The Joint Commission, 2018).

To support and incentivise reporting, leadership engagement and appropriate cultures were felt to be fundamental (The Joint Commission, 2018). Other incentives considered were psychological safety (Jung, Kundu, Edmondson et al., 2021) and feedback. Sudan et al. (2019) found that feedback was positively correlated with reporting, possibly because it made staff more aware or motivated.

As part of the research by Jung et al. (2021), the authors explored the concepts of vulnerability and resilience in PSNMs, and the role of psychological safety in reporting. 'Hits,' 'fortuitous events,' and 'almost

events' are likely to be associated with higher reporting due to increased psychological safety.

6.4.1.3 Responding to reports of near misses

Liszewski (2020) developed a framework for triage of PSNMs using failure modes effects analysis and an analytical hierarchy. PSNMs were scored on likelihood, probability for them to go undetected, and the potential impact if an incident were to happen. Scores were used to identify PSNMs to investigate.

Regarding analysis of PSNMs, Griffey, Schneider, Todorov et al. (2019) developed a taxonomy for categorisation of PSNM reports. The taxonomy uses the National Coordinating Council for Medication Error Reporting and Prevention (2001) taxonomy and has good inter-rater reliability.

Two articles focussed on adapting and applying the Human Factors Analysis and Classification System (HFACS) to radiation oncology and surgical settings, respectively. Judy, Lindsay, Gu et al. (2020) found an analysis could be completed in 8.3 minutes (average) with reasonable agreement amongst staff. Cohen et al. (2018) identified 726 causal factors, mainly associated with preconditions and unsafe acts.

Sharing of learning from PSNMs was again noted to be challenging. Ahn et al. (2019) implemented a quality improvement conference to discuss PSNMs. It was well received by staff who found it educational, therapeutic, and enjoyable.

Following analysis and learning, the literature described various actions. These were mostly weak or intermediate when rated against the Action Hierarchy Tool (appendix 1A). The American Data Network (2019) described a range of actions including policy change (a hard-stop policy for a blood test for all patients receiving an anticoagulant), education (around vancomycin antibiotic management), electronic alerts (auto-notification in electronic records), and changes to communication routes for resuscitation decisions. Other actions included procedures, workflows, and information systems (Chen et al., 2018).

6.4.1.4 Impact of actions following learning from near misses

Some impact of learning from PSNMs was stated without evidence provided (Chen et al., 2018). The American Data Network's (2019) interventions included examples which were described to have led to reduced anticoagulation incidents, however, no evidence was provided to support this claim.

A small number of authors described some evaluation of impact. Goolsarran et al. (2019), following a quality improvement project in MRI imaging, found a reduction in PSNMs from 22 to zero in one year using checking points and alerts. The common cause hypothesis was again referred to (Liszewski, 2020).

Tanz (2018) introduced a good-catch reporting system in response to not learning from PSNMs. They found significant improvements in knowledge, skills, and attitudes in their intervention group and described that the system had improved safety culture. The reporting system itself was the action and there was no evidence provided to support the claims around safety culture.

6.4.2 Additional literature – 2022

Nine academic articles and four grey works were added to the scoping review. They came from a variety of countries, with three from the USA. There were five original research articles, three quantitative non-experimental, one mixed-methods study, and one quality improvement project. There were also three reviews. The articles covered all areas of interest and came from a spread of specialties, seven from the general hospital setting. The academic articles included one publication by the thesis author which had been published as this research progressed (Woodier, Woodier and Moppett, 2022); that article has been included in the nine but will not be included in the following narrative.

The grey works came from the USA (n=2), UK, and Canada. Two reported on good-catch systems, and two were conference abstracts.

Several other good-catch programmes were seen during the search for grey works but were not included as they did not provide new evidence.

The 2022 search identified a scoping review of near-miss research in healthcare (Feng et al., 2022a). Feng et al. (2022a) included 67 articles and found most research had focussed on reporting, the characteristics of PSNMs, and good catches. There had been little research around investigation and outcome evaluation, and the authors concluded that more research is needed to look at how best to guarantee learning from PSNMs.

6.4.2.1 Terminology and definitions

The literature described variation in terms and definitions of PSNMs, as well as other patient safety events. Biro, Rucks, Neyens et al. (2022) considered definitions in anaesthesia and found variation in whether a PSNM is defined as prevented harm or a prevented error. Good catches were again referred to (Montage Health, 2022), with the addition of dental as a care setting with good-catch reporting (Oral Health Group, 2022).

6.4.2.2 Management of near misses

Devin, Cullinan, Looi et al. (2022) developed and validated a retract and reorder tool to quantify prescribing PSNMs. They identified 71 PSNMs across 24,407 orders. Duplicate prescribing was the commonest issue, and none of the events were concurrently reported by prescribers.

A small number of authors considered the further management of PSNMs. Daily briefings were found to be a supportive route for the reporting of PSNMs (Isaksson, Schwarz, Rusner et al., 2022).

Simulation was also found useful to support recognition of hazards (Shaikh, Natale, Till et al., 2022). To further support reporting, Ahmed and Purva (2022) introduced a 'stop the line' initiative¹⁴.

¹⁴ Stop the line – where any member of staff can stop the work until a safety issue is addressed.

To support learning it was suggested that PSNMs should be proactively reviewed through forums (Arnold, Ward and Gandhidasan, 2022). Nguyen, Beidler, Lybarger et al. (2022) also looked to machine learning to see if they could identify high-severity PSNMs in radiation oncology; they thought this has potential. Feng et al. (2022b) specifically considered how organisations learn from PSNMs using the '4I Framework of Organisational Learning.' They concluded that organisational learning behaviour is not conducive to learning due to poor group learning and absorption. There are gaps in learning at individual, group, and organisational levels

6.4.2.3 Impact of actions following learning from near misses

Regarding impact of actions following learning from PSNMs, Smith-Love (2022) updated procedures, fixed faulty equipment, and streamlined processes following learning from PSNMs. They found compliance with the use of barcode scanning for medication administration rose to above 97% and used this as a sign of impact (Smith-Love, 2022).

It was also felt that PSNM to PSI ratios are useful in assessing the culture of reporting and learning in a healthcare organisation (Arnold et al., 2022).

6.5 Conclusions from the scoping review

6.5.1 Reflections on the included literature

The healthcare scoping review included 125 academic articles. Much like Feng et al's (2022a) findings, the majority of the literature was found to consider reporting of PSNMs, with little exploration of how best to investigate, learn from, and evaluate the impact of that learning. This scoping review has provided a more comprehensive coverage of the literature than Feng et al. (2022a) by using broader review questions and including grey works.

6.5.1.1 Comments on the quality of academic articles

A formal assessment of the quality of the articles in this scoping review was not undertaken. However, several limitations of the literature were noted that may undermine the findings:

- There was a paucity of experimental studies, with most research focussed on reporting of PSNMs.
- Definitions for PSNMs were not consistent meaning a PSNM in one article may have been different to another.
- It was often not clear whether actions implemented were the result of PSNMs alone, or whether other PSIs had contributed. Where multiple actions had been implemented, it was unclear which had led to described improvements.
- Conclusions were often drawn of the impact of learning from PSNMs on patient safety without evidence. These included examples where it was assumed that reducing PSNMs meant reductions in harm, even where previous events had not caused harm (e.g. Weiss et al., 2017).

6.5.2 Answering the review questions

The findings of the healthcare scoping review have been used to answer the review questions (6.2.1) in the following sections.

6.5.2.1 What is a near miss?

The review found variation in the terms and definitions used for PSNMs. There is no universally agreed, recognised, and used definition for a PSNM despite World Health Organization (2010) efforts. Regarding terminology, the review found that referring to PSNMs as good catches may be beneficial for reporting. The term good catch creates positive perceptions and may reduce fear. However, it is not clear whether good catches, close calls, and PSNMs are all synonymous.

The review did not provide a consensus as to the features of a PSNM. This lack of agreement may be contributing to the variation in definitions. An intervention may be an important feature of a PSNM.

6.5.2.2 How are near misses managed in healthcare?

The review found limited evidence of established near-miss management systems and processes in healthcare. Instead PSNMs have been studied in relation to specific activities, such as reporting or investigating. There are some examples of specific near-miss programmes, particularly in the USA. However, it is not clear whether those programmes are still operational.

The literature was saturated with consideration of how reporting may be supported, including through safety cultures and design of IRSs. Despite this, under-reporting is a problem. The literature suggests what is needed, such as the right safety culture, but provides limited detail on how to achieve it.

Several articles described interventions that may be beneficial to consider when developing a near-miss management process. These include finding opportunities to identify PSNMs that do not rely on staff reporting, prioritisation of PSNMs for full investigation, the use of taxonomies for categorising reported information, and investigation using qualitative and quantitative approaches.

6.5.2.3 What is the impact of learning from near misses to improve patient safety?

Actions following learning from PSNMs have often focussed on influencing human behaviours, meaning their effectiveness at reliably preventing PSIs is questionable. As per Woodier et al's (2023) publication of elements of this scoping review, 'There is a lack of evidence to date that learning from PSNMs has reduced harm, with assumptions having been made of the link between PSNMs and harmful events...'

Despite limited evidence of impact on patient safety, the literature is positive about the potential benefits of learning from PSNMs. Learning from PSNMs does have evidenced, positive effects on safety cultures.

6.6 Summary

This scoping review has provided an international perspective of the management of PSNMs in healthcare. The literature focusses on reporting of PSNMs, with limited evidence to inform the development of management systems for PSNMs. There is also a lack of evidence that learning from PSNMs leads to improvements in patient safety.

The healthcare literature provides an academic view of the management of PSNMs. To understand the reality of managing PSNMs in English healthcare organisations the qualitative case study (study 2) was undertaken, and findings are presented in the next chapter.

7 Study 2: Near-Miss Management in Healthcare – A Qualitative Case Study

7.1 Introduction

To develop an understanding of the current management of Patient Safety Near Misses (PSNMs) in the English National Health Service (NHS) a Qualitative Case Study (QCS, study 2) was undertaken. This chapter describes the QCS protocol and findings.

7.2 Protocol

Several authors have published templates for QCS (e.g. Ebneyamini and Sadeghi Moghadam, 2018). The templates were reviewed to develop this protocol.

7.2.1 Goal, propositions, and theoretical framework

Definitions of terms used in the QCS goal/objectives are provided in 4.3. This QCS's goal is to formulate an understanding of how PSNMs (phenomena of interest) are managed in English NHS organisations (the cases). The objectives are to understand:

- how organisations define, report, analyse, and learn from PSNMs, and develop actions as a result.
- why PSNMs are reported and how organisations learn from them.
- how PSNMs have impacted on patient safety.

The objectives will provide a view of PSNM management from the perspectives of multiple cases – national bodies (policy and strategy bodies via safety leads) and NHS organisations (via safety leads and frontline reporters).

The draft logic model (5.4.2.4/appendix 5B) will be used as the theoretical framework for the QCS. The draft logic model will help explore the various components of PSNM management.

Propositions are recommended in preparation for QCS (Brereton, Kitchenham, Budgen et al., 2008). The following propositions represent the expectations and beliefs around PSNMs informed by the academic and policy literature (e.g. NHS England, 2015):

- The definition of a PSNM is consistent across the NHS as directed by national policy (National Patient Safety Agency, 2004).
- The management of PSNMs by organisations is a core part of governance processes.
- PSNMs lead to learning and impactful improvements in patient safety, such as reducing Patient Safety Incidents (PSIs) and harm.

7.2.2 Data collection and analysis

Patient safety leads and frontline staff from selected NHS sectors and organisations will be approached. Patient safety leads will provide organisational perspectives, with the hope that frontline staff will provide insights into reporting. The intended sectors are national bodies, acute hospital, mental health, ambulance, and general practice. These represent the main healthcare sectors.

The selection of organisations will be guided by Care Quality Commission (CQC) regulatory rankings for safety. As this research aims to collect evidence to support improvements in the management of PSNMs, high-performing organisations will be approached. For general practices, regional commissioning groups familiar with the performance of practices will be asked to guide selection. Secondary considerations will be size and location of organisations.

7.2.2.1 Sampling

Sampling will be purposive (5.4.2.3). Organisations will be approached via their patient safety teams. Leads for patient safety (participants) will be asked to take part in semi-structured interviews (5.5.1) and to share the questionnaire with frontline staff (5.5.3). The intention is to collect data until theme saturation (5.4.3.2). Further data sources will be field

notes and research memos (5.4.3.3), and policy literature as guided by participants.

7.2.2.2 Analysis

Interviews will be audio recorded with consent and transcribed. Where consent is not obtained for audio recording, thorough notes will be made. All data will be anonymised, collated using NVivo (QRS International, 2022) and stored securely.

Analysis using NVivo will commence following the first interview and will progress alongside data collection. Analysis will follow guidance provided by Braun and Clarke (2006) and use techniques suggested by Yin (2018). The draft logic model will support identification of relationships between activities.

The thesis author will undertake a first coding to identify preliminary themes. These will then be presented to and reviewed by a colleague with experience in patient safety and thematic analysis. Themes will be refined with additional input from the thesis supervisor where required. Findings will also be shared with participants as per 5.4.4.

7.3 Findings – included data sources

7.3.1 Interviews

Data collection took place between April 2019 and March 2020. Participants were approached via patient safety email addresses sourced through healthcare trust websites, or via named general practice managers using the NHS.net email system. Purposive sampling continued until saturation was reached when no new themes were identified; this was agreed with the thesis supervisor. Seventeen interviews were undertaken as per Table 15, six were undertaken face-to-face with field notes made.

Table 15. Participants in the qualitative case study

LFPS – Lead for Patient Safety

Healthcare sector	Organisation	Participant(s)
Acute Hospital (AH)	AH 1 – large, 1,700 beds	LFPS and deputy medical director
	AH 2 – medium, 600 beds	LFPS and lead for medicines safety
	AH 3 – smaller, 400 beds	LFPS
General Practice (GP)	GP 1 – 8,000 patients	LFPS (GP)
	GP 2 – 4,500 patients	LFPS (GP)
	GP 3 – 13,000 patients	LFPS (GP)
	GP 4 – 4,000 patients	LFPS (GP)
	GP 5 – rotational	Academic GP
	GP 6 – 11,000 patients	Practice manager
Mental Health (MH)	MH 1 – inpatient/ outpatient, 9 locations	LFPS and safety manager
	MH 2 – inpatient/ outpatient, 7 locations	LFPS
Ambulance Service (AS)	AS 1 – cover 5 million people	LFPS and safety manager
	AS 2 – helicopter service	LFPS
Clinical Commissioning Groups (CCG)	CCG 1 – primary care	LFPS
	CCG 2 – secondary care	LFPS
National Bodies (NB)	NB 1 – anonymised	Policy lead
	NB 2 – anonymised	Policy lead

7.3.2 Other data sources

Other data sources included national, regional, and local policy, guidance documents, and questionnaire data. Twenty-eight documents were included. Two of the acute hospitals (AH 1 and AH 2) gave

consent for the questionnaire to be distributed to staff. Twenty-six staff responded who were pharmacists (n=19), pharmacy technicians (n=6), and unknown (n=1).

7.4 Findings – summary of the analysis

Coding occurred in three stages with initial, expanded, and rationalised/final (appendix 7A) codes developed. Final coding informed the summary in the following sections and sample quotes are provided. Qualitative questionnaire responses contributed to the coding and a summary of the quantitative responses is shown in appendix 7B. A visual representation of the findings is presented in the logic model format in appendix 7C.

7.4.1 Inputs

Inputs were what was invested into or required for a PSNM programme.

7.4.1.1 The near miss

Terminology

The term 'near miss' was used by all participants and organisations. Several had heard of 'close calls' and 'good catches,' and questioned whether these were more appropriate terms. Nationally it was described that PSNMs are termed "prevented patient safety incidents" and:

"We have tried to move away from the term 'near miss' and would now refer to these incidents as 'no-harm' incidents..." NB2

This national perspective was shared with participants, but none were aware of the move away from the term near miss. Participants challenged why current national policy documents still refer to near misses (NHS England, 2015). Participants thought it important to differentiate PSNMs and no-harm PSIs as their learning is different.

Definitions

All participants provided examples of what they perceived to be a PSNM. Most were medication related; this may have been due to the high-response rate from pharmacists.

“Patient had haloperidol subcut[aneous] prescribed, the nurse drew up oral... realised what she had done and stopped it.” AH2

The majority of participants did not know of a standard definition for a PSNM. Local policies often defined a PSNM, but definitions were not able to be recited. Participants were asked to provide their own definitions and 30 were collected. These demonstrated differences in perceptions about whether a PSNM is a PSI, the proximity of events to a patient, and the potential for harm.

The different perceptions of a PSNM were further demonstrated by the response to the definition question (5.5.2.1). Fourteen participants answered the question (appendix 7D). Fleiss Kappa showed perfect agreement amongst participants that scenario one was an incident ($\kappa=1.00$, 95% CI [0.88, 1.00]); fair agreement for scenario two as an incident (n=9) or near miss (n=5) ($\kappa=0.26$, 95% CI [0.14 to 0.38]); fair agreement for scenario three as a near miss (n=10) ($\kappa=0.29$, 95% CI [0.17, 0.41]); and slight agreement for scenario four as an incident (n=1), near miss (n=7), or non-event (n=6) ($\kappa=0.09$, 95% CI [0.00 to 0.21]).

Features

Participants did not agree on the features of a PSNM. Several felt that a PSI had to happen at some point for there to be a PSNM. This led to debate about whether a PSNM always includes 1) an incident, and 2) a near-miss outcome.

‘... prescribed potentially lethal overdose of a medicine is caught and stopped... 'near-miss' as no harm, but... if the fail point is considered as the lethal dose prescribed... then that could be considered an incident...’ Questionnaire – Anonymous

Participants discussed recoveries (also termed interventions or interceptions) when referring to PSNMs. These commonly involved staff being vigilant and stopping a PSI. A small number of participants discussed recoveries in terms of controls and barriers. Where something had been built to 'catch errors,' this was thought to be a system and its controls working well.

“You could argue it is the [prescribing system] doing its job... Is it a near miss because the doctor shouldn't be prescribing anything the patient is allergic to.” AH3

Several participants also felt that an event could be a PSNM even if it had reached the patient and/or caused harm. Some felt that where the amount of harm to a patient had been reduced, this could be a PSNM.

There was further debate about the language used in the definition of a PSNM and whether they were events that 'could have,' 'potentially,' or 'almost' happened. All participants described the need for a clear definition to help detection and reporting.

7.4.1.2 Near-miss reporting system

Local reporting systems

All participants described local routes for reporting PSNMs. Within acute hospitals, mental health, and ambulance services reporting was via electronic Incident Reporting Systems (IRSs). This meant PSNMs were reported via the same forms as PSIs. The IRSs allowed online reporting via internal websites, and in some cases an app. In primary care reporting was sometimes paper based.

Participants described their experiences of using IRSs for PSNMs. Experiences highlighted poor availability, accessibility, and usability. Sometimes participants could not find a computer to report via. The ambulance service, being mobile, had developed access to their IRS via portable tablets and an app. The app had some implementation issues due to poor internet connectivity.

Usability referred to the ease and comfort with which IRSs were used. Participants described how problems affected efficiency, created errors, and required relying on memory. Reporting was felt to be slow.

“The more cumbersome the reporting mechanism, the less likely people are to share... you really think that wasn't really nearly missed.” GP5

Errors resulted from filling in IRS forms incorrectly because of not knowing what information to enter. This was exacerbated by multiple drop-down boxes and the need to remember details such as the lead for PSIs. The evolution of IRSs had also made reporting increasingly complicated.

“... you add bits on, but I think we got to the situation where lots of things had been put on, so we could capture everything, but actually that would just make more of a barrier...” AH1

Some participants wanted bespoke PSNM reporting forms. One participant also reflected on the differences between paper reporting and electronic; electronic systems were not thought to be simpler or easier to use, rather they just created an “illusion of being less” (MH 1).

Regional and national reporting

Secondary care organisations with electronic IRSs uploaded their PSIs and PSNMs to the National Reporting and Learning System (NRLS, 2.5.1), managed by NHS England. This allowed national aggregation of learning. However, it was heard from several participants at local and national levels that the NRLS “pools” learning from PSNMs and PSIs together.

The general practices did not upload their PSIs or PSNMs to the NRLS. This was because they had not been encouraged to do so, and because paper and some electronic systems were not compatible with the NRLS. Some practices did share their PSIs with their commissioners, but not all:

“I can't think of any near misses that we have reported externally... However, I'm not sure how seriously they would take it even if you did that...” GP6

One participant highlighted the Confidential Reporting System in Surgery (CORESS). CORESS is run by an independent charity for confidential reports by surgeons and theatre staff (CORESS, 2021). CORESS receives PSNMs and PSIs, and shares learning via publications. The participant had not reported to CORESS.

7.4.1.3 Prompts for reporting

Participants described factors that prompted or inhibited reporting of PSNMs. These included the near miss itself, cues, workplace factors, and national prompts.

The near miss itself

The variation in how PSNMs were perceived was felt to impact on their identification and reporting. Staff may not know when a PSNM has happened, or not associate a “positive outcome” with the need to report. Participants also described that it was common for an event to be reported as a PSNM when it was actually a PSI.

The difficulty identifying PSNMs was further demonstrated by one participant where, because no one could agree, they had removed them from teaching:

“I used to train on near misses, but I have given up now because every time I have tried to train on it, somebody in the audience will say no it is not a near miss, it is an incident...” AH3

Participants described how the features of a PSNM do not encourage reporting. As no harm is caused, they are quickly moved on from. Some participants felt that PSNMs did not require reporting if they had been dealt with.

It was widely felt that healthcare focusses on harm, and the more significant the harm, the more likely it is to get organisational interest. Many PSNMs and no/low-harm PSIs will not gain attention.

Cues and workplace factors

Various cues to report PSNMs were described. These included pressure from colleagues, feeling responsible, local safety priorities, encouraging leadership, training, evidence of impact and learning, and the need to report for appraisals. Local prioritisation of PSNMs was felt to be a significant supporter of reporting. Regarding training, most participants described no training on the reporting of PSNMs and some organisations did not include them in induction or mandatory training.

The lack of training was described as “self-perpetuating.” Without training, PSNMs were thought to be unlikely to be reported, but without reporting they could not be included in training. Training relied on individuals.

“... when I previously worked in governance, we had more of a focus... I was doing education sessions with staff to help them understand...” AH2

Other workplace factors influencing reporting included competing demands on staff, and resources to support staff to report and learn.

“... staff are drowning... They will look at the harm, but they won't input the near misses.” MH1

All organisations had policies for the reporting of PSIs. The majority also included the need to report PSNMs. However, none included specific detail on PSNM management and their features. General practices were less likely to have a policy outlining what to do with PSNMs.

National prompts

Participants described limited national direction on the management of PSNMs, with minimal prioritisation or encouragement. There were felt to be “mixed messages” from the Care Quality Commission (CQC), General Medical Council, NHS England, and professional bodies. For example, the CQC specifically mentions near misses in their key lines of enquiry (Care Quality Commission, 2022a), but other bodies and

publications do not (e.g. NHS England, 2021c). Priorities were felt to be “misplaced,” particularly in general practice where the focus was thought to be on performance.

7.4.1.4 Safety culture

Participants felt safety culture was a key factor in the reporting of and learning from PSNMs. However, current safety cultures were seen as a barrier, and organisations were focussed on priorities other than safety.

“... don't think there is a culture of reporting near misses, and I doubt that we vary very much from the national situation.” AH2

A fear of blame was described across the sectors. Blame came from organisations and colleagues who may see reporters as ‘tell-tales.’ Fear had been enhanced by cases in the media.

“... I think it's because of big national cases... there is some potential harm from talking openly and talking about near misses...” GP5

No-blame and just cultures were discussed. These were seen as important in the management of PSNMs and PSIs, but participants did not clarify whether a no-blame or just culture was preferential. Some participants saw them as the same thing. A key component of any culture was thought to be engaged leadership.

“We have got a very hands-on director of nursing who will go down to areas...” AH1

In general practice, because of small and often long-serving teams, open learning cultures were felt to be easier to develop.

“... we all know each other well; we support each other when we have difficult incidents... we have a very supportive culture.” GP2

However, a repeated concern about general practice (from outside of general practice) was that it had a limited focus on learning from PSNMs and PSIs.

Local safety cultures

In response to the culture question (5.5.2.2), for general safety culture, 13 participants responded¹⁵ with a median value of 4.0 (proactive) (IQR 3.0 – 4.0). For PSNMs, 12 participants responded with a median value of 2.0 (reactive) (IQR 1.8 – 2.0). Two organisations (one ambulance and one mental health) described their cultures as pathological. Three organisations described their cultures as generative in general (GP and mental health) and for PSNMs (GP). Full results are available in the appendix (7E/7F).

Twenty-six staff responded to the questionnaire's question around general organisational safety culture. Responses showed a median value of 4.0 (proactive) (IQR 3.0 – 4.0) (appendix 7B/F). Questionnaire responses represented two acute hospital trusts and were specifically from pharmacy. Questionnaire responses were more positive about safety cultures when compared with the QCS participant responses above. This may be indicative of differences in safety cultures between different specialties which has been identified in the literature (Sirriyeh, Lawton, Armitage et al., 2012). The questionnaire did not ask responders to comment on local PSNM safety cultures.

7.4.2 Activities

Activities were what staff did as part of a PSNM programme to meet its goals.

7.4.2.1 Reporting a near miss

All participants described under-reporting of PSNMs. Nursing staff and pharmacists were felt to be the staff most likely to report. It was speculated by participants that other groups may not see reporting as their responsibility.

PSNMs were mostly reported through IRSs. Other routes included case-note reviews, documentation in clinical notes, email or direct

¹⁵ Response options – 1.0 (pathological), 2.0 (reactive), 3.0 (bureaucratic), 4.0 (proactive), and 5.0 (generative).

communication to a line manager, and discussion at safety huddles¹⁶. Safety huddles were felt to be useful but were not widely used.

Where PSNMs were reported outside of IRSs, reports were rarely included in an organisation's PSNM rates as they were separate. For example, dispensing PSNMs in some pharmacies were reported via forms, but were not entered into hospital IRSs:

“... if our checker in the dispensary found something wrong with the prescription, we would class that as a near miss and we would report it on a different system.” AH3

7.4.2.2 Analysis of near misses

Investigation processes

No organisation had a specific process for managing and investigating PSNMs. They were managed through the same processes as PSIs, with limited or no local review/analysis.

“... in all honesty [near misses] join the list of overdue incidents for closure because our attention is drawn to the ambers and the reds...” MH1

Even when looked at, the reported PSNMs were often not found to be near misses according to local views and definitions.

Analysis of a PSNM was often left to the manager overseeing the area where it had occurred. In general practice it was the responsibility of the governance lead doctor. Being locally investigated led some participants to question the quality and independence of investigations.

Participants described how the depth of any investigation is based on the severity of the events. Harm drives investigations and escalation of events. One participant shared a risk matrix used when reviewing PSIs and PSNMs:

¹⁶ Safety huddles – short multidisciplinary team meetings where key messages are discussed.

“... anything that they think might be a near miss or might need escalation, we have got a matrix for it. It gets sent through to our senior incident central team...” AS2

Analysis methods

Participants described various analysis methods and tools used by their organisations and investigators for PSIs. These included Root Cause Analysis (RCA), the Systems Engineering Initiative for Patient Safety (SEIPS), Accimaps, and fishbone diagrams. No specific methods/tools were used for PSNMs, instead relying on whatever was available in a local IRS. For example, one IRS included tick boxes for contributory factors, but these were described as “superficial.” In primary care, Significant Event Analysis¹⁷ (SEA) was used for all incidents and PSNMs.

“[SEA]: a simple template, date, time, who was involved, what happened... there is another page that talks about the outcomes, actions required, and what happens next.” GP5

Some participants thought that categorising PSNMs might be useful to look for trends in themes, but this was not widely done.

“We sometimes would pick out some themes, so if we have had a couple in this area, then let’s look at that...” AH1

Categorising PSNMs was more established for medication incidents when supported by a medicine safety officer. General practices also described categorising PSNMs, but only had a small number of SEAs per year to theme.

7.4.2.3 Sharing learning from analysis

Feedback

Participants described little or no feedback to staff following reporting of PSIs, let alone PSNMs; this was despite the stated expectation in policies. One participant described efforts to improve feedback, but only

¹⁷ Significant Event Analysis (SEA) – the structured analysis of a significant event in general practice (Royal College of General Practice, n.d.).

for more “significant” safety events. For no/low-harm incidents, feedback would likely only be an automated ‘thank you for reporting’ email where an electronic IRS was used.

Wider sharing of learning

All organisations found it difficult to share learning from PSIs and PSNMs with their staff. The best way to share learning was not known and organisations commonly used emails. Other sharing methods included internal meetings, newsletters, intranet or social media, posters, mandatory training, and safety huddles.

“There are a variety of methods and that will change depending on what it is you are trying to share. There are the usual trust-wide emails... we have [safety huddles] in the morning...” AH3

Wider sharing beyond organisations was limited or absent. Most national sharing was via the NRLS except for general practices. However, no learning outputs from the NRLS around PSNMs had been seen by participants. The ambulance service did have a safety group, but the participants were not sure whether PSNMs were discussed. Regionally, one CCG was attempting to share learning from general practice SEAs.

Benefits of sharing learning and feedback

Participants debated the benefits of feedback. The majority saw potential benefits, but some challenged whether it was just another email to read. Frontline staff described limited time to access emails or read bulletins. However, it was thought that sharing learning increased reporting.

It was noted that learning needed to be specific and relevant. Sharing beyond an organisation needed to consider context and ability to translate learning.

“Whether there is merit in sharing that wider with healthcare services is up for debate... sometimes our learning will translate across and sometimes it is quite bespoke...” AH2

Nationally there was a belief that organisations were learning from PSNMs, but this was not evidenced in the QCS. Reporting was conflated with learning.

“... we would assume that many organisations are learning effectively from no-harm incidents as thousands are reported...” NB2

7.4.3 Outputs, outcomes, and impact

Outputs were the products of a PSNM programme resulting from the activities. Outcomes were the changes seen because of the outputs. Impacts were the results of those changes, such as improved safety.

7.4.3.1 Outputs

Outputs were the number of PSNMs reported. Most participants were unable to provide a number of reported PSNMs in their organisations. They thought numbers were small because of under-reporting. Some examples were:

- 200 PSNMs amongst 24,000 incidents (0.8%) in one year (AH 1).
- 3,840 PSNMs amongst 46,000 incidents (8%) in one year (MH 2).
- 3 PSNMs amongst 16 SEAs (19%) in one year (GP 3).

The questionnaire responses provided some insights into PSNM reporting practices of pharmacists. Twenty pharmacists responded to the question ‘how many have you reported in the past one month’ with 16 reporting zero PSNMs ($M=1.25$, $SD=2.74$). Eighteen pharmacists responded to the question ‘how many have you reported in the past one year’ with 15 reporting at least one PSNM ($M=9.78$, $SD=22.87$). Five pharmacy technicians responded to the questions for one month ($M=4.4$, $SD=2.58$) and one year ($M=24.4$, $SD=15.67$). While a smaller sample, technicians reported more PSNMs. The technicians were

based in a dispensary which was known to have its own specific process for reporting PSNMs as per 7.4.2.1. The questionnaire responses are unlikely representative of wider healthcare settings due to the specific nature of pharmacy and known higher reporting (Patterson and Pace, 2016; Traynor, 2015).

7.4.3.2 Outcomes

Outcomes referred to the organisational actions undertaken following learning from a PSNM. Participants described several actions, but it was not possible to clarify whether actions were the result of PSNMs, PSIs, or a combination. Despite some actions, one frontline participant described 'nothing seemed to change.'

The actions were categorised using the Hierarchy of Controls (Figure 2) and the Action Hierarchy Tool (appendix 1A). Actions commonly aimed to administrate for safety, meaning staff were directed how to work safely through policies, or processes were updated with extra checks. Few actions aimed to engineer the workplace to reduce the chance of future PSIs, such as:

'Similar sounding drugs have been physically separated in the dispensaries.' Questionnaire – Pharmacist

There were no actions that would have eliminated or substituted a hazard to reduce the potential for a PSI to occur. Most actions were intermediate or weak as per the Action Hierarchy Tool.

Implementing effective actions was felt to be challenging. Factors affecting implementation included the need for collaboration, limited visibility of small changes to a workforce, and limited infrastructure to bring about change. General practices thought changes would be easier in hospitals because of resources, however, hospitals described that bureaucracy made change difficult.

7.4.3.3 Impact

Participants spoke of perceived impact following actions but provided no formal evidence. There was a widely held belief that learning from

PSNMs reduced PSIs and harm, improved safety cultures, and changed staff behaviours.

“No, no evidence, but I hope and I'm fairly certain that it has prevented future things happening...” GP6

Participants thought impact may be more apparent in areas such as pharmacy and radiotherapy. Other perceived benefits of learning from PSNMs included their role in appraisals, assurance for external auditors and regulators, and their use to improve staff health and safety.

Participants noted that measurement of safety improvements following learning from PSNMs was difficult. It may be subtle, as:

“... there is lots of incremental changes, they are not necessarily easily seen, or the impact is not easily felt by staff in an isolated area.” AH2

Participants agreed that impactful change is more likely to occur from investigating and learning from PSIs and harm, rather than PSNMs.

‘I am struggling to think of changes which have just happened due to near misses. Most were in response to an error... following both near misses and actual incidents...’ Questionnaire – Pharmacist

Some participants also thought that PSNMs may have a negative impact by increasing workload, damaging reputations, and through highlighting risks that organisations have no ability to manage.

7.4.4 Assumptions

A logic model encourages consideration of assumptions made during its development. During the QCS, two assumptions became evident from participants:

1. PSNMs and incidents have the same contributing factors:

“My limited understanding is that for X near misses, a more significant event will happen. Therefore we should have a focus or responsibility to look at near misses in the system to prevent worse things happening.” AH2

2. Learning from PSNMs will improve patient safety:

“...I'm fairly certain that it has prevented future things happening.”
GP6

7.4.5 Other themes

Several other themes emerged from the QCS. In particular, participants compared healthcare and Safety-Critical Industries (SCIs). There were concerns about attempting to translate learning from SCIs to healthcare around management of PSNMs. The industries were felt to be different, with views that healthcare is more complex than many industries because of its unpredictable nature and limited ability to integrate technology.

“Everyone says we need to take lessons from all these other places. How easily those lessons are adapted to a healthcare situation is another matter, and whether you can compare apples and pears, I don't know.” AH3

7.5 Improving management of near misses in healthcare

Participants described what they felt was needed to improve PSNM management. Responses were themed and related to:

- **Existential** – whether a focus on PSNMs is appropriate. The goal of reporting PSNMs needs clarifying, as does the definition of a PSNM.
- **Process** – leadership is needed to prioritise and champion PSNMs, with the development of appropriate safety cultures. Anonymity may be advantageous but should be balanced with accountability. Any process should include feedback and sharing of learning to highlight the actions made because of someone's report.
- **Infrastructure** – specific training and incentives are needed, with better designed IRSs. IRSs should have specific functionality for PSNMs.

7.6 Conclusions

The QCS findings suggest limited or absent PSNM management processes in NHS organisations. No formal processes or programmes were identified, with limited attention to PSNMs and their learning potential. Participants described challenges defining, identifying, reporting, analysing, and learning from PSNMs. As a result no formal evidence was able to be shared of where learning had led to improvements in patient safety.

The propositions around PSNMs, stated in 7.2.1, were not supported by the QCS: the definition of a PSNM is not consistent; management of PSNMs is not a core part of NHS safety management; and there is limited evidence of impactful improvements in patient safety following learning from PSNMs. The QCS also found issues with safety cultures across the NHS that are not always supportive of reporting and learning.

7.6.1 Ensuring rigour

To ensure the credibility of the QCS findings, a rigorous methodology was followed. The study protocol was reviewed in line with Höst and Runeson's (2007) checklist. The multiple cases and sources of data were felt to provide a broad view of different contexts in the NHS and allow triangulation and generalisation of findings. Furthermore, a theoretical framework (the draft logic model) was used to support analysis, research memos were made to track the analysis, and participants were asked to review draft findings.

7.6.1.1 Participant verification

Participant verification occurred as described in 5.4.4. Twenty-five participants were contacted to provide verification. Five participants responded representing acute hospitals (n=2), primary care (n=2), and mental health (n=1). Further opportunities to share and verify findings arose during the course of the research including presentations at various conferences and events (see list of presentations).

Free-text responses from participants verified the findings of the QCS. The findings were described as “very comprehensive.” There were examples of where the findings had prompted consideration of local processes around PSNMs:

‘I feel challenged to think about our identification and analysis of near misses for learning beyond the odd near-miss SI [serious incident].’

One participant from mental health challenged the finding around staff recognition of near misses; they felt their staff did not ‘have any problems understanding what a near miss is.’ However, other participants felt that limited understanding was a significant issue.

Participant verification confirmed the concerns about whether safety learning is translatable from SCIs to healthcare. However, all agreed that healthcare needed to be more proactive with its approach to safety.

7.7 Summary

The QCS found that NHS organisations are often not effectively learning from PSNMs. While the QCS considered a small sample of organisations, saturation in the findings was reached. Alongside the scoping review (study 1) findings in chapter 6, the QCS findings demonstrate the limitations in PSNM management in healthcare.

As per the aim of this research, there is a need to look beyond healthcare to understand how best to manage and learn from PSNMs. The next chapter will provide the findings from the scoping review of the SCI literature (study 3) in relation to how those industries manage near misses.

8 Study 3: Learning from Near Misses in Non-Healthcare Industries – A Scoping Review

8.1 Introduction

The healthcare scoping review (study 1) and Qualitative Case Study (QCS, study 2) demonstrate that healthcare has yet to establish effective near-miss management systems. As per the protocol in 6.2, the scoping review was broadened to explore how Safety-Critical Industries (SCIs) manage and learn from near misses (study 3). This chapter describes the findings from the SCI literature.

8.2 Scoping review – safety-critical industry findings

The appendix provides the PRISMA summaries (6C/8A), frequency counts of relevant literature characteristics (8B) with a diagrammatic representation (8C), and a table of the final included SCI scoping review academic articles 2000 to 2022 (8D). Rejected articles are available via the supplementary materials link.

8.2.1 Summary of the literature – 2000 to May 2018

The scoping review included 84 academic articles. Of these, 50 pertained to near misses alone with the rest including other event types. Stage-two searches identified 53 articles, with the rest from stage-three searches.

The articles included 66 original research, with the rest being opinion (n=10), reviews (n=4), and book chapters (n=4). Of the original research articles, 38 used quantitative methodologies and all were non-experimental. Several included correlational or probability components. There were 17 qualitative and 11 mixed-methods studies.

The majority of articles were published in the United States of America (USA) (n=41), with 50 articles published since 2010. Articles commonly

considered analysis of or learning from near misses, and then reporting or impact. The SCIs varied but were most commonly 'processing' which included chemical and oil and gas (n=25). Other more common SCIs were rail (n=12), maritime (n=12), and where several SCIs were referred to in one article (n=10). There were fewer articles involving SCIs such as aviation and nuclear.

The scoping review included 160 grey works. Of these, 84 were specific to near misses alone, and 43 originated from the stage-two search. They predominantly originated in the USA (n=64) and focussed on reporting and analysis. There were also multiple works from the UK (n=49). The sources included legislation/policy/guidance (n=39), conference abstracts or presentations (n=39), technical reports (n=26), and non-academic articles (n=26). The SCIs were most commonly aviation (n=40), maritime (n=26), rail (n=23), and processing (n=22).

8.2.2 Terminology and definitions of near misses

8.2.2.1 Terminology

'Near miss' was the commonest term used across the literature (in 62 academic articles). This was despite the term being seen as pejorative (Lochbaum, 2015). 'Close call' was also used (e.g. Bliss, Rice, Hunt et al., 2014; Figures-Esteban, Hughes and Gulijk, 2017, Network Rail 2018a; 2018b). Other rarely used terms included 'lucky catches' and 'diving saves' (Colwell, 2002), and 'near hits' (Wallace, 2000).

The literature debated whether near misses are synonymous with close calls. Some authors felt they are synonymous (Sheridan, Cardosi and Hannon, 2004; Shimazoe and Burton, 2013). However others thought differently. Gnoni and Saleh (2017), for example, described a close call as the cause behind a near miss.

The term 'precursor' was also used, particularly in nuclear and space. Smith and Borgonovo (2007) defined precursor events as 'sequential decision problems under uncertainty with an initiating event that may require diagnosis and action to control the progression of the incident

and not to let the sequence reach the worst consequence.’ There were again some views that precursors are synonymous with near misses (e.g. Corcoran, 2004; Pariyani, Seider, Oktem et al., 2010; Wullems, Toft and Dell, 2013), while others thought they are different (International Atomic Energy Agency, 2012). A near miss could be an immediate precursor to an incident (Saleh, Saltmarsh, Favarò et al., 2014). If there is a difference between a precursor and a near miss, then it may be difficult to describe (Gnoni and Saleh, 2017).

The literature demonstrated how SCIs use their own terms for some near-miss type events. These include aviation’s ‘Airproxes’ (UK Airprox Board, 2016), maritime’s ‘near groundings’ (Mazaheri, Motewka, Nisula et al., 2015), and rail’s ‘Signals Passed At Danger’ (SPAD) (Office of Rail and Road, 2022).

8.2.2.2 Definitions

The literature described near misses as either SCI-specific (examples in Table 16), or more generic, such as health and safety (Health and Safety Executive, 2021). A table summarising the various definitions identified during the scoping review is available via the supplementary materials link.

The literature demonstrated inconsistencies in the broad definitions of near misses across several SCIs. Inconsistencies were seen in chemical processing (Cavalieri and Ghislandi., 2010; Phimister, Oktem, Kleindorfer et al., 2003), maritime (Rudan, Komadina and Ivče, 2012), nuclear (Nuclear Institute, 2015), and rail (Wullems et al., 2013).

Table 16. Context specific near-miss examples

Industry	Example	Source
Aviation – near loss of an aircraft	‘A situation in which, in the opinion of a pilot or a controller, the distance between aircraft, as well as their relative positions and speed, was such that the safety of the aircraft involved was, or may have been, compromised.’	UK Airprox Board, 2016

Chemical processing – near release of a chemical	‘Any pressure relief device which opens due to an actual overpressure... it could be argued a physical explosion would have occurred, but for the operation of the relief device.’	Wincek, 2016
Fire – near injury to firefighters	‘When on the scene of a fast-moving fire, it’s natural for firefighters to focus on the tasks at hand. In this instance, overlooking the downed power line was easy because of the vegetation.’	International Association of Fire Chiefs, 2018
Maritime – near collision of vessels	‘... ships come into such close proximity to another vessel or a structure that there is a possibility of damage.’	Royal Navy, 2017
Nuclear – near release of radioactive material	‘During a routine changeover of a reactor auxiliary cooling water pump, operators inadvertently started to close the wrong pump discharge valve.’	International Atomic Energy Agency, 2012
Rail – near collision between stock and another	‘... an unsafe event or act specifically involving a Train or On Track Machinery or On Track plant.’	Network Rail, 2017
Space – near loss of a module or crew	‘... the Apollo 12 rocket was struck by lightning during launch. As a result, the crew module’s instruments went offline, cutting off telemetry to the ground.’	Barr, 2010

Clarifying a definition

Authors debated how best to define a near miss. Considerations were given to broadness of a definition, the role of interventions, and how language influenced perceptions. Authors had differing views about whether broad/generic or narrow/context-specific definitions are needed. Advocates for broad definitions stated benefits such as ensuring nothing is missed and to collect large data sets (Fabiano and

Currò, 2012; Gnoni and Saleh, 2017; Phimister et al., 2003). To support reporting, authors suggested encouraging staff to report 'any situation which may need improvement' (Cavaliere and Ghislandi, 2010).

The advocates for context-specific definitions felt they support reporting through their focus, with examples of lists of near misses available in chemical (Center for Chemical Process Safety, 2003; Nesmith, Keating and Zacharias, 2013), fire (Jobush, 2005), and nuclear (International Atomic Energy Agency, 2012; 2020).

The definitions, whether broad or narrow, often included an intervention to prevent progression of events. There was some debate around 'how close' the intervention needs to be for events to be a near miss (Sheridan et al., 2004).

Regarding interpretation of definitions, Tinsley, Dillon and Cronin (2012) defined two types of near miss – the 'vulnerable' (something almost happened) and the 'resilient' (something was avoided). They described danger in seeing near misses as resilient as this may inhibit responses to future, similar situations, and result in riskier decisions (Dillon, Tinsley and Burns, 2014; Dillon and Madsen, 2011; Tinsley et al., 2012). For example, a person who survives a hurricane may be less willing to evacuate in the future (Dillon and Tinsley, 2008). Similarly, if near misses are seen as false alarms, it may reduce willingness to respond in the future (Barnes, Grunfest, Hayden et al., 2007).

To combat the resilient view of near misses, Dillon and Tinsley (2008) suggested viewing systems as vulnerable. This can be done by sharing narratives around near misses and vulnerabilities (Dillon, Tinsley and Cronin, 2011; Tinsley and Dillon-Merrill, 2005).

Choosing a definition(s)

The literature did not conclude as to whether a single broad, or multiple narrow/specific definitions for a near miss are required. Whatever the definition or definitions chosen, they need to avoid defining away the near miss (Tamuz, 2004) and be well-communicated (Ritwik, 2002).

An alternative to the broad versus narrow debate is to consider different categories of near miss. Bliss et al. (2014) defined six types of close calls and described that learning could be undermined if they are misinterpreted. For example:

- **Signalled close call** – emergency signal is activated (it may be set too sensitive) indicating imminent danger which does not occur.
- **Unsignalled close call** – no signal is activated (it may be set too conservative), or the signal is not detected by an operator, no consequence occurs.

8.2.3 Reporting

8.2.3.1 Detection

The literature described systems to support detection of near misses. In maritime the use of Automatic Identification Systems (AIS) supports automated and semi-automated detection of proximity and collision risk (e.g. Kim, Jeong and Lee, 2017; Kim and Jeong, 2016; Szłapczyński and Niksa-Rynkiewicz, 2018). The use of AIS is limited because of no international definition of a maritime near-miss collision (e.g. Goerlandt, Montewka, Lammi et al., 2012; Chang, Yeh, Peng et al., 2015; van Iperen, 2012; van Westrenen and Ellerbroek, 2017). AIS data and the use of ‘fuzzy’ rules¹⁸ have potential to detect real-time critical proximity situations (Zhang, Goerlandt, Kujala et al., 2016).

Other automated systems seen included those that monitored, controlled, and changed systems to bring processes back to normal operating; these were seen in chemical processing (Oktem, Pariyani, Seider et al., 2013), aviation (Brooker, 2005), nuclear (Boafo, Nasimi, Zhang et al., 2017; Wincek, 2016), and rail (Aminmansour, Maire and Wullems, 2014a, 2014b).

The literature also described proactive identification of potential near-miss points in processes using performance data (Saks, Multer and

¹⁸ Fuzzy logic – the relationship between inputs and outputs that are not precise.

Blythe, 2004) and simulation. Simulation has been used in nuclear to identify faulty system states (Di Maio, Vagnoli and Zio, 2015; Di Maio, Rossetti and Zio, 2017), aviation to consider human reliability (Kirwan, Gibson and Hickling, 2008), and oil and gas to identify failure modes (Youngblood and Duffey, 2015). Real-world research was also undertaken by Keillor, Ellis, Craig et al. (2011) by flying helicopters near each other to explore how pilots responded.

8.2.3.2 Reporting systems

Various Incident Reporting Systems (IRSs) were described in the literature, several specific to near misses. A table summarising the IRSs identified during the scoping review is available via the supplementary materials link. IRSs exist at company, national, and multinational level. Some are specific to near misses, while others include all types of events. Some are confidential, while others are anonymous. In UK civil aviation, for example, the following IRSs were identified:

- **Company** – company-owned IRSs, such as the British Airways' Safety Information System (BASIS) (SkyBrary, 2017).
- **National (UK)** – The Civil Aviation Authority (CAA) receives mandatory occurrence reports from companies via a standard form (Civil Aviation Authority, 2016).
- **National (UK)** – The 'Confidential Human Factors Incident Reporting Programme' (CHIRP) is a voluntary and confidential reporting system (CHIRP, 2018).
- **National (UK)** – the UK Airprox Board receives reports of Airproxes (UK Airprox Board, 2016).
- **Multinational (Europe)** – the European Co-ordination Center for Accident and Incident Reporting System (ECCAIRS) is a digital platform for central reporting of mandatory incident reports at European level (ECCAIRS, 2020).

Some authors described examples of IRSs specifically for near misses, including the US National Fire Fighter Near-Miss Reporting System (NFFNMRS). The NFFNMRS collects and shares firefighter near-miss

experiences (International Association of Fire Chiefs, 2018), is confidential, and can be anonymous. It uses an online form with free text and selections. Two questions are mandated – event description and lessons learned.

8.2.3.3 Supporting reporting of near misses

The literature described interventions used by SCIs to support reporting of near misses. These are summarised in Table 17.

Table 17. Interventions to support reporting of near misses in safety-critical industries

Further citations available via the supplementary materials link

Intervention	Description	Sources (e.g.)
Leadership support	Organisational leaders at all levels encourage reporting and support an appropriate culture.	Lappalainen et al., 2011; Phimister et al., 2003; Ritwik, 2002
Promotion and engagement	Involving staff in developing definitions and systems. Incentivise programmes. Provide education on reporting.	Nesmith et al., 2013; Storgård et al., 2012; Taylor and Lacovara, 2015
Safety culture and protection	Remove the fear of blame in the culture, with openness and positivity.	Harrison, 2015; McSweeney et al., 2013; Rasmussen et al., 2013;
Clarifying definitions	Staff can be involved in developing definitions and examples.	Clancy, 2011
Provide feedback	Provide feedback on the results of reports and outcomes.	International Atomic Energy Agency, 2012; Kanse and van der Schaaf, 2001; Madsen et al., 2016

Reporting infrastructure	Develop automatic detection, multiple routes for reporting, easy access, and appropriate questions. Fast internet.	Davies et al., 2000; Multer et al., 2013; Pope and Orr, 2017
Resource	Programmes for near misses need time and money resource.	Ritwik, 2002

Implementation programmes, organisational support, and resources were noted to be important when introducing near-miss reporting systems. Without these, implementation was found to be challenging (Multer, Ranney, Hile et al., 2013; Raslear, Ranney and Multer, 2008), and it is difficult to sustain programmes (Kerrigan, 2015).

The use of incentives or rewards to support reporting was contentious. Some authors felt rewards give the wrong signals to staff (Storgård, Erdogan, Lappalainen et al., 2012) and may lead to risk amplification (International Maritime Organisation, 2006a). However, several companies use incentives, for example, Ganymede (2018) incentivise reporting with donations to the Samaritans and a quarterly award to staff with a voucher for the best report.

Reporting of near misses in SCIs was described to be supported by legislation, regulation, policy, and guidance (further citations available via the supplementary materials link). For example, in civil aviation, mandatory reporting is directed by International (International Civil Aviation Organisation, 2016), European (Regulation (EU) 376/2014), and UK (Civil Aviation Authority, 2016) regulations. The CAA also encourages voluntary reporting of other occurrences (Civil Aviation Authority, 2016).

Accessibility and functionality

Accessibility and functionality of IRSs were referred to as significant influencers on the reporting of near misses. Multiple routes of reporting were seen in some companies including electronic systems, diaries,

phone lines, emails, and text systems. van der Schaaf and Kanse (2004) developed a confidential diary for staff in chemical processing plants to report their own near-miss recoveries. Results provided insights into how near misses may be under-reported because they are not seen as 'consequential.' In the energy sector Clancy, Lea and Hyrmak (2011) created a 'snag list' linked to a database to collect and monitor reports; they had 29 near misses reported in 12 months.

Phimister et al. (2003), in their study of local reporting in the chemical processing industry, questioned whether near misses should be reported via the same systems as incidents, or whether there should be separate and bespoke systems. They found that 60% of near misses were submitted via a local, specific near-miss system and the rest via another IRS. They concluded that systems should be merged for ease of reporting and elimination of duplication.

Regarding functionality, authors described how IRSs need to support the reporter to know what to report and how. There was evidence of systems doing this through built-in definitions (Smith, 2013), easy to use interfaces, and automated filling (Taylor and Lacovara, 2015). Free text was recommended to not constrain the reporter (Hughes, Shipp, Figueres-Esteban et al., 2018).

Some IRSs were seen to use specific questions when a near miss is reported. These included 'why the situation did not become more severe' (Davies, Wright, Courtney et al., 2000; Wallace et al., 2003; Wright and van der Schaaf, 2004) and 'what were the potential consequences and recommendations' (Kanse and van der Schaaf, 2001). Taxonomies and coding systems were found to be useful, with the need to explore recoveries for near misses, such as was shown in Table 11.

Reporting culture and anonymity

The safety culture of companies and industries were commonly referred to when considering reporting. There were descriptions of no-blame (e.g. Lappalainen, Vepsäläinen, Salmi et al., 2011; Rasmussen,

Drupsteen and Dyreborg, 2013; Storgård et al., 2012) and just cultures (Chamber of Shipping, 2015; Maritime and Coastguard Agency, 2014; McSweeney, Craig, Curry et al., 2013). Some industries, such as maritime, were described to have blame cultures (e.g. Köhler, 2010).

The terms 'just' and 'no-blame' were sometimes used interchangeably. For example, the International Atomic Energy Agency (IAEA) referred to both just and no-blame cultures in their 2012 document (International Atomic Energy Agency, 2012). However, some authors felt that no-blame cultures are not feasible, nor desirable (Eurocontrol, 2006). Rather, companies should strive for just, open, and positive cultures (Dillon, Tinsley and Madsen, 2016; Phimister et al., 2003; Rasmussen et al., 2013). There were several examples of safety culture programmes in aviation (Harrison, 2015; Haskins, 2016), maritime (e.g. International Maritime Organisation, 2006b), and rail (Network Rail, 2013).

Anonymity of reporters was also debated (Köhler, 2010; Korman, 2016; Multer et al., 2013; Ritwik, 2002). The majority of IRSs seen were confidential with information being de-identified after reporting. Rail-related literature described challenges with anonymity as it limits available information and follow up (Multer et al., 2013). However, maritime literature felt anonymity is needed due to a blame culture (Köhler, 2010).

8.2.4 Responding to near-miss reports

8.2.4.1 Prioritising near misses for investigation

Some authors described mechanisms to review and assess each near miss to determine the level of investigation needed. Near misses assessed to be significant or high risk (based on potential harm and likelihood) may be prioritised for full investigation, similar to any catastrophic accident (Tinker and Keim, 2014). Assessment tools were seen in aviation (NASA, 2011a; Sheridan et al., 2004, UK Airprox Board, 2016), chemical (Shah, 2014), maritime (Mariner Personal

Safety, 2016), nuclear (Operating Experience and Learning Group, 2015; Sattison, 2004), and oil and gas (Ritwik, 2002).

Prioritisation assessment tools varied, with some criticism that tools may ignore less common, but more hazardous near misses if they only focus on risk (Shah, 2014). The assessment and prioritisation of near misses should consider factors such as frequency, controls overcome, levels of protection, whether there is an immediate obvious cause, likelihood of recurrence, and consequences if the situation was slightly different (Gnoni and Lettera, 2012; International Maritime Organisation, 2008; Nesmith et al., 2013; POWER, 2016; Ritwik, 2002).

Gnoni and Lettera (2012) compared two systems for prioritisation – a matrix (Petroleum Development Oman, 2012) versus a near-miss risk index. They found that the index allowed clearer prioritisation, but the matrix (Table 18) was simpler and quicker.

Table 18. Near-miss matrix adapted from Petroleum Development Oman (2012)

Severity	Consequences				Likelihood				
	People	Asset	Environment	Reputation	Never heard of	Heard of	>1/year in the industry	>1/year in the company	>1/year in any location
0	No injury	No damage	No impact						
1	Slight								
2	Minor								
3	Moderate								
4	Permanent	Major							
5	Fatalities	Massive							
Low potential									
Medium potential									
High potential									

8.2.4.2 Investigation processes for near misses

Several investigation processes for near misses were described across the SCIs. They ranged from simple to complex. At the simplest level, Forck (2010) described a Root Cause Analysis (RCA) process called STORM in the energy sector which involved seeing the near miss, telling the group at the next briefing, owning the hazard to eliminate it, reviewing and reminding, and moving on.

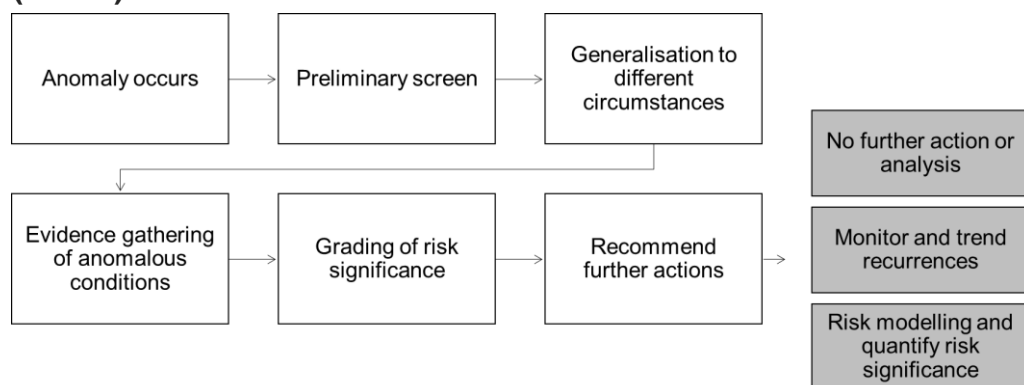
Bodies were described to exist in some SCIs to investigate specific events, such as the UK Airprox Board (UKAB). The UKAB investigates all Airproxes using a panel of experts to consider the controls involved (UK Airprox Board, 2016). This panel approach was also seen in rail as part of the USA Confidential Close Call Reporting System (C3RS) (Raslear et al., 2008), the German ZEMA Accident Database (Uth and Wiese, 2004), and in USA aviation (Federal Aviation Administration, 2012).

Investigation processes were seen to be quantitative and qualitative. The UK's Critical Incident Reporting and Analysis System (CIRAS, 2018) for rail was described to be managed by staff with psychology degrees who undertake quantitative and qualitative/discourse analysis on all reports (Davies et al., 2000). CIRAS analysis includes categorising proximal, intermediate, and distal (managerial) factors based on a model adapted from nuclear. Potential consequences and recovery codes are also used by CIRAS for near misses with thematic analysis of qualitative, and statistical analysis of quantitative data. Hermeneutics¹⁹ was also found to have previously been used (Wallace et al., 2003). CIRAS's approach demonstrates the role of trending pooled data over time. Trending of themes following categorisation was also described in the NMFFRS (Firehouse, 2005; Taylor, Davis, Barnes et al., 2015a; Van Ert, 2009) and the ZEMA Database (Uth and Wiese, 2004).

¹⁹ Hermeneutics – the study of the interpretation of text to imply meaning.

Precursor analysis programmes (example in Figure 5) were seen in some SCIs (e.g. Taylor, van Wijk, May et al., 2015b), specifically nuclear (Sattison, 2004; Smith and Borgonovo, 2007), oil and gas (Skogdalen and Vinnem, 2012), and space (NASA, 2011a, 2011b). Precursor programmes aim to review anomalies to look at how they could result in negative outcomes. Simulation had been used as part of some precursor programmes (Youngblood and Duffey, 2015).

Figure 5. Precursor accident programme adapted from NASA (2011b)



In the UK nuclear industry ‘operating experience programmes’ (2.4.2.1) were described. An operating experience programme should include identification and reporting of internal experiences, collection of external experiences, screening of experience, immediate review of events of specific interest, investigation and in-depth analysis of relevant experiences, trending, and review of themes to recognise developing issues (International Atomic Energy Agency, 2010).

8.2.4.3 Analysis tools

No particular analysis tool for near misses was consistently used or advocated for across the literature. Selecting and using a method is not simple and requires time and money for staff to develop and retain proficiency (Global Aviation Information Network, 2003). Tools have also evolved as industries mature. For example, aviation has moved from event and fault trees to more system-focussed methods and barrier analysis (Baines Simmons, 2018). Changes in tools happen

when industries realise that certain tools are no longer adequate (Vaughen and Muschara, 2011).

The Center for Chemical Process Safety (CCPS) (2003) described that no single tool does everything and so a combination of tools based on culture, experience, and the nature of an incident are required. Other industries also did not advocate for a single tool (Global Aviation Information Network, 2003; Saks et al., 2004), but some showed preferences as per Table 19.

Table 19. Preferential analysis tools

HFACS – Human Factors Analysis and Classification System
 TRACer – Technique for the Retrospective and Predictive Analysis of Cognitive Errors

Tool	Industry	Source	Notes
HFACS	Aviation	Scarborough and Pounds, 2000; Shorrock and Kirwan, 2002	Codes for air-traffic control have been developed, but most causal factors were classified as failures at the person level.
	Fire	Omodei et al., 2005	
	Rail	Baysari et al., 2008; 2009; Reinach and Viale, 2006; Zhou and Lei, 2018	Useful to categorise events in rail. May miss some factors and rail-specific moderation is needed. Specific codes have been developed and found to be reliable.
TRACer	Aviation	Shorrock and Kirwan, 2002	Found to be valuable with the potential for prospective application.
	Fire	Omodei et al., 2005	
	Maritime	Ventikos et al., 2015	
	Rail	Baysari et al., 2008; Rail Safety and Standards Board, 2005	Found useful for categorising events but may miss some factors. A preferred railway analysis technique in the UK.

Barrier	Aviation	Baines Simmons, 2018; Civil Aviation Authority, 2015; UK Airprox Board, 2016	
	Chemical processing	Bragatto et al., 2017; Center for Chemical Process Safety, 2003; Collins et al., 2016; Rathnayaka et al., 2011; Vastveit et al., 2017	Thought to be useful for near misses. The methodology can be extended to use Bayesian mechanisms.
	Nuclear	International Atomic Energy Agency, 2005	
	Oil/ gas	Shehab, 2017; Skogdalen and Vinnem, 2012	
	Rail	Figueres-Esteban et al., 2017; Hughes et al., 2018	

RCA and its associated methods, such as event trees, were described as used in some SCIs (Nesmith et al., 2013; Phimister et al., 2003; Smith, 2013; Vaughn and Muschara, 2011). Bayesian²⁰ analysis was also part of several tools (Oktem et al., 2013; Pariyani, Seider, Oktem et al., 2012; Rathnayaka, Khan and Amyotte, 2011).

Other analysis tools referred to in the literature included: Tripod-beta in oil and gas (Bruin and Swuste, 2008); the Functional Resonance Analysis Method (FRAM) in rail (Fukuda, Sawaragi, Horiguchi et al., 2016); human reliability and error analysis tools such as Technique for Human Error Rate Prediction (THERP) in aviation (Kirwan et al., 2008) and rail (Rail Safety and Standards Board, 2005); failure modes and effects analysis in chemical processing (Center for Chemical Process Safety, 2003; Phimister et al., 2003) and space (NASA, 2011a, 2011b); and fault semantic networks²¹ for safety verification in nuclear (Boafo et al., 2017). Several authors had developed bespoke tools including in coal (Sun, 2014), oil and gas (Gordon, 2002; Gordon, Flin and Mearns,

²⁰ Bayesian modelling – a statistical approach to data that uses probabilities; may be used to predict the probability of near misses.

²¹ Fault semantic networks – a graphical way of representing relationships between concepts.

2005), aviation (International Civil Aviation Organisation, 2012), chemical processing (Koo, Kim, Kim et al., 2009; Oktem et al., 2013; Pariyani et al., 2012; Taylor et al., 2015b), and maritime (Rathnayaka et al., 2011).

8.2.4.4 Aggregation and coding frameworks

It is impractical to review and analyse all near misses and so aggregation of information from multiple near misses was advocated for (Hughes et al., 2018), and encouraged by national and international bodies (International Atomic Energy Agency, 2005, 2018; International Civil Aviation Organisation, 2016). Some SCIs and countries have legal requirements to aggregate near misses, such as in US chemical processing (Wincek, 2016).

The literature described coding frameworks against which all near misses and incidents could be categorised. These were seen in aviation (e.g. Aviation Safety Reporting System, 2018; Eurocontrol, 2009; Tiller and Bliss, 2017), chemical processing (Kanse and van der Schaaf, 2001; Wallace, 2000), fire (e.g. Smith, 2005; Taylor, Lacovara, Smith et al., 2014; Taylor and Lacovara, 2015), maritime (ForeSea, 2018), nuclear (Nuclear Institute, 2016), oil and gas (Fabiano and Currò, 2012), and rail (e.g. Raslear et al., 2008; Rail Safety and Standards Board, 2018; Wright and van der Schaaf, 2004). Two example coding frameworks seen were:

- **Nuclear** – the UK National Operating Experience Learning Group (NOELG) uses a framework based on the Swiss Cheese Model (1.3.3) and guidance from the World Association of Nuclear Operators (WANO), which identifies root causes and causal factors (Operating Experience and Learning Group, 2016). Aggregating and trending of near misses is an expected part of operating experience (International Atomic Energy Agency, 2012, 2018).
- **Rail** – the UK CIRAS uses a taxonomy to categorise causal and recovery factors. The CIRAS taxonomy showed reliability for failure

factors of 90% and for recovery factors 100% (Wright, 2005; Wright and van der Schaaf, 2004).

Aggregation of near-miss data was described as important to trace back deficiencies (Wallace, 2000), identify areas for attention, track the effects of safety actions (Kanse and van der Schaaf, 2001), detect signals (Tamuz, 2004), and identify areas for future analysis (International Atomic Energy Agency, 2005). Aggregation was the focus of research to improve data analysis, including using approaches such as data mining²² (Bruce, 2008; Figueres-Esteban et al., 2017; Hughes et al., 2015, 2018; Nesmith et al., 2013), Bayesian modelling (Meel, O'Neill, Levin et al., 2007), and the use of fuzzy coding (Taylor et al., 2014).

There may be opportunities for future automation of aggregation. However, to date aggregation has been limited by data quality and incorrect categorisations (Hughes et al., 2018). Reporting cultures in some SCIs also mean that there may not yet be enough data to aggregate (Nesmith et al., 2013).

Supporting analysis

The literature described the need for investigations to be undertaken by trained investigators, and for there to be an infrastructure that supports analysis. Investigators need to be experts in safety analysis, and ideally multiple investigators are needed to avoid bias (Figueres-Esteban et al., 2017). Analysis tools should be embedded within companies' safety management systems (Center for Chemical Process Safety, 2003) and allow for retrospective (causal) and prospective (hypothetical expansion to what could have happened) review of incidents (Gnoni and Lettera, 2012). Investigations must include analysis of all aspects of the system (Omodei, McLenna and Reynolds, 2005) and reports should show a clear understanding of the system involved (Mazaheri et al., 2015).

²² Data mining – a process of cleaning and exploring data with the production of models for analytics; may be used to explore aggregated near-miss data.

8.2.5 Learning from near misses

8.2.5.1 Value of sharing learning

The literature described the perceived value of sharing learning following the investigation of near misses. Authors believed that sharing helped companies understand hidden risks and the safety of facilities (Di Maio et al., 2015), explore safety cultures (Kadri, Peters and Van Ommeren, 2013), identify areas for strategic focus (Office of Rail and Road, 2015), prevent future incidents (Nesmith et al., 2013), and increase safety awareness (Storgård et al., 2012). Near misses 'do not offend' and allow discussion (International Maritime Organisation, 2006a), are rich in number (Wang, 2006), and staff have a personal stake in learning from them (Morris and Moore, 2000).

Near misses were found to sometimes be unseen and undervalued, potentially because learning is not transparent. This was exemplified by the NASA space shuttles which had a series of 'secret' near misses prior to the catastrophic events; these were not appreciated as precursors and not analysed until it was too late (Corcoran, 2004). Similarly, in aviation, there have been examples of near misses not being acted upon until several incidents or a major accident has occurred (Madsen, Dillon and Tinsley, 2016).

In contrast, some authors suggested that learning from near misses is not always certain as they are ambiguous and can be construed in various ways (Morris and Moore, 2000). There were examples of lessons from past near misses not being heeded (Goodman, 2007). There may be an initial burst of attention to a near miss, but vigilance decreases over time (Dillon, Rogers, Madsen et al., 2013). Learning from safety events may therefore be more likely when there is a clear negative outcome to evoke behaviour change (Tinsley and Dillon-Merrill, 2005). There was thought to be greater learning from 'big' events (Tinsley and Dillon-Merrill, 2005); this was echoed in mining (Sun, 2014), aviation (Button and Drexler, 2006), chemical (Phimister et al., 2003), and oil and gas (Shimazoe and Burton, 2013).

8.2.5.2 Modes of sharing learning

People learn in different ways and therefore translation of learning to meet needs is required (Vastveit, Boin and Njå, 2015). Various modes of learning were described across SCIs. The commonest forms of sharing learning rely on staff accessing and reading information, and include emails, bulletins, annual reports, and newsletters (e.g. International Association of Fire Chiefs, 2018; UK Airprox Board, 2018). In chemical processing, incident summaries were found to have mixed impact (Vastveit, Orszak, Njå et al., 2017). In maritime, 'safety flashes [alerts]' were referred to with the intent that they are reviewed by recipients and reflected upon (International Marine Contractors Association, 2018). In fire there were examples of calendars (International Association of Fire Chiefs, 2018; Van Ert, 2009) and the incorporation of near misses into simulation scenarios via an app (Laws, 2014).

Various databases for learning are also available, particularly in chemical processing (e.g. Morrison, 2004; Nivolianitou, Konstandinidou, Kiranoudis et al., 2006; Uth and Wiese, 2004). While it was not clear how databases lead to sharing of learning, they have roles in project planning, mapping incident profiles, and comparing incidents. Databases need to be searchable, accessible, accurate, pertinent, valid, standardised, secure, and allow fuzzy query (Sepeda, 2006). Near misses should be separable from other events as this would otherwise undermine learning (Harding, 2005).

A small number of authors suggested ways in which near misses might be better learned from. NASA, for example, use 'pause and learn'²³ to examine near misses over time to prevent loss of vigilance (Dillon et al., 2013, 2014). Bias caused by near misses may be ameliorated by presenting probability information about the potential outcomes (Tinsley and Dillon-Merrill, 2005); this was exemplified using the Challenger disaster where staff did pay attention to prior foam near misses on the

²³ Pause and learn – a moment to reflect and learn from what has happened (NASA, 2010).

shuttle, but due to an escape each time, a lower probability of disaster was perceived leading to risky decisions. Dillon and Tinsley (2008) suggested that learning needs to highlight that systems are vulnerable.

Feedback to reporters

The process of feeding back to reporters was of limited consideration in the literature, although it was thought to be important to encourage reporting. There were comments that feedback is important, but it is often too long to read, or dismissed (Erdogan, 2011; Storgård et al., 2012). Feedback programmes were noted in the nuclear industry where 'operating experience' provides feedback and sharing between companies (International Atomic Energy Agency, 2018; Sattison, 2004).

8.2.6 Actions following learning from near misses

Examples of actions following learning from near misses were described in the literature. McSweeney et al. (2013) undertook an analysis of the mitigation actions in maritime and found that, based on the Hierarchy of Controls (Figure 2), 15% aimed to eliminate, 39% attenuate (physical barrier), 44% administrate (policy or label), and 2% protect staff.

Where there were examples of actions, these included equipment changes in maritime (Craig, 2015), and changes in standards in chemical (Kadri et al., 2013). However, no evidence of impact was provided in relation to those actions. In the US fire industry there was evidence of several changes as a result of learning from the NFFNMRS, including changes to processes for dealing with violent calls, new approaches to people slumped over wheels, and increased wearing of body armour (Van Ert, 2009); again, no evidence of impact was provided.

8.2.6.1 Impact of actions

Impact on behaviour

Not all impact described in the literature related to safety. Near misses were found to impact on behaviour depending on how their outcomes were viewed. As described above, the near-miss bias can 'conspire' to blind managers to near misses with normalisation of deviance. This means the more people escape consequences, the safer they feel (Dillon and Madsen, 2011). The near-miss bias was also seen in the military where surviving a near miss led to greater risk-taking on returning home because of perceived invincibility (Killgore, Cotting, Thomas et al., 2008).

Perceived impact

Any impact referred to in the literature was most often perceived. That impact included enhancing of safety cultures in maritime (Erdogan, 2011), the development of leadership skills in fire (Baran, Scott and Bonilla, 2013), and safety in general. Regarding safety impact, such as reduced harm, there were assumptions described that learning from near misses had directly resulted in reductions in harmful incidents (Hodges and Sanders, 2014), with some authors referencing the common cause hypothesis (3.3.1.1) (e.g. Forck, 2010; Nesmith et al., 2013; Oktem et al., 2013).

Evidence of impact

A small number of authors described evidence of impact of actions, but all provided limited detail (Saks et al., 2004; Wincek, 2016). In chemical processing, Wincek (2016) described that sharing information on smouldering events (classed as near misses) in oil systems had resulted in facilities surveying their own systems, insulation improvements, and improved monitoring of potential leak points; this had resulted to a 30% reduction in smouldering incidents.

8.2.6.2 Measurement of impact

The literature described difficulty showing the impact of learning from near misses on safety and risk. It was recognised that systems are not static, meaning it can be hard to learn from near misses as incidents may recur in different contexts (Rasmussen et al., 2013). The NFFNMRS had lost funding due to an inability to show impact (Kerrigan, 2015).

The use of near-miss rates as a safety metric was debated with several authors seeing rates as leading indicators of safety (e.g. Fabiano and Currò, 2012; Grabowski et al., 2007a, 2007b; Kadri et al., 2013; Nesmith et al., 2013), while others described them as lagging (Center for Chemical Process Safety, 2011). However, whether they are leading or lagging, they are good indicators of system-safety conditions (Center for Chemical Process Safety, 2011). Near-miss rates were also used as accounting metrics for workforce health and safety (Sustainability Accounting Standards Board, 2018), and for providing assurance to management around safety in employee evaluations (Craig, 2015).

There was no clarity provided in the literature around how to evaluate a near-miss programme. The International Atomic Energy Agency (2012) described the need for any evaluation to consider elements such as reporting levels, peer review, ratio of internal versus external identified issues, trend evaluations, and the ratio of near misses to significant events.

8.2.6.3 Challenging the value of near misses

Several authors described a lack of evidence that learning from near misses leads to improvements in safety. This in part may have been because some companies were immature with their use of data (Erdogan, 2011). In aviation it was challenged as to whether the data from Airproxes/Near Miss Air Collisions (NMACs) actually leads to an increased understanding of incidents (Button and Drexler, 2006), or represents a 'relentless' collection of data (Korman, 2016). Aviation

near misses may also be financially costly because of their impact on the reputation of air travel (Button and Drexler, 2006).

In chemical processing the benefits of learning from near misses on risk reduction was also unclear, and any improvements had previously been the result of learning from incidents (Phimister et al., 2003). It may be that only certain near misses can lead to safety improvements, being the ones where there was an evident warning of significant outcomes (Madsen et al., 2016).

The literature also questioned whether near misses are sufficient to motivate change. This was exemplified by actions that had not been taken following near misses (Shimazoe and Burton, 2013) with the recurrence of near misses. Examples included Network Rail not acting on recommendations from the Rail Safety Standards Board (The Construction Index, 2018), and companies not responding to CIRAS's recommendations (Saks et al., 2004).

8.2.7 Other findings

While not a primary objective of the review, the literature provided other insights that were of benefit to this thesis. These related to evaluation of safety in SCIs, causal links between near misses and incidents, and the role of safety management systems.

8.2.7.1 Evaluating safety

The literature described challenges measuring safety in SCIs. In aviation there were concerns about using 'pseudomarkers' of safety such as Airproxes/NMACs which may not be useful as a guide to aviation safety (Button and Drexler, 2006).

8.2.7.2 Causal links

Several authors referred to similarities in the causal factors of near misses and incidents. However, the basis of those statements was unclear. The common cause hypothesis was often quoted, and several authors used the hypothesis to compare the occurrence of near misses

and incidents to produce ratios for evaluation of safety improvements. For example, in chemical processing, Bridges (2000, 2012) showed how that, in the late 1990s, the ratio of near misses to incidents reported was in the range of 0 to 20; 20 years later it had increased to up to 50.

Some authors challenged the common cause hypothesis and that the link between near misses and incidents is not as simple as previously thought. Button and Drexler (2006) challenged the link between Airproxes and actual incidents, and in other industries the link was described as 'theoretical' (Fabiano and Currò, 2012). The common cause hypothesis was seen as too simplistic to describe how incidents occur, but it may be useful to incentivise reporting (Köhler, 2010).

In rail, research has evaluated the common cause hypothesis in specific situations. Wright and van der Schaaf (2004) described 'qualified support for the common cause hypothesis' following testing when looking at SPADs. They found that three of the 21 causal factors considered showed differences in proportions between injuries, damage, and near misses. They acknowledged that this was in one domain and that the hypothesis needs to be proven or disproven before assumptions can be made for different incident types.

8.2.7.3 Safety management systems

In the included literature several authors referred to Safety Management Systems (SMSs) and the contribution near misses make to company or industry-wide SMSs (Bragatto et al., 2017; Gnoni and Saleh, 2017; Kadri et al., 2013; McSweeney et al., 2013; Meel et al., 2008; Rail Safety and Standards Board, 2018; Wang, 2006). The SMS was seen as a fundamental part of safety management, but is not always embedded in an industry, for example in maritime (McSweeney et al., 2013).

8.3 Updating the scoping review

8.3.1 Additional literature – June 2018 to 2021

Sixteen academic articles (14 from the stage two search) and 17 relevant grey works were added to the scoping review. The majority of the academic articles considered near misses alone (n=15) and came from across the world, most commonly the USA (n=4) and Australia (n=3). There were 15 original research articles, most commonly quantitative, non-experimental (n=8). There was a single opinion piece/editorial. The articles covered all the areas of interest with the exception of 'definition.' Most commonly they considered reporting and were from maritime (n=6). Other SCIs were rail (n=4), processing (n=3), and aviation (n=2).

The grey works mostly considered near misses alone (n=13) and came from the UK (n=6) or USA (n=5). They included conference abstracts/presentations (n=5), overviews of updates to incident reporting systems or creation of new systems (n=5), and non-academic articles (n=4). The grey works focused on 'reporting' or 'analysis' across rail (n=5), processing (n=5), and maritime (n=4).

8.3.1.1 Terminology and definitions of near misses

Near miss was the term used in all the academic articles. There was more variation in the grey works, although near miss was the most common term. Other terms included close call, particularly in rail (e.g. Kenealey, 2018; Federal Railroad Administration, 2019), and 'high-potential event' which referred to a 'near miss that could, in other circumstances, have realistically resulted in one or more fatalities' (International Association of Oil & Gas Producers, 2020). Network Rail (2020) had added a new type of close call called a 'design close call.'

There was limited research found around definitions. In aviation it was felt to be easy to define a near miss because separation standards exist for aircraft; however, in other SCIs definitions are less clear. When defining a near miss, the number of barriers involved and the amount of

energy needed to stress those barriers should be considered (Paradies, 2020). It was recognised by authors that clear guidance and consistent definitions are needed (Paradies, 2020; Sommerville, 2021).

One author suggested changing the term near miss to 'near hit' as this may be a more positive term (Sommerville, 2021). It was also recognised that near misses are context dependent with potential effects, in processing industries, on humans, infrastructure, chemicals, community, and the environment (Fiedler, 2019).

8.3.1.2 Reporting

Significant under-reporting of near misses was described in maritime (Bhattacharya, 2020). Lower ranking crew were found to believe that reporting is more a regulatory obligation than a commitment to safety and were less likely to report (Georgoulis and Nikitakos, 2019; Hasanspahić, Frančić, Vujičić et al., 2020). Near-miss reporting in maritime was also found to be limited by barriers such as difficulty identifying the near misses, limited training in identification and reporting, limited familiarity with reporting systems, complexity of reporting forms, poor attitudes to reporting, and a blame culture (Hasanspahić et al., 2020).

There were examples of how the rail industry had attempted to automate detection of near misses. Banerjee, Santos, Hempel et al. (2019) used a fish-eye lens and algorithm in railyards to detect people and their proximity to objects. Trespassing on railway lines (and near misses with trains) was also detected automatically using artificial intelligence (Zhang, Trivedi and Liu, 2018; Zaman, Liu and Zhang, 2018).

There was evidence of work being undertaken in maritime to identify collision risk (e.g. Fang, Yu, Ke et al., 2019; Du, Valdez Banda, Goerlandt et al., 2021; Jeong and Li, 2020; Szlapczynski and Szlapczynska, 2021). Hassel, Grossmann, Aalberg et al. (2020), for example, developed and evaluated a model that identified 476 ship-domain violations and 46 near collisions; the authors used this to

identify an event ratio for maritime. Zhou, Wong, Loh et al. (2019), in another study, used fuzzy logic to predict the risk of near misses during tanker voyages.

Interventions described to have the potential to increase near-miss reporting were:

- **Clarification** – of what a near miss is and what reporting is trying to achieve (Kloeckner Metals, 2020).
- **Improving access** – to reporting systems via an app that uses a simple form, escalates reports, and allows addition of photos (Kenealey, 2018). Simplicity was felt to be important (Sommerville, 2021), and Kloeckner Metals (2020) use a simple card system for reporting.
- **Incentivisation** – Kloeckner Metals (2020) uses financial incentives, but others felt this was inappropriate (Georgoulis and Nikitakos, 2019).
- **Timely feedback** – to positively reinforce reporting efforts (Sommerville, 2021).
- **Culture** – a no-blame culture and an independent reporting ability (Georgoulis and Nikitakos, 2019). An engaged top down and bottom-up approach is needed (Kloeckner Metals, 2020).
- **Mandatory procedures** – for reporting and investigation of events (Volker Rail, 2019).

One article challenged the often-quoted belief that ‘increasing numbers of near-miss reports represents an improved safety culture.’ Georgoulis and Nikitakos (2019) found no clear evidence that safety culture onboard ships and within companies improved by increasing the number of reports; they concluded that identifying and learning from significant and rare near misses is more important.

The literature again described examples of near-miss reporting systems and processes (e.g. Kloeckner Metals, 2020; Hasanspahić et al., 2020; Federal Railroad Administration, 2019). Kloeckner Metals’ (2019) reporting process uses cards which asks for potential severity, what

was observed (e.g. rushing, frustration, fatigue, and complacency), and errors seen (e.g. eyes or mind not on task). They have had 17,000 reports since its creation in 2018.

'Positively Engage Employee Risk' (PEER) was a near-miss reporting programme seen in mining (PEER Safety Leadership, 2022). The developers recommend proactivity (watching for warning signs and signals), employee engagement (with psychological safety and a positive safety culture), and easy reporting (a simple contact point rather than needing to gather all information in one sitting) (PEER Safety Leadership, 2022).

A novel approach to reporting was seen in chemical processing through scenario-based incident registration (Verschoor and Zitman, 2019). This aims to provide a structured process for reporting with selection of specific scenarios from a set of barrier diagrams (Bowties) and assessment of the effectiveness of the barriers. Specific questions are asked of each barrier, and this helps a company to identify their strength.

In mining there were calls for reporters to also undertake 'check' and 'act' activities. These identify, rank, and mitigate risks, with assigning of probability and consequences to hazards, and the making of suggestions for improvements (Haas, Demich and McGuire, 2020)

Thoroman, Goode and Salmon (2018) undertook an evaluation of 20 near-miss reporting systems across various SCIs against a systems-based criteria. None of the systems fulfilled the full criteria but were all able to identify actors and contributing factors proximal to events. Some also captured information on how incidents were prevented. The criteria were based on Rasmussen's seven tenets of accident causation (Rasmussen, 1997):

- Safety is an emergent property of complex systems.
- Threats to safety are caused by multiple contributory factors.
- Threats to safety can result from a lack of vertical integration.
- Lack of vertical integration is due, in part, to a lack of feedback.

- Work practices are not static and migrate over time.
- Migration occurs at multiple levels.
- Migration can cause system defences to degrade.

Thoroman et al. (2018) concluded the need for systems to understand emergence and system migration, but that this is limited and so hinders the use of data.

Reporting of near misses was also considered from a theoretical perspective. In rail, a model of reporting behaviour was developed using causal loops which included incident observation, risk perception, reporting attitudes (habits and utility of reporting systems), intentions, and management commitment (Bugalia, Maemura and Ozawa, 2021).

The literature also highlighted that companies need to develop formal near-miss reporting systems within their SMSs (Haas et al., 2020).

8.3.1.3 Responding

There were further insights into the monitoring of reports and how they should be acted on. For example, Volker Rail's (2019) policy describes the role of duty persons, that reporting should occur within two hours, evidence should be preserved, and levels of investigation should be determined. Their policy uses a risk table to identify the need for local versus formal investigation. Events with no/low-harm receive a local investigation if they are likely to recur. Analysis was referred to in relation to the domino theory (1.3.1) and the Swiss Cheese Model (1.3.3), with tools including the five whys, barrier analysis, and cause and effect (Volker Rail, 2019).

Regarding analysis, RCA (Volker Rail, 2019; PEER Safety Leadership, 2022) and Accimaps (Thoroman, Salmon and Goode 2020) were described by some companies to be used for near misses. Thoroman et al. (2020) advocated for the use of systemic methods such as Accimaps and had used Rasmussen's risk management framework to analyse 16 serious incidents (near misses) from aviation (Thoroman, Goode, Salmon et al., 2019).

Within the US fire service there was a move to focussing on human performance. This followed a realisation that near misses commonly occur from 'good people making poor choices or committing human error' (International Association of Fire Chiefs, 2019).

Regarding sharing learning, the literature provided examples of databases for collecting reports (International Association of Oil & Gas Producers, 2020; International Association of Fire Chiefs, 2019; Network Rail, 2020). Network Rail, for example, have a 'design close call dashboard' which contains data from across industry partners (Network Rail, 2020).

The volume of the data in databases had resulted in efforts to use artificial intelligence to mine text (Ansaldi, Pirone, Vallerotonda et al., 2019; Ansaldi, Simeoni, Di Francesco et al., 2020). However, challenges were found because of generic terms, repeated words, varying report quality, and ambiguities.

Murphy (2019), in their thesis focussed on sharing learning in the energy sector, identified that 'networks' play important roles in learning, but there is no best network. Consideration needs to be given to (Murphy, 2019):

- spatial distribution and opportunities for people to meet
- the use of technology, particularly with a distributed workforce
- social media for distributed workers to discuss issues
- team leader skills for engaging and feeding back to teams, and
- what organisations want to achieve through a process of learning.

Murphy (2019) also identified potential benefits in discussing several events related to a particular process, rather than focussing on one event in isolation. They also suggested using small tests before presenting incidents and coming back to an incident at a later date to see if staff remember key messages.

8.3.1.4 Impact of actions

The literature did not include any actions made following learning from near misses and therefore no evaluation of impact. However, the literature did provide exploration of how the numbers of near misses may relate to the number of incidents.

Bhattacharya (2020) explored whether increased reporting of near misses was associated with decreased incidents. Over a three-year period of increasing near misses, using Pearson's correlation, the authors did not identify any correlation between near misses and incidents reported. They concluded that increasing reporting did not improve safety, it just increased the number of reports.

In contrast, Kloeckner Metals (2020) stated that 'We have seen safety performance improve dramatically in that same time period and have also seen a marked improvement in our Safety Perception Survey results year over year,' and Network Rail (2020) described a direct relationship between the number of close calls raised and the number of accidents in design projects. No evidence was found to support the statements of the two companies.

It was acknowledged that, while near misses may not be fully understood because of the quality of data in a database, information assists identification of hazards, human factor issues, and failure modes that may not have previously been recognised (International Association of Oil & Gas Producers, 2020).

8.3.1.5 Other findings

The concept of the safety pyramid and assumptions of similar causes of incidents and near misses were again referred to by authors. There was no evidence provided as to the basis of those assumptions (Kloeckner Metals, 2020; Georgoulis and Nikitakos, 2019; Bhattacharya, 2020). Thoroman et al. (2018) described how the common cause hypothesis has been supported by several analyses across multiple industries, however other authors have found the concept of the safety triangle to not be as straightforward as once thought. For example, some studies

have shown little evidence of a relationship between the occurrence of minor incidents and subsequent severe outcomes (Haas et al., 2020).

There was advocacy by authors for seeing near misses as successful safety outcomes, and for focussing on the protective factors in systems that lead to successes, rather than the traditional retrospective view of near misses (Thoroman et al., 2020).

8.3.2 Additional literature – 2022

Eight academic articles (all from the stage two search) and three relevant grey works were added to the scoping review. Six academic articles considered near misses alone and came from across the world. There were seven original research articles and one review article. Four research articles were quantitative non-experimental, and three were mixed-methods studies. The articles covered all the areas of interest except 'impact,' from maritime (n=4), processing (n=3), and multiple industries (n=1).

The grey works were from Greece (non-academic article in maritime), Italy (conference abstract in multiple industries), and the UK (a reporting system in rail). All related to identification and reporting of near misses.

The literature continued to highlight the challenges with under-reporting of near misses, particularly in maritime. There is a need for a greater commitment to safety, feedback, a no-blame culture, and anonymity in maritime (Safety4Sea, 2022). To support reporting, London North Eastern Rail had developed a close call reporting app, the first in the UK (The Distance, 2022). Automated detection of near misses continued to be explored in the literature including through the use of AIS data in shipping (Breihaupt, Bensi and Copping, 2022; Xin, Yang, Liu et al., 2022) and smart technologies such as radiofrequency identification (Elia, Gnoni, Tornese et al., 2022).

Regarding analysis, HFACS was used in maritime (Bicen and Celik, 2022) and chemical processing (Carra, Monica, Di Girolamo et al., 2022). Bicen and Celik (2022) used HFACS to review causes of near

misses in tanker operations and found that investigations focussed on the human element and actions often orientated around training and checklists. Carra et al. (2022) found that incorrect human behaviours were precursors to events and described the need for behavioural interventions. In mining, a survey was used to support investigation of near misses (Zeqiri, Hetemi, Uka et al., 2022); the authors also referred to the common cause hypothesis.

Vallerotonda, Ansaldi, Pirone et al. (2022) used machine learning to automatically extract and manage information from incident records from several Seveso²⁴ establishments. They found the machine learning approach to be ‘powerful.’

Two academic articles considered the use of near-miss management systems in SCIs (Gnoni, Tornese, Guglielmi et al., 2022; Hasanspahić, Vujičić, Kristić et al., 2022). Hasanspahić et al. (2022) integrated and evaluated a system in a shipping company which included supporting policies, near-miss classification, estimation of risk levels, and coding using event and corrective action codes. Data from their system could be used in statistical analysis, and the corrective action coding was made against a hierarchy of controls (Hasanspahić et al., 2022).

Gnoni et al. (2022), in their review of near-miss management systems across industries, found that many companies do not have systems in place, including in aviation, maritime, nuclear, and rail. They did note that construction was more likely to have systems in place. Gnoni et al. (2022) described two factors that contribute to effective near-miss management systems – strong management support and training, and reliable tools for data analysis and knowledge sharing. Their review also noted that there is still debate around the definition of a near miss and that near misses could be seen from both a Safety I and Safety II perspective (1.3.5).

²⁴ Seveso plants/installations – ‘establishments where certain quantities of dangerous substances are present’ (European Environment Agency, n.d.).

8.4 Conclusions from the safety-critical industry scoping review

8.4.1 Reflections on the included literature

The SCI scoping review mapped and described the literature surrounding the management of near misses in SCIs. To the knowledge of the thesis author, this is the first time the literature has been collated in this way. During the review, the following were noted:

- There was a paucity of academic articles relating to aviation and nuclear compared with processing, maritime, and rail. This was surprising as aviation and nuclear are referred to as the 'ultra safe' SCIs (Vincent and Amalberti, 2016).
- There was a larger volume of evidence from SCIs available in the grey works in comparison with academic sources; evidence may be unpublished.
- There was limited evidence in relation to the actions taken by SCIs following learning from near misses and the impact of those actions on safety.
- The SCI literature focussed more on analysis in contrast to healthcare's focus on definitions and reporting. This may represent differences in the maturity of near-miss management systems between SCIs and healthcare.
- The safety theory and analytical approaches described by some SCI companies were aligned with traditional models of safety that have since been challenged due to their simplicity and lack of recognition of how systems influence safety. Examples included the use of RCA.
- The excluded literature often originated in the construction industry. While not described as a SCI, construction was found in Gnoni et al's (2022) review to often have near-miss management systems (see 8.4.2.6).

8.4.1.1 Comments on the quality of included academic articles

A formal assessment of the quality of the articles included in this scoping review was not undertaken. Assessment of quality is not expected as part of a scoping review. The limitations noted in 6.5.1.1 in the healthcare scoping review were further noted in relation to the literature from SCIs.

8.4.2 Answering the review questions

The findings of the SCI scoping review have been used to answer the review questions (6.2.1) in the following sections.

8.4.2.1 What is a near miss?

The review found various types of near miss dependent on the industry and/or context. Where broad definitions are used, similar to the findings of the healthcare scoping review, definitions vary with no clear agreement of the features of a near miss. Broad definitions are more common when referring to health and safety near misses.

Each SCI has specific types of near misses that are clearly defined. These are often unique to a SCI and are described in lists of events that should or must be reported. In some, but not all SCIs, lists are standardised through international policies.

The majority of near misses described in the review involved events that included an intervention. The SCI literature confirms that interventions are a component of a near miss, preventing onward progression of events. There is debate, but no consensus, about the types of interventions involved in a near miss, how many interventions/barriers need to be overcome to be a near miss, and the language used in definitions that may influence perceptions of the importance of reporting events.

Regarding terminology, 'near miss' was found to be commonly used in SCI-related literature but is not the only term. There is debate around

whether all terms are synonymous. Some industries have specific terms for near misses that are descriptive of the events, such as Airprox.

8.4.2.2 How are near misses managed in safety-critical industries?

The review provided examples of management systems and processes in companies and across SCIs for near misses. However, there was limited detail about those systems and processes, and their maturity was seen to vary (Gnoni et al., 2022). The presence and effectiveness of systems may not be as advanced as externally perceived. The review also highlighted the role of SMSs in SCIs and that near misses contribute to these.

The review provided insights into efforts made by SCIs to improve reporting and learning from near misses. Despite efforts, SCIs face similar barriers to reporting as found in the healthcare scoping review, resulting in under-reporting. There are potential benefits in providing staff with multiple routes to report near misses, reporting systems that are not just internal to companies, automated detection of near misses, and the use of incentives. Leadership and appropriate safety cultures are also important. A just culture is suggested to be appropriate, but a no-blame culture may be required where blame is rife.

Safety event management, and specifically near misses, across SCIs is directed by regulations, standards, policies, and guidance. These create expectations for reporting and learning conditions. Where regulations exist, companies are inspected against those regulations.

Regarding analysis of near misses, the review acknowledged that not all reported events can be investigated. It is therefore appropriate to prioritise which near misses are to receive an in-depth analysis, while categorising all near misses against a standard taxonomy to support identification of themes. System-focussed analysis tools are advocated for, such as HFACS, Accimap, and barrier analysis. The review also highlighted the potential role of databases for learning from near

misses, but there is limited detail about how best to share and use the learning.

8.4.2.3 What is the impact of learning from near misses to improve safety/quality in safety-critical industries?

The literature in this review, while commonly stating perceived value in learning from near misses to improve safety, provided little evidence around actions taken to improve safety and their impact. There are difficulties evaluating the impact of actions on safety.

Several authors referred to the common cause hypothesis and the link between near misses and incidents to justify learning from near misses. However, in comparison to the healthcare literature, there were some guarded views about the validity of the hypothesis. Some authors have evaluated the hypothesis with varying results.

A small number of authors also challenged whether focussing on near misses was beneficial for learning or was just an exercise in data collection. There are concerns that near misses may not be a credible metric for safety, and that addressing near misses may not correlate with reductions in incidents and improvements in safety. Near misses may have other benefits beyond safety including helping to support improvements in efficiency.

8.4.2.4 What can healthcare learn from the way safety-critical industries manage near misses?

The SCI scoping review suggested that SCIs face some of the same challenges healthcare faces when trying to define, report, and learn from near misses. Similar to healthcare, there are varying safety cultures in SCIs, difficulties disseminating learning and providing feedback to reporters, and the use of analytical methods based on outdated safety theories. There is comparable research in SCIs and healthcare around encouraging and supporting reporting of near misses.

In contrast to healthcare, the SCI review demonstrated how companies and SCIs often have management systems for near misses which contribute to wider SMSs. These systems require resource and are directed by policy and regulation. It is important to have structured and resourced systems for the management of near misses. The SCI literature is unclear about how best to implement those systems, rather it describes some important considerations such as: ensuring senior support for any programme; supporting reporting with automation and multiple routes; investing appropriate resources; implementing a standardised taxonomy for reporting, prioritisation, investigation, and learning from near misses that considers interventions/recovery factors; and investigating some, but aggregating information from all near misses.

The review also highlighted the potential benefits of viewing near misses from different safety perspectives. This will influence how they are perceived and learned from. Near misses can be seen from a Safety I (focus on causes) or Safety II (focus on recoveries) perspective.

8.4.2.5 Need for further research

The QCS and healthcare scoping review concluded with the need to look beyond healthcare to help understand how best to manage and learn from near misses. The SCI scoping review has provided some insights to help with that understanding but has not provided clarity on how best to define, manage, and learn from near misses. There is no standard method for the design and implementation of a near-miss management system, rather there are principles based around van der Schaaf's (1992) work almost 30 years ago (Gnoni et al., 2022).

The QCS and healthcare scoping review also identified a lack of evidence that learning from near misses has contributed to improvements in patient safety. The SCI scoping review has not challenged this finding, with a further lack of evidence available from

SCIs. There is a need to better understand whether learning from near misses leads to improvements in safety.

8.4.2.6 Near-miss management in construction

Gnoni et al's (2022) review of near-miss management systems included 22 (out of 60) papers which related to construction. The thesis author reviewed the papers for insights that may be of benefit to this research. There is a focus on near-miss research in construction, potentially because the benefits of learning from near misses are being explored.

The construction literature described: the potential benefits of automatic detection of near misses, such as between humans and equipment on sites, using technology such as smartphones (Zhang, Cau and Zhao, 2019); the benefits of structuring reporting against a classification system to allow for deeper learning and future auto-text classification (Fang, Luo, Xu et al., 2020); and the role of more systemic approaches to near-miss analysis (Raviv and Shapira, 2018).

The construction literature did not provide any evidence of the impact of learning from near misses on safety.

8.5 Summary

This scoping review has provided insights into how near misses are managed and learned from in SCIs. However, the insights do not fully answer the research questions. Further research is required to understand the value of learning from near misses to improve safety and how best healthcare might manage patient safety near misses.

The next chapter will provide the protocol for and findings of the grounded theory (study 4). Grounded theory was undertaken to better understand how near-miss management functions in operational SCI settings.

9 Study 4: Managing Near Misses in Safety-Critical Industries – A Grounded Theory

9.1 Introduction

To further understand how near misses are managed in Safety-Critical Industries (SCIs), and to help develop principles around how best near misses may be managed, a Grounded Theory (GT, study 4) methodology was followed. This chapter describes the GT protocol and findings. Quotes from GT participants are included.

9.2 Grounded theory protocol

A GT protocol has been developed in line with the principles described in chapter 5. The protocol follows the Straussian approach as this aligns with the thesis author's philosophical stance (5.4.3). The protocol considers the works of several authors who have developed the original GT approach such as Morrow and Conger (2016), Murphy, Klotz and Kreiner (2017), and Tweed and Charmaz (2011).

9.2.1 Initial aims

Definitions of terms used in the GT aims are provided in 4.3. The primary aim of the GT is to understand how SCIs use near misses to improve the safety of their activities and minimise harm to service users, staff, and objects, such as the environment. The goal is to develop a set of principles around how best near misses can be managed. The primary aim is intentionally broad to not limit early evidence gathering.

A secondary aim of the GT, informed by the findings of the scoping reviews (studies 1 and 3), is to understand whether learning from near misses in SCIs has shown impactful improvements in safety.

9.2.2 Data collection and analysis

The phenomenon of interest is the ‘management of near misses.’ Primary data collection will be via semi-structured interviews (5.5.1) with lead staff in safety and human factors in SCIs, and the sharing of questionnaires with their operational staff (5.5.3). It is expected that these various staff will provide organisational and operational views of the management of near misses.

Representative companies/bodies across the SCIs will be approached through pre-existing contacts and internet searches. The approach will aim to sample SCIs and will include operational (those delivering the service, e.g. passenger rail operators), regulatory, policy-making, and investigatory companies/bodies.

Participants will be provided with an information sheet and asked to provide written consent which will include consent to audio record interviews. Where consent for recording is not provided, extensive notes will be taken. Where possible, interviews will be undertaken face-to-face at the place of work of the participant. This will allow the interviewer (the thesis author) to experience the context within which a participant works. This is important to help understand and explore social concepts (Manderson, Bennett and Andajani-Sutjahjo, 2006).

Following interviews, recordings will be transcribed in their entirety. All audio transcripts, notes, and associated documents collected will be collated using NVivo (QRS International, 2022).

9.2.2.1 Choosing the safety-critical industries

Due to the number of industries described as SCIs, it will not be realistic to undertake interviews across all of them and still achieve theoretical saturation (5.4.3.2). Therefore, the initial focus will be on transport industries (aviation, maritime, and rail). These industries are clearly defined and accessible. Further SCIs will be added as guided by theoretical sampling.

During the undertaking of the GT, theoretical sampling suggested the importance of including a non-transport industry. Nuclear was repeatedly described by participants to be an exemplar SCI and was included.

9.2.2.2 Sampling

Sampling of companies/bodies will be initially purposive (5.4.2.3) and will then become theoretical (5.4.3.2) as guided by participants and findings. Safety lead participants will be asked to share the questionnaire with operational staff in their companies.

Further data sources will be field notes where interviews are undertaken at places of work (5.5.4), and research memos as theory development progresses (5.4.3.3). No sample size has been preselected due to the nature of the research. Sampling will continue until theoretical saturation.

9.2.2.3 Analysis

Analysis of the data will commence following the first interview and progress alongside data collection. Analysis will use NVivo and follow the approach described in 5.4.3.1 with open, axial, and selective coding, using a constant-comparative approach.

During early coding, sensitising questions (5.4.3.1) (Vollstedt and Rezat, 2019) will be used to support the thesis author to become familiar with the data. During axial coding, the coding paradigm described in 5.4.3.1 will be used because of its value in helping to generate theory (Corbin and Strauss, 1990).

Analysis will be undertaken independently by the thesis author and verified by a second reviewer with experience in qualitative methodologies and safety investigation. Theories will be refined to produce the findings.

9.3 Data sources in the grounded theory

9.3.1 Interviews

Data collection took place between April 2020 and November 2021. Participants were approached via generic safety, governance, human factors and media email addresses sourced through company/body websites. Thirty-five interviews were undertaken across aviation (n=12), maritime (n=7), nuclear (n=7), and rail (n=9). Table 20 describes the SCIs, companies/bodies, and participants in the GT. Due to the nature of the sampling, the order in which interviews were undertaken was dependent on how prior participants directed the research. Interviews broadly occurred in three phases.

Table 20. Grounded theory participants and their industries

SL – Safety Lead; HFL – Human Factors Lead

Industry	Code	Company	Phase	Participant(s)
Aviation (A)	AATC	Air traffic control	1	HFL (2)
	ACP1	Commercial (passenger) 1	2	SL
	ACP2	Commercial (passenger) 2	2	SL pilot
	AHC1	Helicopter civil 1	1	SL pilot
	AHC2	Helicopter civil 2	2	SL pilot
	AM1	Military 1	1	SL
	AM2	Military 2	2	Air engineer
	AM3	Military 3	2	SL pilot
	AN1	National 1 – investigation	1	SL
	AN2	National 2 – investigation	1	SL
	AN3	National 3 – investigation	2	SL
	AN4	National 4 – regulatory	1	Policy lead
Maritime (M)	MP	Passenger (cruise)	2	SL
	MMT	Merchant (tanker)	2	SL
	MM	Military	2	SL

	MV	Voluntary	2	SL
	MN1	National 1 – investigation	1	SL
	MN2	National 2 – regulatory	2	SL
	MN3	National 3 – policy	2	Policy lead
Nuclear (N)	NP1	Power station 1	3	SL
	NP2	Power station 2	3	SL
	NP3	Power station 3	3	SL
	NM1	Military (weapons) 1	3	SL
	NM2	Military (weapons) 2	3	SL
	NPR	Production (research)	3	SL
	NN	National – regulatory	2	Policy lead
Rail (R)	RP1	Passenger 1	1	SL
	RP2	Passenger 2	2	SL
	RF1	Freight 1	2	SL
	RF2	Freight 2	2	SL
	RI	Infrastructure	1	SL
	RN1	National 1 – regulatory	2	SL
	RN2	National 2 – investigation	2	Safety lead
	RN3	National 3 – strategy	2	Research lead
	RN4	National 4 – investigation	2	HFL

9.3.2 Other data sources

Other data sources in the GT included national, regional, and local policy and guidance, field notes, meeting observations, and research memos. Fifty-five documents were included following identification by participants.

Nine interviews were undertaken face-to-face with field notes made. The field notes described observations while visiting participating companies/bodies. Two national meetings for the sharing of cross-sector learning in aviation and nuclear were also observed with field

notes made. Six research memos described the rationale behind the theoretical sampling and theory generation.

One company (rail) and one of the national meetings observed (nuclear) consented to sharing the questionnaire with staff. No responses were received from rail. Seven responded from the nuclear industry across power generation, decommissioning, and defence; responses were included in the qualitative analysis and added to the definition and culture question data.

9.4 Analysis and findings – open coding

The thesis author read each data source to sensitise themselves to the contents. Initial, open coding was then undertaken, structured by industry, to identify the phenomena of interest. Per industry, the following phenomena of interest for axial coding were identified:

- Safety of SCIs.
- Reporting of near misses in SCIs.
- Responding to reported near misses in SCIs.

9.5 Analysis and findings – axial coding

Axial coding started to identify the theories/principles grounded in the data by exploring emerging relationships between concepts and the phenomena of interest. Each of the phenomena of interest is explored in the following sections. Appendix 9A provides the NVivo axial coding structure.

9.5.1 Phenomenon 1 – safety of safety-critical industries

All participants agreed that their industries are ‘safety critical,’ in that:

“When things go wrong, they can go wrong seriously.” MN2

However, there were differing views around whether they are 'safe.' Safety across an SCI was not seen as homogenous, with different parts having different levels of safety.

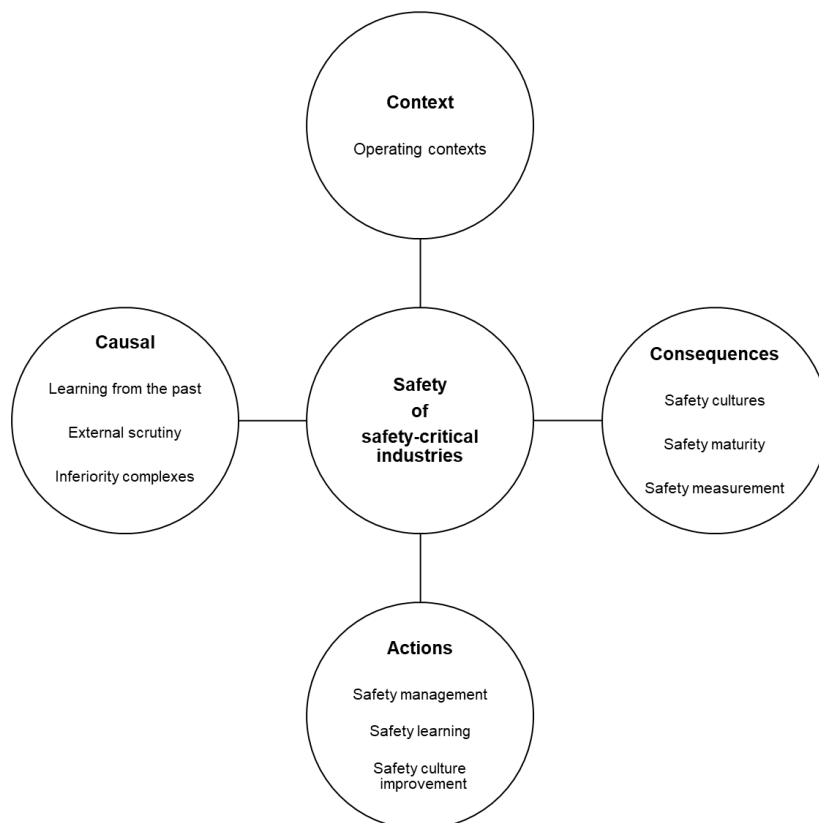
“There is no graduation of harm in air traffic, it's either 500 people get killed or nothing. There is no bit in the middle really.” AATC

There were concerns that external views of SCIs may not appreciate the variability in safety, or that safety is different in and across different industries.

“... you identified that this is a high-reliability industry, I'm not entirely convinced that that is the case. I think outwardly that's the case, but we are just distant from the accident to be honest... I don't think we have ever really tested ourselves against that definition.” AATC

A summary of the coding paradigm for phenomenon 1 is shown in Figure 6.

Figure 6. Coding paradigm for phenomenon 1 – safety of safety-critical industries



9.5.1.1 Causal conditions

Causal conditions were the drivers/factors that led to safety and the safety focus in SCIs. Themes included learning from the past, external scrutiny, and inferiority complexes.

Learning from the past

Participants described that, in general, two factors had led to the current safety of their SCIs – ‘catastrophes’ and ‘blame cultures.’ Catastrophes had led to past, significant changes such as formation of safety bodies for confidential reporting (e.g. CHIRP, 2018) and independent investigation (e.g. Air Accident Investigation Branch, 2021), and technological advances.

“Over time the safety records have improved, no doubt that the big bang incidents, like Ladbroke Grove, have had the biggest impact on change, leading to new technologies, prioritisation of safety, understanding data, high scrutiny...” RN2

Harm had resulted in safety improvements in the SCIs, for example:

“... the double fatality really changed minds and probably fast tracked some of the changes... we can't get away from the fact that big accidents cause big responses.” RN3

Each SCI was described to have had historical, blame-focussed safety cultures, for example:

“If they dink the aircraft... just culture didn't exist...they just got sacked.” AN4

Recognition that poor safety cultures led to incidents had resulted in activities to improve cultures. Improvements were still felt to be required in parts of all the SCIs, particularly in maritime and nuclear.

“[We are] on a safety culture drive at present... prompted by poor reporting culture... needed to address walking past unsafe conditions, and not reporting on unsafe conditions on platforms.” NM1

External scrutiny

Participants described the regulations for their SCIs which include the need to develop just cultures (e.g. The Civil Aviation (Investigation of Air Accidents and Incidents) Regulations, 2018), mandatory reporting (e.g. International Civil Aviation Organisation, 2016), and the implementation of Safety Management Systems (SMSs) (e.g. Office of Nuclear Regulation, 2017). Participants felt that SMSs are particularly important in maintaining safety.

Some participants challenged whether regulatory mandating of reporting some safety events forced their focus and narrowed organisational learning.

“Some close calls aren't reportable... so that thing he did at the air show, he miscalculated...He managed to recover the aircraft... so we don't get told... What should have been recognised was that it was not the display he was supposed to have done... [then the Shoreham air crash occurred].” AN4

The public and media were also thought to be a driver for safety. In aviation and rail, the public focus and media attention were felt to be a significant motivator. In contrast, in maritime, limited media attention was thought to mean less impetus to focus on safety, except when there is an oil-spill.

Inferiority complexes

Participants described how their SCIs may see themselves as inferior to others with regards to safety. This means they strive to be safer and learn from each other. Examples seen included aviation learning from nuclear, and maritime from rail. Participants were also keen to learn from healthcare because:

“The perception is that the NHS does it well, some aspects seem to be ahead of the game with just culture and patient safety investigation. Each industry has its good parts and we should be learning from each other.” MV

9.5.1.2 Context

Context referred to the wider factors that influenced the safety of SCIs. Themes identified were the regulatory environment (9.5.1.1) and operating contexts within which SCIs undertake activities.

Operating contexts

Participants described how contexts, within which their SCIs operate, affect safety. Parts of SCIs were described as technologically advanced with the presence of multiple controls to help prevent incidents; in these parts safety was thought to be “easier” to achieve.

“I think we have a massive advantage and so no wonder we are potentially a high reliability organisation, because it is really hard to bump aircraft into each other.” AATC

However, each SCI was also described to have many “moving parts” meaning that referring to, for example, ‘nuclear safety’ is an oversimplification. While an SCI may be seen as ‘safe,’ safety varies across an industry.

“... unlike aviation which is very safe, and the safety records are extremely high, the maritime world is not safe, it is fraught with danger...” MN1

9.5.1.3 Actions

Actions referred to the activities undertaken by companies/bodies that created safety in SCIs. Actions identified were safety management, safety learning, and safety culture improvements.

Safety management

All participants described their SCIs’ SMSs at company and pan-industry level. SMSs are part of safety infrastructures and allow structured approaches to the monitoring of risks and improvement of safety. In nuclear for example:

“... safety management system overseeing this which incorporates all the safety processes with accountable/responsible people.” NP1

SMSs are a regulatory requirement across the SCIs. In rail, the industry-wide SMS supports risk assessment, analysis, and risk modelling. Rail companies can use the SMS to understand their risk profile in comparison with the rest of the industry.

SMSs collate safety intelligence from various sources, not just incident and near-miss reports. Other sources include human performance assessments, experience reports, and audits.

“... other data sources as well, looking at other people's intelligence, so trusted organisations, other states, intelligence reports or annual reports. Pulling that information and adding it to ours.” AN4

Safety learning

Across the SCIs there are bodies that focus on learning from safety events. These were felt to create a focus on safety and made SCIs safer. The bodies include the aforementioned confidential reporting and independent investigation bodies and learning networks such as the Nuclear Operating Experience Learning Group (NOELG) (Nuclear Institute, 2015) and the UK Flight Safety Committee (UKFSC) (UK Flight Safety Committee, 2019). Rail has a particular body focussed on safety, standards, and strategy (Rail Safety and Standards Board).

Safety culture improvement

Participants described their activities to create cultures of safety in their companies/bodies. Where these cultures were more apparent, participants felt their companies were safer. Reporting, learning, supportive, and just cultures were described. Just culture was seen as preferential to a no-blame culture.

“In aviation from day one you are trained in a reporting culture and a culture of safety where people are looking out for each other...”

not a no-blame culture... we used to have that but have now moved to a just culture.” AN1

Participants were asked how they had developed the safety cultures in their companies/bodies. Various interventions were described with the fundamental factors thought to be management and leadership, and their defending of the culture. Safety cultures were also included in mandatory training. However, developing a culture was described as “slow” and “not necessarily visible.”

9.5.1.4 Consequences

Consequences referred to the outcomes of safety-related activities. Themes identified were the continuing occurrence of safety events and variation in safety maturity across and within SCIs.

Safety measurement

Participants described how safety in their SCIs is often assumed as it is difficult to measure. Historically, incident rates have been used as a measure, but with reduced incidents, new metrics have been needed. Examples described included human performance measures (International Atomic Energy Agency, 2005) and the amalgamation of data sources in SMSs.

Continuing safety events

Incidents were described to continue to occur across the SCIs, despite efforts to learn and improve. While rail, nuclear, and aviation participants had no doubt that significant incidents had decreased, particularly those involving service users, they still occurred. Incidents involving staff injuries are still common.

Examples of harmful incidents to service users included deaths on the railways (Rail Accident Investigation Branch, 2022) and aviation deaths (Air Accidents Investigation Branch, 2022). Airprox events regularly occur and are potentially increasing (UK Airprox Board, 2021). In international maritime, it was described that two ships sink each week with regular fatalities.

Participants thought that incidents are more likely occur in specific areas of each SCI. Areas suggested included night rail, merchant maritime, general, and business aviation.

“... business aviation for example there is more operational pressure. The owner of the aircraft is usually sat behind you with the door open saying I want to go now; I have got a meeting.” AN4

Participants acknowledged that it is not possible to prevent all incidents, however, this should not mean they “give up.” In many areas incident rates have plateaued at a low level, but sometimes “blips” are seen which coincide with periods of high demand.

“Back in the 1970s we were having oil spills almost every week. Ships were being lost. Now we have seen technical development, interest in GPS, on safety and navigation, better training, better equipment etc. We have plateaued at a certain level of accidents.” MM

While incidents still occur, it was thought that the contributors to them has changed. An aviation participant, for example, described that:

“... the number of accidents have decreased in the last 50 years... the first twenty odd years were improvements in technical (aircraft are built better). The second epoch was more to do with human factors... we are now looking at systemic and organisation factors... we kind of reached the plateau and we are just trying to nibble it down as much as we can.” AN2

All participants referred to ‘Heinrich’s or Bird’s triangle’ (3.3.1.1) (Bird and Loftus, 1976; Heinrich, 1931) and used these to justify focus on low-level events or near misses to reduce incidents. However, a small number challenged the validity of the hypothesis. They considered that the modern focus on near misses was solely because of necessity due to having limited incidents to investigate.

Several companies had tried to quantify their own safety triangles. They found them different to that described in the original research; this worried them.

“I would say annually we are probably looking at somewhere in the region of 500 or so on the passenger side and probably 300 on the colleague side. Not much of a triangle I suppose.” RP1

Safety maturity

The maturity of safety cultures in SCIs was felt to be linked to the occurrence of safety events. Participants considered that the low levels of incidents in their SCIs is in part the result of positive safety cultures; they were unable to provide evidence to support this.

“... we have had two fatalities in five months because the information is very similar, and it is their lack of safety culture that put them in that position. Had they been able to share that information and not had it tied up, that fatality could potentially have been avoided.” MN3

Safety cultures across the SCIs were generally considered to be positive but varied. In rail, for example, the safety cultures in freight and night rail are “very different” to passenger. Maritime’s safety culture was a recurrent concern, for example:

“... We are not very honest about how safety culture is in our industry. We are not open to sharing ideas or data... the perception is that we have a great safety culture, but we don’t...” MN3

Some companies and SCIs were described as safety leaders, for example, Sellafield Power Station. However, during the undertaking of the GT, the BBC covered a story related to Sellafield being a ‘toxic mix of bullying and harassment’ with concerns around working cultures and its impact on nuclear safety (British Broadcasting Corporation, 2021).

Blame was described to still exist in parts of rail, maritime, and aviation.

“... it's not about sacking somebody; it's about making sure they're safe. And I think we're quite a long way from that level yet.”

RF1

Participants shared that their companies, with the exception of maritime, use culture measures to understand leadership and safety. In maritime and certain parts of nuclear there are ongoing efforts to improve safety cultures, with acknowledgement that they have only recently started to focus on culture.

Local safety cultures

In response to the culture question (5.5.2.2), for general safety culture, 23 participants responded²⁵ with a median value of 4.0 (proactive) (IQR 3.0 – 4.0). For near misses, 14 participants responded with a median value of 3.5 (bureaucratic/proactive) (IQR 2.3 – 4.0). There were no pathological cultures, and two generative general cultures in maritime and nuclear. Full results are available in the appendix (9B/9C).

Other consequences

Across the SCIs, the successes seen with improvements in safety were also thought to have had unintended consequences. With incidents becoming less common, resources have been reduced or redirected from safety to other priorities.

“... tend to reduce the resources available to safety until we get to the point where things are becoming unsafe, and they investigate. You see this in all the sectors... if you think not having an accident is expensive, try having an accident.” AN2

Reduced resources limit the ability of safety teams to be proactive or look beyond what is required by regulation.

²⁵ Response options – 1.0 (pathological), 2.0 (reactive), 3.0 (bureaucratic), 4.0 (proactive), and 5.0 (generative).

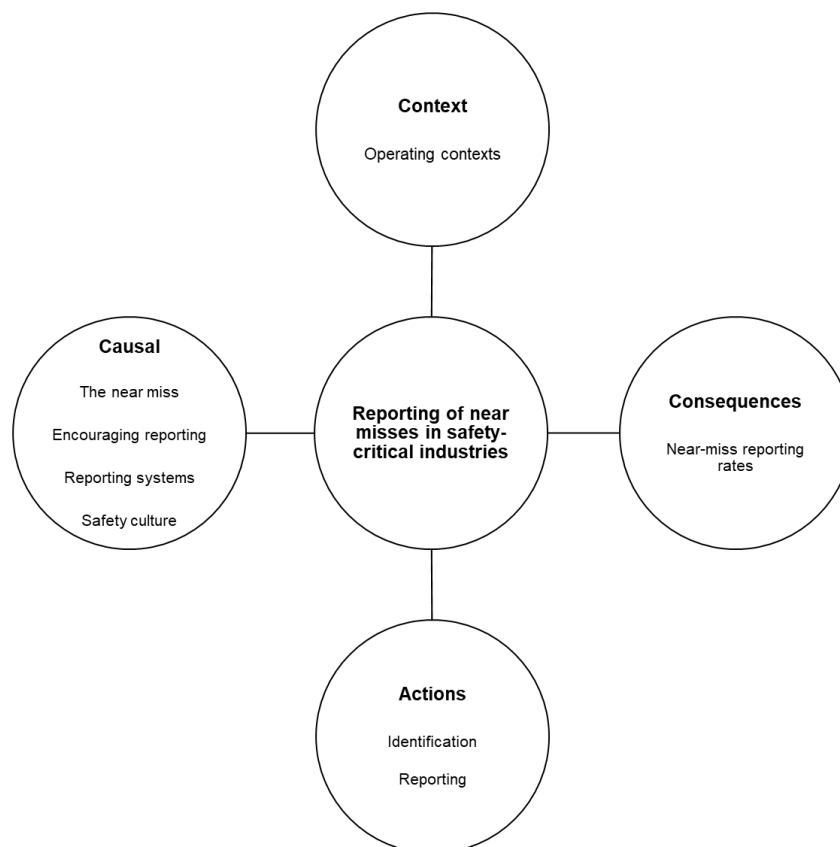
“We don’t look at the whole thing anymore because the amount of work we have got, and my team is that small – the biggest one in Europe, but still small for the amount of work we want to do.” AN4

There were also concerns that some SCIs have not “kept up” with modern safety science theory. This was exemplified by continued use of traditional investigation models and approaches, such as Root Cause Analysis (RCA). In aviation, several participants did not feel that human factors science had been embedded in their investigation processes.

9.5.2 Phenomenon 2 – reporting of near misses

Reporting referred to the identification and reporting of near misses. All participants advocated for the reporting of near misses. A summary of the coding paradigm for phenomenon 2 is shown in Figure 7.

Figure 7. Coding paradigm for phenomenon 2 – reporting of near misses



9.5.2.1 Causal conditions

Causal condition themes, driving the reporting of near misses, were the near miss, encouragers of reporting, the design of reporting systems, and safety culture.

The near miss – terminology

The near miss itself was a causal condition for reporting. Participants described how terminology and definitions influence reporting. SCIs vary in their use of the term 'near miss.' It was heard to be formally used in maritime and rail, but not by others. 'Close call' is also used in rail, however, a close call (Network Rail, 2018a) in UK rail is different to a near miss (Network Rail, 2018b).

“... whereas close calls, they were trying to get people to report unsafe acts and conditions, so if you categorise it like that, as opposed to operational near misses.” RP2

Aviation and nuclear participants described that their industries do not formally refer to 'near misses' in UK operations. In these SCIs, the term is a “colloquialism.” International research commonly refers to 'near misses' (8.2.2.1) and in nuclear some companies may use it to provide a focus on a specific issue.

“We tend to not use the term near miss, except in a specific context; they have accidental near misses like I almost fell, but from the nuclear safety side, near misses are more thought of as minor events which is a better description.” NP2

Participants felt that labelling events, such as by referring to them as near misses, hinders reporting because it requires staff to try to identify what type of event has occurred. There were advocates for the reporting of anything hazardous.

“We always say to people, if you are in doubt and you think that's a bit uncomfortable, then report it. One person's near miss is one person's not a problem.” RN4

The near miss – definitions

Participants from each SCI described definitions for events that they termed a near miss. Where national documents provide definitions, participants often knew these. Participants from maritime were less clear whether there is a national/international definition for a near miss; the International Maritime Organisation (IMO) defines it in their publications (International Maritime Organisation, 2001).

Participants thought that it may be difficult for other industries, such as healthcare, to learn from how their SCIs define near misses. This is because of the specifics of industries, their operations, and contexts. Definitions may be context-specific.

Participants described various types of near misses in their companies/bodies. There are general versus specific, and health and safety versus operational near misses. Examples provided included:

- **General** – ‘A sequence of events and/or conditions that could have resulted in loss. This loss was prevented only by a fortuitous break in the chain of events and/or conditions...’ (International Maritime Organisation, 2001).
- **Specific** – “... member of public nipping over a crossing, not expecting a train, [manual pedestrian] gate open and assumed safe to walk across” (RF1).
- **Health and safety** – ‘An event not causing harm but has the potential to cause injury or ill health...’ (Health and Safety Executive, 2021).
- **Operational** – “... a submarine that was stuck in a downward travel or dive, but this was rectified before any collision with the sea floor. This is just getting away with catastrophe and loss of the boat” (NM1).

Health and safety near misses were described to occur across the SCIs and are informed by the Health and Safety Executive (2021).

Operational near misses are different and SCI-specific. The safety cultures surrounding the different types of near misses were described to be different, with the just culture being more apparent for operational-type near misses.

“It depends if you are talking about the ship or the person. For the ship it is obviously where they get close, but don't touch. That is more a just culture I think...” MN3

Participants felt that SCIs were more focussed on operational-type near misses, rather than health and safety. Some operational examples included those in Table 21.

Table 21. Examples of operational near misses from the grounded theory

Industry	Example	Source
Aviation	“If somebody said there was a near miss, I would think two aircraft nearly crashed, whether it was on the ground or in the air.”	AN4
Maritime	“...the Costa Concordia was an incident, a near miss would have been the ship going off plan, not following navigation controls and narrowly missed running aground.”	MN1
Nuclear	“A near miss would be a reactor shutdown, it results in a commercial hit rather than harm.”	NP2
Rail	“The official one is that a near miss is when a train has to apply its brakes to avoid hitting a person.”	RI

In general, when defining a near miss, participants described them as outcomes that ‘almost happened,’ but did not because an intervention had occurred. The interventions could be luck, planned human, unplanned human, or controls built into systems.

Aviation and nuclear participants commonly referred to ‘barriers’ as the controls in their systems. In these industries when barriers function as intended, the system is functioning normally. However, if multiple barriers are breached (i.e., defence in depth overcome, see 2.4.2.3) without an outcome, or human intervention is needed to prevent an outcome, then those situations are considered near misses.

“Most regulator reportable events are defence in depth events. For example, one barrier not working, but the other three were. There were no consequences, but what we should have in place was not as available as we thought.” NP1

Aviation and nuclear participants also described events that they consider to be near misses, but that have a consequence. For example, ‘A worker decontaminating a piece of equipment...unknown to him a highly radioactive component was lodged inside. During cleaning, the lodged component came loose and fell into a waste container later to be discovered by workers [and exposing them to radioactivity]’ (International Atomic Energy Agency, 2012).

Some SCIs also have events that participants considered to be near misses, but that are termed incidents. This is because they represent events that have the potential to cause a significant outcome and therefore require attention. For example, in aviation a ‘Loss of control (including partial or temporary) regardless of cause’ is termed a ‘serious incident’ (International Civil Aviation Organisation, 2016), but was described as a near miss.

In developing a clear and usable definition of a near miss, participants agreed that “you need to nail the definition.” However, participants also acknowledged that their SCIs have not necessarily “nailed” their definitions. There was agreement that an intervention, recovery, or control is a key feature of a near miss.

In supporting staff to understand definitions and to minimise different interpretations of events, some SCIs have developed resources to help staff distinguish event types. Examples of leaflets and diagrams were provided. Appendix 9D shows one example from maritime.

Responses to the definition question

22 SCI participants provided responses to the definition question (appendix 5E/5.5.2.1) and appendix 9E provides the full findings. Fleiss Kappa showed perfect agreement for scenario one as an incident

($\kappa=1.00$, 95% CI [0.93, to 1.00]), fair agreement for scenario two as an incident (n=14) ($\kappa= 0.27$, 95% CI [0.20, 0.35]), fair agreement for scenario three as a near miss (n=14) ($\kappa= 0.23$, 95% CI [0.15, 0.31]), and very good agreement for scenario four as a non-event (n=21) ($\kappa= 0.86$, 95% CI [0.78, 0.94]). The comparison of these responses to healthcare are discussed in 11.3.

Encouraging reporting – incentives

Participants described the various approaches to encourage reporting of near misses. Factors such as Incident Reporting System (IRS) usability, anonymity, and training were felt to be important. Safety culture was also felt to be a significant factor influencing reporting.

Various incentives were described to motivate staff to report, such as celebrating reports, giving awards, reporting weeks, financial rewards, and real-time monitoring of reports with competition.

"Near miss of the week (or month) is identified and the originator is rewarded with shopping vouchers or similar." Nuclear Operating Experience Learning Group (participant)

More personal reasons for reporting were also described. Examples included the emotion associated with a near miss, the fear of the command chain, and in some cases reporting to support career progression (military promotion boards).

"To be fair and a credit to many drivers, because they are usually so upset, they just report it themselves." RN4

To drive staff to report, they need to see the benefits of reporting near misses. Feedback was thought to be an essential part of this.

"The most important aspect to encourage reporting is providing feedback even if you are not going to change anything." Nuclear Operating Experience Learning Group (participant)

However, not all companies were described to have effective feedback mechanisms, and feedback was not always thought to be useful.

“... [under-reporting] part of this is thought to be because of the lack of a sensitive response or adequate response from the actual organisation. This includes no feedback on individual cases or cumulative cases to the reporters.” UK Flight Safety Committee (participant)

A few participants questioned whether feedback is lacking because the benefits of reporting near misses are difficult to show. This means even minimal gains and benefits should be taken advantage of.

“... those marginal gains become more unconscious to people and therefore we have to keep pushing the data out to say positively this is where we are at...” AM1

Encouraging reporting – anonymity

Reporting of near misses was heard to commonly occur via confidential processes, rather than anonymous. Some participants described anonymous options. However, it was recognised that:

“... by all means it can be anonymous. The preference would be that we work and keep on promoting a just culture where it's a no-blame culture.” MP

Confidential rather than anonymous reporting was felt to be the best approach as it balances access to information and accountability. However, a negative is that individuals may feel colleagues are “telling tales.”

“Some track workers see it cynically as something to do over staff, tell tales and this suppresses the open and honest aspect.” RN1

Encouraging reporting – regulation

As described, regulation was seen as a significant driver of reporting. In some SCIs, for certain types of near misses, participants described “we have to report them.” This did not include all near misses and so safety leads had expectations that non-regulated near misses would be voluntarily reported; expectations were not always met.

Reporting systems

IRSs were seen as a critical factor in the encouragement of reporting. Multiple routes of reporting were felt to be needed.

“Take them in various ways – forms, email, verbal (line supervisor, safety rep, colleague etc.), direct into corrective action database, dedicated phone line.” Nuclear Operating Experience Learning Group (participant)

One route alone for reporting was not felt to be sufficient. For example, in one aviation company, three routes for reporting are available – a formal IRS, flight safety logs, and a separate anonymous confidential reporting system. Each transport SCI has a confidential reporting route independent of companies.

Participants agreed that “everyone” needs access to IRSs. Several companies had tried an app approach, but some had struggled with development and Wi-Fi connectivity.

“... is there something we can do on a phone app and just put in five lines of “this is what happens” and then forget about it – but we haven’t managed to do anything as simple as that.” AM3

Alternative routes for reporting shared include logbooks, briefings, proactive review of performance data, and “internet scraping.”²⁶

“We also have a flight safety log...they should hopefully go to find the flight safety logbook with a biro and say I have just done this, or nearly done this...” AM1

Regarding usability of IRSs, there was evidence of inefficient systems with poor aesthetics, difficult navigation, and error-forcing design. Several companies have tried to update their IRSs, but the stigma of poor usability remains. The costs of updating IRSs are also significant.

²⁶ Internet scraping – automated collection of data from the internet using search algorithms.

“... when we looked at [System X] they wanted £150,000 for their basic Ford Fiesta. We then spoke to people who had [System X] who said it is a very good system but as you grow and start to understand the data within near misses around correct trending and start to do proper data analysis, each little pack comes at a price.” AM3

Some, but not all companies had specific near-miss reporting forms. These were structured differently to incident forms and asked different questions which were sometimes bespoke.

“We are very excited about seeing if it's their [crew] first month on board or their final month on board...” MP

Some reporting forms had auto-population to speed up entry. There were also examples of where only limited detail was needed to be entered at the time of reporting, with follow-up processes to seek further information. Follow-up helps with data quality but requires resourcing.

Safety culture

A positive, open, and just safety culture was advocated for by all participants and thought to be fundamental to drive reporting. Culture was felt to start with induction and needs to be a constant factor throughout training, updates, meetings, etc. All companies were heard to include near misses in their training to create a “culture of reporting that includes near misses.” The training includes how to report near misses and their ‘just’ management.

9.5.2.2 Context

Contextual factors influencing the reporting of near misses were regulation and resourcing (9.5.1.2), and the reporters themselves. Staff from different professional and cultural backgrounds were known to have different thresholds for reporting near misses. These differences were thought to be more noticeable in companies with poor safety cultures.

“... in the control room there are specific people who are highly trained and know when and what needs reporting. The wider staff are less aware of what needs reporting, you get different levels from different groups.” NP2

It was also acknowledged that hierarchies influence reporting.

“I put that down to a hierarchical structure which is probably similar to the healthcare system in so much that it would be the junior staff who would not feel that they are able to report.” MP

9.5.2.3 Actions

Actions associated with the reporting of near misses were the identification of the near miss, and its physical reporting.

Identification

Automated alerting to and recording of near misses was discussed by participants from aviation, nuclear, and rail. In aviation, performance systems support identification of near misses. Aviation also has collision avoidance systems.

“TECAS [Traffic Collision and Avoidance System], that is a critical control, the last technological barrier we have got between that and a mid-air collision. It is not going to work with every aircraft. Sometimes it is non-existent... but it is critical, and it performs well.” AN4

In nuclear, control systems provide warnings if barriers are stressed or degraded. These warnings may be activated in situations that could be considered a near miss, for example, a ‘level 1 anomaly’ is where warnings have been activated, but defence in depth has been maintained (International Atomic Energy Agency, 2013).

In rail, ‘Signals Passed At Danger’ (SPADs) trigger alarms for signallers. There is no automatic reporting meaning a signaller or driver is then required to report the near miss.

Reporting

The activity of reporting near misses was heard to commonly occur via IRSs. Several companies have separate IRSs for near misses and other event types depending on their source.

“... where defects are identified on trains then we have a separate defect reporting process, so those are flagged and repaired, the train taken out of service immediately...” RP1

In some companies there are also different IRSs for different staff groups, such as pilots and engineers. Most companies were described to have processes to draw together information from various reporting systems to inform SMSs.

“... used the opportunity to bring near misses into the same event reporting system as everything else, they are treated in the same way as all other events, it’s a work in progress...” NM2

However, in some companies, attempting to collate safety intelligence has resulted in duplicate reporting. Collation of all intelligence was seen as important to provide a “holistic” view of the safety of a company.

9.5.2.4 Consequences

Consequences of reporting near misses were the reports themselves and what was subsequently done with them. The post-reporting processes are considered under the next phenomenon.

Near-miss reporting rates

There was felt to be under-reporting of near misses across the SCIs. Participants were confident that incidents are being reported, but not all near misses. Examples of near-miss reporting rates provided by participants are shown in Table 22.

Table 22. Near-miss reporting rates shared by participants

Industry	Examples	Source
Aviation	"... about 300 [Airproxes] per year..."	AN2
	"1 high risk, to 45 medium risk, to 1400 low risk..."	ACP1
Maritime	"... between 10 and 15% now [of near misses reported]. And that's been a three-year increase from where we started which was zero... 1033 raised [reports], with 267 are near miss..."	MP
	"5000 reports per year, in 2019 including 650 injuries and 3500 near misses/hazards; ratio of 1:4 in 2019, when they started in 2015 it was a 1:2... a 300% increase in reporting over the past 5 years and I don't know whether this is a good thing..."	MV
Nuclear	"Anywhere between 40-60 [near misses] per month out of around 250 events raised."	NM2
Rail	"... about 500 per year. 50% get taken forward. Those numbers are static over the past 5 years."	RN2
	"We don't have near misses; maybe one per week."	RF1

Some companies did not know their near-miss rates because of limited data. No company was satisfied that they knew about all the near misses. In one nuclear company, near misses were described as:

"Near Misses are new to [us] and we haven't quite developed the level of maturity we need to ensure that all near misses are consistently reported." NM2

When considering near-miss rates, participants invariably referred to 'Heinrich's or Bird's triangle' to compare them with incident rates. There were mixed views on whether high rates of reporting are good or bad. High-reporting rates were thought to signify a "good safety culture," but some participants questioned when high rates mean "a problem." There were also concerns that lots of reports limit the ability of companies to identify low frequency and high-impact risks.

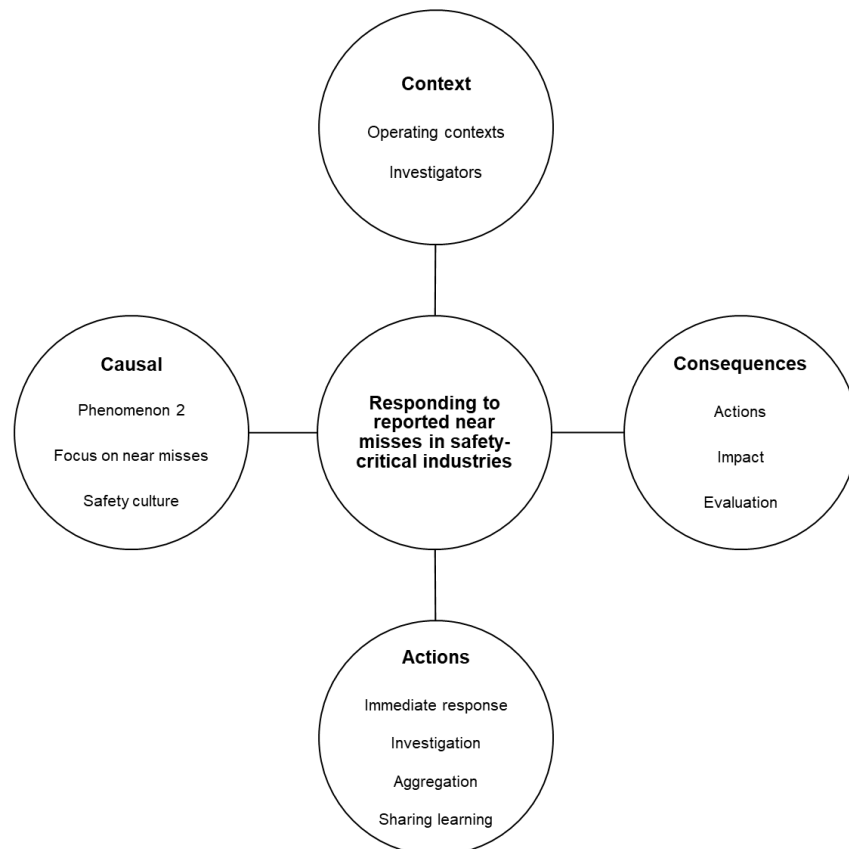
“It has been a success in many ways but there is also concern that we are not learning enough systemwide we are sitting on the data and not making the most of the opportunities of the data being there. Because we don’t truly understand what’s in there.” RN3

The consensus amongst participants was that reporting of all near misses is not needed, rather just a representative and high-quality sample.

9.5.3 Phenomenon 3 – responding to reported near misses

Responding referred to the processes to extract learning from reported near misses to support improvements in safety. A summary of the coding paradigm for phenomenon 3 is shown in Figure 8.

Figure 8. Coding paradigm for phenomenon 3 – responding to reported near misses



9.5.3.1 Causal conditions

Phenomenon 2 was a causal condition for the actions in phenomenon 3. However, participants described that the reporting of a near miss is not always enough to stimulate a response. SCIs need to have “the right focus” which is linked to the safety culture.

Focus on near misses

Aviation, nuclear, and rail participants described being able to focus on near misses because demand from incidents are low. They were keen to seek opportunities to learn, of which near misses are one.

“... this is the product of success; we had a good two and a half years with no real serious incidents... So, the ability to learn without catastrophe is fairly embedded in what we do.” RI

Maritime participants described how they are less able to focus on near misses because incidents are still common.

Participants also described how more contemporary views of safety are moving the focus away from incidents towards near misses and “successes.” Examples shared included consideration of “precursors,” “weak signals,” and “Safety II.” Precursors or weak signals were thought to be similar to near misses.

Some companies were undertaking projects to improve learning from near misses. These were more common in maritime and rail, but there were parts of aviation and nuclear where more was felt to be needed.

“The near-miss reporting mechanism was only implemented at the back end of 2019. We are still embryonic in terms of maturity level... if you consider Birds Triangle theory... We are not there yet.” NM2

Safety culture

Safety culture has been described in relation to the reporting of near misses (9.5.2.1). Culture was also felt to be linked to the management of near misses and the focus placed on them. As per 9.5.2.1, safety

cultures relating to near misses are sometimes different from those for incidents. This suggests that there is a different value placed on incidents and near misses by companies/staff.

9.5.3.2 Context

Contextual factors influencing responses to near-miss reports again included resources available and the regulatory context (9.5.1.1). Participants also described the need for trained and experienced investigators.

Investigators

Investigator roles in SCIs are often professional roles that require training dependent on the level of investigation. Investigators need subject matter knowledge and often specialise in one area of investigation, such as engineering. In the SCIs, being an investigator was seen as a positive career step. However, not all companies were thought to have enough investigation resource.

“Frankly, it’s a handful of part-timers here and we are at full stretch; we can’t do in depth statistical analysis. It’s hard enough dealing with the reports.” MN1

9.5.3.3 Actions

Actions following reporting of a near miss were the immediate response to make situations safe, escalation of reports, investigation, and learning.

Immediate response

Immediate response included mitigation of any ongoing risk (such as grounding aircraft), assessment of the severity of a near miss, determination of the level of investigation, and escalation to other bodies such as regulators and/or independent investigation branches.

Participants described how their company mitigation processes generally involve team leaders, shift managers, signallers, and others who were available 24/7 to respond.

“After a Near Miss is reported any immediate containment/preventative action is taken.” NM2

Rapid responses also mean near misses are often reviewed quickly, although there are company differences.

Assessment of severity involves “review” or “screening” of events to look at factors such as likelihood, repeatability, potential severity (if it had continued to completion), whether the issue was systemic, how it was detected, and what controls/defences remain. Some participants felt that looking at potential severity is “worthless” because everything has a catastrophic potential. There were examples of simple and more complex assessment methods shared, such as:

Simple: “We basically ask two questions: what is the most credible outcome and what is the effectiveness of remaining barriers?” AC2

Complex: “Reports are screened on a daily basis, categorised with how to respond. Near misses are screened by significance and various levels against an international coding system.” NP2

Participants described that assessing whether there is value in pursuing an in-depth investigation of a near miss is challenging.

“The real challenge for the sites with the resources they have got, and the volumes, is how do you separate that stuff out... how you focus your efforts to get the maximum benefit.” NN

The intent of severity assessments is to provide an understanding of the potential risks associated with a near miss and therefore the depth of any subsequent investigation. This assessment helps safety teams identify potentially significant risks amongst high numbers of reports.

Near misses were described to be more likely to be recommended for in-depth investigation if the potential outcome was significant, the near miss was recurrent, and/or the controls to prevent an incident had been degraded.

Where a near miss is recurrent it is important for investigators to:

“... include asking the question of why the actions from last time were not implemented or did not work.” NP1

Regarding external reporting of near misses, all the participants companies have criteria for a safety event to be reported to regulatory bodies (e.g. International Civil Aviation Organisation, 2016).

Investigation

Formal investigation of near misses was described to be reserved for more significant near misses. Investigations are commonly tiered depending on severity, such as the following described by a maritime participant:

1. Local shipboard investigation by line manager.
2. Local shipboard investigation overseen by the master.
3. Company investigation overseen by the executive team.
4. External investigation undertaken by the regulator.
5. External independent investigation undertaken by the Marine Accident Investigation Branch (MAIB).
6. Confidentially investigated through CHIRP.

Investigations are often undertaken by a team of investigators and some companies use panels to bring together perspectives and experiences.

“We have a panel of about 28 specialists... goes back and fore until we get a reasonable report about what has happened with a response from the company.” MN1

Various analysis methods were shared for the investigation of near misses, with no standard. The methods often consider and assess controls. Barrier analysis tools were felt to be useful because there is “a limited number of things that could go wrong” and the barriers are often already engineered into the system.

Other methods or tools described included fault event trees, Accimap, safety climate tools, and bespoke tools developed by companies. Several companies, including some in aviation and nuclear, were heard to use root cause analysis and its associated techniques such as the “five whys.” Participants described a need for industry-specific tools, but also flexibility.

The quality of investigations were described to vary within and across SCIs. Some participants felt more learning could be achieved and that current investigations are too basic, involve too much speculation, and are “more case review than investigation.”

Outputs of investigations are commonly in the form of investigation reports. Depending on the company these are made public (e.g. Air Accidents Investigation Branch, 2022). Some investigations also grade near misses as to their potential outcome and how far through a sequence the events had progressed before interception. For example, a rail participant described low potential (unsafe conditions) and high potential (event occurred with no harm) near misses. In aviation, Airproxes are categorised depending on their potential risk (UK Airprox Board, 2016).

Aggregating and trending themes

All participants described the importance of looking for themes across reported near misses (and other events). Ideally every near miss should be themed to track trends over time.

“You can learn from your near misses in two ways. One is the bulk data way, the SPAD way... Or indeed single near-miss type accidents, where the difference between a track worker being hit and not being hit...” RN4

Some SCIs “code” [categorise] every near miss. Categorisation involved qualitative analysis of reports using taxonomies and then review using quantitative methods to look for areas for further action.

“... tells us what to look for, where to focus our flight data monitoring and most of our significant interventions have come from near-miss reporting where we have been able to set up a flag within flight data monitoring... We have amazed ourselves picking up the sort of things in the data...” ACP2

Categorisation needs to be done by experienced staff to be reliable, and taxonomies need to be valid. Aviation and rail participants described examples of statistical analysis of themes and the exploring of data using mining; these techniques are still in the research phase.

Multiple taxonomies were identified within and across the SCIs. These commonly incorporate a set of event codes (where, when, who) and a set of contributory codes. One taxonomy seen in rail also includes recovery codes for near misses (Wright and van der Schaaf, 2004).

In one aviation company, data from categorisation has been integrated into ‘Bowtie diagrams’ (a barrier-analysis tool). These are used in near real-time, based on intelligence received from their SMS. Each Bowtie covers a common type of serious incidents (several of which are near misses).

Sharing learning

Sharing learning was described to include feedback to staff, particularly reporters, and across SCIs. Direct feedback to reporters was described as “ineffective” across all companies and SCIs, despite it sometimes being a regulatory requirement.

“... there is good reporting in the nuclear industry, but they are not so good at the feedback thing... need to focus on the feedback loop to identify the value added because at the moment it is difficult to see...” NM1

Methods of sharing were heard to commonly involve documents with the expectation that recipients read them. These include magazines, digests, bulletins, newsletters, and posters. Each company has a magazine and when visiting companies the thesis author saw these

scattered across tables in waiting areas. Some industries have mandates for staff to evidence their reading of documents; this was particularly evident in aviation.

“... we have to read it before we go flying. It's something that you need to be aware of... we don't do that often because we don't want to swamp our audience...” ACP1

However, where not mandated, staff were thought to be unlikely to read documents, particularly if they do not see them as relevant, or if information is not accessible.

Sharing learning in and across an SCI in an accessible and engaging way was described as “challenging.” Cross-industry sharing examples were found in aviation and nuclear via the aforementioned UKFSC and NOELG, respectively. However, it was heard that the NOELG had been finding it difficult to meet regularly and COVID-19 had impacted on learning opportunities.

Databases were another common form of sharing learning described. These may be internal to companies or cross-industry with access for registered users. It was not clear how often they are accessed or how they are used.

“The database contains all our incidents... if it is coded to the right level, we can just go in and pull all the information out. It has been over twenty years and has just been built on and built on...” AN4

Alerts, videos, and the use of social media are also used, all with benefits and drawbacks. Rail has used videos re-enacting incidents which had received feedback as engaging but upsetting.

“... we filmed it, and it was quite graphic. And at the end of the editorial board, we're in two minds... if you cut that bit, then you're going to lose the impact of this.” RF1

Participants did not know what the most effective way to share learning is. However, they described the need for learning to be rapid and relevant to those who are expected to learn from it.

“Traditionally [the safety team] would select reports... I don't fly, I don't know what is important for people. So why would I make that decision? One of my safety pilots should be making that decision.” ACP2

National sharing forums, such as NOELG, were felt to be valuable. The role of confidentiality in those meetings is important.

“Operating experience, OPEX, is a valuable source for learning about and improving the safety and security of nuclear facilities and activities.” NN

Learning was also heard to be incorporated into training, which again was felt to be valuable.

“All of these things feed into our simulator and training programme and when we come to our annual simulator checks we look at training experiences, verbal feedback, and we feedback to our safety database...” ACP2

9.5.3.4 Consequences

Consequences were the development of actions following learning from near misses and their impact on safety. Participants questioned whether their safety intelligence was being effectively used to improve safety in companies and industries. Where multiple reporting routes are available for reporting, a lack of interoperability of systems means some intelligence may not reach a SMS. This results in “learning in silos” and frustration from having to duplicate reports.

“We are working at the moment to get more automatic linking between the company systems and our information system to work around the need for double entry and standardisation for recording of incidents.” RN3

There were also concerns that sharing repeated learning from near misses could be negative.

'... they potentially also have a risk of normalisation of near misses as well by sharing the constant learning.' UK Flight Safety Committee (participant)

Actions following learning

Participants described how learning from near misses is used as a performance metric, leading indicator, lagging indicator, and measure of safety culture. However, participants found it difficult to describe where actions had been implemented following learning from near misses.

Limited actions as a result of near misses were thought to be because of limited investigation and learning. Near misses are more influential at a strategic level to raise awareness of risks and anticipate potential events.

"Everything is telling us we are very close to having a biggy. What is interesting is, because we put a target on our close calls, our figures were skewed..." RI

There were some limited examples of actions made following learning from near misses in rail, nuclear, and aviation. Learning had led to procedural, process, and engineering actions in those industries.

Examples were:

Nuclear: "... we ran trend analysis on what were on face value low level defects... we picked up from low level near miss reports that they had increasing loss of containment events on some chemical systems. Ultimately this resulted in fleet wide action to address the issue." NP2

Aviation: "... it provided medium term conflict detection, gained controllers more time, so in terms of the controller task, if a conflict is coming up through the barrier that the air space didn't spot... the controller at the front line will now see it... providing "what if" and "what else" tools..." AATC

Impact of actions

Participants were asked to provide evidence of impact from actions made as a result of learning from near misses. Participants described their beliefs that improvements in safety have resulted from actions in nuclear, rail, and aviation. However, in most cases, supportive evidence could not be provided. Examples of impact shared were:

Nuclear: “a refined process was implemented supported by training. The number of confined space incidents has dropped off markedly.” Nuclear Operating Experience Learning Group (participant)

Rail: “SPAD risk decreased notably in the first six years of the millennium, from 6.0 FWI [Fatalities and Weighted Injuries] in April 2000 to 1.2 FWI in April 2006. This is a reduction of 81%. There have been further reductions in SPAD risk since then.” RN3

Where the examples of impact were provided, they were specific to a near-miss type, such as SPADs. These often aligned with specific improvement programmes, such as that delivered by the Office of Rail and Road (2022).

More commonly, impact was described as perceived or was non-safety related.

“... feel there is evidence of near misses and events having a positive effect on management and performance of the plants but not necessarily safety... commercial impact because of the near misses in that they have improved performance and therefore a financial benefit.” NP2

Participants commonly based their perceptions of benefits of learning from near misses on safety by extrapolating the common cause hypothesis (3.3.1.1).

“So, from looking at those near misses and the data and identifying a trend and then linking them all together across the platforms of those ships... we have now avoided a death.” MM

Participants considered why there was limited evidence of impact following learning from near misses. They thought that learning from near misses:

- is only assumed and does not lead to improvements in safety.
- is hidden, subtle, and slow, so impact is not visible.
- is one form of intelligence to inform SMSs and so near misses contribute to learning, rather than being a sole source of learning.

More commonly participants were able to describe situations where learning from near misses had been ineffective, resulting in repeated near misses or incidents. One example was the near misses that had occurred prior to the crashes of the Boeing 737 Max 8 aircraft.

The recurrence of near misses also led participants to question the effectiveness of previous actions undertaken.

“We introduced these tools and patted ourselves on the back and then we would have an absolute horror. We recently had an incident where the tool wasn’t providing the support the controller thought it was, so there was a misunderstanding.” AATC

Evaluation of impact

Participants felt learning from near misses is valuable, however, evidencing that value is challenging. This may in part be because the data companies hold is too limited.

“The impact of near misses is difficult to note as the SMS isn’t mature enough. There are examples of where a big incident has led to change, less so for a near miss.” MV

Or the evidence of value is subtle.

“When it works best it is where you have problems, you go out and learn and adapt, and its where you have those continuous improvement programmes... Doing this continuously is difficult because of continuous change, it becomes hard for the business to know where you are sat.” NPR

It was also felt to be difficult to prove the absence of harm.

“How do you prove a negative? I have no idea, in the six years I have been doing it, how many lives I have saved.” AN2

To evidence value, participants felt that looking at trends over time may be a useful approach. Looking at a specific near miss in isolation is unlikely to be beneficial.

“Maybe if we get loads of these, we might think we have a problem with the craftsman/design etc. That is really hard as you need someone to join the dots.” NP1

Overall, however, participants had little doubt that “big incidents” are more likely to lead to actions and improvements.

“The Exxon Valdez was an extreme example that led to double hulling the ships... that was an argument that was put forward in 2006...” MM

9.5.4 Summary of findings from the axial coding

The axial coding provided a broad understanding of the management of near misses in the selected SCIs. It also provided insights into the operating contexts of the SCIs and their own perceived levels of safety.

The SCI participants challenged external, simplistic views that their industries consistently have positive safety cultures and high levels of safety. Safety in SCIs is not as homogenous as potentially believed by those in healthcare. The operating contexts of the SCIs also makes comparison between industries difficult because priorities and risks are different.

The findings led the thesis author to reflect as to whether maritime was an appropriate SCI to include in the GT. While maritime is safety critical, compared to aviation, nuclear, and rail, the perceptions of those working in maritime were that their industry is neither safe nor has positive safety cultures. While near misses were recognised, they were described as a more recent consideration. The findings from maritime

have been retained for the GT because the focus of this research is on identifying best-practice, to which the maritime findings can contribute.

9.5.4.1 Features of a near miss

The findings of the axial coding help determine some of the features of a near miss. Definitions were found to be bound to the contexts within which the near misses occurred, and in all cases an intervention was described to be needed for events to be a near miss.

Comparing the SCI and healthcare responses to the definition question provides interesting insights into similarities and differences between the industries. Most SCI participants did not describe scenario four as a near miss, rather they felt it a 'non-event.' They described it in a positive nature as the system doing as designed and intended, accounting for human fallibility. A barrier had been developed that reliably prevented an incident occurring. In contrast, healthcare staff perceived scenario four as a near miss. Through discussions with participants, these findings were thought to be suggestive of differences in system understanding and safety cultures. One SCI participant described the conscious or subconscious tendency of those in healthcare to want to "find someone to blame" meaning an intervention will always be perceived negatively.

9.5.4.2 Management of near misses

Each participant described a process in their company for managing near misses, but they faced challenges supporting reporting and extracting learning. Across the SCIs, no participant was satisfied with their company's local reporting and questioned whether they could do more. Reports are prioritised for investigation, and the majority of SCIs categorised their reports against a taxonomy to allow trending of contributory, and sometimes recovery factor themes. There was evidence of some taxonomy standardisation, particularly in nuclear.

9.5.4.3 Actions and impact

The findings provided limited further evidence of actions undertaken following learning from near misses and their impact on safety, beyond perceived benefits. This may be because near misses are used as contributory safety intelligence for company and SCI-wide SMSs, rather than being considered as standalone events. The role and importance of SMSs is a clear theme.

9.6 Analysis and findings – theoretical coding

Theoretical or selective coding is the final stage of GT and integrates axial codes into cohesive theories. Theories explain patterns in the data and may be considered principles that have emerged from the GT. The following sections provide an overview of the principles (Table 23) that emerged from this GT. The principles were verified with participants, and it was believed that theoretical saturation had been reached.

The coding structure from NVivo used to develop the principles is provided in appendix 9F. The principles related to:

- safety management of near misses in SCIs, and
- supporting reporting and learning from near misses in SCIs.

Table 23. Principles of how safety-critical industries manage near misses

Principles	
Safety management of near misses in safety-critical industries	
1	Learning from near misses alone is unlikely to lead to safety improvements.
2	Regulated safety management systems are used to monitor and improve safety, to which near misses contribute.
3	Safety across an industry is not homogenous, with variation in maturity and cultures.
4	Significant and harmful safety events lead to greater motivation to improve safety.
5	Safety-management practice is not directly transferable from other industries to healthcare.

6	It is preferential for industries to predict and prevent, rather than react to events.
7	Investigation of safety events (including near misses) is a professional role that requires training and resource.
Supporting reporting and learning from near misses in safety-critical industries	
8	Not all near misses are the same, with industry and context-specific variation.
9	A near miss involves interruption(s) that prevent progression, particularly where unplanned and involving a human.
10	Just and learning cultures are important, but not the only factors that support near-miss reporting and learning.
11	Confidential is preferable to anonymous reporting, but anonymity may support reporting of near misses.
12	There are two ways to learn from near misses – investigation and theming.
13	Prioritise near misses with the most learning potential for investigation.
14	Undertaking barrier analysis identifies the contributory and recovery factors associated with near misses.

9.6.1 Summary of the principles

The following sections provide a brief overview of each principle in turn.

9.6.1.1 Learning from near misses alone is unlikely to lead to safety improvements.

Participants were unable to evidence that learning from near misses alone improved safety in SCIs. Near misses contribute to safety intelligence collated by SCIs to monitor, evaluate, and improve system safety. Near misses may also provide learning to support improvements in other aspects of quality, such as efficiency and safety culture.

9.6.1.2 Regulated safety management systems are used to monitor and improve safety, to which near misses contribute.

SCIs have SMSs which draw together safety intelligence to provide a holistic understanding of safety and risk in and across industries. Intelligence sources include incidents, near misses, hazards, human performance assessments, reliability analyses, inspection reports,

service user experience reports, observations from walkarounds, and audits. A safety management approach recognises that incidents alone do not provide a comprehensive understanding of risk. SMSs are mandated by regulators and some SCIs have to evidence their SMSs and processes to be operational.

9.6.1.3 Safety across an industry is not homogenous, with variation in maturity and cultures.

SCIs are required to balance competing priorities, of which safety is one. In operational, customer facing parts of SCIs, safety is described as the main priority. However, in other parts of an SCI, such as mechanical departments, safety may not be a priority. This variation is influenced by different roles, priorities, scrutiny, and safety cultures.

Some participants challenged external views of their SCIs as safe and/or high reliability. While participants described efforts to maintain and improve safety, some companies were felt to be reactive, poor at learning, and have “toxic” safety cultures. In general, there are “pockets” of poor safety practice in each SCI, with the exception of maritime where safety concerns were heard across the industry.

9.6.1.4 Significant and harmful safety events lead to greater motivation to improve safety.

SCIs have histories that include significant, catastrophic events with extensive loss of life. In all cases the numbers of those events have decreased, but they still occur. SCI staff find it easier to report, and companies find it easier to implement actions following learning from significant and harmful events. In contrast there are concerns that near misses and non-significant events do not provide the motivation to bring about change.

9.6.1.5 Safety-management practice is not directly transferable from other industries to healthcare.

Participants described how SCIs are different to each other and healthcare, and challenged whether some of the principles around how

they manage safety are transferrable. The various industries have different priorities and risks. SCIs are often technologically advanced having spent years improving safety through engineered controls and automatic detection systems. Other, human-orientated industries will be less able to develop these types of controls.

9.6.1.6 It is preferential for industries to predict and prevent, rather than react to events.

Participants, where company safety levels and resource allowed, stated a preference to consider safety through different perspectives. Safety II was thought to be potentially beneficial to support prediction and prevention of events. SCIs want to address “unsafe acts or behaviours” earlier in event sequences.

9.6.1.7 Investigation of safety events (including near misses) is a professional role that requires training and resource.

In SCIs, investigators are investigation and subject matter experts with training and support. Investigator roles are seen as professional roles, with different training requirements for different types of investigation.

9.6.1.8 Not all near misses are the same, with industry and context-specific variation.

SCIs do not have one type of near miss. There are different types depending on the industry and context. SCIs have health and safety, and operational near misses, with specific and general definitions.

Participants saw operational near misses as occurrences that are specific and relevant to their industries. Examples include near collisions in maritime, rail, and aviation, and near meltdowns or radiation releases in nuclear.

9.6.1.9 A near miss involves interruption(s) that prevent progression, particularly where unplanned and involving a human.

A core feature of a near miss is that an interruption has prevented progression of events. The interruption may be termed a recovery, control, intervention, or interception. SCIs describe near misses as catastrophic events that ‘almost happened.’ The term ‘interruption’ has been chosen as it implies both active intervention by something or someone, but also that it could be by luck that events do not progress.

Where an interruption has been designed into a system, such as a control, and acts as intended, this was not necessarily seen as a near miss by participants. However, where there are no or limited controls to prevent progression of events, then those events may be termed or referred to as a near miss.

9.6.1.10 Just and learning cultures are important, but not the only factors that support near-miss reporting and learning.

Participants recognised the need for appropriate safety cultures in their companies. Just cultures are preferential to no-blame in order to maintain accountability and support information gathering and learning. SCIs have developed models for safety cultures to aspire to (e.g. World Association of Nuclear Operators, 2013).

Other factors that support reporting and learning include multiple routes to report, usable reporting systems, incentives, training in event identification, and feedback showing the benefits of reporting.

9.6.1.11 Confidential is preferable to anonymous reporting, but anonymity may support reporting of near misses.

Participants described mainly confidential reporting systems. Confidential and anonymous reporting both have benefits and drawbacks. Anonymity may remove fear, particularly where a just culture is not mature. However, anonymous reporting limits information,

loses the ability to follow up with reporters, and undermines accountability.

The transport SCIs have independent, external organisations that support anonymous reporting with a no-blame focus. These provide alternative reporting routes outside of companies.

9.6.1.12 There are two ways to learn from near misses – investigation and theming.

SCIs learn from near misses via 1) investigation, and 2) theming. Investigations are unable to be undertaken on all near misses, so prioritisation is used. Theming occurs via categorisation against taxonomies to allow later trending of the factors that contributed to and recovered near misses. Themes are used to inform SMSs to help identify safety risks to address, and to inform future strategy. Themes are also used to help support evaluation of actions.

9.6.1.13 Prioritise near misses with the most learning potential for investigation.

SCIs assess the priority of each near miss to investigate. Assessment considers the potential value of allocating resource to an investigation. Prioritisation considers factors such as likelihood, controls overcome, method of detection, and recurrence; it is therefore important to ensure this type of information is collected from reporters.

Regarding controls, participants felt that near misses resulting from planned (system designed) controls represent the system doing as designed. There is therefore greater value in investigating near misses where there has been an unplanned (human) intervention/recovery to help identify learning to develop better controls.

9.6.1.14 Undertaking barrier analysis identifies the contributory and recovery factors associated with near misses.

Participants described several analysis tools, but there is a preference for those that explore the role of controls. Barrier analysis allows

consideration of contributors to events and the controls in place to prevent progression. It also allows consideration of where events have occurred, but controls could be placed to prevent further progression to minimise harm.

9.7 Conclusions from the Grounded Theory

The primary aim of the GT was to understand how SCIs use near misses to improve safety, and to develop a set of principles around how best to manage near misses. The GT has provided 14 principles surrounding the safety management of near misses, and more specifically their reporting and how to learn from them. These principles may inform developments of near-miss management systems in healthcare and potentially the SCIs themselves.

A clear finding of the GT was that SMSs have a significant role in the management of safety in SCIs, and near misses contribute to these. SMSs were not referred to by healthcare participants in the Qualitative Case Study (QCS, study 2), nor in the healthcare scoping review. There may be opportunities for healthcare to consider the role of a SMS in monitoring and improving patient safety at organisational and national levels.

A secondary aim of the GT was to understand whether learning from near misses in SCIs has shown impactful improvements in safety. There was limited evidence of actions following learning from near misses described, and therefore limited evidence of impact. Conclusions are unable to be drawn about whether learning from near misses leads to impactful improvements in safety in SCIs. It is unlikely to be near misses alone that contribute to safety, rather their addition to intelligence in a SMS.

9.7.1 Ensuring rigour

To ensure the credibility of the GT findings, and to provide trustworthy principles, a rigorous methodology was followed as stated in the

protocol. Intelligence was triangulated from various sources and a second reviewer participated in the coding process. The findings and principles were verified with participants (5.4.4). Research memos were written as the research progressed acknowledging the role of the reviewers in the research (reflexivity), and how the theory was developed.

Reflexivity (5.4.3.3) refers to the influence researchers have on their own research and the undertaking of self-aware analysis. For transparency, the thesis author and second reviewer had previously held roles in clinical healthcare, patient safety, and investigation. None of those roles had involved a focus on near misses and the second reviewer approached the research with no preconceived ideas. The author declared that he had been exposed to a perceived lack of near-miss management in healthcare organisations and believed that management of near misses was likely to be better in SCIs.

9.7.1.1 Participant verification

Participant verification occurred as described in 5.4.4. Thirty-nine SCI participants were contacted to provide verification. Ten participants responded, representing aviation (n=4), nuclear (n=3), rail (n=2), and maritime (n=1). Further opportunities to share and verify findings arose during the course of the research through presentations at various conferences and events (see list of presentations), including attendance at the NOELG (20 participants).

In general, the free-text responses from participants were all supportive of the findings of the GT, with the addition of some clarifiers and extra information as described below. The findings were described as:

'Excellent recommendations, but an awful lot to implement.' Safety lead, military aviation

There were examples of where the findings had prompted SCIs to consider their local processes around near misses.

'I will feed this back into the team that are trying to encourage near miss reporting.' Safety lead, nuclear

Two nuclear participants wished to clarify findings related to their industries. One participant challenged the finding that 'all near misses were not reported' in the SCIs. Their belief was that this was not the case in their power plant, with good reporting of near misses. The other participant clarified that, in their part of the industry, they did not have any automatic detection of near misses.

Comments helped clarify and expand on potential opportunities to better manage and learn from near misses. It was agreed that terms and definitions require clarifying and that the distinction of near misses as a result of system controls, human interruptions, and luck is important.

There was debate around the finding that 'not all near misses require reporting.' While it was agreed that reporting of every near miss was not needed, not advocating for all may undermine reporting.

'I agree that not all [near misses] need reporting, but we would encourage colleagues across the business (rail) to do so whenever possible. For trend analysis, the more reports received, the more attention an issue is likely to receive.' Safety lead, rail

Reporting systems for near misses and culture were reiterated as vital to support reporting. A single point to access a reporting system was felt to be most appropriate, but the system needs to ensure engagement of reporters and ask specific questions relevant to near misses. One participant wanted to clarify the role of anonymity in reporting:

'Anonymous reporting should be an option available when local culture does not support open reporting.' Safety lead, nuclear

Regarding safety culture, just culture was agreed as preferable to a no-blame culture. However, it was challenged that a just culture is difficult to implement when individuals in organisations do not role model just behaviours; human resource departments were specifically noted as

problematic. It was reiterated that a just culture needs leaders to drive it.

‘Safety culture is a perpetual 'hearts and minds' process and one error in the culture process can set it back years.’ Safety lead, aviation

To support analysis, barrier analysis tools were again supported. In nuclear the use of human-reliability analysis tools was also felt to be of benefit.

Participants agreed that knowing how best to disseminate learning from near misses remained challenging. There were concerns that sharing of learning is not happening locally or nationally. Sharing learning may be improved by incorporation in programmes of work, such as simulation. The national learning forums were thought to be beneficial but required a clear purpose.

‘National learning forums need to be carefully defined to ensure that there is a positive purpose, rather than just a forum for sharing events, with no follow through.’ Safety lead, nuclear

The participants acknowledged the limited evidence available for the impact of learning from near misses on safety. It was agreed that value is perceived, and that the way to prove impact is through examples of where learning has not happened, and incidents have occurred.

Participants felt that there needed to be greater emphasis on evaluating actions made following learning from near misses. While acknowledging this to be difficult, suggestions included linking to leading measures and common hazards.

‘I haven't seen anything around challenge and assurance. If changes are brought in how are they assured, tested, validated, risk assessed? How are they linked to event reports to justify the changes and the risk reduction?’ Safety lead, aviation

The debate around the validity of the common cause hypothesis also prompted interest.

'... comments on Bird's triangle are interesting, I would like to know more.' SCI, unknown

A further suggestion, from a small number of participants, was the need for greater resource to help learn from near misses. This would support prioritisation of near misses for investigation, and trending of themes. Current technology is limited in its ability to extract learning from reports other than what has happened.

9.7.1.2 Additional learning

The participant verification also included additional comments of relevance to this research around wider safety management and SMSs. While there were concerns about translating some safety learning from SCIs to healthcare, some principles such as the use of a SMS were felt to be relevant.

Regarding a SMS, one participant was surprised that healthcare did not recognise the SMS concept. SMSs were thought to be important for healthcare to consider, but there was warning about the amount of investment it would take.

'A SMS is a serious undertaking and the scale of investment (resources, will, culture) that are required should not be underestimated. Culture cannot be imposed...' Safety lead, aviation

Participants challenged external perceptions of the safety maturity and levels of safety of the SCIs. Reporting and learning from near misses is unlikely to be as advanced in SCIs as perceived externally. Some participants also felt that healthcare will never be able to be like aviation because of the different contexts. A small number of participants felt there needed to be more proactivity in safety management in SCIs which included looking for 'what went well.'

9.8 Summary

14 principles emerged from the GT for the safety management of near misses. To the thesis author's knowledge, this is the first time that

principles such as these have been described. The principles, in addition to the findings of the QCS (study 2), scoping reviews (studies 1 and 3), and wider GT provide the evidence to answer the research questions.

The GT also found that there are unknowns in relation to near misses, such as how best to share learning and whether learning leads to improvements in safety. The next chapters will synthesise the findings of this research for discussion and answer the original research questions.

10 Synthesising the Research Findings – How are Near Misses Managed and Learned From?

10.1 Introduction

The findings of this research provide evidence to answer the original research questions (4.2.1). The findings also challenge the perceived value of learning from Patient Safety Near Misses (PSNMs), and whether healthcare should seek to learn from Safety-Critical Industries (SCIs). This chapter answers the first two research questions and discusses the challenges raised by the findings.

10.2 Expert verification

The research findings were presented to three Expert Verifiers (EVs) who were independent of the research (5.4.4). The intent was to verify findings with individuals who have experience of national patient safety policy, and who may be responsible for implementing recommendations from this research. Feedback from EVs is included throughout the following sections. The EVs were:

1. Chartered Specialist in Ergonomics and Human Factors and director of national healthcare safety investigations, with experience working for regulatory and policy bodies.
2. Chartered Specialist in Ergonomics and Human Factors and national healthcare safety scientist and educator, with experience working in the nuclear sector.
3. Registered nurse who has held head of patient safety roles in an acute hospital and mental health trust, with experience working in national policy.

10.3 Management of patient safety near misses

Research question (4.2.1): How are patient safety near misses managed and learned from in healthcare, and what impact has learning from near misses had on patient safety?

The purpose of learning from PSNMs is to identify actions that will help improve patient safety (e.g. Aspden et al., 2004; Department of Health, 2002). Patient safety is defined in relation to preventing harm to patients (2.5) and so improvements in patient safety are evidenced by reducing or preventing harm.

This research found limitations in how healthcare manages and learns from PSNMs. To date, there is limited evidence that learning from PSNMs has resulted in reduced harm to patients. These findings are based on a scoping review of the international healthcare literature (study 1), and on a Qualitative Case Study (QCS, study 2) of the English National Health Service (NHS).

In 7.4, three propositions were made for the QCS. None of those propositions were found to be true: there is no consistent definition for a PSNM across the NHS; PSNMs are not consistently part of organisational safety management; and PSNMs have not been evidenced to reduce harm to patients.

10.3.1 Managing and learning from patient safety near misses

The QCS's findings are presented in the logic model in appendix 7C. None of the NHS organisations in the QCS had specific processes for managing PSNMs. PSNMs, like incidents that cause no harm, often lead to little or no review or action. Organisations face problems defining, identifying, reporting, analysing, learning from, and implementing effective actions in response to PSNMs. Verification of these findings with QCS participants and the EVs suggested that they are representative of their experiences.

Using the Systems Engineering Initiative for Patient Safety (2.5.3) (Holden and Carayon, 2021) the factors found to be contributing to the

limited management of PSNMs in healthcare have been collated and are summarised in appendix 10A.

10.3.1.1 Improving management and learning

Management includes the defining, reporting, prioritising, and analysis of PSNMs to identify learning which can be used to direct actions to improve patient safety. The healthcare scoping review provided several recommendations to address the under-reporting of PSNMs (Table 8) such as improving safety cultures, incentivising reporting, and making Incident Reporting Systems (IRSs) usable. The reviewers noted that many of the recommendations state the need for improvements, but not necessarily how to go about making those improvements.

The scoping review also highlighted other potential opportunities to improve management of PSNMs. These include: identifying ways to recognise and report PSNMs that do not require staff to do so (8.2.3.1); considering how best to prioritise valuable PSNMs for investigation (8.2.4.1); and aggregating/theming information about each PSNM using a taxonomy (8.2.4.4).

The above opportunities to improve management of PSNMs are limited and rely on staff recognising and reporting a PSNM. However, the scoping review and QCS highlighted two issues with relying on staff – there is no clear and agreed definition of a PSNM, and staff do not have the time nor sometimes the motivation to report safety events that result in no harm.

Clarifying the definition

The scoping review and QCS demonstrated the need for consistency in the definition of a PSNM, and that this is required before other improvements in management can be pursued. The EVs also recognised the need for consistency, but that there are a multitude of definitions for PSNMs.

The cause of the multitudinous nature of definitions for a PSNM was not specifically investigated. However, the scoping review and responses to

the definition question suggested differing interpretations of a PSNM. The scoping review did not evidence that the features of a PSNM have ever been described. This is contributing to the ambiguity described by QCS participants as there is no agreement as to what a PSNM is. If there is no agreement, then staff cannot be expected to identify and report PSNMs. Inconsistencies in definitions also mean research into PSNMs may not be comparing similar event types (Woodier et al., 2023).

10.3.1.2 Unanswered questions

One EV summarised the limitations in healthcare’s management of PSNMs:

“Near misses I think are poorly recognised, understood, reported, captured, or whatever... there isn’t the mechanism or understanding of the value of reflecting and identifying near misses.” EV3

Limitations were found at all stages of the near-miss management process. These have been articulated as unanswered questions for healthcare in Table 24 and will be answered in the following chapters.

Table 24. Unanswered questions to support management and learning from patient safety near misses

Question	Sub questions
What is a patient safety near miss?	What is the best term? What are the features?
How can identification and reporting of patient safety near misses be supported?	How can staff be supported to report? What is the right design of a reporting system? What is the right safety culture?
How are patient safety near misses best analysed to extract learning?	What analysis tools should be used? What is the most appropriate taxonomy?
How is learning from patient safety near misses best shared?	What method of sharing is best? How can learning be evaluated?

10.3.2 Impact of learning from patient safety near misses

Any evidence of successful impact of learning from PSNMs was found in the scoping review. The following summarises the findings based on a publication of the scoping review by the thesis author and colleagues (Woodier et al., 2023).

10.3.2.1 Actions following learning

This scoping review found several actions that had been developed and implemented following learning from PSNMs with the aim of reducing future PSNMs, other safety events, and harm. Actions were often administrative, aimed at staff via creation of or updates to policies. This echoed findings of other authors around the focus of actions (Liberati, Peerally and Dixon-Woods, 2018).

According to action hierarchies (1.3.3.1), more effective actions are likely to be those that eliminate hazards, substitute hazards for something less hazardous, or engineer a way to reduce the potential for hazards to progress to harm (National Institute for Occupational Safety and Health, 2022). In the scoping review no substitution or elimination actions were found. There were some engineered actions which focussed on improving digital systems and technology, such as verification functions (e.g. Adelman et al., 2013). However, the engineered actions often still relied on a human to respond which could undermine their effectiveness and questions whether they were true engineered solutions, or rather administrative.

10.3.2.2 Impact following learning

The scoping review identified several academic articles that claimed harm had been reduced following learning from PSNMs. These claims were based on the belief that where PSNMs had been reduced, it was reasonable to conclude that harmful events would also be reduced (e.g. Adelman et al., 2013; Lozito et al., 2018). This assumes that the causes of PSNMs are the same as incidents, as per the common cause hypothesis (explored further in 12.2.1.3); the validity of the hypothesis

has been challenged (Manuele, 2003; 2011). Some authors also concluded that harm would be reduced, even though the events that had been reduced had previously not caused harm (e.g. Weiss et al., 2017; Smith-Love, 2022).

The scoping review found limited evidence that learning from PSNMs had reduced harm to patients. It did identify that learning from PSNMs may help improve safety cultures (e.g. Lozito et al., 2018; Tanz, 2018). The lack of evidence of impact led the EVs to question other types of safety event:

“This is interesting, this has helped me think around the whole learning from death agenda... does it truly prevent or improve mortality and I would be very surprised if we could evidence that.”
EV3

10.3.2.3 Unanswered questions

It cannot be concluded that there is no impact of learning from PSNMs on safety, rather there is currently limited evidence of impact. The lack of evidence will be influenced by the known under-reporting, variation in definitions, and challenges evaluating safety (1.5). These limitations have also been articulated as unanswered questions in Table 25 and will be answered in following chapters.

Table 25. Unanswered questions around action and impact following learning from patient safety near misses

Question	Sub questions
How can effective actions be developed following learning from patient safety near misses?	How can learning be used to develop actions? How can learning be evaluated to assess its impact on safety and quality?
What is the impact of learning from patient safety near misses?	What is the impact on patient safety? On other facets of quality?

10.3.3 Reservations about learning from other industries

Some QCS participants had reservations about learning from SCIs. Reservations were about the translation of near-miss management ideas from SCIs into healthcare. Of particular concern were the differences in the contexts of the industries and that direct translation may be inappropriate. The EVs agreed and this will be considered further in 12.3.

“All the safety critical industries share certain elements, but I do think that healthcare has particular challenges over other industries.” EV2

10.4 Management of near misses in safety-critical industries

Research question (4.2.1): How are near misses managed and learned from in safety-critical industries, and what impact has learning from near misses had on safety?

Statements in the academic (e.g. Leape et al., 2002) and grey (e.g. Aspden et al., 2004) literature describe how SCIs, such as aviation, effectively manage and learn from near misses. While management and learning processes for near misses in SCIs were identified by this research, management in SCIs was not as consistently mature or as advanced as this original thesis posited (4.2). It may be that near misses are undervalued in all industries, as exemplified by Corcoran (2004).

This research found that many SCIs have policy-driven and regulated safety management processes that incorporate learning from near misses. The quality of the management and learning varies, and there is limited evidence that learning from individual near misses has resulted in safety improvements. These findings are based on the scoping review of the SCI literature (study 3) and the views of the participants who contributed to the Grounded Theory (GT, study 4).

10.4.1 Managing and learning from near misses

Compared to healthcare, SCIs are more likely to have processes for reporting and learning from near misses. They also have supporting regulations, infrastructures, and safety cultures. However, the research findings question whether the current focus on near misses in SCIs is because they are beneficial to learn from, or out of necessity because of low numbers of incidents. GT participants felt it was the latter, with reference to maritime's lack of focus on near misses potentially being due to continuing incidents.

The GT highlighted how management of near misses varies depending on the safety maturity of an SCI/company. There was evidence that some companies have not yet fully implemented processes to manage near misses (Gnoni et al., 2022). Where there are processes, there is limited information available about how they operate.

The GT made apparent the infrastructure in SCIs to support the management of safety, including near misses. Infrastructure includes: training in event recognition and reporting; duty personnel with responsibilities to respond to reports; trained investigators; and tools to support prioritisation, analysis, and aggregation of information. SCIs have multiple routes internal and external to companies for reporting, with national and independent bodies that provide confidential and sometimes anonymous reporting routes (e.g. CHIRP, 2018).

Safety culture was a stated priority for many companies in the scoping review and GT (e.g. Office of Nuclear Regulation, 2019), and there was a preference for just cultures. There was evidence of safety culture improvement programmes in each SCI with staff specifically employed to support those improvements.

Despite safety cultures being a priority, GT participants described how they varied in and across companies; this was also demonstrated by responses to the culture question (appendix 9B/9C). One EV described how safety cultures in some SCIs may not be as mature and as just as externally believed:

“The phrase ‘that will never happen’ is what you hear a lot. People have been doing the job for thirty years and they won’t credibly acknowledge that bad things can happen.” EV2

10.4.1.1 Safety management systems

SCIs have Safety Management Systems (SMSs) to which near misses contribute. SMSs were commonly referred to in the scoping review (e.g. Gnoni et al., 2022) and were described as a fundamental part of safety in the GT. Individual near misses may be limited in their learning potential, but aggregation of themes from several near misses contributes to SMSs, actions, and improvements in safety. SMSs are considered further in 10.5.

10.4.1.2 Definition of a near miss

The concept of a near miss is recognised across SCIs as where something almost or could have happened. The term was found in the scoping review but seems to be rarely used in operational settings unless referring to health and safety near misses (Health and Safety Executive, 2021).

Events termed or thought to be near misses are different in each SCI. However, the scoping review and GT highlighted that they commonly involve an interruption in the sequence of events (e.g. Sheridan et al., 2004); similar was found in the healthcare components of this research.

Near-miss definitions are otherwise dependent upon the context within which they occur. GT participants felt health and safety near misses are different to operational near misses, with different reporting and learning cultures. Operational near misses, such as where two ships almost collide, are SCI specific and GT participants described these as the focus.

10.4.1.3 Reporting near misses

SCIs have many of the same challenges as healthcare when trying to support near-miss reporting (e.g. Hasanspahić et al., 2020). In SCIs

there have been efforts to automate recognition of some near misses, with several examples found in the scoping review (e.g. Banerjee et al., 2019; Zhou et al., 2019.) However, despite evidence of efforts, the scoping review highlighted that reporting levels vary. All but one GT participant felt there was under-reporting, with maritime participants being particularly negative. One EV noted that reporting in SCIs has not necessarily reached a point where people will report themselves:

“... within nuclear that would still be rare where people would put their hand up and say ‘a bad thing nearly happened while I was doing this’...” EV2

Reporting of near misses and other safety events in SCIs is also affected by the design of IRSs (e.g. Köhler, 2010). GT participants were consistently negative about their IRSs, and the scoping review highlighted the need for systems to be well designed (e.g. Pope and Orr, 2017). To make reporting easier some companies require limited information when reporting, with follow up via phone (e.g. CIRAS, 2018) Thoroman et al. (2018) highlighted how, even when near misses are reported, IRSs do not always collect the information required to understand the system’s contribution.

10.4.1.4 Responding to reports

SCIs have processes to review, analyse, and learn from reported near misses. They are learned from via quantitative (aggregation/theming) and qualitative (investigation) methods. The scoping review described the importance of having a mixed-methods approach (e.g. Davies et al., 2000) and the GT evidenced that aggregation/theming is part of safety management in most SCIs. Some near misses receive a full investigation, depending on factors such as their risk of recurrence and potential harm, while all are categorised against a taxonomy to aggregate information and identify themes (e.g. International Civil Aviation Organisation, 2014; Tiller and Bliss, 2017).

Investigation approaches across SCIs vary from simple to complex. GT participants and the scoping review commonly referred to barrier-based

approaches (e.g. Baines Simmons, 2018). This was confirmed by the EVs, but with some reservations about the approach:

“In the nuclear industry Bowtie model/Safety 1 is all powerful and I think that is useful to a point, but it stops being useful and you get diminishing returns on ever increasing investment.” EV2

The scoping review also identified the use of other investigation tools such as the Human Factors Analysis and Classification System (HFACS) in aviation, rail, and maritime (e.g. Bicen and Celik, 2022). Whichever approach is used, it should consider the system in its entirety (Thoroman et al., 2020).

The quality of investigations and learning from near misses was found to vary across SCIs. There were concerns shared by GT participants that investigations do not include enough consideration of the human factors involved and fail to prevent recurrence of events. There were also concerns that learning from near misses, and safety events more generally, is poorly shared in a way that engages staff. The best way to disseminate learning is not known.

10.4.2 Impact of learning from near misses

The scoping review described limited actions following learning from near misses in SCIs; there is therefore limited evidence of their impact on safety (e.g. Saks et al., 2004; Wincek, 2016). More commonly, where the literature commented on impact, it was perceived and based on the common cause hypothesis (e.g. Nesmith et al., 2013; Oktem et al., 2013) (considered further in 12.2.1.3).

A small number of GT participants described examples of potential impact following learning from near misses. On deeper exploration it was not possible to conclude whether near misses had directly led to the safety improvements or contributed amongst other intelligence. Where near misses have specifically contributed to improvements, this may have been where there has been a drive in relation to a specific

near miss, such as seen with Signals Passed At Danger (9.5.3.4) (Office of Rail and Road, 2022).

The scoping review identified challenges with the evidencing of impact following learning from safety events (Raslear et al., 2008). A small number of authors also challenged whether near misses had, could, or would lead to safety improvements (e.g. Button and Drexler, 2006; Korman, 2016; Madsen et al., 2016).

10.4.3 Reservations about learning from the industries

GT participants had mixed views about whether safety-related learning from SCIs is translatable to healthcare. Some participants were supportive of sharing learning between industries as they are constantly striving to improve. Other participants were more guarded about sharing, particularly because of concerns that healthcare may have a skewed view of safety in some SCIs with expectations beyond what is currently delivered. This will be considered further in 12.3.

10.5 Introducing safety management systems

GT principle (9.6.1.2): Regulated safety management systems are used to monitor and improve safety, to which near misses contribute.

The SCI scoping review and each GT participant described the role of SMSs in SCIs. There was no mention of SMSs during the healthcare research. SMSs in healthcare are not widely used, understood, or part of regulation unlike in other industries (Dixon-Woods, Martin, Tarrant et al., 2014; Healthcare Safety Investigation Branch, 2021).

A SMS is a ‘... systematic and proactive approach for managing safety risks... [an] integrated approach to managing safety including the necessary organisational structures, accountabilities, policies and procedures’ (Civil Aviation Authority, 2014). A SMS should be part of the culture of an organisation and requires leadership to drive its implementation and functioning.

A SMS has two parts in that it manages and promotes a strong safety culture, and provides an organised approach to safety (Grote, 2012). While there is not complete agreement on the key components of a SMS (Thomas, 2012), as an example, the Civil Aviation Authority (2014) describe how a SMS includes the following:

1. **Safety policy and objectives** – including management commitment, accountabilities, key safety personnel, and related documents.
2. **Safety risk management** – including hazard identification, risk assessment and mitigation, and safety investigation.
3. **Safety assurance** – the monitoring, measurement and review, and continuous improvement of safety.
4. **Safety promotion** – including training and education.

10.5.1 Benefits of a safety management system

As per 1.5, the evaluation of safety and the impact of interventions to improve safety is challenging. Similarly, evaluation of the impact of SMSs is challenging with a historical lack of empirical evidence associated with their use (Thomas, 2012). Various authors have looked to develop instruments to evaluate the impact of SMSs, such as Stozler, Friend, Truong et al. (2018) who developed an instrument for the aviation industry.

A search of the literature, however, demonstrates some evidence that positive investment in SMSs leads to positive returns in safety. For example:

- Thomas (2012) reviewed 19 studies that considered SMSs in aviation, maritime, and rail. They concluded that where certified SMSs are embedded, there are lower numbers of accidents/incidents.
- Lee, Kim and Kim (2012) considered occupational health and safety management systems in construction. They found that accident rates in the largest construction companies in Korea were lower where they had certified SMSs.
- Ali, Wyse, Odeniyi et al. (2022) evaluated an SMS in a natural gas company via staff perceptions, internal audit, and review of secondary

data. They identified a positive relationship between the SMS and safety performance.

Healthcare may benefit from a SMS to support a unified and proactive approach to safety (Healthcare Safety Investigation Branch, 2021). This approach will support a move away from ‘... the status quo... until something is proven dangerous and harmful,’ to focussing on trying to prove safety now and in the future (Leary, 2021). The EVs agreed:

“... where do you get the most bang for your buck... by cultivating your data... Pull it together – that is where we put our focus.” EV1

During presentation of this research to national bodies there was challenge that the NHS already has a SMS in the ‘Learning From Patient Safety Events’ (LFPSE) system (NHS England, 2018a). However, the LFPSE does not meet the requirements of a SMS (Civil Aviation Authority, 2014) and is a repository for incident reports from parts, not all of the NHS.

10.6 Review of the original research questions

The original thesis behind this research (4.2) was that healthcare has yet to implement effective management systems to learn from near misses to improve patient safety, and SCIs can offer guidance to healthcare about how best to implement systems. This research supports the first part of this thesis but does not fully support the thesis that SCIs effectively learn from near misses to improve safety.

This research has identified fundamental challenges that question the exhortations for healthcare to learn from PSNMs to improve safety (3.5.2.1):

1. There is no consistency in what healthcare describes as a PSNM.
2. There is limited evidence demonstrating that learning from near misses in healthcare and SCIs has led to improvements in safety.
3. There is a reluctance for healthcare to learn about safety management from SCIs.

10.6.1 Updating the research aims and questions (written retrospectively)

In light of the emerging research findings, during evidence collection, the research aims and questions were updated. Methodologically this is appropriate as GT seeks to be inductive (Foley and Timonen, 2014), with research directed by the findings (Charmaz, 2008). The methodologies and methods did not require changing.

The updated aims of this research were to clarify the concept of a PSNM for healthcare and to explore whether learning from PSNMs is justified. If justified, the aim was to identify what guidance SCIs (that have successfully implemented near-miss management processes) can offer healthcare.

The research questions were updated to:

1. What are the features of a near miss, and what is a PSNM?
2. Based on current evidence, is a focus on learning from PSNMs in healthcare justified, and is learning from SCIs appropriate?
3. If a focus is justified, how can findings from healthcare and SCIs contribute to implementation of PSNM management systems to improve safety?

10.7 Summary

This research provides a comprehensive insight into the management of near misses in healthcare (particularly the NHS) and SCIs.

Healthcare lacks systems and processes to manage PSNMs with little evidence that learning contributes to improvements in patient safety.

Processes are more established in SCIs, but demonstrating impact of learning from near misses has been challenging.

Before healthcare can consider how best to learn from PSNMs there is a need to clarify the concept. The next chapter will consider the definition of a PSNM.

11 Synthesising the Research Findings – The Features of a Patient Safety Near Miss

11.1 Introduction

The definition of a Patient Safety Near Miss (PSNM) varies with limited consistency across individuals, organisations, and national/international healthcare bodies. The healthcare scoping review (study 1) found no evidence that the features of a PSNM have been comprehensively described.

Clarification of the features of a near miss and specifically a PSNM are required to support consistency in definitions. This chapter synthesises the research findings to develop an evidence-based summary of the features of a near miss and proposes a definition for a PSNM.

11.2 The case for a consistent definition

A proposition made in the Qualitative Case Study (QCS, study 2) was that the ‘definition of a PSNM is consistent...’ This research found no consistent definition across the NHS or wider healthcare via the scoping review, despite international and NHS efforts (e.g. National Patient Safety Agency, 2004; World Health Organization, 2010). The inconsistencies in definitions are a longstanding and persistent issue (Castro, 2014; Marks et al., 2013; Yu et al., 2005).

Some QCS and Grounded Theory (GT, study 4) participants challenged whether clarification of the definition of a PSNM is needed because staff “should be reporting everything.” This research identified the following benefits of clarifying the definition of a PSNM; it:

- supports staff understanding of the different types of safety event (e.g. Yu et al., 2005).
- supports reporting of specific events when under-reporting is known to be rife (e.g. Hamilton et al., 2018).

- clarifies the specific learning value of PSNMs compared with no-harm incidents (e.g. Martin et al., 2005; Schildmeijer et al., 2013).
- allows research to compare like-with-like events (Woodier et al., 2023).
- may help address assumptions that PSNMs are being learned from in healthcare, when there is limited evidence that they are (10.3.2).

Clarification of a definition allows standardisation. Standardisation has been demonstrated to support efficiency and safety in healthcare (e.g. Leotsakos, Zheng, Croteau et al., 2014). However, it should also be acknowledged that any attempts to standardise can remove specificity (Wears, 2015) and this research found debate around whether broad or specific definitions for PSNMs are beneficial.

Many definitions of a PSNM are broad and generic, such as the World Health Organization's definition (3.5.1). In contrast, many SCI definitions of a near miss are specific to situations and events (Table 16). Standardisation of a broad definition, while providing consistency, may inhibit reporting because the definition may become ambiguous. This questions whether highly-specific definitions of PSNMs for particular clinical situations may be beneficial. This will be debated further in 13.3.3.

11.3 The features of a near miss

Features refer to the attributes that make events a near miss, rather than another type of safety event such as a no-harm incident. While this research found no clear agreement on the features of a near miss, themes arose from the findings that can help determine those features.

11.3.1 Near misses are context-specific

GT principle (9.6.1.8): Not all near misses are the same, with industry and context-specific variation.

In the evidence collected for this research, near misses were commonly referred to as an outcome. That outcome varies depending on who or

where the near miss is defined; this is contributing to variation in definitions.

For many QCS and GT participants, and in the scoping reviews, a near miss commonly related to events that did not involve harm to someone or something. This is also inferred in the Eindhoven Model (Figure 3) (van der Schaaf, 1992). However, this research also found examples of near misses that involve some degree of harm, such as:

- **Aviation** – crew incapacitation in flight (International Civil Aviation Organisation, 2016).
- **Nuclear** – overexposure of the public in excess of statutory limits (International Atomic Energy Agency, 2013).
- **Healthcare** – low blood pressure during surgery requiring treatment because of omitted preoperative medication (Ferroli et al., 2012).

GT participants described the above SCI examples to be near misses because there are no significant outcomes. In the aviation example there is no impact on the aircraft or passengers, and in the nuclear example, no visible outcome to the public. The Expert Verifiers (EVs) questioned the impact on the flight crew and potential long-term ramifications of radiation exposure to the public.

The findings suggest that a near-miss outcome is dependent on the context within which it occurs, such as to whom it occurs. In some industries a near miss may result in some harm, while in others it does not. This highlights the importance of context-specific definitions and that a near miss in one industry may be different in another.

11.3.1.1 Context-specific definitions

In healthcare and some SCIs, definitions used for near misses are broad. In contrast, definitions in several SCIs are specific, such as:

- **Maritime** – list
- **Aviation** – ‘A situation in which, in the opinion of a pilot or a controller, the distance between aircraft, as well as their relative

positions and speed, was such that the safety of the aircraft involved was, or may have been, compromised.’ (UK Airprox Board, 2016)

The above examples were termed ‘operational-type’ near misses by GT participants. Each includes a context (e.g. maritime), subject (e.g. ship), situation (e.g. close proximity of another vessel), and potential outcome (e.g. collision).

GT participants and the SCI scoping review (study 3, e.g. Nesmith et al, 2013) were supportive of having lists of ‘near misses’ to support identification, encourage reporting, and to show their importance; lists were less common in healthcare, but seen in pharmacy, transfusion, and radiotherapy specialties (e.g. Mandal et al., 2005). GT participants also described the need to remove ambiguity around any definition. For example, ‘closeness’ for a maritime near collision is often not quantified (Rudan et al., 2012).

11.3.2 Near misses involve interruptions

GT principle (9.6.1.9): A near miss involves interruption(s) that prevent progression, particularly where unplanned and involving a human.

A clear theme from across the QCS, GT, and scoping reviews was that events interpreted as ‘near misses’ involve interruptions. Table 26 provides examples of ‘near misses’ and their interruptions.

Table 26. Examples of near misses and their associated interruptions shared by research participants

Industry	Event	Interruption
Healthcare	Patient prescribed a medicine they are allergic to	Nurse checks patient allergies prior to administration and identifies the event
Aviation	Two aircraft are flying on courses that will bring them into close proximity	Cockpit systems alert pilots and evasive action is taken

Maritime	Two ships are sailing on courses that will cause them to collide	Navigator monitors track of other ship and gives order to change course
Nuclear	Temperature in the reactor begins to climb	The reactor system automatically reduces temperature to normal operating levels
Rail	Train passes a red signal into an area of track where a train appears ahead	Train driver applies the emergency brakes

Interruptions are referred to by other terms depending on the context, such as defences, controls, barriers, recoveries, and interventions. For consistency, interruption will be used in this thesis to represent where the progression of events has been prevented.

The recognition that interruptions are a feature of a near miss was felt by some GT participants to be obvious. However, the definition question responses (appendices 7D/9E) suggest that this is not apparent to everyone with debate around what an interruption is and where it acts.

11.3.2.1 Types of interruption

The definition question findings demonstrate the variation in the views of individuals across healthcare and SCIs as to what is perceived as a near miss. Each of the three scenarios that resulted in no-harm were termed near misses by several participants. This suggests that a near miss may be defined wherever there has been an interruption, whether it be luck (patient did not react to the medicine), human (nurse prevented administration), or engineered (system prevented prescribing). However, the differences in responses to scenario four (system prevented prescribing) between healthcare (50.0% termed it a near miss) and SCI participants (95.5% termed it a non-event) suggest the definition of a near miss depends on the effectiveness of an interruption.

The role of 'luck

'Luck' is included in some definitions of a near miss and refers to where the outcome is brought about by chance, rather than through a planned intervention. For example, Sheikhtaheri (2014) in 6.3.2.3 describes types of near misses where chance or an unplanned intervention has prevented progression of events or harm.

Luck may be considered an interruption in events, albeit not involving an apparent action. As per Sheikhtaheri (2014), luck and unplanned interventions are comparable; they both represent where there is no planned control to prevent progression of events to become an incident.

11.3.2.2 Effectiveness of an interruption

Effectiveness refers to how reliable an interruption is at preventing an incident. The Hierarchy of Controls (Figure 2) provides principles to help consider which controls (the interruptions) may be more effective (National Institute for Occupational Safety and Health, 2022).

Effectiveness is inversely related to the amount a human has to do to ensure a safe outcome.

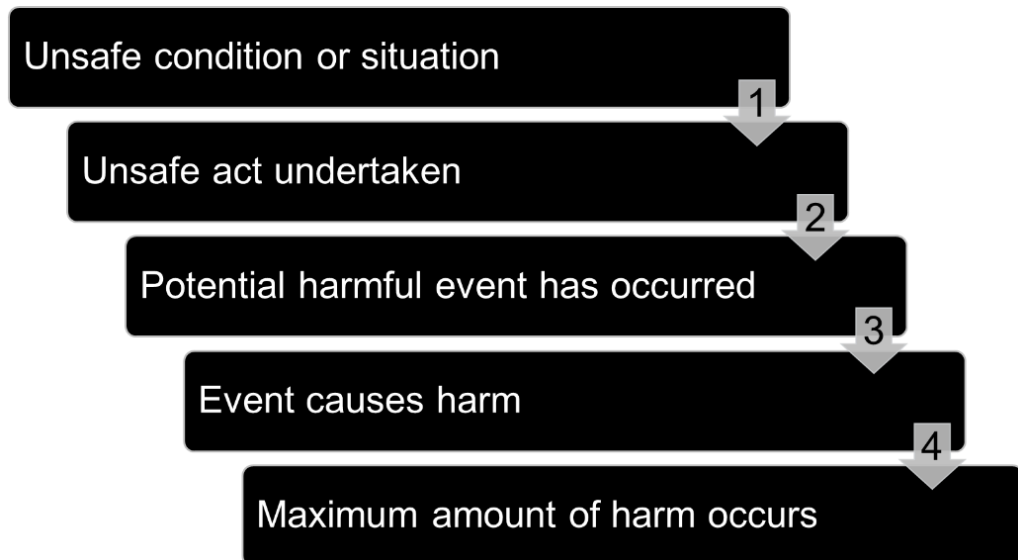
Returning to the definition question, on discussion with SCI participants they described seeing scenario four as the system doing as designed to account for the fact that humans will not always identify and catch hazards. From their perspective a near miss involves a human interruption or luck, rather than a designed and planned system-interruption.

11.3.2.3 Location of interruptions

Participants questioned the point at which an interruption must act for events to be considered a near miss; this was also questioned in the scoping review (Sheridan et al., 2004). Figure 9 summarises the four points identified during this research where, if an interruption occurs, events may be considered a near miss. The figure highlights, again, the variation in the interpretation of a near miss. For example, some may perceive a near miss to have occurred when an unsafe condition is

rectified (1), while others may perceive a near miss to have occurred where harm has occurred, but not the maximum amount possible (4).

Figure 9. Points at which a near miss may be considered to have occurred



In contrast to the GT, QCS participants more commonly thought that a near miss related to an interruption just prior to the point of an incident (point 3 in the above figure). Several participants described how the “essence” of a near miss is that it is a “near incident.”

The debate around the location of interruptions has led some authors to define different types of near misses depending on the point of the interruption. Network Rail (2018a), for example, refer to points 1 and 2 in the above figure as ‘close calls’ and as ‘precursors’ to near misses. Ginsburg et al. (2009) describes minor and major near misses depending on the proximity of the interruption to the point of incident.

This research found no consensus as to the location of an interruption for events to be a near miss. If the value of a near miss is in understanding the interruption, then it does not necessarily matter where it acts, as long as it prevents progression of events. The difference in views of the GT and QCS participants described above

may suggest that the definition of a near miss depends on the safety maturity of an industry/organisation/company:

- **More mature** – with good reporting cultures may seek the reporting and rectifying of all unsafe conditions, acts, or adaptations/variations; these may be considered near misses in those systems and may align with a Safety II perspective (see 12.2.2.1).
- **Less mature** – with more limited understanding of near misses and poorer reporting, may consider an initial focus on near misses as interruptions just prior to the point of an incident; these may also be easier to conceptualise and align with Safety I and barrier-analysis approaches (see 13.5.3.1).

Defence in depth

Nuclear participants spoke about ‘defence in depth’ (2.4.2.3) in relation to near misses. Multiple planned interruptions are required to provide effective defences to incidents. A near miss may be considered to have occurred when multiple interruptions have not prevented progression of events and there are only limited interruptions left, or the remaining interruptions rely on humans (e.g. Center for Chemical Process Safety, 2003). The layers of defence degraded during events are included in nuclear event definitions and are used to prioritise events for investigation (International Atomic Energy Agency, 2013).

11.3.2.4 Interruptions and the Eindhoven Model

The Eindhoven Model of near misses (Figure 3) describes interruptions at two points – ‘defences’ and a ‘recovery.’ Defences are the ‘...safety rules, training programmes, and redundant safety equipment...,’ and recoveries are ‘...the capability to find (intuitively) original solutions to unexpected problems’ (van der Schaaf, 1995). In the Model it is the recovery interruption that defines the near miss.

Comparison of this research’s definition question responses and the Eindhoven Model are shown in Table 27. SCI responses commonly aligned with the Model’s terminology. Healthcare responses also aligned for scenarios 1 to 3, but there was more variability. The greatest

variability in responses was between SCI and healthcare responses to scenario 4. These findings suggest that healthcare’s perception of the interruption in a near miss can originate from either human (recovery) or system (defence), while the SCI perception is that a defence functioning as intended is not a near miss, as per 11.3.2.2.

Table 27. Comparison of the definition question responses and the Eindhoven Model

Scenario	Eindhoven Model interruption	Eindhoven Model term	Healthcare (n=14)	SCI (n=22)
			Commonest response	
1	Nil	Incident	Incident (n=14)	Incident (n=22)
2			Incident (n=9)	Incident (n=14)
3	Recovery	Near miss	Near miss (n=10)	Near miss (n=14)
4	Defence (engineered functionality)	Return to normal	Near miss (n=7)	Non-event (n=21)

Where GT participant responses to the definition question did not align with the Eindhoven Model is around the role of humans in defences. van der Schaaf’s (1995) definition of recoveries and defences includes situations where humans are involved, whether unplanned (recovery) or planned by following a safety rule (defence). However, GT participants described the rationale for terming scenario 4 as a non-event was that it did not rely on a human. This suggests an SCI perspective that, if a human intervenes, whether planned or unplanned, a recovery has occurred.

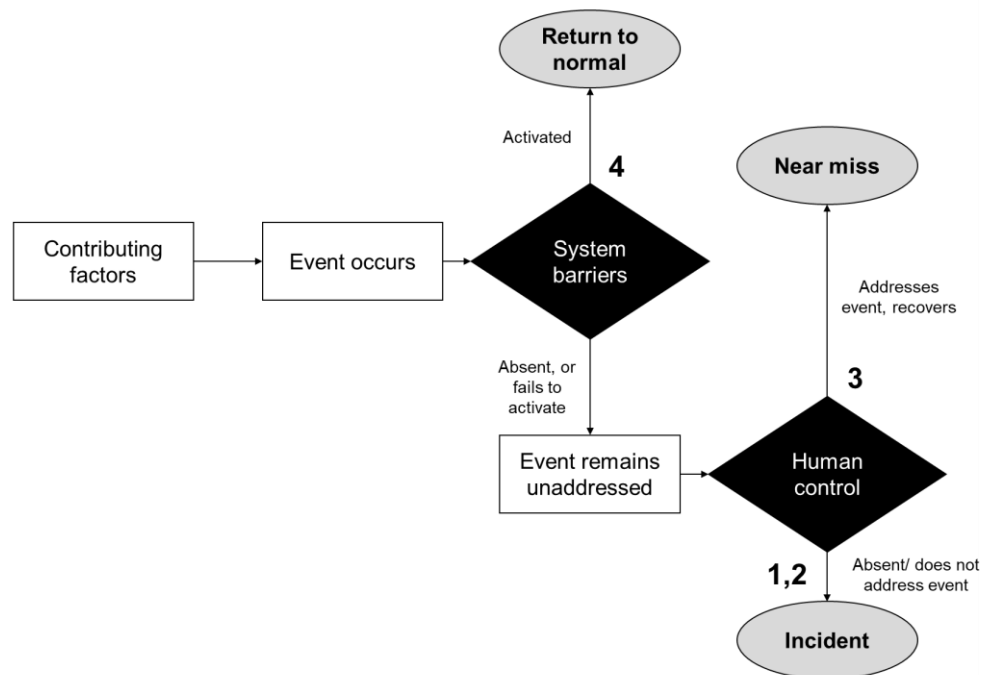
The differences found between GT participant responses and the Eindhoven Model potentially represent how thinking around the effectiveness of safety interventions has evolved since the early 1990s. The need to mitigate for human fallibility has become increasingly recognised as systems-thinking has advanced. Using barrier-

management terminology (1.3.3.1), any interruption requiring a human is a control, but will never be a barrier because it cannot be assumed to always be successful (Chartered Institute of Ergonomics & Human Factors, 2016). Recognising where human controls act to prevent incidents provides opportunities to develop barriers.

Based on the above findings an update to the Eindhoven Model is proposed (Figure 10).

Figure 10. The 'Updated Eindhoven Model' based on research findings

Numbers represent scenarios from the definition question



11.3.3 Near misses are complex, not linear

This research found that near misses are often portrayed as a linear set of events (e.g. Henneman and Gawlinski, 2004). The Eindhoven Model also describes a near miss as a sequence similar in nature to the Domino Model (1.3.1). However, while this linear view may help understanding, it is based on traditional models of incident causation and is unlikely to be how incidents occur in modern, complex systems

(Underwood and Waterson, 2013). Seeing near misses as linear may undermine their learning value.

Safety science researchers have increasingly recognised that incidents are not linear and instead arise from the interaction of multiple factors (Leveson, 2011). Very rarely will safety threats be dependent on the result of a single decision or action (Rasmussen, 1997). Therefore, seeing near misses in relation to single interruptions is too simplistic (Thoroman et al., 2018). Some industries are increasingly recognising the role of multiple contributors to incidents and are therefore designing layers of protection in systems to reduce the chance of factors combining to cause incidents.

11.3.4 Near misses highlight vulnerabilities

There are potential benefits in reframing near misses as positive events or successes (e.g. Wallace et al., 2017). This is demonstrated by healthcare good-catch programmes, particularly in the United States of America, and evidence that seeing near misses as ‘good catches’ positively encourages reporting and vigilance (Mahlmeister, 2006). Due to the known variation in definitions, this research found that a good catch may not always be synonymous with a near miss (e.g. Herzer et al., 2012).

GT participants and the SCI literature had concerns about reframing near misses as positive events, false alarms, or as evidence of resilience. This was because the ‘marketing’ of events influences engagement and how people behave (Barnes et al 2007; Tinsley et al., 2012). If near misses are seen as representing resilience, this may inhibit future actions with people making riskier decisions (Dillon et al., 2014; Dillon and Madsen, 2011; Tinsley et al., 2012). Dillon et al. (2011) encourage the portrayal of near misses as system vulnerabilities to be learned from.

11.3.4.1 Language of definitions

The language used in the definition of a near miss can portray it as positive or negative. Reflections by participants on language suggested that healthcare commonly uses terms such as “could of,” “prevented,” and “good fortune” (e.g. Ardenghi et al., 2007; Carpucho, 2011), and SCIs use the term “almost.” Participants felt that “almost” suggested vulnerability and being close to catastrophe. Similarly, Kundu et al. (2021) found people are more willing to report a near miss if it is termed as ‘almost happened’ rather than ‘could have happened.’

11.3.5 Summary of the features of a near miss

Research question (10.6.1): What are the features of a near miss...?

The following features were shared with the research participants and the EVs who felt them to be appropriate, based on the evidence, and in line with modern safety science. They agreed with focussing on and prioritising learning following events where humans or luck are the interruption.

Feature 1 – a near miss is bound by its context.

A near miss is context-dependent. The context helps define the near miss and must recognise the elements of the system within which it occurs.

Feature 2 – a near miss involves an interruption(s).

A near miss involves an interruption in the sequence of events. In complex systems, near misses are contributed to by multiple factors and involve multiple interruptions.

Feature 3 – the types/numbers of interruptions are context dependent.

The context also defines the interruptions. The complexity of a system and the safety risks help determine what, where, and how many interruptions must be activated for events to be defined a near miss.

Feature 4 – a human interruption or luck represents a significant near miss.

An interruption that relies on a human or luck will not be consistently reliable and effective. Human interruptions represent points where design of more effective interruptions (barriers) could be considered. Luck represents an absence of any planned control.

Feature 5 – a near miss represents a vulnerability.

While the reporting of a near miss should be seen as a positive, seeing a near miss as a positive situation may negatively influence risk perceptions and actions. If the wrong language is used, near misses could be 'defined away' (Crandall et al 2018). Near misses are 'almost' events.

11.4 Patient safety near misses

Research question (10.6.1): ... what is a patient safety near miss?

The above features of a near miss can be used to define a PSNM. To do this requires consideration of the specifics of the healthcare context and the role of the patient.

11.4.1 The role of the patient

Across the QCS and healthcare scoping review there was debate as to whether events that reach a patient and cause no harm, and events interrupted before reaching a patient, both represent PSNMs (e.g. Yu et al., 2005). There are also outcomes termed PSNMs which have resulted in harm to patients (e.g. Moreno and Zuberi, 2019).

The presence of the patient adds complexity when attempting to define a PSNM. The patient is the centre of care and therefore important to consider in any definition. As found by an Institute for Safe Medication Practices (2009) poll, most respondents interpreted a PSNM as where events had not reached a patient; the majority of participants in this research agreed. There is a distinct point at which interruption of events

changes the outcome from an incident (harm may occur) to a near miss (where physical harm cannot occur).

Feature 6 – a PSNM involves interruption(s) to prevent events reaching a patient.

Some QCS and GT participants challenged whether the above distinction between a PSNM and incident is required, or whether it adds complexity. This research suggests that it is important because the learning potential of no-harm incidents and PSNMs are different (considered further in 12.2).

11.4.2 A definition of a patient safety near miss

Applying the above features of a near miss means that a definition of a PSNM must include the patient, single or multiple interruptions by humans or luck, and imply vulnerability. Based on the findings of this research the following broad definition for a PSNM is proposed and recommended.

Recommendation – a patient safety near miss is ‘an interruption of events by person or persons involved in the care of a patient, or luck, which otherwise would have had the potential to reach and cause harm to that patient.’

The EVs agreed that the above definition was based on the findings of this research.

As a context-specific definition (see 11.3.1.1), the above definition has a context (healthcare), subject (the patient), situation (hazardous events), and potential outcome (reach the patient). In comparison with international definitions of PSNMs, the proposed definition aligns with the World Health Organization’s (2010) (3.5.1) definition in that ‘it did not reach the patient,’ but differs by including human interruption(s) and the recognition that a near miss is different to an incident. The above proposed definition is more detailed than the WHO’s definition and highlights the importance of focussing on PSNMs that result from human intervention or luck.

11.4.2.1 Limitations of the proposed definition

The above definition is rooted in the findings of this research. It contrasts with the views of some research participants and literature. However, it is pragmatic, recognises the learning potential of a near miss, and clarifies how events relate to a patient.

As with previous definitions of PSNMs, a limitation is the potential difficulty healthcare staff may have interpreting and applying it in practice. This was also recognised by the EVs:

“I can completely see the logic in the notion that, if a recognised system has acted as a kind of mitigation that is essentially not an incident, I think trying to get people to understand that would be a challenge.” EV1

Operationalising the definition will be considered in 13.3.3, but from a frontline staff perspective, knowing the definition is unnecessary as long as staff are supported to report events where something ‘almost happened.’

11.5 Summary

Prior to this research the features of a near miss had not been described. With clarification of the features of a near miss an evidence-based definition for a PSNM has been proposed.

Following the paucity of evidence of the impact of learning from PSNMs, the next chapter will debate their value and whether it is appropriate for healthcare to aim to learn from PSNMs and SCIs.

12 Synthesising the Research Findings – Justifying Learning from Near Misses

12.1 Introduction

This research found limited evidence that learning from near misses in healthcare and Safety-Critical Industries (SCIs) has resulted in improved safety through reductions in harm. This chapter synthesises the research findings to draw conclusions about the value of learning from Patient Safety Near Misses (PSNMs) and the appropriateness of healthcare learning from how SCIs manage near misses.

12.2 Justifying learning from patient safety near misses

Research question (10.6.1): Based on current evidence, is a focus on learning from patient safety near misses in healthcare justified?

At the commencement of this thesis it was assumed, based on statements from national healthcare bodies (e.g. Department of Health, 2002), that learning from PSNMs was beneficial and appropriate. As this research progressed, limited evidence was found of the impact of learning from PSNMs on patient safety and harm to patients (Woodier et al., 2023).

While an absence of evidence of impact is not the same as evidence of absence, the findings were a surprise to the thesis author, research participants, and Expert Verifiers (EVs). A further surprise was the limited evidence of impact on safety in SCIs. The following sections will discuss the findings of this research and whether it justifies a focus on PSNMs in healthcare.

12.2.1 Evidence for and against a focus on near misses

This research found the following that highlight the potential benefits of healthcare allocating resources to learn from PSNMs:

- All Qualitative Case Study (QCS, study 2) and Grounded Theory (GT, study 4) participants believed that learning from near misses had led to or would lead to improvements in safety by reducing or preventing harm. Similar beliefs were described in the scoping reviews (studies 1 and 3, e.g. Chen et al., 2018; Hodges and Sanders, 2014).
- Research has shown that actions following learning from near misses can lead to reductions in future near misses (e.g. Smith-Love, 2022). Applying the common cause hypothesis suggests that incidents and potential harm will also be reduced, with associated financial savings (e.g. Early et al., 2011; Yoon et al., 2015).
- Research has shown how learning from near misses impacts on other facets of safety and quality, such as staff satisfaction, teamworking, leadership, productivity, and safety cultures (e.g. Erdogan, 2011; Fargen et al., 2013; Kusano et al., 2015; Loh et al., 2017; Wallace et al., 2017).
- Limited evidence of impact following learning from near misses is influenced by difficulties evaluating the impact (see 12.2.1.1), rather than there being no impact.
- There have been several incidents which were preceded by near misses in SCIs (e.g. Corcoran, 2004) and healthcare (e.g. Mahlmeister, 2006). Where learning is not taken from near misses, harmful events later occur.
- Safety science provides a theoretical justification for focussing on learning from near misses for which there is face validity (12.2.2).

This research also found the following which contrasts with above and challenges a healthcare focus on learning from PSNMs:

- Evidence that learning from near misses leads to improvements in safety is anecdotal and without quantifiable proof. Some research has found that learning from near misses has no or unclear impact on safety (e.g. Bhattacharya, 2020; Button and Drexler, 2006; Korman, 2016).
- Reliance on the common cause hypothesis to justify the impact of learning from near misses on incidents and harm requires the

hypothesis to be valid. The validity of the hypothesis has been questioned (see 12.2.1.3).

- The positive impact of learning from near misses on safety cultures is undermined by the unknown link between culture, incidents, and safety. Dekker (2019) highlights that there is limited evidence that improved cultures result in reduced harm.
- A review of historical literature (see 12.2.1.2) shows that there has never been clear, published evidence of the positive impact of learning from near misses on safety. This suggests that impact is assumed and based on the common cause hypothesis.
- Where harmful events were preceded by near misses, drawing conclusions on causality is at risk of counterfactual reasoning (Hopkins, 2014). The tendency to create possible alternatives to events that have occurred may limit the validity of those conclusions.
- Harm is more motivating than a near miss; this undermines the theoretical benefits of learning from near misses and efforts to take a Safety II view (see 12.2.1.4).

12.2.1.1 Identifying effective actions and evaluating impact

This research found several factors that make learning from near misses, implementing actions, and evidencing impact, difficult.

Research participants and the scoping reviews highlighted how poor investigation (e.g. Erdogan, 2011) results in learning that is insufficient to motivate action (Shimazoe and Burton, 2013). The implementation of actions following learning is also a recognised challenge, particularly when systems are not static. Near misses and incidents may reoccur in different ways despite best efforts (Rasmussen et al., 2013).

Research participants also alluded to an ‘implementation gap.’ The implementation gap has been highlighted as the cause of continuing avoidable harm in the National Health Service (NHS). It represents the gap between the identification of initiatives to reduce harm, and the actioning of those initiatives. Patient Safety Learning (2022a) describe that, in the NHS, the gap is due to absence of a joined-up approach to

safety, poor systems for sharing and acting on learning, lack of oversight and evaluation, and unclear leadership.

With regards to evidencing impact, it has already been described how notoriously difficult it is to evaluate safety (1.5). There is a lack of tools to measure action and impact of recommendations (Patient Safety Learning, 2022a). For near misses, evaluation is further confounded by the fact that measurement of impact requires proving the absence of something (harm) (Vincent et al., 2014). The lack of ability to prove impact has resulted in funding being withdrawn from near-miss programmes in SCIs (Taylor and Lacovara, 2015), and will hinder healthcare's introduction of programmes because of its need for evidence-based interventions.

Further research is recommended to identify how best to evaluate the impact of actions following learning from near misses.

12.2.1.2 Searching for additional evidence of impact

The lack of evidence of impact prompted questions about the source of the beliefs that learning from near misses has resulted in improved safety. During participant verification it was questioned whether the evidence of impact in SCIs was available in research prior to 2000 (the limit of this research's scoping reviews) because some SCIs had been looking at near misses for a long time. The literature review was therefore extended.

A further search of Web of Science was undertaken using the search terms ((ALL=('near miss*')) OR (ALL=('close call*')) OR (ALL=('near hit*')) OR (ALL=('good catch*'))) and limiting results to pre 2000 (14,709 results) and SCIs (1,401 results). Review of titles and abstracts identified limited research evidencing the impact of learning from near misses on SCI safety and harm. As with articles after 2000, there were statements that learning from near misses can support improvements in safety (Brazier, 1994; Jones, Kirchsteiger and Bjerke, 1999; Uth, 1999). Uth (1999) noted that it 'seems' important to report and analyse near

misses and Brazier (1994) described how a near miss may indicate a breakdown in a company's Safety Management System (SMS).

Jones et al. (1999) undertook a review of near-miss reporting and its role in improving safety performance. They described examples of where unsafe situations had been identified and rectified prior to a safety event occurring. They also provided a case study where an 'inverse proportionality between the number of reported near misses and the number of accidents' had been identified; when the focus on near misses reduced, accidents increased. On exploration, much like in the scoping review (e.g. Bridges, 2012; Yoon et al., 2015), Jones et al. (1999) referred to the common cause hypothesis and the work of Bird and Germain (1984), Heinrich et al. (1980), and Tye (1974) to justify the reduction in incidents.

12.2.1.3 Validity of the common cause hypothesis

This research suggests that beliefs around the impact of learning from near misses on safety have perpetuated from the common cause hypothesis. This has led to assumptions that, by reducing near misses and other low-level events, significant incidents and harm will be reduced. To make these assumptions, the hypothesis needs to be valid.

The common cause hypothesis infers that the causal factors of near misses and incidents are the same (3.3.1.1). If the hypothesis is valid, taking the 'free lessons' from near misses will help improve safety (Barach and Small, 2000a). However, the hypothesis is controversial, and its validity has been challenged (Manuele, 2003; 2011).

A search of the literature found several studies that have attempted to evaluate the common cause hypothesis in various industries, but none in healthcare. Findings are mixed with some support for the hypothesis (Alamgir, Yu, Gorman et al., 2009; Andriulo and Gnoni, 2014; Konstandinidou, Nivolianitou, Kefalogianni et al., 2011; Marsh and Kendrick, 2000; Wright and van der Schaaf, 2004) and some not finding it valid (Button and Drexler, 2006; Fabiano and Currò, 2012; Köhler,

2010; Wright and van der Schaaf, 2004). It seems that the validity is dependent on the type of incident and industry.

The common cause hypothesis may also be too simplistic for the realities of near misses and incidents in complex systems such as healthcare and SCIs. Thoroman et al. (2019) note that previous studies of the common cause hypothesis looked at single incident types, single root causes, were focussed on individuals and equipment, did not consider variations in normal work, and did not consider protective factors. The hypothesis does not account for the complexity of modern sociotechnical systems within which events occur. One EV also had reservations about the common cause hypothesis:

“It bears no resemblance to any further research that I have read. The idea, the common cause hypothesis, we know in an emergent system is not the case... I think it’s an assumption.” EV2

Due to the limitations of the previous studies on the common cause hypothesis, Thoroman et al (2020) have undertaken research to evaluate the validity of the hypothesis for aviation near-miss reports. There may be some support for the hypothesis, in specific aviation near-miss event types, when using Accimap to consider protective factors. It may be that common cause can be inferred for simple, linear near misses and incidents with obvious and single contributory factors. However, near misses and incidents are often not simple, particularly when they occur in complex systems.

Further research is recommended to help understand the validity of the common cause hypothesis in healthcare before it can be truly concluded that reducing PSNMs reduces harm to patients.

Incident ratios

Incident ratios, from which the common cause hypothesis originates, were referred to in the scoping reviews (e.g. Arnold et al., 2022; Bridges, 2012) and some GT participants were concerned that their company incident ratios did not mimic the original ‘fixed’ ratios as described by authors such as Bird and Germain (1966).

Incident ratios have also had their validity questioned in modern, complex systems (Manuele, 2011). Much of the original research on ratios was not done in complex SCIs and assumed incidents to be linear. Incident ratios may no longer be useful in the evaluation of safety, particular in complex industries. However, participants felt ratios could be useful as educational tools to demonstrate the different types of safety event.

12.2.1.4 Harm is more motivating than a near miss

GT principle (9.6.1.4): Significant and harmful safety events lead to greater motivation to improve safety.

All research participants agreed that harm is the key motivator for reporting of and action after a safety event. Harm to patients and families (the first victims) may also result in harm to second (moral injury to the care provider) and third (reputational injury to the organisation) victims.

On an organisational level, societal pressures and policy drive a focus on harm (Breckenridge, Gray, Toma et al., 2019). One QCS participant described how organisations “owe” it to patients to investigate why they were harmed. On an individual level, harm engages and enables mindful actions (Institute for Healthcare Improvement, 2018), and alongside shame, guilt, and embarrassment, is a significant motivator (Lickel, Kushlev, Savalei et al., 2014).

The influence of harm on reporting and action means that near misses are less likely to motivate action. Some near misses which provide greater evidence of vulnerabilities may be more motivational (Madsen et al., 2016) and require highlighting. This was demonstrated by one QCS participant who described how a PSNM had resulted in an in-depth investigation because it echoed aspects of a historical, high-profile NHS incident (Patient Safety Learning, 2001).

12.2.2 Theoretical benefits of learning from near misses

Safety science provides a theoretical justification for focussing on learning from near misses for which there is face validity. Gnoni et al. (2022) describe how near misses can be viewed from two perspectives:

- **Safety I** – considers safety from a retrospective and reactional perspective (Hollnagel, 2014) in that incidents are caused by failures in parts of a system, have specific causes, and can be fixed by removing causes (Ham, 2021). System-focussed investigation approaches help identify contributory factors.
- **Safety II** – which originates from resilience engineering, considers safety from the perspective of how systems (people and organisations) adapt under varying circumstances with the aim of reaching intended outcomes (Dekker, 2019).

Near misses have been traditionally viewed from a Safety I perspective (Gnoni et al., 2022) and this research found evidence that many industries investigate near misses to identify their contributory factors and interruptions. To do this, SCIs commonly use barrier-based approaches (e.g. Baines Simmons, 2018) or the Human Factors Analysis and Classification System (HFACS) (e.g. Zhou and Lei, 2018). Healthcare was found rarely to investigate PSNMs and when they do, root cause analysis is commonly used without exploration of interruptions.

12.2.2.1 Moving from Safety I to Safety II for near misses

Several research participants and the SCI literature described the potential benefits of moving towards a reframing of safety using the Safety II approach. This would turn the focus to the resilience of systems and could be applied to near misses (Thoroman et al., 2020). A resilient system is one that monitors, responds, anticipates, and learns (Hollnagel, 2017).

The Safety II approach has potential benefits over Safety I because of its focus on 'work as done' and the continuous adaptations that people and the system make (Hollnagel, 2012). With respect to near misses, it

aims to identify protective factors and adaptations that result in successful outcomes, rather than contributory factors to why an interruption is needed (Thoroman et al., 2020). It may be particularly beneficial in healthcare because systems are often complex, adaptive, and nonlinear (Verhagen et al., 2022). All EVs were supportive of the Safety II perspective.

“I am much more a fan of the Safety II perspective of how does work go well on a good day, tell me about that, looking at the adaptations people need to make and saying well how can we capture the adaptations that are good.” EV2

The appeal of Safety II for healthcare is increasingly evident (Iflaifel, Lim, Ryan et al., 2020). However, adoption has been affected by ‘challenges with the concept’s credibility, practicality and scientific evidence base’ (Verhagen et al., 2022), and because there is limited guidance for its application. Several methods have been developed to support application of Safety II with the most well-known being the Functional Resonance Analysis Method (FRAM) (Hollnagel, 2012). However, Patriarca, Di-Gravio, Woltjer et al. (2020) describe a ‘lack of validation studies and evidence for effectiveness’ and, while FRAM has been used widely, studies have struggled to show that processes have improved.

12.2.2.2 A pragmatic approach for near misses

The above discussion implies that Safety I and Safety II are opposed, and the literature describes an ‘antagonistic’ debate about the benefits of one over the other (Verhagen et al., 2022). Similar was heard during this research with several participants describing the need to change from Safety I to Safety II because it is “better.”

Taking a Safety II view of near misses may be beneficial, but the unanswered question about its effectiveness undermines its credibility. Verhagen et al. (2022) describe how Safety I and Safety II are different but should be seen as complementary perspectives. Pragmatically

there is likely to be benefit in looking at near misses from both perspectives and it can be argued that a near miss lends itself to both:

- **Safety I** – an investigation into a near miss aims to identify the contributory factors to events and the actions (interruptions) of the system (including the humans involved) that prevented an incident.
- **Safety II** – identification of actions allows consideration of system resilience through how it monitors, responds to, and anticipates deviations to ensure a return to normal.

The Safety I component describes the ‘what and why’ of a near miss and the Safety II component allows exploration of system resilience. As found to be common in SCIs, a barrier-based analysis approach may be useful for the Safety I perspective. However, it may also be too simplistic due to its often-linear nature, and so Safety II methods such as FRAM are potentially supportive if guidance is available for their use in healthcare.

Recommendation – patient safety near misses are considered from Safety I and Safety II perspectives in order to provide complimentary views of the factors that contribute to near misses, the interruptions/controls involved, and the resilience of systems.

12.2.3 Near-miss contributions to safety management systems

GT principle (9.6.1.1): Learning from near misses alone is unlikely to lead to safety improvements.

GT principle (9.6.1.6): It is preferential for industries to predict and prevent, rather than react to events.

As described in 10.5, SMSs are fundamental in the safety of SCIs. GT participants described how, rather than learning from individual near misses, they contribute to the safety intelligence collected in a SMS. It is therefore not learning from near misses alone that leads to safety improvements, it is learning from aggregated safety intelligence. The SMS approach allows industries to be proactive and look to assure safety, rather than react to harm.

Healthcare has yet to implement SMSs at local or national levels (Dixon-Woods et al., 2014; Healthcare Safety Investigation Branch, 2021). Based on the finding of this research, introduction of SMSs in healthcare would be beneficial with PSNMs contributing as one source of safety intelligence. SMSs may also help address several of the factors leading to the known implementation gap in healthcare (12.2.1.1).

Recommendation – the National Health Service develops and implements a safety management system in order to support improvements in patient safety.

12.2.4 Answering the research question

Returning to the research question (10.6.1), this research found limited clear evidence to date that justifies the role of learning from PSNMs to reduce harm and improve safety. Evidence of impact of learning from near misses is often anecdotal, assumed, or based on theory that has been challenged. The common cause hypothesis is a significant factor leading to assumptions that learning from near misses is appropriate, but it has yet to be validated in healthcare. However, there is also no clear evidence that learning from PSNMs is detrimental to patient safety, and it may advance safety indirectly through effects on safety culture and leadership.

There is a need for further research to evidence the benefits of learning from PSNMs alone on patient safety. However, there is likely benefit in considering near misses as part of a safety management approach as one form of safety intelligence contributing to a SMS. SMSs are widespread in SCIs, are felt to be fundamental to assure the safety of systems and have been shown to positively influence safety (10.5).

Based on the findings of this research there is not enough evidence to redirect already stretched NHS-safety resources from focussing on harmful incidents in healthcare to a focus on PSNMs. While it is acknowledged that some serious incidents will be potentially

unpredictable (Leveson, 2011), healthcare “owes” it to patients and families to understand what and why something caused them harm. There is also significant media and political pressure to focus on incidents. One EV described:

“You have got limited resource and also it is the bad stuff, we have got families, we have got patients we have got staff – that natural justice, needing to be engaged versus us going ‘something nearly happened, but we’ll look at that instead’.” EV1

However, this research is not suggesting that PSNMs are disregarded. There are several reasons to suggest that efforts, where possible, should attempt to improve their management. These include:

- Healthcare should aim to learn from every safety event because they each offer unique insights into systems. PSNMs provide a lens on interruptions in systems and their effectiveness.
- It is likely that healthcare would benefit from the introduction of SMSs to which PSNMs would be a significant contributor. PSNMs therefore need effective management to ensure they are appropriately recognised and learned from.
- Healthcare has attempted to learn from incidents for a long time, but the hoped for improvements in patient safety have not been seen (Peerally et al., 2017). Learning from PSNMs offers an alternative and currently underused route to learn.
- At face value and based on safety theory, learning from PSNMs has the potential to build system resilience and potentially prevent harm.

Recommendation – patient safety near misses should be effectively managed to support their future contribution to safety management systems in order to identify safety gaps and potential improvements.

12.3 Healthcare learning from safety-critical industries

Research question (10.6.1): ... and is learning from safety-critical industries appropriate?

QCS and some GT participants had reservations around whether healthcare could or should translate safety-related learning from SCIs. The literature echoes those reservations (Gaba, Singer, Sinaiko et al., 2003; Hudson, 2003; Liberati et al., 2018; Macrae and Stewart, 2019). Gaba et al. (2003), for example, argue that healthcare is different to other industries due to its fragmented structure, variability, under regulation, and informal training. The reservations found contradict exhortations for healthcare to learn from SCIs around how they manage and learn from near misses.

Healthcare has often sought to emulate the way SCIs manage safety-critical processes. There is evidence of successful translations of learning from SCIs to healthcare (e.g. Catchpole, Sellers, Goldman et al., 2010; Kapur, Parand, Soukup et al., 2016). However, not all translations have been successful. Checklists, for example, have not seen the aviation benefits translated to healthcare potentially because the differences in contexts have not been appreciated (Catchpole and Russ, 2015).

12.3.1 Contextual differences between industries

GT principle (9.6.1.5): Safety-management practice is not directly transferable from other industries to healthcare.

This research found differences between the contexts of SCIs and healthcare that should be acknowledged when attempting to translate learning. This EVs agreed:

“... all the safety critical industries share certain elements, but I do think that healthcare has particular challenges over other industries... it is a particularly challenging environment, a variable, uncertain and complex environment.” EV2

The following differences were found:

- **Company priorities** – varies with flux between income generation, finances, user experience, and safety. QCS participants felt healthcare is more focussed on demand and finances, than safety. Some GT participants felt SCIs are focussed on safety because it influences reputation and income.
- **Regulation** – SCIs are heavily regulated with established safety processes, independent bodies, attention to safety cultures, and SMSs. Healthcare safety is less regulated.
- **Safety maturity** – SCIs are thought to be more ‘safety mature.’ Low numbers of incidents mean SCIs can focus on near misses; healthcare cannot. Cultures are a focus in many SCIs having addressed technological and team issues (Hudson, 2007).
- **Safety actions** – SCIs are able to implement engineered solutions to prevent incidents. Technological advances have significantly contributed to SCI safety (Hudson, 2007). Safety improvements in healthcare often focus on humans (Liberati et al., 2018) because of the nature of the industry; technological opportunities are limited.
- **Safety resources** – SCIs have more safety resources than healthcare. SCIs have professionalised the role of safety investigators. This is a current focus of the Healthcare Safety Investigation Branch (HSIB) (2022).

The EVs felt that the ability for SCIs to manage risks using technology is a significant difference to healthcare. This means healthcare cannot reach the same levels of safety.

“... think the discrepancies and variables of risk in healthcare is much higher and is not as mechanistic as a lot of industries have and healthcare probably has a lot less control over those.” EV1

12.3.2 Collaborative learning opportunities

Despite the negative views of some participants about healthcare learning from SCIs, other participants felt there were opportunities for the industries to learn from each other. The safety science, safety

management processes, and principles around safety in general were seen as similar. This research also found similarities in safety culture and maturity, both positive and negative, between parts of some industries and healthcare.

Participants thought that these similarities offered opportunities to share safety principles. Some GT participants also felt their industries would benefit from learning from healthcare, such as around how it regulates professionals, supports staff, and investigates incidents at a national level. Participants described how bodies such as the HSIB can help develop investigation expertise in SCIs.

12.3.2.1 Healthcare's resistance to learning from others

During the research it became apparent that many SCIs have, what was described as, "inferiority complexes." GT participants explained how these complexes lead to companies and industries being open to learn from others. Similar inferiority complexes were not referred to by QCS participants or in the healthcare scoping review.

The literature describes an unwillingness for healthcare to learn from others and the NHS may be blind to its needs for improvement (Amalberti, Auroy, Berwick et al., 2005; Bagnara, Parlangeli and Tartaglia, 2010). This was demonstrated by the healthcare responses to the culture question, and by the national perception that organisations are learning from PSNMs when this was not found to be the case (7.4.1.4). Responses suggested more positive cultures than one would be led to believe by national publications and the Government (e.g. Hunt, 2015); whether this was due to naivety, wishing to protect the reputation of organisations, or was representative, is unclear.

Feeling inferior and constantly wishing to learn are factors in the development of high reliability (Sutcliffe, 2011). Many authors describe the need for healthcare to strive for high reliability by exhibiting those characteristics (Gaba et al., 2003). However, healthcare's potential unwillingness to learn, and its blindness to cultural and safety issues, will be barriers to building reliability. Other barriers include the

resistance of individuals in healthcare to abandon autonomy (Amalberti et al., 2005), and a culture that struggles to accept fallibility (Bagnara et al., 2010).

12.3.2.2 Simplification of industrial safety

GT principle (9.6.1.3): Safety across an industry is not homogenous, with variation in maturity and cultures.

This research found that safety maturity, cultures, and levels are not homogenous across an industry. This was demonstrated by the description of, for example, the differences in safety across passenger, freight, and night rail.

GT participants were concerned that external observers do not recognise the variation in safety in SCIs. Rather than ‘learn from aviation’ the focus should be on ‘learn from parts/components/specific examples in aviation.’ EVs also challenged whether the safety maturity of SCIs is as advanced as externally perceived, and whether high reliability is sometimes assumed by a lack of significant safety events.

“We don’t know whether that is because we have a really well-designed system... or whether it is just that actually we haven’t been pushed very hard.” EV2

No GT participant described their SCI as fully effective at managing safety, nor their industries as ‘safe.’ There are still occurrences that shock an industry (e.g. The Guardian, 2021). However, it was agreed that safety and near-miss management in parts of some SCIs is more advanced than healthcare; this was also demonstrated in the scoping review where near-miss research was focussed on analysis and impact in SCIs, in contrast to reporting in healthcare.

For industries to learn from each other it must be identified what learning is appropriate, and that differences in contexts will affect implementation. This may help to ensure learning is effective and will reduce the risk of poor translation of concepts.

12.3.3 Answering the research question

Returning to the research question (10.6.1), this research found reservations around healthcare seeking safety-related learning from SCIs. Direct translation of learning is unlikely to be successful.

However, different industries have similar safety processes, and the fundamental safety science is the same. There are therefore principles of safety management that are applicable across industries.

Historical failures to translate learning from SCIs to healthcare did not account for differences in context. If learning is to be taken from SCIs, healthcare must ensure that key elements of that learning are not 'missed, mistranslated, or inappropriate' (Macrae and Stewart, 2019). Translation needs to be done with consideration of the nuances and specific characteristics of healthcare (Kapur et al., 2016).

Recommendation – healthcare should identify and learn from how safety-critical industries have applied near-miss and safety management principles, with recognition of the different contexts before applying directly to healthcare.

12.4 Summary

There is much anecdotal evidence, face validity, and individual belief that learning from near misses is valuable, reduces harm, and improve safety. Near misses are one form of intelligence contributing to SMSs. Principles around the management of safety and near misses in SCIs may be applicable to healthcare with appropriate consideration context.

Where resources allow, healthcare should implement systems to manage PSNMs and the next chapter will provide recommendations around how best to do this.

13 Synthesising the Research Findings – Managing Patient Safety Near Misses

13.1 Introduction

This chapter synthesises the research findings to make recommendations to inform the development of a Patient Safety Near-Miss Management System (PSNMMS) and answers the outstanding questions for healthcare described in Table 24 and Table 25. The intended recipient of the recommendations is the English National Health Service (NHS).

This chapter is structured in line with the logic model used throughout this research (5.4.2.4/appendix 5B), and recommendations have been used to update the draft near-miss management programme logic model. The final, evidence-based logic model for a PSNMMS is presented in appendix 13A.

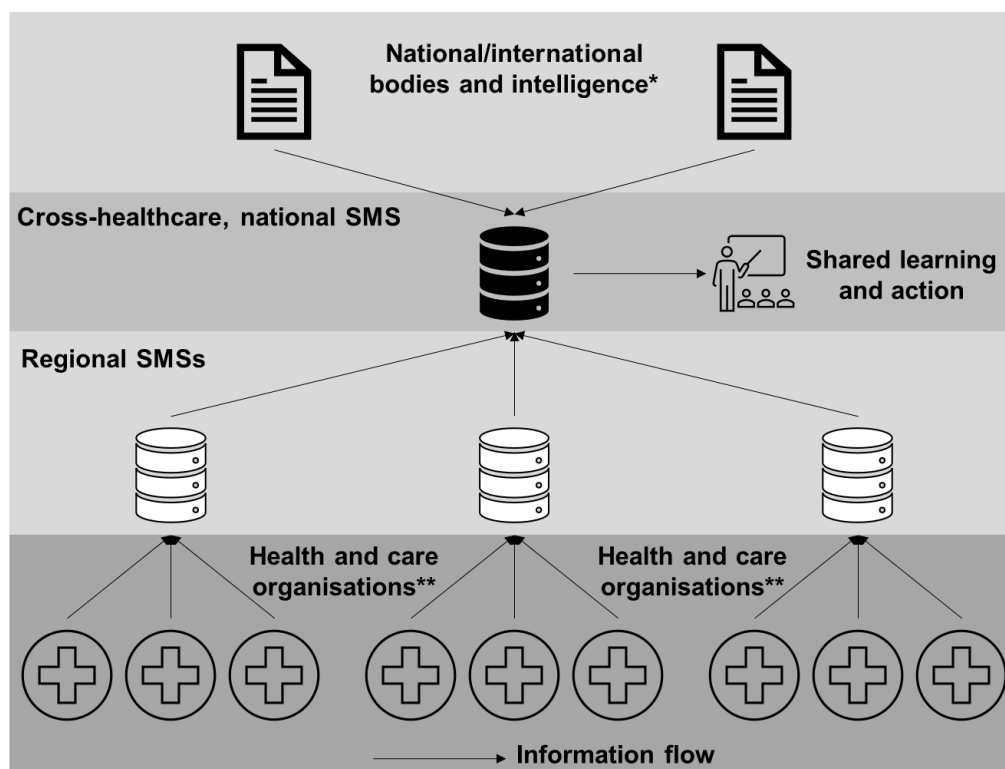
13.2 Vision

Research question (10.6.1) – how can findings from healthcare and safety-critical industries contribute to implementation of a patient safety near miss management system to improve safety?

13.2.1 Long-term vision

This research recommends that the NHS develops and implements a Safety Management Systems (SMS) in the NHS (12.2.3). An industry-wide SMS at national level is a long-term vision, collating safety intelligence from various sources (Figure 11). With increasing maturity of the SMS, further SMSs may be developed at regional and local organisation levels that communicate with the national system. The Expert Verifiers (EVs) agreed that a SMS is needed and will help define the most significant risks for healthcare to address.

Figure 11. Vision of example intelligence sources for a safety management system structure in the NHS



* National and international intelligence from healthcare bodies such as service and professional regulators, information and standards, quality improvement, advisory groups, and professional associations (Oikonomou et al., 2019). Also includes non-healthcare intelligence, such as from SCIs and research.

** Intelligence from healthcare organisations informs regional SMSs. Intelligence includes incident reports, audit insights, inspection reports, claims, and patient experience reports.

13.2.2 Short-term vision

The consideration of SMSs in the NHS is new, and they will take time to implement. In the shorter-term, the vision is that PSNMMSs are developed at the healthcare organisation level. An effective PSNMMS will be one that supports all the necessary tasks to ensure PSNMs are learned from, which includes their identification through to the evaluation of impact. It will be important for any PSNMMS to align with the principles of a SMS (10.5) for future contribution to a SMS.

Recommendation – the National Health Service should develop and implement patient safety near-miss management systems in line with the findings of this research. Systems will later contribute to a safety management system when implemented.

13.3 Context

Context refers to the situation and setting within which a PSNMMS is implemented. Context must be understood to appreciate the benefits and limitations of a PSNMMS, and to support successful implementation. Context includes the assumptions made around a PSNMMS, the intended healthcare settings for implementation, the definition of a PSNM, the position and work of national NHS-safety bodies, and other external factors.

13.3.1 Assumptions

The following assumptions have been made when recommending the PSNMMS. That:

- the PSNMMS will be implemented in the NHS in England with its associated policy, regulatory, and governance infrastructure.
- the definition of a PSNM is agreed and consistent.
- learning from PSNMs is appropriate and beneficial.
- learning from PSNMs leads to improvements in patient safety and reductions in avoidable harm to patients.
- resources are sufficient to support a focus on PSNMs, while continuing to learn from Patient Safety Incidents (PSIs).

13.3.2 Healthcare organisations

The recommendations for the implementation of a PSNMMS in the following sections are intended to be relevant to any healthcare setting, from large acute hospital to general practice. However, it is acknowledged that different parts of the NHS have different safety cultures, safety maturity, priorities, and resources. For example,

national patient safety resourcing and programmes often focus on acute hospital settings (e.g. NHS England, 2022a) and primary care has been historically less involved in national patient safety efforts (NHS England, 2021c).

13.3.3 The definition of a patient safety near miss

Chapter 11 debated the features of a PSNM and provided a standard definition for use in a PSNMMS. While the proposed definition (11.4.2) is generic, there may be benefits in having specific definitions for PSNMs to help with their identification. Whatever the definition(s), it needs to minimise the 'near-miss bias' (3.4), imply vulnerabilities (11.3.4), and not define away events (Tamuz, 2004).

Specific definitions are used in several Safety Critical Industries (SCIs) (8.2.2.2) and some parts of healthcare (6.3.2.2). Specific definitions support a focus on key risks but may limit breadth of reporting.

However, as there is currently little or no reporting of PSNMs in the NHS, there may be benefit evolving reporting from specific examples of PSNMs to those meeting the broad, generic definition (11.4.2) as maturity of a PSNMMS increases. As used by Wilson et al. (2020), a Delphi approach may help with development of standardised PSNM lists for different settings and specialties.

13.3.3.1 Aligning with national bodies

NHS England's Patient Safety Incident Response Framework (PSIRF) provides for healthcare organisations to define their own lists of incidents for investigation based on local risk profiles (NHS England, 2022a). It also provides a national list of incidents based on the national risk profile. As above, similar would be beneficial for PSNMs to encourage a focus on specific events where there may be concerns of system vulnerabilities. Currently PSIRF does not reference PSNMs.

The national risk profile highlights the recurrence of PSIs involving medication, patient falls, and recognition of deterioration. Examples of PSNMs that align with the national risk profile may include:

- A patient is prescribed a medicine to which they are allergic. Bedside checks by an administering healthcare professional identifies that the medication is contraindicated prior to administration. The medication is cancelled, and an appropriate alternative is prescribed.
- A patient at high-risk of falling is found wandering on a ward without support or a chaperone. A healthcare professional intervenes and safely returns the patient to their bed.
- A patient's vital signs are recorded to be abnormal, potentially representing sepsis, but the healthcare professional does not recognise the abnormalities. A short-time later a second healthcare professional notes the abnormal observations and initiates treatment.

At the time of writing NHS England was in the process of implementing its Learning from Patient Safety Events (LFPSE) database (NHS England, 2018a), an update to the National Reporting and Learning System. LFPSE includes four reporting categories – incident, outcome, risk, and good care. The findings of this research suggest limitations in NHS England's approach by them not specifically considering PSNMs.

Learning will be lost if PSNMs are not recognised as specific events with focus on the understanding of their interruptions. Concerns with LFPSE's categories have also been raised by others (Patient Safety Learning, 2022b). The findings of this research have been shared with NHS England. NHS England have since referred to PSNMs in LFPSE guidance and they are included in the 'incident' category with all other incidents (NHS England, 2023b).

13.3.3.2 Terminology

The term 'near miss' is common in healthcare and persists despite attempts to change it (National Patient Safety Agency, 2004). It may not be the most ideal term with evidence to suggest that 'good catch' can improve reporting (e.g. Lozito et al., 2018). The variation in definitions found in this research highlights that different terms may not be synonymous.

The EVs agreed that the term 'near miss' is confusing, but also felt that the suggested national term 'patient safety incident (prevented)' placed the focus on the incident rather than its prevention. Precursor was suggested as a potential option as is used in other industries (e.g. Saleh et al., 2014). A precursor may be considered as the events immediately prior to a near miss. However, the term was not heard to be used in healthcare or seen in the healthcare scoping review (study 1); it would therefore mean introducing a new and unrecognised term. Any term needs to be descriptive and easily understood. It must avoid 'defining away' the event and its importance (Tamuz, 2004). For those reasons, using terms such as 'good' and 'prevented' may be detrimental by portraying PSNMs as successes rather than representing vulnerabilities (11.3.4).

Based on this research's findings there is evidence and support for recommending a change in terminology for a PSNM. However, the most appropriate term to use is not clear. To make a change across the healthcare system would be a significant challenge as was evidenced by the complete lack of Qualitative Case Study (QCS, study 2) participant awareness of the NHS's previous attempts in the 2000s.

It may be pragmatic to continue to use the term 'near miss' as it is engrained in the NHS. The findings of this research around safety cultures also suggest that the term itself is not the issue, rather it is how staff are 'dealt with' following reporting. The term 'good catch' and its positive connotations may not be required if organisational cultures justly respond to reports of PSNMs.

13.3.4 External factors

External factors are those beyond a PSNMMS that influence its functioning. This research found several factors that would support the implementation of, and value gained from PSNMs. These include supporting regulation, independent reporting, and investigation bodies, learning networks, and training support.

13.3.4.1 Supporting regulation

Regulation for safety management in the NHS is limited, complex, and fragmented (Oikonomou, Carthey, Macrae et al., 2019), particularly when compared with SCIs. The Care Quality Commission (CQC) is responsible for healthcare regulation in England. At the time of writing the CQC was implementing a new, single oversight framework (Care Quality Commission, 2022b). The new and old frameworks note that reporting and learning from safety events and incidents are required, but they do not specifically reference PSNMs (Care Quality Commission, 2022c).

Regulation is potentially beneficial as it provides external scrutiny. Regulatory oversight will support organisations to allocate resources and attention to learning from PSNMs, implement SMSs, develop appropriate safety cultures, and share learning. However, it is acknowledged that regulation alone is not enough to support a consistent focus on safety and PSNMs. This was described by the EVs:

“There is an assumption if you have a licensed site, you are a responsible licensee, so you are responsible for marking your own homework...” EV2

13.3.4.2 Supporting policy and guidance

Part of any SMS/PSNMMS are the associated policies, protocols, and other documents (Civil Aviation Authority, 2014). These provide support for system functioning and how intelligence is aggregated for learning. National and local organisation policies are required to describe the expectations for defining, reporting, and learning from PSNMs, and for future SMSs.

The NHS is directed to deliver services in line with the NHS Standard Contract. The 2022/23 Contract notes that organisations must comply with NHS England’s guidance around PSIRF and upload data to the LFPSE (NHS England, 2022b). Nowhere does the standard contract mention PSNMs. Based on the findings of this research, as per 13.3.3.1, the NHS is missing the learning potential offered by PSNMs.

National and local organisation level alignment is needed to ensure PSNMs are learned from.

Managing public perceptions

During exploration of NHS England's PSIRF and potential synergies between it and a PSNMMS, it became apparent that those working in healthcare have concerns about the public perceptions of PSIRF.

PSIRF is seeking to reduce the number of investigations in the NHS, with the focus on learning value rather than harm (NHS England, 2022a). Similarly, a redirection of resource and focus to PSNMs would move the focus from harm. A reorientation of patient safety to not investigate harms may not be palatable for some members of the public or the Government.

This thesis, at present, is not recommending reorientation of resource toward PSNMs at the detriment of investigating incidents (12.2.3). However, any future consideration would need public and patient involvement, co-design, and a clear rationale.

13.3.4.3 Independent healthcare bodies

SCIs benefit from independent bodies with remits for receiving safety event reports and investigation of specific events including near misses (e.g. CIRAS, 2018). Equivalent exist to some degree in the NHS, but they are more limited.

The Healthcare Safety Investigation Branch (HSIB) is the independent investigator of PSIs in the NHS in England. Its purpose mirrors those of the transport safety investigation branches and it has the same powers (Health and Care Act 2022). However, HSIB's resource is small, limiting breadth to a focus on harm.

The NHS has no independent, confidential, or anonymous body for the reporting and investigation of PSNMs outside individual organisations and LFPSE. The exception is the Confidential Reporting System in Safety, which is based on aviation and maritime confidential reporting bodies, but it has a specific remit (CORESS, 2021).

13.3.4.4 National learning forums

Various national opportunities to share learning across industry partners are available in SCIs (e.g. the UK Flight Safety Committee). While these receive insights from regulators and investigation bodies, they are 'independent.' These forums provide confidential sharing opportunities, the likes of which are not available in the NHS.

A similar setup to the UK Flight Safety Committee for healthcare was explored during the undertaking of this thesis with potential interest from HSIB and the EVs. QCS participants agreed that such a forum would be beneficial as long as it had a clear purpose and goal. Like the SCI equivalents, it could include input from the CQC, NHS England, and HSIB, but be led and managed by its membership.

13.3.4.5 Education providers

GT principle (9.6.1.7): Investigation of safety events (including near misses) is a professional role that requires training and resource.

This thesis has referred to safety concepts that may be less familiar to some in healthcare, such as SMSs and Safety II. Implementation of a PSNMMS will require education to provide the knowledge and skill required to take maximum learning from PSNMs.

HSIB is working to develop an education programme that includes aspects of what is proposed in this PSNMMS (Healthcare Safety Investigation Branch, 2022). HSIB is also legislated to professionalise the patient safety investigator role (Health and Care Act 2022). In several SCIs, the role of the safety investigator is an expert role requiring appropriate competencies.

13.3.5 Context and external factor recommendations

Based on the findings of this research the following are recommended:

- development of specific definitions for PSNMs using a Delphi approach, aligned with local and national risk profiles.
- continued use of the term 'near miss' and creation of supportive conditions within which they are reported and learned from.
- development of local and national policies and procedures that align learning from PSNMs between organisations and national levels.
- specifying PSNMs, and the value they offer to learning about system resilience, in NHS England's LFPSE and PSIRF, and their difference to no-harm incidents.
- regulation by the CQC to include a focus on learning from all types of safety-events including PSNMs, improving safety cultures, and implementation of SMSs.
- development of an independent and confidential national reporting function for PSNMs to aggregate and learn about system resilience; this may be an added function to LFPSE.
- development of national/regional learning forums for the confidential sharing of learning from safety events, run by the forum membership with input from national safety bodies.

13.4 Inputs

Inputs refer to what is invested into a PSNMMS to drive its activities and outputs. They relate to the design and management of the system and supporting infrastructure and safety cultures. Aspects such as policies, procedures, resources, and training were discussed under 13.3.4.

The PSNM itself is also an input. Staff need training to be able to identify a PSNM (13.3.4.5). The lists of PSNMs described in 13.3.3 will support identification, as will visual tools such as in appendix 9D.

13.4.1 System design, implementation, and management

van der Schaaf (1991) described the components of a near-miss management system. The findings of this research suggest that those components remain relevant today for a PSNMMS and have informed the design of systems in SCIs.

A PSNMMS should include the following²⁷:

- **Detection** – identification and reporting.
- **Selection** – prioritising for investigation.
- **Description** – collecting relevant information.
- **Classification** – coding of key information.
- **Computation** – aggregation of codes and theming.
- **Interpretation** – of themes and findings for action.
- **Monitoring** – of actions for their effectiveness and impact.

The implementation and ongoing management of a PSNMMS requires strong and consistent leadership (Gnoni et al., 2022). Where leadership has wavered, systems fail (e.g. Kerrigan, 2015; Medmarx, 2009). The NHS is challenged by high-turnover of staff meaning consistency in leadership is difficult. This highlights the need for clear responsibilities in job roles for the management of PSNMs.

Implementation also requires clarification for staff of the role and aim of a PSNMMS, who is expected to engage with it, and their responsibilities (Kloekner Metals 2020). Reporting of PSNMs should be an obligation for everyone, rather than for certain staff groups. In both healthcare (e.g. Traynor, 2015) and SCIs (e.g. Georgoulis and Nikitakos, 2019) certain staff groups see reporting as the responsibility of others.

A quality improvement approach may support implementation and allow for iterative adaptation to local contexts, barriers, and user needs (Crandall et al., 2018; Illingworth, 2015).

²⁷ van der Schaaf's (1991) components of a near-miss management system have been linked to relevant aspects of this PSNMMS and are shown in italics.

13.4.2 Supporting safety cultures

GT principle (9.6.1.10): Just and learning cultures are important, but not the only factors that support near-miss reporting and learning.

Fundamental to the implementation of a PSNMMS is the safety culture of a host organisation and industry. A safety culture has several elements (World Association of Nuclear Operators, 2013), but this research found that 'learning' and 'just' are the most important. There is a preference for 'just' rather than 'no-blame' cultures. 'Just' is preferential because it maintains accountability and supports appropriate responses to PSNMs (Dekker and Breakey, 2016).

13.4.2.1 Building a just culture

The concept of and need for a just culture is widely stated across industries with descriptions of its elements. A succinct example found during this research describes a just culture as (Health Quality Council of Alberta, 2023):

- **Transparent** – clarity about how staff actions will be assessed.
- **Responsive** – appropriately with a systems-based approach.
- **Understanding** – that humans are imperfect, but also accountable.
- **Supportive** – staff with respect, dignity, and compassion.
- **Respectful** – by not blaming, naming, or shaming.

While there are statements for what is needed for a just culture, the supportive actions to develop and sustain those cultures are less clear. Research participants were able to state the need for, or presence of a just culture, but not how it had been reached. Several speculated that stable leadership and trust were involved.

The literature agrees that leadership and trust are important contributors to a just culture. Leadership has been found to improve cultures and potentially lower risks (Ginsburg, Chuang, Berta et al., 2010; Nævestad, Blom and Phillips, 2020). Trust represents a belief that an organisation will follow and protect the just culture. To build

trust, present and visible leadership, integrity, and sufficient communications are required (van Marum, Verhoeven and Rooy, 2022). Visibility of the just culture in SCIs is contributed to by including reference to it in ‘everything they do,’ including in inductions and mandatory training (9.5.2.1); this was not heard to occur in healthcare. Murray, Clifford, Larson et al. (2022) also suggest that to develop and maintain a just culture requires expectation setting, clear accountabilities, engaged leadership, training, and the understanding of staff perceptions. SCIs often seek to understand staff perceptions using safety climate surveys such as the Just Culture Assessment Tool (JCAT) (Petschonek, Burlison, Cross et al., 2013); culture/climate surveys were found to be less common in healthcare.

Problems with a just culture

It was not clear whether all participants in this research understood the concept of ‘just’ and some conflated it with ‘no-blame.’ Dekker (2019) describes how simplistic views of safety culture may undermine its implementation and effectiveness; safety cultures are not comparable, consistent, or coherent.

The concept of ‘just’ may itself be flawed. This is because processes will always seek to contradict a just culture’s aims and it is difficult to delineate between acceptable and unacceptable behaviours (van Marum et al., 2022). For example, human resource and legal processes may have different goals in a PSNM investigation. EVs also highlighted a competition between the just culture and other healthcare processes:

“It is great that people are thinking about the whole concept of just culture... when it comes to the sharp end of [human-resource] type processes... that is different...” EV3

To attempt to support the delineation between acceptable and unacceptable behaviours, checklists have been developed in SCIs (e.g. Baines Simmons, 2022) and healthcare (e.g. NHS England, 2018). These suggest that the delineation is simple, which is not the case in reality (Dekker and Breakey, 2016).

Restorative just culture

Dekker and Breakey (2016) describe the potential benefits of taking a 'restorative' approach to just culture. This takes a more moral view of events with the creation of justice by deciding on the needs of people following an incident and seeking to repair associated harm. It contrasts with a typical just culture which seeks justice through 'shades of retribution' (Dekker and Breakey, 2016).

As with a just culture, the question is how to implement a restorative just culture. No participants in this research suggested awareness of the concept. Dekker (2018) has published a checklist to help develop a restorative just culture and several organisations have published their approaches. For example, Mersey Care (UK) use interventions including (Kaur et al., 2019):

- 'rumour busting' with factual information for all staff after an incident
- stopping staff suspensions unless evidence suggests this is required
- removal of judgmental language from policies and procedures
- a focus on staff support processes.

13.4.2.2 Culture is part of the solution

The evidence surrounding the relationship between safety cultures and safety/incidents is limited (Guldenmund, 2000). In this research, participants debated whether increasing or decreasing numbers of PSNMs were representative of a good safety culture (6.3.5.1).

Dekker (2019) highlighted that there are some organisations with 'great safety culture' that have significant incidents, and others with 'observed deficiencies' that do not generate more incidents. Safety science theory also suggests that no matter how good a safety culture is, incidents will still occur because of the emergent properties of complex systems (Leveson, 2011).

Addressing a safety culture alone will not be enough to support improvements in reporting and learning from PSNMs, and ultimately safety. Conditions also need to be optimised to support reporting and

learning, such as through leadership, well-designed management systems, and staff engagement. A culture of safety is also one that realises that risks cannot always be eliminated and may only be mitigated to as low as reasonably practicable (2.4.2.3).

13.4.3 Reporting systems and infrastructure – *detection*²⁸

The design of systems for staff to report PSNMs is fundamental. Without available, accessible, and usable systems, it is well recognised that staff will not report PSNMs or incidents.

13.4.3.1 Availability and accessibility

The literature describes the need for Incident Reporting Systems (IRSs) to be designed to support reporting (e.g. Chang et al., 2005; Pope and Orr, 2017). IRSs also need to be available and accessible. Availability in this context means that routes to report PSNMs are in existence.

Accessibility refers to the need for those routes to be usable by people with different needs.

Organisations do not always support staff to report PSNMs and PSIs because they have not addressed fundamental barriers to reporting. These include the availability of hardware to access reporting systems, and reliable Wi-Fi. Similar has been highlighted in national investigations of incidents as a contributor to staff not using digital systems in support of safety (e.g. Healthcare Safety Investigation Branch, 2023).

Reporting routes

There are benefits in having multiple routes via which staff can report PSNMs. Routes may include paper forms, electronic IRSs, apps (The Distance, 2022), smart technologies (Elia et al., 2022), briefings (Isaksson et al., 2022), education and simulation (Shaikh et al., 2022),

²⁸ Van der Schaaf's (1991) components of a near-miss management system have been linked to relevant aspects of this PSNMMS and are shown in italics.

learning forums (Arnold et al., 2022), huddles and hotlines (American Data Network, 2019).

Simulation is widely used in SCIs to evaluate processes and stress systems to assess for vulnerabilities. For example, oil and gas use simulation to assess for failure modes (Youngblood and Duffey, 2015) and nuclear for identifying faulty system state (Di Maio et al, 2017). In healthcare, simulation is underused, with its application most commonly to medical education in imitated situations (Bienstock and Heuer, 2022). There is some but limited use of simulation for testing systems to identify potential sources of PSNMs/PSIs (e.g. Fent, Blythe, Farooq and Purva, 2015; Woodier, Dowling, Gill et al., 2015).

Paper-based reporting may be beneficial to support accessibility for certain groups. Paper 'flight safety logs' for aviation mechanics and engineers were found to be a useful way to support those staff to report near misses. In chemical processing, confidential reporting diaries have been used (van der Schaaf and Kanse, 2004). In healthcare, levels of digital literacy are also a known issue that affect digital accessibility (Health Education England, 2016) and may mean some staff can better engage with paper reporting.

Multiple sources, a single destination

Whether all safety events should be reportable via one IRS, or whether separate IRSs are required for different events, is debated. Separate systems may highlight the importance of particular event types, but it is more efficient to have a single IRS (Phimister et al., 2003). Whatever the reporting system used, configuration needs to ensure the questions asked of PSNMs explore their specific features (see 13.4.4.3). A single question set for all safety events is not appropriate and will lose learning from PSNMs.

If multiple systems are used for reporting, they must be interoperable and avoid the need for duplicated reporting. Interoperability is required to allow aggregation and review of intelligence at a single destination.

Healthcare is challenged with the interoperability of its digital systems (e.g. NHS Digital, 2023) and the EVs noted:

“I can see how potentially things could get convoluted with reporting systems... so are we in danger of having 15 parallel reporting systems.” EV3

Bypassing the human reporter

Reporting of a PSNM requires someone to identify the events and report them. This is challenging, particularly when an event causes no outcome and when there is limited time. There are benefits in looking to bypass the need for staff to report PSNMs with automatic detection and reporting systems.

Automatic detection and reporting opportunities are limited in healthcare and further research is required. There may be opportunities to exploit digital systems and technologies to help detect PSNMs, such as through test ordering systems (Devin et al., 2022) and smart infusion pumps (Aljaber and Waterson, 2021).

13.4.3.2 Design of reporting systems – *description*

Participants in this research regularly shared frustrations about the usability of electronic IRSs in their organisations/companies. IRS interface design may limit their use and a system may not provide the functionality to collect the information needed to help learn from events (Thoroman et al., 2018).

Data sets for reporting systems

The World Health Organization (2020) has published guidance on the establishment and effective use of IRSs for learning from PSIs. The guidance advocates for a minimum data set of information to be collected by IRSs (World Health Organization, 2016). This data set is provided via the World Health Organization’s (2010) International Classification for Patient Safety (ICPS).

The ICPS aims to support standardisation of collected incident data, globally. This research found examples of where the ICPS is being

used in IRSs (e.g. Datix, 2016), but also where it has been locally adapted. Adaptation means terminology and data fields are no longer standardised which may undermine future aggregation of information and learning in SMSs. NHS England was contacted to understand whether the ICPS had informed the LFPSE taxonomy (NHS England, 2022c). No reply was received from NHS England and the taxonomy seen during this research does not align with all aspects of the ICPS. The ICPS data set is for PSIs but is relevant to PSNMs. However, it does not collect information about all the features of a PSNM identified as valuable in this research, such as details about interruptions.

Functionality of reporting systems

Functionality in this context refers to whether an IRS works in a way that supports learning from PSNMs. An IRS needs to be designed to help understand the system within which a PSNM has occurred (Thoroman et al., 2018). This research found limited functionality designed into IRSs for PSNMs.

This research found no definitive description of the functionality an IRS should have for PSNMs. Findings suggest benefits in linking IRSs with a taxonomy that allows categorisation of key information about PSNMs, and ensuring the content is confidential. An IRS should be able to acknowledge how systems contribute to safety through emergence, consideration of multiple contributory factors, and migration of work practices (Rasmussen, 1997; Thoroman et al., 2018).

Confidentiality of reporting systems

GT principle (9.6.1.11): Confidential is preferable to anonymous reporting, but anonymity may support reporting of near misses.

While anonymity may be useful to support reporting, it limits the information collected (Multer et al., 2013) and prevents application of just culture principles. Confidentiality, rather than anonymity, was found by this research to be preferable, particularly in healthcare and industries in which professional regulation and accountability is important (e.g. Nursing and Midwifery Council, 2018).

During this research, review of local IRSs highlighted concerns as to whether systems are truly confidential. Details of reporters and those involved in PSIs were visible to large numbers of staff who had “back end” access to IRSs. This may undermine trust and highlights the importance of ensuring information is blinded except to those who must know. The EVs noted:

“... to get the most out of it I need to understand the context...there is a balance between maybe the confidential idea, not everyone gets to see it, but if I want to speak to you.” EV1

Anonymity may be useful when there are significant concerns about reporting cultures; this was identified in parts of maritime (Köhler, 2010). No pathological safety cultures were found in the QCS in this research (appendix 7E), however, there is evidence to suggest that pathological cultures exist in some parts of the NHS (e.g. British Broadcasting Corporation, 2023; The Royal College of Midwives, 2021).

Usability of reporting systems

Usability in this context refers to how easy the interface of an IRS is to use. Participants reported actual and perceived usability issues with IRSs across healthcare and SCIs. IRSs need to be easy to use, and staff need to perceive them as easy to use otherwise they won't (Al-Rayes, Aldar, Al Nasif et al., 2020).

There is little guidance about how best to design IRSs for the user, other than the need for drop-down fields, free-text fields, and automated completion of details. There is research about user-interface design and user experience in relation to other systems, but not IRSs. Principles of good user-interface design may be useful to consider for IRS, but systems would also benefit from focussed evaluation and improvement by experts working in the fields of human-computer interaction and user experience; further research is recommended.

13.4.4 Taxonomy for patient safety near misses – *classification*

A taxonomy is a structured way of classifying or categorising information about safety events and their causes. A taxonomy is an important element of a PSNMMS and SMS to standardise the categorisation of information to later help identify themes across multiple reports or sources of intelligence. The majority of IRSs seen in this research had some form of taxonomy, but they were not consistent across an industry or had been adapted locally. Some taxonomies are categorised to at the time of reporting by the reporter, and some are categorised to later by safety teams; it was suggested that later categorisation by specialist staff is beneficial but requires resource.

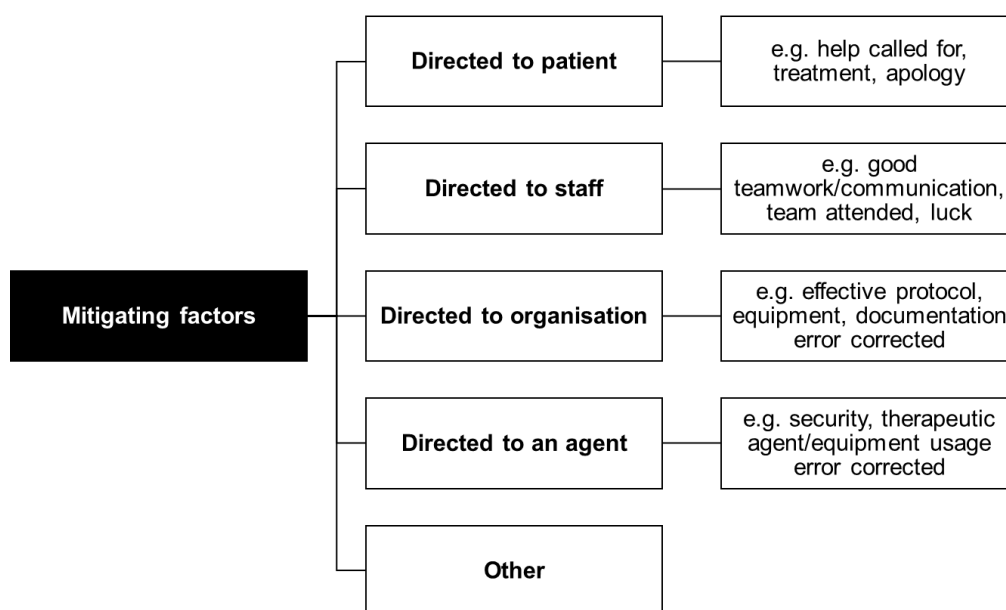
13.4.4.1 Selecting a taxonomy

There are many healthcare taxonomies available. Some are generic (e.g. World Health Organization, 2010) and others are specialty specific (e.g. National Coordinating Council for Medication Error Reporting and Prevention, 2001). The selection of an appropriate taxonomy needs to consider whether it can categorise important elements of a PSNM including:

- event characteristics (e.g. location and staff type involved)
- contributory factors (why did the events occur)
- interruptions (that prevented progression of events).

A review of healthcare taxonomies found only one (the ICPS) that considers interruptions. The taxonomy planned for LFPSE does not clearly include interruptions or mitigating factors (NHS England, 2022c). The ICPS includes interruptions as ‘mitigating factors,’ defined as ‘an action or circumstance which prevents or moderates the progression of an incident towards harming a patient’ (Figure 12) (World Health Organization, 2010).

Figure 12. Mitigating factors in the World Health Organization's (2010) International Classification for Patient Safety



While the ICPS collects information on mitigators/interruptions, the level of detail will not extract all the information required about the features of a PSNM (11.3). The ICPS focuses on what happened, with limited consideration of the complexity of the healthcare system, how interruptions have been activated, and whether they were successful. It depicts safety events as linear, which is known to be a flaw in healthcare's view of safety (Peerally et al., 2016).

13.4.4.2 Developing a recovery taxonomy

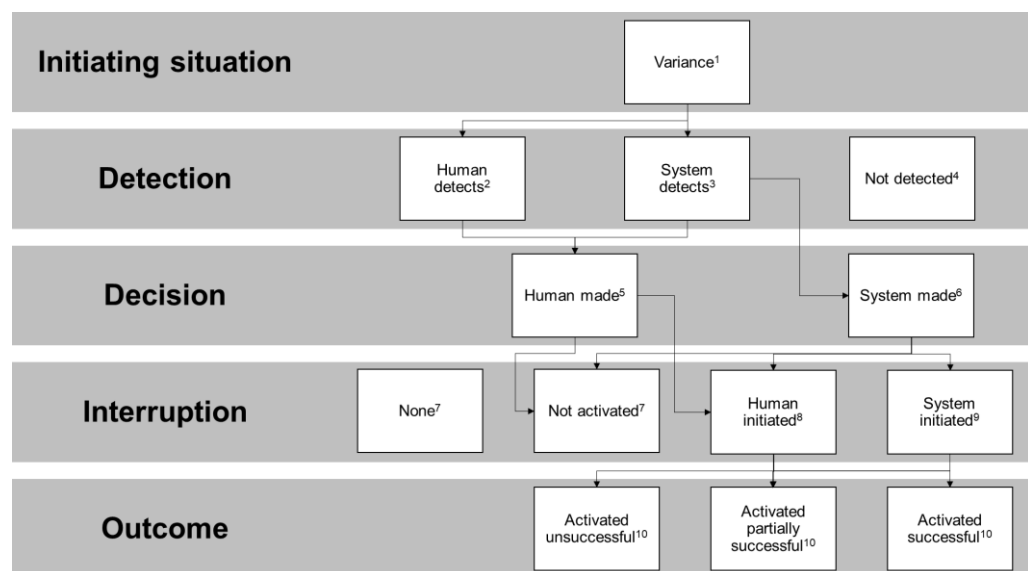
Further research is recommended to develop a taxonomy to account for how PSNMs occur, the role of systems, and the categorisation of interruptions (recoveries). The taxonomy would have the potential to support reporting and later aggregation of learning from PSNMs in a PSNMMS, and a SMS.

Developing a valid taxonomy for PSNMs is outside the scope of this thesis. However, a preliminary review of the literature was undertaken to consider the elements of such a taxonomy. Several authors have developed 'error recovery' taxonomies in industries such as engineering

(Jambon 1998) and computer systems (Sridharan, Liberty and Kaeli, 2008), and in healthcare (Henneman and Gawlinski, 2004). In general, these recovery taxonomies include the following stages, based on the work of Zapf and Reason (1994) – initial event, diagnosis (detection, localisation, and explanation), and recovery (planning and correction). Recovery taxonomies also consider whether recovery opportunities are planned or unplanned, and whether they were successful.

Using insights from the above error recovery taxonomies the categories presented in Figure 13 and appendix 13B were drafted for interruptions/recoveries in PSNMs.

Figure 13. Draft interruption/recovery taxonomy for patient safety near misses



Taxonomy training

Staff need to be trained to use a taxonomy to ensure information is reliably classified. This means that any taxonomy needs to be simple and easy to follow. The challenges of using a taxonomy were highlighted when CIRAS was approached by the thesis author for a copy of their recovery codes (Wright and van der Schaaf, 2004). CIRAS have stopped using their earlier codes having replaced them with something simpler.

13.4.4.3 Using the taxonomy for questioning

The questions asked of a reported PSNM need to ensure they seek information about the features of the near miss and must align with the chosen taxonomy. Questions may be asked at the time of reporting, or during a follow-up meeting with safety staff (as is done by some reporting bodies, e.g. CIRAS, 2018). It may be preferential for minimal information to be collected at the time of reporting to minimise the burden on reporters. However, this requires resource to follow-up reports and means anonymity cannot be used; it may be impractical in healthcare due to the number of reports.

The pertinent questions to ask of a PSNM have been found to include the contributory factors to the events, how the events were detected, and what and how many interruptions were involved. Detection is important to understand as it helps identify situations where there is no system-designed detection mechanism, therefore relying on humans.

Based on the findings of this research, and linked with the taxonomy in Figure 13, the following questions have been developed to ask of any reported PSNM. Research on the taxonomy should include exploration of the value of these questions and their validity.

- Who or what identified the potential for an incident to occur?
- Were there earlier opportunities to identify the potential for an incident?
- When the potential for an incident to occur was recognised, what actions were undertaken?
- Has this situation occurred before?
- What is the likelihood of the situation happening again?
- What would be the consequences if the actions had not stopped the incident?

13.4.5 Input recommendations

Based on the findings of this research the following are recommended:

- leaders in healthcare organisations should seek to develop just cultures and maintain trust in those cultures.
- PSNM reporting is confidential, with identifiable information only visible to those who must have access, and only when required.
- PSNM reporting is made available and accessible to staff via multiple routes that communicate with a central system.
- reporting systems are designed for the needs of the various users to ensure ease and efficiency.
- reporting systems for PSNMs ask questions applicable to the features of a PSNM, including collection of information about what recovered the situation and the associated sociotechnical system.
- identification of the potential for PSNMs and system vulnerabilities is supported using simulation.

13.5 Activities

Activities refer to the actions undertaken as part of a PSNMMS. The activities are dependent on inputs and external factors. Identification of PSNMs (13.4.3.1) and training (13.3.4.5) have been considered previously. The following sections focus on the activities of reporting, investigation, and learning.

13.5.1 Reporting – *detection*

While important to encourage the reporting of all PSNMs, not all will be needed to identify learning (Hewitt and Chreim, 2015; Wu and Marks, 2013). The conditions for reporting must be right to support staff to undertake the activity. Conditions discussed in previous sections included safety culture (13.4.2), IRS design (13.4.3.2), training (13.3.4.5), and policy (13.3.4.2). The activity of reporting is also affected by factors that motivate staff to report; this research found that rewards and time are important.

13.5.1.1 Rewards

Motivation to report PSNMs can be extrinsic or intrinsic. Many efforts to incentivise reporting focus on providing a reward to extrinsically motivate the behaviour (e.g. Wallace et al., 2017). Extrinsic motivation relies on someone getting something in return for an act, such as gifts (Ryan and Deci, 2000). However, the ethics of providing rewards, especially financial, are questioned and may skew reporting (Georgoulis and Nikitakos 2019). Rewarding of reporting is also unlikely to be sustainable.

The need for extrinsic motivation may indicate a problem with the conditions within which staff are reporting; rather than feeling empowered to report, staff are being pushed and pulled to report. With appropriate safety cultures and leadership engagement (The Joint Commission, 2018), and psychological safety (Jung et al., 2021), extrinsic motivators may not be required.

Intrinsic motivation is where people are engaged and motivated to undertake a behaviour because they find it rewarding. It is associated with improved work engagement (Zeng, Takada, Hara et al., 2022) and should motivate staff to report PSNMs. The Institute for Healthcare Improvement (2018) describes the benefits of ‘unleashing’ internal motivation, which may be done through the sharing of public narratives, providing feedback on beneficial outcomes of reporting, and celebration. Celebration can lift individuals and teams, and influence values. Dillon et al. (2011) also advocate for describing near misses as ‘vulnerabilities’ to motivate actions that minimise future risk.

Psychological safety

A theme raised by some participants in this research was the need for ‘psychological safety’ to support reporting and learning from PSNMs (6.4.1.2). Jung et al., (2021) found that describing PSNMs in different ways affects psychological safety.

Psychological safety is the ‘shared belief held by members of a team that the team is safe for interpersonal risk-taking’ (Edmondson, 1999).

To develop psychological safety, O'Donovan and McAuliffe (2020) describe 13 enablers at organisational, team, and individual levels. These include the need for familiarity amongst team members, integrity, leader and peer support, and a focus on improvement.

13.5.1.2 Time to report

Reporting of PSNMs may be forgotten or not done because staff do not have time. Time is short in the NHS with only 24% of staff reporting 'never or rarely [having] unrealistic time pressures' (Survey Coordination Centre, 2022). With workloads reported to be increasing in the NHS, alongside a decreasing workforce (British Medical Association, 2022), time to report will be decreasing. It is therefore important to consider alternative ways to identify PSNMs and make reporting mechanisms efficient (13.4.3.1). Time is a valuable resource, and staff will want to avoid wasting time on reporting PSNMs if they do not perceive it to be valuable.

13.5.2 Response – *selection*

The receipt of a report of a PSNM should prompt immediate consideration of actions to mitigate the risk of future incidents. Less immediate actions include escalation of certain PSNMs that may represent systemic problems, and selection/prioritisation of PSNMs for investigation. Without these responses, PSNMs may fall into a 'black hole' (Jefferies et al., 2012c) and leave unchecked vulnerabilities. The literature provides examples of where previous near misses have not been addressed and incidents have occurred (e.g. Madsen et al., 2016).

13.5.2.1 Prioritisation tools

GT principle (9.6.1.13): Prioritise near misses with the most learning potential for investigation.

Prioritising high-risk PSNMs for investigation will ensure resources are allocated to those that are thought to represent significant system

vulnerabilities. Tools can support prioritisation, but there was no consistently used and validated tool for PSNMs found in this research; considerations for a tool were described.

A prioritisation tool for PSNMs needs to be valid for the healthcare system and further research is recommended. Considerations of a tool may include factors such as frequency of the PSNM, controls overcome, levels of protection remaining, and likelihood of recurrence (e.g. Gnoni and Lettera, 2012; Ritwik, 2002). A tool also needs to be easy to use and reliable. Gnoni and Lettera (2012) compared two tools and found that while an index allows clearer prioritisation, a matrix is simpler and quicker.

In Table 9, the tool developed by Thornton et al. (2011) is shown. While developed for radiography PSNMs, it is worded generically and includes all the considerations for prioritisation described above. It also includes a hierarchy of controls to help assess their effectiveness. However, it is quantitative, and the output is a hazard score which requires interpretation.

13.5.3 Investigation – *classification and interpretation*

GT principle (9.6.1.12): There are two ways to learn from near misses – investigation and theming.

The investigation of PSNMs has traditionally taken a Safety I approach, and this is where the evidence base exists. Despite Safety I and Safety II being sometimes portrayed as contrasting and competitive processes, this research found benefits in viewing PSNMs through both approaches (12.2.2.2). A Safety I approach allows investigation of contributory factors and controls, while Safety II allows consideration of protective factors and resilience. The EVs agreed:

“So we investigate in the context of what has happened, but with the added ‘what usually happens.’ So it is the whole spectrum, the Safety 2 approach to understand the day-to-day work that leads to things happening.” EV1

13.5.3.1 Investigation of individual near misses

GT principle (9.6.1.14): Undertaking barrier analysis identifies the contributory and recovery factors associated with near misses.

A systems-focussed investigation of a PSNM should seek to identify the contributory factors and explore the presence and effectiveness of interruptions. To do this requires trained investigators, ideally in teams to avoid bias (Figueres-Esteban et al., 2017), and appropriate investigatory tools (Gnoni et al., 2022). Tools must support exploration of the system (Mazaheri et al., 2015) and allow expansion of findings to consider 'what if' (Gnoni and Lettera, 2012). The systems-based approach is important to avoid the following:

“Everybody comes out and says, ‘we must learn from this, and it must never happen again.’ The danger is they learn the wrong thing, they reinforce the wrong thing, you get blame and retrain.”

EV2

Selecting an analysis tool

This research found no preference for a specific analysis tool or framework for PSNMs. There has been exploration of the use of Accimap (Thoroman et al., 2020), the Human Factors Analysis and Classification System (HFACS) (Bicen and Celik, 2022; Cohen et al., 2018; Judy et al., 2020), the Technique for the Retrospective Analysis of Cognitive Errors (Shorrock and Kirwan, 2002), and barrier-based approaches (e.g. Civil Aviation Authority, 2015).

Of the analysis tools, HFACS and barrier approaches were repeatedly found to be useful and were advocated for by several authors in the SCI scoping review (study 3), and Grounded Theory (study 4) participants. HFACS originated in the military (Wiegmann and Shappell, 2001) and has been widely used, including in healthcare (e.g. Diller, Helmrich, Dunning, et al., 2014; Woodier et al., 2022). It is based on the Swiss-Cheese Model which, due to criticisms of its outdatedness, have led to criticisms of HFACS (e.g. Larouzee and Le Coze, 2022). There are concerns that it is static, too linear, and simplistic, and has the potential

to focus on human elements, rather than wider systems (Bicen and Celik, 2022; Diller et al., 2014).

Barrier approaches allow retro- and prospective consideration of contributory factors and barriers/controls (interruptions) to threats (Chartered Institute of Ergonomics & Human Factors, 2016). They also accept that some incidents will occur and so examine the barriers/controls to mitigate harm.

There may be benefit in healthcare using barrier approaches in a dynamic way as is done in some SCIs. For example, the Civil Aviation Authority (2015) have 'Bowtie diagrams' for common near misses that are updated based on intelligence; similar could be done for common PSNMs, such as near-miss patient falls or incorrect medication administrations.

It must be acknowledged that barrier approaches, much like any investigatory approach, only offer a lens with which to view PSNMs. Future research may identify more appropriate approaches for the investigation of PSNMs. One EV challenged whether barrier approaches are too simplistic for "complex healthcare systems." However, the use of barrier approaches is an improvement for healthcare over what has been traditionally used. Introduction of barrier approaches may be a step forward, rather than the definitive approach to use, and may be more appropriate for some PSNMs over others depending on their complexity. Analysis tools are known to evolve as safety maturity evolves (Vaughen and Muschara, 2011).

Application of Safety II principles

Future learning from PSNMs may benefit from taking a Safety II perspective (12.2.2.1). PSNMs lend themselves to Safety II because of the need to appreciate work as done, and because they result from people or systems adapting to variation (Ottewill and Owens, 2020). Approaches such as the Functional Resonance Analysis Method (FRAM) may assist with examining the adaptations in work as done in a PSNM. There is currently a lack of validation studies and limited

guidance on how to apply FRAM in healthcare (Patriarca et al., 2020; Verhagen et al., 2022); further research is recommended.

While the evidence base for Safety II in healthcare is built, Safety II principles may be useful to consider during the investigation of PSNMs. The following, developed by the thesis author, may be useful to consider as part of any investigation of a PSNM (adapted from Hollnagel, 2014; Hollnagel, Wears and Braithwaite, 2015; Woods et al., 2017):

- Identify who does the work, speak to them, and observe how they work (work as done and why people make the decisions they do).
- Ask people what they or the system did to anticipate risks to result in a positive outcome (equivalence of successes and failures).
- Ask people what adjustments they had to make in their work, and why, to achieve the outcome (approximate adjustments).
- Recognise that causes to incidents are not stable and will change.
- Recognise that both positive and negative outcomes are emergent rather than resultant and cannot be anticipated beyond understanding regular events.

13.5.3.2 Aggregation of all near misses

A PSNMMS should include a process for the aggregation of information about all reported PSNMs. This allows clustering of findings to look for themes and system deficiencies (Wallace, 2000), areas for attention (Kanse and van der Schaaf, 2001), signals of problems (Tamuz, 2004), and areas for future analysis (International Atomic Energy Agency, 2005). Aggregated information can also contribute to a SMS. The EVs agreed with the need for aggregation, as do the World Health Organization (2020).

The selection of a taxonomy for a PSNMMS was considered in 13.4.4. The activity of aggregation involves the categorising of information against the taxonomy. It is a manual process of secondary analysis and various national healthcare bodies offer training and guidance to help

identify themes across data (Healthcare Safety Investigation Branch, 2022; NHS England 2022d).

Manual categorisation is time consuming and requires skills in secondary analysis. Automated approaches to analysis are being explored, but they are currently limited by the nuances of the information and variation in terms and spellings. Future opportunities look to include automated data mining (e.g. Hughes et al., 2018) and Bayesian modelling of data (Meel et al., 2007).

13.5.4 Learning from near misses – *interpretation*

All evidence sources in this research described the need to ‘learn’ from PSNMs. However, what was meant by ‘learning’ and what was seen as the purpose of learning was not always clear.

The process of learning is the acquiring, processing, retaining, and recall of information for a purpose (Gandhi and Mukherji, 2022).

Jacobsson, El and Akelsson (2012) describe how learning from safety events happens at individual, team, organisation, and national levels, and the purpose of learning at each level is different. The literature provides some insights into learning from safety events, but it is fragmented (Le Coze, 2013) with unanswered questions about how best to approach learning (Ramanujam and Goodman, 2011).

Specifically for PSNMs, there are gaps in learning at individual, group, and organisational levels (Feng et al., 2022b).

13.5.4.1 Organisational learning

Organisational learning is where much of the literature has previously focussed (Drupsteen and Guldenmund, 2014). Learning from PSNMs in organisations occurs through reporting and investigation, and with the purpose of making recommendations to prevent future PSIs. For learning to be effective, PSNMs need to be reported and all the steps in a PSNMMS process need to be effective.

However, as found in this research, there is under-reporting of PSNMs, poor quality investigations, limited aggregation, and difficulties turning

findings from investigations into effective recommendations. There is also limited understanding of how learning occurs in the workplace (Schilling and Kluge, 2009), and it is likely that poor group learning, and absorption undermines an organisation's ability to develop its memory of events (Feng et al., 2022b). Organisational learning is often 'single loop,' meaning that it focuses on causes of events in isolation (Drupsteen and Guldenmund, 2014; Lukic et al., 2010).

Organisational memory

The concept of 'organisational memory' refers to knowledge that has been 'accumulated from past experiences, which resides in the organization and can be utilized towards making decisions' (Bhandary and Maslach, 2017). Research participants described the loss of organisational memory due to the passage of time and limited recording of knowledge.

To maintain organisational memory, knowledge needs to be stored in ways that can be processed and accessed. Technological solutions are increasingly providing these stores, such as via databases. How best to store and access that information is debated, but 'learning agencies' (people who learn on behalf of an organisation, and transfer and embed that learning) and the use of 'bowtie [barrier analysis] models' have been found to be useful facilitators (Chevreau, Wybo and Cauchois, 2006).

Databases

Safety event databases are beneficial because they provide a collation of information about events from which risks may be identified. To do this requires information to be aggregated in a standardised way against a taxonomy, be accessible, and be able to be mined (Ansaldi et al., 2020). Databases can support expansion of learning from single loop (Lukic et al., 2010), to double loop by exploring wider organisational factors (Argyris and Schön, 1996).

The LFPSE is the current national database for collation of safety events in the NHS. However, as described in 13.4.4.1, there are

reservations about the level of detail of the LFPSE taxonomy and its limited recognition of PSNMs. The LFPSE is also not accessible to healthcare organisations, only NHS England. Whether LFPSE will be minable is awaiting to be seen.

13.5.4.2 Individual and team learning

Individual and team learning occurs through the sharing of information about safety events with the purpose of building awareness and changing behaviours (Jacobsson et al., 2012). This research found that, in general, staff want learning to be shared following PSNMs, but there is little confidence in sharing processes in healthcare and some SCIs.

Sharing processes are often passive, commonly requiring staff to read information. There are some, more innovative approaches available such as 'just in time learning' (Yen et al., 2009), appreciative inquiry learning forums (Clinton and Getachew, 2003), simulation, and videos.

There is no evidence-based approach for how best to share learning with individuals and teams following PSNMs or other safety events; further research is recommended. This research identified some principles that may be considered when sharing learning with teams. Learning should be available and accessible via multiple routes, rapid and relevant, engaging, and orientated toward behaviours.

GT participants described how the most appropriate learning to share should be judged by the recipients of the learning. This was exemplified by pilots identifying learning to share with other pilots, rather than someone who does not fly.

Learning for behaviour change

Ramanujam and Goodman (2011) describe that learning following safety events should be aimed at a 'change in the repertoire of behaviours...' of individuals and teams. Sharing should build knowledge and understanding amongst staff around what actions to take in the future. This is particularly relevant in healthcare as safety controls often rely on staff actions. However, the potential for learning to change staff

behaviours is known to be limited and is a weak control (National Institute for Occupational Safety and Health, 2022).

A review of the literature shows that some authors have considered how to improve behaviour-based learning after safety events. While there are gaps in evidence, principles include (Hovden, Størseth and Tinmannsvik, 2011; Lukic et al., 2010; Murphy, 2020; Ramanujam and Goodman, 2011):

- **Understand learning** – train teams in the concept of learning and help them understand how people learn.
- **Effective investigation** – system-focussed, detailed, and quick investigations with articulation of behavioural implications that arise.
- **Revealed changes** – actions should be undertaken quickly and visibly, with evaluation of their impact.
- **Develop a learning process** – including how learning will be managed and how teams will engage with it.
- **Create the conditions** – in which to learn by developing psychological safety and by using learning-orientated questions.

Specific to PSNMs, the literature suggests that learning groups and networks are beneficial as they allow people to learn together (Chevreau et al., 2006; Murphy, 2020). Networks are important and people should be given opportunities to meet. Organisations should also use technology and social media to share learning (Murphy, 2020).

Other beneficial methods to support learning from PSNMs include discussion of several events around a theme (particularly a specific process), with small tests and take away messages (Murphy, 2020), and the use of 'pause, learn and repeat' (8.2.5.2) (Dillon et al., 2014). To engage learners it is again important to highlight that PSNMs represent system vulnerabilities (Dillon et al., 2011; Tinsley and Dillon-Merrill, 2005).

13.5.4.3 Feedback

Feedback mechanisms for near misses are often limited or non-existent. Some research participants questioned the role of feedback.

There has been limited research into the role and benefits of feedback, but it looks to improve future reporting of PSNMs (Sudan et al., 2019).

The purpose of feedback from safety events needs to be defined by organisations (Lindberg, Hansson and Rollenhagen, 2010). That purpose may be to express thanks, encourage further reporting, influence safety cultures, or to change behaviours. The purpose influences when and how feedback is given. If feedback has an individual learning role, then it needs to support recipient self-reflection (Lindberg et al., 2010), which requires appropriate feedback conditions (Jug, Jiang and Bean, 2019).

13.5.5 Activity recommendations

Based on the findings of this research the following are recommended:

- incentives for reporting of PSNMs should look to unleash the intrinsic motivation of staff through feedback on the impact of reports and celebration.
- reported PSNMs should be prioritised to identify those which will be valuable to investigate because they represent significant system vulnerabilities.
- investigation of individual PSNMs should consider events from both Safety I and Safety II perspectives.
- all PSNMs should be categorised against a consistent taxonomy which includes codes for how events were recovered; aggregated data should be reviewed regularly to identify safety risks and themes.
- organisations should look to maintain organisational memory through databases of aggregated safety information that are accessible and can be mined.
- the purpose of sharing learning and feedback from PSNMs should be defined by organisations to help identify how best to share that learning.

13.6 Outputs, outcomes, and impact

Outputs refer to the actions undertaken because of the activities to investigate and learn from PSNMs. Impact then refers to the effects of those actions and ultimately whether they reduce future harm to patients and improve safety.

13.6.1 Implementing actions (outputs)

Actions made following organisational learning from PSNMs are often weak (6.3.5.1) (e.g. Liberati et al., 2018). They are often aimed at education or changing staff behaviours, rather than improving the design of systems (Woodier et al., 2023). To develop more effective actions, investigations need to understand systems and where conditions can be optimised to support staff performance.

Healthcare safety investigations are now a major focus for the NHS with increasing recognition of the need to optimise systems. However, available resources, capability, and capacity undermine the ability for recommendations to be turned into effective actions (Healthcare Safety Investigation Branch, 2022). Organisations need support through resource and capability building to help ensure effective actions are implemented.

13.6.2 Outcome and impact of learning – *monitoring*

A PSNMMS needs to be able to evidence its impact on patient safety. The lack of evidence of impact to date following learning from PSNMs suggests that this is not straightforward, and the measuring and monitoring of safety are difficult (Vincent and Amalberti, 2016). There was limited guidance found across all the industries in this research around how best to evaluate impact; further research is recommended.

Vincent et al. (2014) describe the need to evaluate safety from the perspectives of past harms (what has happened), reliability and sensitivity to operations (what currently happens), and anticipation and preparedness (what may happen). This aligns with the expectations of a

SMS to learn from leading and lagging indicators as they offer safety insights from different perspectives (Reiman and Pietikäinen, 2012).

It is debated as to whether a near miss is a lagging (e.g. Center for Chemical Process Safety, 2011) or leading indicator (e.g. Kadri et al., 2013; Nesmith et al., 2013). The push for more leading indicators in safety has resulted in a view that lagging indicators are flawed or not useful (Travers, 2016). The findings of this research suggest that PSNMs can offer intelligence to support evaluation from both a leading and lagging perspective.

13.6.2.1 Near misses as lagging indicators of safety

Lagging indicators are measures of things that have already happened. From a PSNM perspective, rates of PSNMs or PSIs may act as indicators of 'past (actual or potential) harm.' Near-miss rates are often used in research to indicate the potential impact of learning from previous PSNMs and the effectiveness of actions (e.g. Tseng et al., 2018; Weiss et al., 2017). Ratios of near misses to other event rates are also often used in SCIs, but the validity of ratios has been questioned (12.2.1.3).

The value of using event rates is challenged by the known under and inaccurate reporting that occurs (Macrae, 2016). It is also unclear whether event rates are a useful marker of safety. There was disagreement amongst authors and participants in this research as to whether increasing or decreasing near-miss rates represent improved safety; Bhattacharya (2020) found no correlation between near misses and incidents/safety. Rather than looking at crude numbers, it may be more beneficial to look at trends over time. Principles from 'measurement for improvement' may be useful to help see where variation in rates has occurred from common cause or special cause factors (NHS Institute for Innovation and Improvement, 2017).

Other lagging approaches using PSNMs include: monitoring of near-miss risk indexes²⁹; quantification or ranking of action effectiveness and their success rates; and the identification of absence of learning from PSNMs.

Ranking of action effectiveness

There is interest in the evaluation of the potential effectiveness of actions (outputs) following learning from safety events. While an indirect marker of safety, effectiveness contributes to evaluation about whether actions are likely to be effective at preventing future incidents, such as was discussed in 6.3.5 and 8.2.6.

To evaluate effectiveness, the Hierarchy of Controls (Figure 2) is used in SCIs (e.g. Hasanspahić et al., 2022) and healthcare (e.g. Canadian Patient Safety Institute, 2012; Sehgal and Milton, 2021). However, the Hierarchy originates from a non-healthcare industry, is theoretical, and only provides a 'presumed' degree of effectiveness (Liberati et al., 2018). Despite its limitations, the EVs felt the Hierarchy is a useful "guide."

13.6.2.2 Near misses as leading indicators of safety

The literature describes the need for evaluation to be proactive with the use of indicators that change prior to any actual change in the level of risk (Kjellén, 2009). These leading indicators can highlight vulnerabilities prior to any safety event occurring. Whether PSNMs can be considered as leading indicators depends on the direction they are viewed from (Travers, 2016).

The findings of this research suggest that PSNMs can be considered from a leading perspective as they provide insights into reliability and what may go wrong in the future. PSNMs can identify where variability is occurring in processes (reliability) and may highlight potential system vulnerabilities which need addressing (anticipation and preparedness).

²⁹ Near-miss risk index – a tool for assessing the 'severity and risk of near-miss events...' (Mullen et al., 2016).

The investigation of PSNMs can also help identify new measures of patient safety that may provide a leading and holistic view. Examples found during this research include:

- **Human Reliability Analysis (HRA)** – uncommon in healthcare compared to other industries (Sujan, Embrey and Huang, 2020). PSNMs and PSIs may indicate where processes are unreliable, and approaches such as Systematic Human Error Reduction and Prediction Approach (SHERPA) may help organisations understand why (Hughes, Baber, Bienkiewicz et al., 2015). The use of quantitative outputs from HRA can inform probabilistic safety assessments as used in some SCIs (e.g. Di Maio et al., 2015).
- **Dynamic risk assessment** – certain factors have been identified to contribute to PSNMs. Measurement of those factors may increase sensitivity to where the likelihood of a safety event is increasing. Examples include the relationship between workload and PSNMs (Campbell, Harlan, Campbell et al., 2021).
- **Safety promotion factors** – for every factor that contributes to a PSNM, there will be a ‘safety promoting factor’ that can be measured (Reiman and Pietikäinen, 2012). Examples include fatigue (vigilance and energy), stress (motivation), and resources (Patankar and Taylor, 2016).
- **PSNM safety climate measurement** – safety climate can be considered a safety performance indicator (Guldenmund, 2000), but with acknowledgment that the relationship between culture and safety has not been validated (13.4.2.2).

13.6.3 Outcome and impact recommendations

Based on the findings of this research the following are recommended:

- recommendations and actions following learning from PSNMs should look to optimise the systems within which staff work to help address vulnerabilities.
- organisations require support through resource and development of capabilities to design and implement effective actions.
- while research identifies how best to evaluate the impact of learning from PSNMs, organisations should consider their safety from the perspectives of past harms, reliability and sensitivity to operations, and anticipation and preparedness.
- the principles of measurement for improvement could be used to explore variation in PSNM rates and whether there is common cause or special cause factors.
- insights are gained about the potential effectiveness of actions to improve patient safety by considering using the Hierarchy of Controls.

13.7 Summary

To the thesis author's best knowledge, this chapter is the first time an evidence based PSNMMS for healthcare has been described based on learning from healthcare and SCIs. The hope and intent of the PSNMMS is to improve the management of PSNMs and support improvements in patient safety. This research has also identified several areas where more knowledge is required to better understand how best to learn from PSNMs.

The next and final chapter will summarise the findings and recommendations of this research and return to the original thesis.

14 Conclusions, Limitations, and Future Research

14.1 Summary of findings

Since the 1990s healthcare has been exhorted to be more like aviation and other Safety-Critical Industries (SCIs) by learning from near misses to improve safety. The findings of this research show that some 30 years later, healthcare has not implemented effective processes to manage and learn from Patient Safety Near Misses (PSNMs), with an absence of evidence that learning has reduced harm to patients. The reasons for the lack of progress are multifactorial, but in part relate to the lack of a consistent definition of a PSNM and no guidance about how best to implement PSNM management systems.

Exploration of near-miss management in SCIs provides insights into how PSNM management in healthcare might be achieved. However, there is also limited evidence that learning from near misses has led to improved safety in SCIs. Rather, most advances in safety have come following significant and catastrophic events, technological advances, and the aggregation of learning from various sources of intelligence in Safety Management Systems (SMSs). It was unclear whether focus on near misses in SCIs was because they added value to safety learning, or out of necessity due to low numbers of incidents.

This research found several assumptions being made in the management of safety, both in healthcare and other SCIs, and that these assumptions are driving safety-related thinking. This research has highlighted 1) how the common cause hypothesis, the validity of which has been challenged, may be influencing thinking about the positive value of learning from near misses, and 2) that safety culture is seen as fundamental, but the relationship between culture and overall safety has not been clearly established.

The findings of this research suggest that healthcare may benefit from developing and implementing a SMS; there is evidence that SMSs positively contribute to safety. However, implementation of an SMS is a long-term vision and so, in the meantime, this research proposes a standard definition of a PSNM that captures the essential features of a near miss, and makes recommendations, based on insights from safety management in SCIs, to help improve the management of PSNMs in healthcare.

14.1.1 Returning to the original thesis

The findings of this research support the original thesis (4.2) in that healthcare has yet to implement effective systems to learn from PSNMs to improve patient safety. The findings provide some support to the thesis that SCIs effectively learn from near misses to improve safety, but there is evident variation, and the role of near misses in learning is not as clear as externally perceived. SCIs may have processes to support the reporting and management of near misses, but the findings of this research suggest that it is not near misses alone that lead to improvements in safety, and big changes are often the result of catastrophic events.

14.1.2 What this research adds

This research adds the following to the evidence base surrounding PSNMs:

- a standard definition of a PSNM following identification of the essential features of a near miss.
- a series of recommendations for the management of PSNMs to support reporting and learning to improve patient safety.
- that it is assumed that learning from near misses (in healthcare and SCIs) leads to improvements in safety, but there is limited evidence.

Beyond just PSNMs, this research adds the following in support of patient safety:

- SCIs can offer healthcare principles around how best to manage PSNMs and incidents, but translation should recognise the differences in contexts and that SCIs may not be as safety mature as externally perceived.
- healthcare would benefit from exploring a safety management approach to patient safety, with the potential implementation of a SMS.

14.2 Conclusion

It has long been believed that learning from PSNMs leads to improvements in patient safety, much like learning from near misses in SCIs contributes to their safety. However, an absence of evidence of impact from learning in healthcare and SCIs suggests that assumptions are being made based on traditional views of safety that are no longer valid for modern-day complex systems. Further research is required to understand the relationship between learning from PSNMs and patient safety.

Rather than near misses alone contributing to improved safety, it is likely that the intelligence they offer around contributory factors and controls in systems is beneficial when considered alongside other safety intelligence. This more holistic safety management approach is lacking in healthcare.

While there remain fundamental questions around the value of learning from PSNMs and their contribution to safety management, from a face validity perspective they offer insights into system vulnerabilities and therefore, should resource allow, their reporting and learning from should be encouraged. To effectively manage PSNMs a consistent definition is required, and they should be prioritised, investigated, aggregated, and acted on in line with the findings of this research.

Traditional approaches to investigating incidents where harm has occurred have not offered the benefits hoped for in healthcare. The alternative approaches described in this research call for patient safety

to turn its focus to understanding and optimising systems, creating barriers to incidents, and building resilience.

14.2.1 Recommendations for future research

This research identified several gaps in the evidence around how best to support reporting of and learning from PSNMs to improve patient safety. Further research is required to:

- develop patient safety evaluation methodologies to evaluate actions following learning from PSNMs and their impact.
- validate the common cause hypothesis for PSNMs and incidents, across common incident types in modern healthcare systems.
- identify routes by which PSNMs can be identified and reported that do not rely on staff.
- identify the most appropriate design features for incident reporting systems to support user engagement with reporting and collection of information about the specific features of PSNMs.
- develop a PSNM taxonomy that accounts for the system factors that contribute to events and interrupts/recovers them.
- develop and validate a prioritisation tool so that high-risk PSNMs can be identified and acted on.
- expand the evidence base for the use of Safety II approaches to examine PSNMs, including tools for analysis.
- to identify the most effective methods for sharing learning from PSNMs to support behaviour change.

14.2.2 Recommendations for a patient safety near miss management system

Acknowledging the above gaps in evidence, this research identified several findings that are relevant to developing management systems for PSNMs and future SMSs in healthcare. It is recommended that:

- a PSNM is ‘an interruption of events by person or persons involved in the care of a patient, or luck, which otherwise would have had the potential to reach and cause harm to that patient.’

- PSNMs are considered from Safety I and Safety II perspectives to provide complimentary views of the factors that contribute to near misses, the interruptions/controls involved, and the resilience of systems.
- the National Health Service (NHS) develops and implements a SMS to support improvements in patient safety.
- PSNMs should be effectively managed to support their future contribution to SMSs to identify safety gaps and potential improvements.
- healthcare should identify and learn from how SCIs have applied near-miss and safety management principles, with recognition of the different contexts before applying directly to healthcare.
- the NHS develops and implement PSNM management systems in line with the findings of this research. Systems will later contribute to a SMSs when implemented.

14.3 Limitations of this research

The research in support of this thesis took place over several years. During that time much changed because of the COVID-19 pandemic. The pandemic limited face-to-face opportunities for visits and interviews. Despite the impact of the pandemic, participant verification suggests that systems and processes for safety in healthcare and SCIs continue as before, meaning that the findings remain relevant.

From a methodological perspective, the approaches used in this research were appropriate to answer the questions. The methods used were effective except for the culture question and questionnaire. The culture question was designed to help understand and compare safety cultures across healthcare and the SCIs. However, as described by Dekker (2019), safety cultures are not comparable, consistent, or coherent; this undermines the validity of the culture question in this research. The questionnaire was also of limited value because of the

difficulties disseminating it to staff and engagement; these are known limitations of the method.

The scoping reviews (studies 1 and 3) provided a comprehensive description of near-miss management in healthcare and SCIs. Search terms aimed to capture a range of evidence, but due to variation in terminology and definitions it is unlikely that all evidence will have been identified. The variation also means that events termed a near miss in one article, may have been termed or defined differently in another.

The scoping review identified a paucity of experimental research into the investigation of and learning from near misses in healthcare and SCIs. Much of the evidence was descriptive, based on theory and the experiences of individuals and organisations. This highlights the need for further research to broaden the evidence base and that this research is relevant and needed.

The participants for the Qualitative Case Study (QCS, study 2) and Grounded Theory (GT, study 4) represented broad, but not comprehensive, coverage of healthcare and the SCIs. Healthcare organisations included the main settings, but not all. The GT SCIs were initially only transport but were broadened to nuclear to provide a non-transport perspective. Adding other industries, such as chemical processing to the GT, and construction to the scoping review and GT, would have offered further insights. Construction is not defined as an SCI, but the research shows that work in relation to near misses is underway in that industry.

While only a sample of healthcare settings and SCIs were included, the thesis author believes saturation was reached in the QCS and GT. Findings also suggest that, while definitions and terms may differ across industries, the principles around near-miss management are similar. The findings of this research are therefore likely to be applicable in multiple industries, acknowledging the need to ensure the different contexts are considered.

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16 Appendices

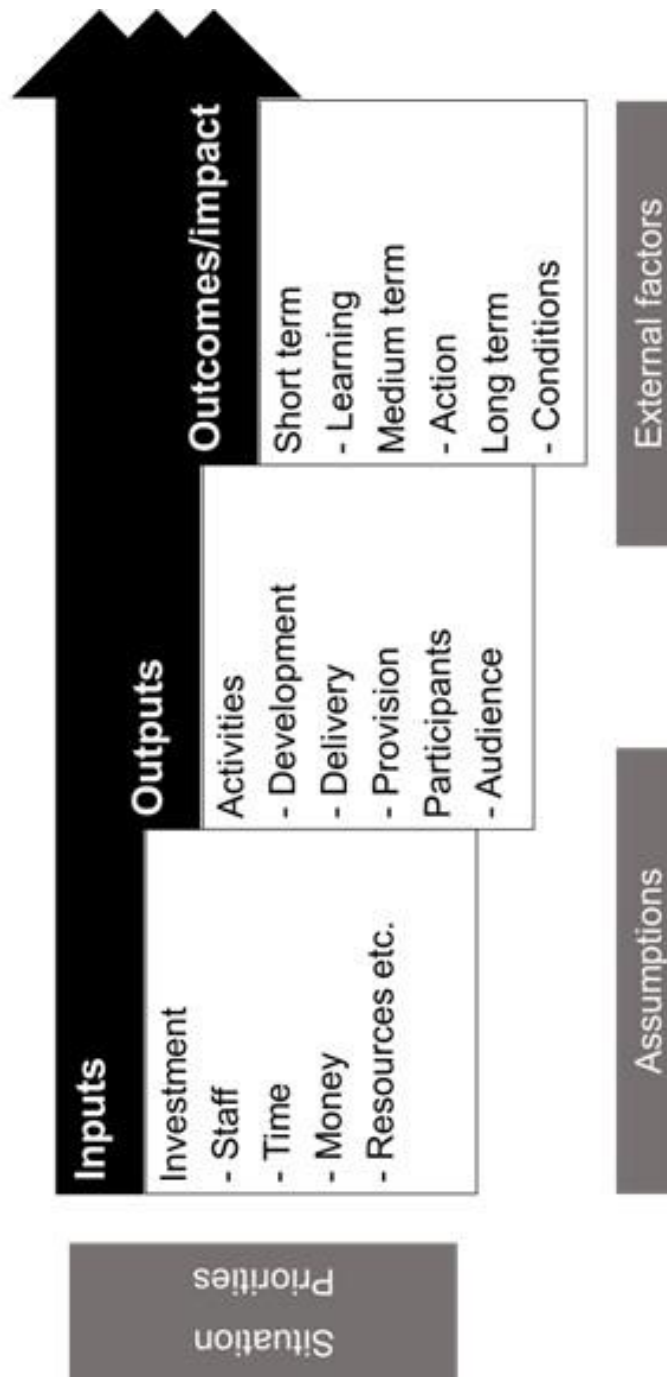
Chapter 1 appendix

Appendix 1A – Action Hierarchy Tool adapted from the National Patient Safety Foundation (2015)

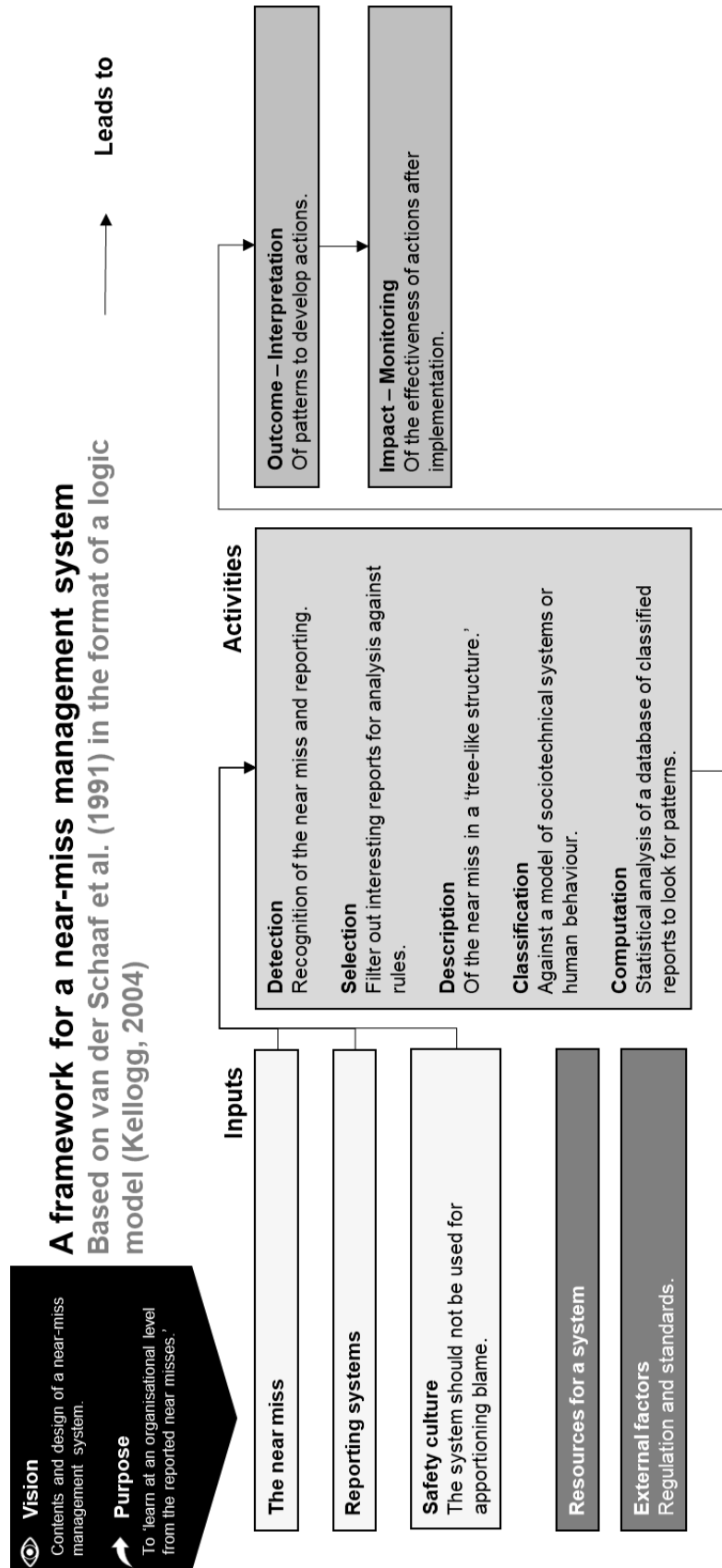
Strength	Category
Stronger	Physical/architectural changes
	New devices with usability testing
	Engineering control (forcing function)
	Simplify process
	Standardise equipment or process
	Tangible involvement by leadership
Intermediate	Redundancy
	Increasing staff/decreasing workload
	Software enhancements
	Eliminate distractions
	Education using simulation
	Checklist/cognitive aid
	Eliminate look and sound-alikes
	Standardised communication tools
	Enhanced documentation and labelling
Weak	Double checks
	Warnings
	New procedure/process
	Training

Chapter 5 appendices

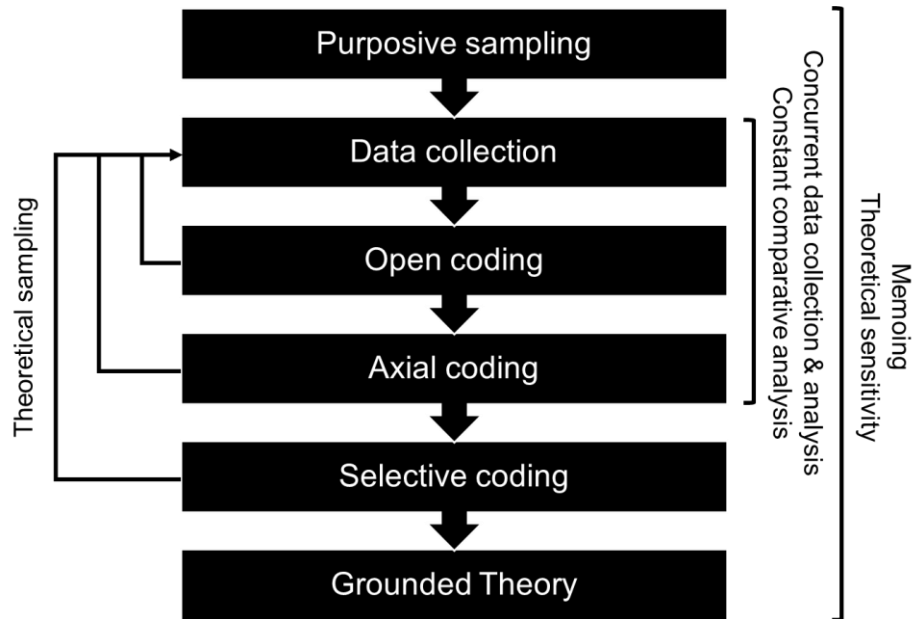
Appendix 5A – Generic logic model based on Kellogg (2004)



Appendix 5B – Near-miss management programme – draft logic model adapted from van der Schaaf et al. (1991)



**Appendix 5C – Steps for undertaking grounded theory
adapted from Chun Tie et al. (2019)**



Appendix 5D – Final interview questions (abbreviated)

Introduction
1- Date, time, and location?
2- Describe your role and type of organisation/industry?
Definitions and reporting
3a- How would you interpret the term 'safety-critical' and is your organisation one?
3b- What does 'near miss' mean in your organisation? What are their features?
4a- Tell me about an example of a 'classical' near miss in your organisation?
4b- How do you convey to your staff the understanding of a near miss to help recognition?
4c- Tell me about how near misses are reported in your organisation?
Analysis
5- What happens after a near miss is reported in your organisation?
Impact
6a- What evidence do you have of the outcomes/impact of near-miss reporting/analysis in your organisation?
6b- How do you share learning about near misses?
Culture
7- What evidence is there to demonstrate the culture around near misses in your organisation?
Infrastructure
8a- What do you have in place to implement the near miss programme you have described?
8b- What would you need to implement a near miss reporting and analysis programme?
Final thoughts
9- Is near miss reporting and analysis a priority for your organisation?
10- Can healthcare learn from your organisation?
11- Can the researchers contact you again in the future?

Appendix 5E – Definition question based on Henneman and Gawlinski (2004)

Scenario
<p>Mr H has been admitted with a suspected heart attack. Mr H starts complaining of chest pain that is characteristic of a heart attack. Mr H is allergic to aspirin, and this is documented in his medical notes. A nurse reviews Mr H and identifies that he is likely having a heart attack, so rings a doctor. The Doctor is with another sick patient and so discusses the patient on the phone with the nurse. Four scenarios follow:</p>
Outcomes
<ol style="list-style-type: none">1. Doctor tells the nurse to administer aspirin to Mr H. The nurse administers it; no checks are done. Mr H has a significant allergic reaction.2. Doctor tells the nurse to administer aspirin to Mr H. The nurse administers; no checks are done. Mr H has no reaction and recovers.3. Doctor tells the nurse to administer aspirin to Mr H now; they will prescribe it later. The nurse checks with Mr H whether he is allergic to anything before administering the aspirin. Mr H informs the nurse that he is allergic to aspirin and so it is not administered.4. Doctor tells the nurse that Mr H will require aspirin and that they will prescribe it now. Doctor prescribes via the electronic prescribing system which cross-checks the patient's records. The system identifies that Mr H is allergic to aspirin and alerts the Doctor, so it is not prescribed.

Appendix 5F – Levels of safety culture maturity from the Manchester Patient Safety Framework (National Patient Safety Agency, 2006)

Maturity level		Description
1	Pathological	Why waste our time?
2	Reactive	We do something when we have an incident?
3	Bureaucratic	We have systems in place to manage identified risks.
4	Proactive	We are alert for risks that might emerge.
5	Generative	Risk management is part of everything we do.

Appendix 5G – Final questionnaire questions (abbreviated)

5. What do you understand by the term "near miss?"
6. Describe an anonymised example of a near miss from your organisation.
7. On the scale, please rank how often the following statements occur:
7.a.1. YOU report a near miss in your organisation?
7.a.2. YOU get feedback on near misses YOU have reported?
7.a.3. Learning is shared with YOU from other's near misses?
7.b. Where do you believe your organisation's safety culture is?
8. In the past one month I have reported this number of near misses.
9. In the past 12 months I have reported this number of near misses.
10. What makes a situation a near miss in your organisation in your experience?
11. What encourages you to report near misses in your organisation?
12. Why do you think you are asked to report near misses in your organisation?
13. What supports you/makes it easier to report near misses in your organisation?
14. What prevents you from reporting near misses in your organisation?
15. How can near-miss reporting be changed in your organisation?
16. What changes have you seen as a result of near misses?
17. How do you learn about near misses in your organisation?
18. How would you like best to learn about near misses in your organisation?
19. In relation to near misses, what does your organisation do well that others can learn from?

Chapter 6 appendices

Appendix 6A – Healthcare scoping review protocol updates

Update	Rationale
Exclude maternity, obstetric and neonatal near misses	These are different to patient safety near misses.
Exclude healthcare health and safety near misses	These are focussed on staff rather than patients.
Exclude case studies without exploration, and healthcare where near misses were not the primary focus	High volume in review outputs. Case studies did not provide generalisable findings. Evidence focussing on harmful incidents sometimes included near misses. These sources did not provide evidence for the review question.
Exclude asteroid near misses	These near misses are different to those occurring in industries where efforts can be made to avoid them.
Add 'near hit' to search	A further term identified that may represent a near miss.

Appendix 6B – Final search strategy MedlineOVID®

1. Near Miss, Healthcare/ or "near miss*".mp.
2. "close thing*".mp.
3. "near thing*".mp.
4. "narrow escape*".mp.
5. "close shave*".mp.
6. "near harm*".mp.
7. "near error*".mp.
8. "close call*".mp.
9. "lucky escape*".mp.
10. "almost event*".mp.
11. "almost history*".mp.
12. "close encounter*".mp.
13. "good catch*".mp.
14. "sentinel event*".mp.
15. "warning event*".mp.
16. "near hit*" .mp.
17. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. SELF REPORT/ or report*.mp.
19. explor*.mp.
20. record*.mp.
21. describ*.mp.
22. descrip*.mp.
23. analys*.mp.
24. analyz*.mp.
25. investigat*.mp.
26. review*.mp.
27. "Root Cause Analysis"/
28. manage*.mp.
29. collect*.mp.
30. detect*.mp.
31. Classification/
32. ACCIDENT PREVENTION/
33. RISK ASSESSMENT/
34. defin*.mp.
35. evaluat*.mp.
36. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
or 32 or 33 or 34 or 35
37. 17 and 36

Appendix 6C – PRISMA summary

SCI – safety-critical industry

PRISMA	2000 – 2018 May	2018 June – 2021	2022
	Healthcare and SCI*	Healthcare	Healthcare
Identified through database searching:	36,829	1,416	374
Duplicates removed:	22,463	1,041	249
Screening title and abstract:	22,463	1,041	249
Excluded:	22,196	1,017	229
Full-texts assessed:	267	24	20
Excluded:	81	10	11
Included in synthesis:	102 (84 SCI)	14	9

Appendix 6D – Frequency counts – academic articles (scoping review healthcare 2000 – 2022)

Year	Count
2000 – 2009	52
2010 – 2017	44
2018 A/B*	6/2
2019	5
2020	5
2021	2
2022	9
Total:	125

*2018A (January to end May) 2018B (June to end December 2018)

Type of article	2000-2017	2018 A/B	2019 - 2021	2022	Total
Book chapter	4	0	0	0	4
Opinion	21	0	0	1	22
Research	62	6/2	10	5	85
Review	9	0	2	3	14
Total:	96	8	12	9	125

Research	2000-2017	2018 A/B	2019 - 2021	2022	Total
Mixed	9	1/0	1	1	12
Qualitative	14	0	0	0	14
Quality improvement	3	2/1	1	1	8
Quantitative	36	3/1	8	3	51
<i>experimental (quasi)</i>	1	0	0	0	
<i>experimental (randomised control)</i>	1	0	0	0	
<i>nonexperimental</i>	34	3/1	8	3	
Total:	62	8	10	5	85

Focus area	2000-2017	2018	2019 - 2021	2022	Total
Definitions	30	1	3	2	36
Reporting	44	5	5	4	58
Analysis and learning	38	3	6	3	50
Impact and change	27	2	1	2	32

Country (top 5)	2000-2017	2018 A/B	2019 - 2021	2022	Total
United States of America	61	3/2	10	3	79
United Kingdom	9	1/0	0	1	11
Canada	9	0	1	0	10
Australia	6	1/0	0	1	8
Netherlands	3	0	0	0	3
Other	8	1	1	4	14
Total:	96	8	12	9	125

Care setting	2000-2017	2018 A/B	2019 - 2021	2022	Total
General hospital	87	5/2	12	7	114
Mental health service	2	0	0	0	2
Nursing facility	1	0	0	1	2
Other	3	0	0	0	3
Primary medical care	3	1/0	0	1	4
Total:	96	8	12	9	125

Specialty (top 5)	2000-2017	2018	2019-2021	2022	Total
General/ multiple	28	1/0	0	2	31
Medication/ pharmacy	12	1/0	1	2	16
Surgery (inc. paediatric and interventional)	14	1/1	0	0	16
Radiotherapy	7	1/0	4	1	13
Nursing (hospital)	5	0	1	1	7
...	30	3	6	3	42
Total:	96	8	12	9	125

Appendix 6E – Publication types, countries, and specialties of the academic articles (scoping review healthcare 2000 – May 2018)



**Appendix 6F – Included academic articles (scoping review
healthcare 2000 – 2022) (n=125)**

Y – Yes, N – No

OR – Original Research, RV – Review, OP – Opinion/commentary

D – Definitions, R – Reporting, A – Analysis, L – Learning, I – Impact

NM – Near Miss, GC – Good Catch, CC – Close Call

Reference	NM alone	Country	Type	Main focus	Specialty	Primary term
Adelman et al., 2013	Y	USA	OR	D,R,I	General	NM
Ardenghi et al., 2007	Y	Italy	OR	R,I	Transfusion	NM
Arnold, 2017	Y	Australia	OP	A	Radiotherapy	NM
Arnold et al., 2022	N	Australia	RV	L,I	Radiotherapy	NM
Aspden et al., 2004	N	USA	Book	R,A	General	NM
Aston and Young, 2009	Y	USA	OR	R,L	Emergency	NM
Barach and Small, 2000b	Y	USA	RV	R,I	General	NM
Barnard et al., 2006	Y	Canada	OR	D,R	Multiple	GC
Battles and Shea, 2001	Y	USA	OR	A,L	Education	NM
Berry and Krizek, 2000	Y	USA	OP	A,I	General	NM
Beyea et al., 2006	N	USA	OP	R,L	General	NM
Biro et al., 2022	N	USA	RV	D	Perioperative	NM
Bonrath et al., 2015	Y	Canada	OR	R,A,L	Surgery	Other
Brecher, 2014	Y	USA	OP	R,I	Emergency	GC
Callum et al., 2001	Y	USA	OR	R,A,I	Transfusion	NM
Capucho, 2011	Y	Brazil	OP	R	Medication	NM
Carthey et al., 2001	N	UK	RV	D,R,A	Surgery	NM
Champion, et al., 2008	N	USA	OP	D	Surgery	Other
Chang et al., 2005	N	USA	RV	D	General	NM

Clinton and Getachew, 2003	N	UK	OR	D,R,A,I	Mental health	NM
Cohen et al., 2018	Y	USA	OR	A	Surgery	NM
Cohoon, 2003	Y	USA	OR	L	Nursing	NM
Cooper et al., 2018	N	UK	OR	D	Primary care	NM
Coyle, 2005	Y	USA	OP	R	General	CC
Crandall et al., 2018	Y	USA	OR	R	Paediatric	NM
Crane et al., 2015	Y	USA	OR	R,I	Primary care	NM
Cure et al., 2011	Y	USA	OR	A	Outpatient	NM
Currie et al., 2009	Y	USA	OR	R,I	Nursing	NM
Davey, et al., 2008	N	UK	OR	A,I	Paediatric	Other
Dekker, 2011	Y	USA	Book	R,A	General	CC
Deraniyagala et al., 2015	N	USA	OR	R,I	Radiotherapy	NM
Devin et al., 2022	Y	Ireland	OR	R	Medication	NM
Dooley et al., 2001	Y	Australia	OR	D,R,A,L	Medication	NM
D'Souza et al., 2004	Y	Australia	OR	R	Medication	Other
Early et al., 2011	Y	USA	OR	I	Medication	NM
Etchegaray et al., 2005	Y	USA	OR	D	General	CC
Fargen et al., 2013	Y	USA	OR	I	Surgery	Other
Feng et al., 2022a	Y	China	RV	R	Multiple	NM
Feng et al., 2022b	Y	China	OR	L	Nursing	NM
Feroli et al., 2012	Y	Italy	OR	R	Surgery	NM
Ford et al., 2012	N	USA	OR	I	Radiotherapy	NM
Galvan et al., 2005	Y	USA	OR	R	Surgery	NM

Ginsburg et al., 2009	N	Canada	OR	D,I	General	NM
Goolsarran et al., 2019	Y	USA	OR	I	Radiology	NM
Grabinski et al., 2021	Y	USA	OR	A	Emergency	Other
Greenham et al., 2018	N	Australia	OR	R,A,I	Radiotherapy	NM
Griffey et al., 2019	N	USA	RV	A	Emergency	NM
Guffey et al., 2011	Y	USA	OR	R,I	Perioperative	NM
Habraken and van der Schaaf, 2010	Y	Netherlands	OR	A	Medication	NM
Hamilton et al., 2018	Y	USA	OR	R	Surgery	NM
Hartvigson et al., 2020	Y	USA	OR	R	Radiology	NM
Henneman and Gawlinski, 2004	Y	USA	OR	D	Nursing	NM
Herzer et al., 2012	Y	USA	OR	D,I	Perioperative	GC
Hewitt and Chreim, 2015	Y	Canada	OR	I	General	NM
Hurley et al., 2008	Y	USA	OR	D	Medical	NM
Hyman et al., 2012	Y	USA	OR	I	Medication	NM
Isaksson et al., 2022	N	Sweden	OR	R	General	NM
Jacobs et al., 2008	N	USA	RV	D	Surgery	NM
Jefferies et al., 2008	Y	Canada	OR	D	Multiple	NM
Jefferies et al., 2012a	Y	Canada	OR	D	Mental health	NM
Jefferies et al., 2012b.	Y	Canada	OR	I	General	NM
Jefferies et al., 2012c	Y	Canada	OR	I	Multiple	NM
Judy et al., 2020	N	USA	OR	A	Radiotherapy	NM
Jung et al., 2020	Y	USA	OR	D,R	Radiotherapy	NM
Kanse et al., 2006	Y	Australia	OR	R,A,I	Medication	NM

Kaplan and Fastman, 2003	N	USA	RV	A	General	NM
Kaplan et al., 2002	Y	USA	OP	R,A	Transfusion	NM
Kaplan, 2005	Y	USA	RV	D,A	Transfusion	Other
Kessels-Habraken et al., 2010	Y	Netherlands	OR	D	General	NM
Killen and Beyea, 2003	Y	USA	OP	R,L	Perioperative	NM
Kodama and Kanda, 2010	Y	Japan	OR	A	General	NM
Kundu et al., 2019	Y	USA	OR	D	Radiotherapy	NM
Kusano et al., 2015	Y	USA	OR	R,A,I	General	NM
Lipshutz et al., 2015	Y	USA	OR	D,R,A	Critical care	NM
Liszewski, 2020	Y	Canada	OR	A	Radiotherapy	NM
Loh et al., 2017	Y	Singapore	OR	R,A,L,I	Surgery	Other
Lombardi et al., 2016	Y	USA	OR	I	Medication	NM
Lozito et al., 2018	Y	USA	OR	R	General	GC
Madden and Milligan, 2004	Y	UK	OP	D	Maternity	NM
Mahlmeister, 2006	Y	USA	OP	R,I	General	NM
Mandal et al., 2005	Y	UK	OR	R	Surgery	NM
Marks et al., 2013	Y	USA	OP	D	General	CC
Martin et al., 2005	Y	USA	Book	D,R	Oncology	CC
McCafferty and Polk, 2004	Y	USA	OP	A	Surgery	NM
Mick et al., 2007	Y	USA	OR	D,R	Oncology	GC
Miller and Chaboyer, 2006	Y	Australia	OP	R,A	Nursing	NM
Mosaly et al., 2013	Y	USA	OR	A	Radiotherapy	GC
Mullen et al., 2016	Y	USA	OR	R,A	Radiotherapy	NM

Nashef, 2003	Y	UK	OP	D	General	NM
Novak et al., 2016	Y	USA	OR	A	Radiotherapy	NM
Nyflot et al., 2015	Y	USA	OR	R,A	Radiotherapy	NM
Parnes et al., 2007	N	USA	OR	A,I	Primary care	CC
Pfoh et al., 2021	Y	USA	RV	D	Ambulatory care	NM
Putnam et al., 2016	Y	USA	OR	R,I	Surgery	GC
Rosenorn-Lanng and Michell, 2014	Y	UK	Book	A	General	Other
Rudolphi et al., 2019	Y	USA	OR	R	Nursing	NM
Schildmeijer et al., 2013	N	Sweden	OR	R	Surgery	NM
Shaikh et al., 2022	N	USA	OR	R	Emergency	NM
Sheikhtaheri, 2014	Y	Iran	OP	D	General	NM
Siegenthaler et al., 2005	N	Switzerland	OR	D	Transfusion	NM
Simmons et al., 2008	Y	USA	OR	R,A,I	Oncology	NM
Singh et al., 2003	Y	UK	OR	D,R,I	Surgery	NM
Smith-Love, 2022	Y	USA	OR	I	Medication	NM
Sorokin et al., 2002	Y	USA	OP	R	Medicine	CC
Sudan et al., 2019	Y	USA	OR	R,L	Emergency	NM
Tamuz and Thomas, 2006	N	USA	OR	D	General	GC
Tamuz et al., 2004	Y	USA	OR	D,R	Medication	CC
Tanz, 2018	Y	USA	OR	R,L,I	Education	GC
Taylor et al., 2007	N	USA	OR	R	Paediatric	GC
Thornton et al., 2011	Y	USA	OR	A	Radiology	NM
Traynor, 2015	Y	USA	OP	R,A,I	Medication	GC

Tseng et al., 2018	Y	Taiwan	OR	A,I	Medication	NM
Vanderford et al., 2014	Y	USA	OP	A,I	Medication	NM
Wagner et al., 2006	Y	Canada	RV	R,I	Nursing homes	NM
Wallace et al., 2017	Y	USA	OR	R,I	General	NM
Waterson et al., 2020	Y	UAE	OR	R,A	Medication	NM
Watson, 2006	Y	USA	OP	R	Perioperative	CC
Weiss et al., 2017	N	USA	OR	R,L,I	Oncology	NM
Woloshynowych et al., 2005	N	UK	RV	A	General	NM
Woodier et al., 2022	Y	UK	OP	D,A,L	Primary care	NM
Wu and Marks, 2013	Y	USA	OP	I	General	CC
Yen et al., 2009	Y	USA	OR	R,L	Nursing	NM
Yoon et al., 2015	Y	USA	OR	R,A,L,I	Surgery	NM
Yu et al., 2005	N	Australia	RV	D	Medication	NM
Zwart et al., 2011	N	Netherlands	OR	R	Primary care	NM

Chapter 7 appendices

Appendix 7A – Qualitative case study rationalised/final codes

NM – Near Miss

Name	Files	References
1 Inputs	53	589
NM reporting systems	15	59
Local systems	6	6
National systems	6	8
Perceptions of local systems	11	42
Regional systems	2	2
Prompts for reporting	31	240
Local	25	178
National	8	12
The NM itself	22	50
Safety culture	11	28
Impeding NM	8	13
Supporting use of NM	6	11
The NM itself	49	262
Features	34	169
Recognising a NM	27	30
2 Activities	24	204
Analysis NM	16	71
Methods	7	12
Reporting NM	12	21
Alternative routes	12	21
Sharing learning from NM	15	112
Feedback	6	14
Methods	11	81
Value	6	8
3 Outcomes and impact	36	168
Impact	27	86
Evidence	12	16
Perceived	22	67
Outcome	8	41
Output	29	41
4 Assumptions	4	4
5 Future opportunities	29	199
Analysis	8	13
Defining	8	13
Learning	8	16
Process	15	55
Reporting	23	98
Value	3	4

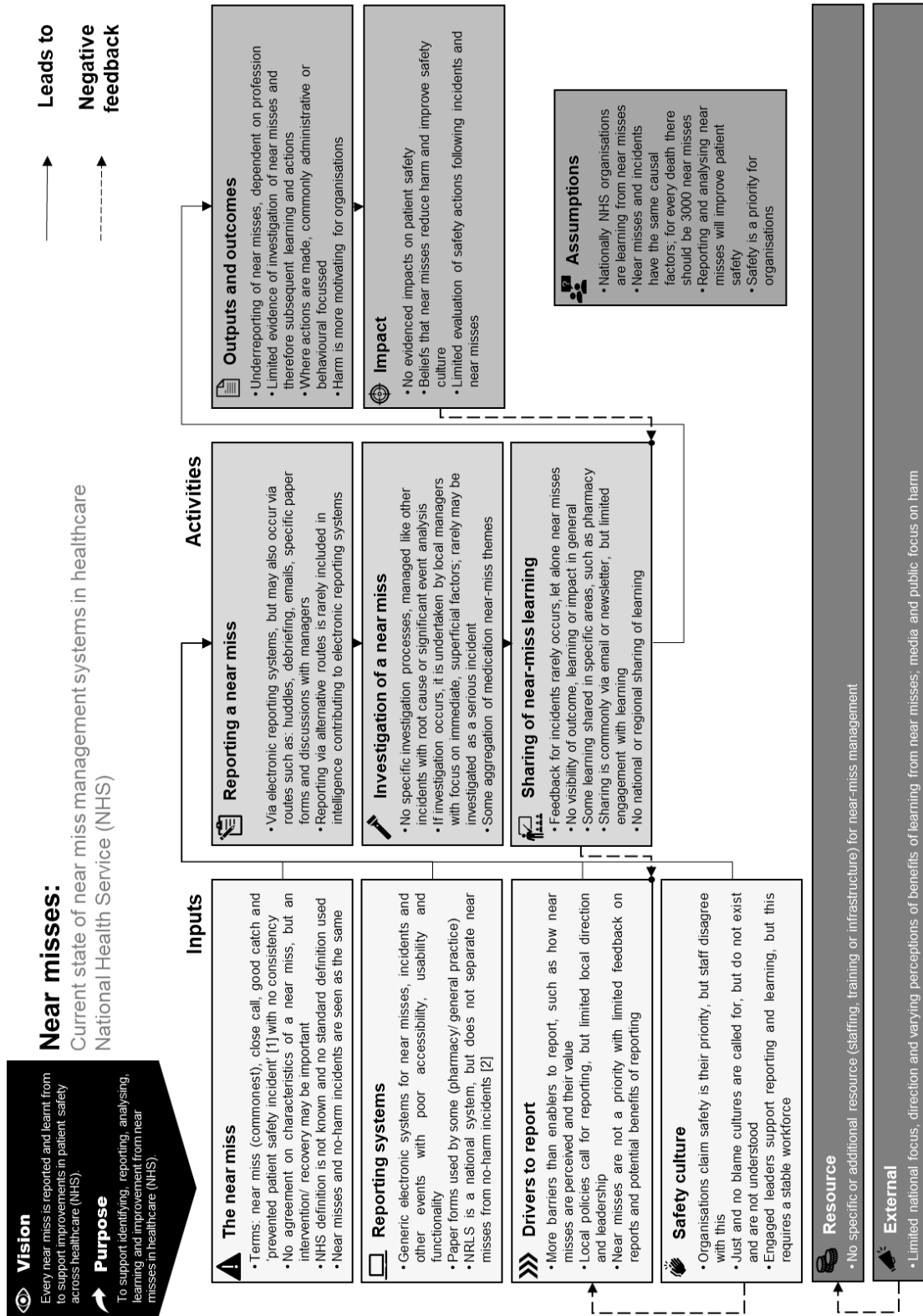
Appendix 7B – Qualitative case study questionnaire responses

Role and years in practice	Frequency
Pharmacist	19
1-5	7
6-10	4
11-15	6
16-20	1
Less than 1 year	2
Pharmacy technician	6
1-5	2
6-10	2
11-15	1
21+	1
Blank	1
Total	26

Frequency/ question	How often...do/is		
	YOU report a near miss?	YOU get feedback?	is learning shared with YOU?
Frequently	8	9	8
Never	1	1	2
Occasionally	13	13	13
Rarely	4	3	3
Total	26	26	26

Where do you believe your organisation's safety culture is?		
Culture	Frequency	Valid %
Pathological	0	0
Reactive	0	0
Bureaucratic	9	34.6
Proactive	14	53.8
Generative	3	11.5
Total	26	100.0

Appendix 7C – Patient safety near miss management in healthcare – a logic model based on the qualitative case study³⁰



³⁰ [1] National Patient Safety Agency, 2004; [2] National Patient Safety Agency, n.d.

Appendix 7D – Definition question – healthcare responses

Care setting of participants		
Setting	Freq	Valid %
Acute hospital	2	14.3
General practice	4	28.6
Mental health	3	21.4
National	3	21.4
Ambulance	2	14.3
Total	14	100.0

Terminology of scenarios		
	Freq	Valid %
Scenario 1		
Incident	14	100.0
Scenario 2		
Incident	9	64.3
Near miss	5	35.7
Scenario 3		
Incident	1	7.1
Near miss	10	71.4
Non event	3	21.4
Scenario 4		
Incident	1	7.1
Near miss	7	50.0
Non event	6	42.9

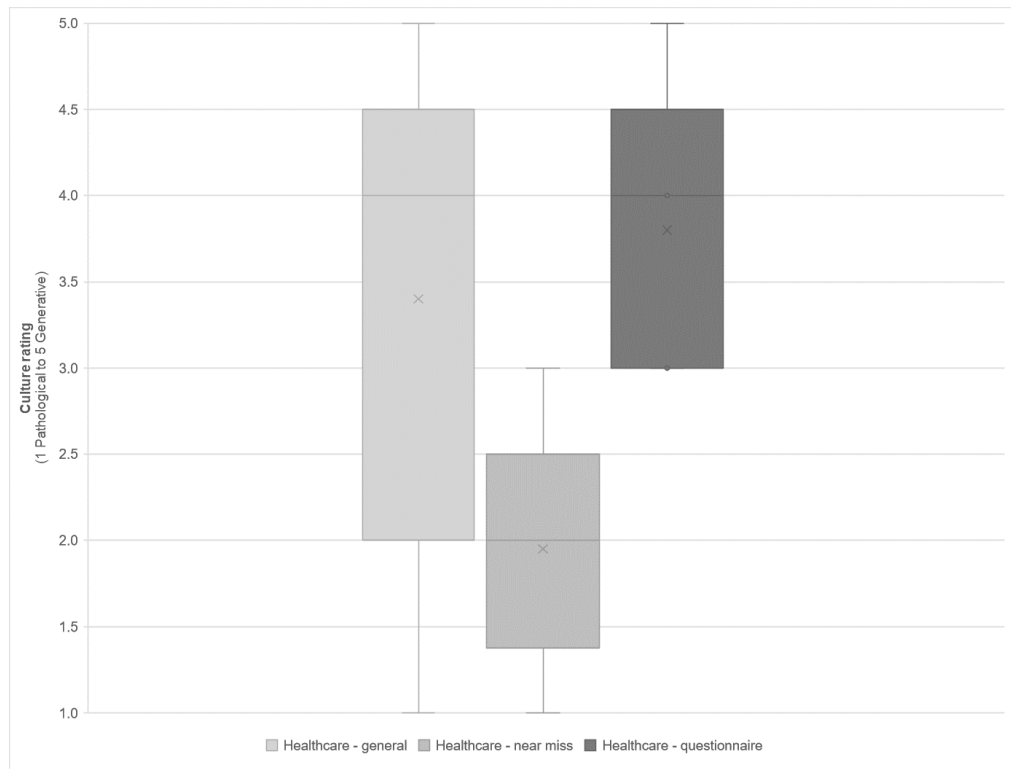
Fleiss Kappa						
	Kappa	Asymptotic			95% Confidence Interval	
		Standard Error	z	Sig.	Lower Bound	Upper Bound
Scenario 1						
Agreement	1.00	0.06	16.52	0.000	0.88	1.00
Scenario 2						
Agreement	0.26	0.06	4.27	0.000	0.14	0.38
Scenario 3						
Agreement	0.29	0.06	4.81	0.000	0.17	0.41
Scenario 4						
Agreement	0.09	0.06	1.54	0.12	0.00	0.21

Appendix 7E – Culture question – healthcare responses

Culture		General	Near miss
Number	Valid	13	12
	Missing	0	1
Mean		3.4	2.5
Median		4.0	2.0
Std. Deviation		1.2	1.1
Interquartile range		3.0 – 4.0	1.8 – 2.0

Culture		
	Freq	Valid %
General		
Pathological (1)	1	7.7
Reactive	2	15.4
Bureaucratic	3	23.1
Proactive	5	38.5
Generative (5)	2	15.4
Total	13	100.0
Near miss		
Pathological (1)	1	8.3
Reactive	7	58.3
Bureaucratic	2	16.7
Proactive	1	8.3
Generative (5)	1	8.3
Total	12	100.0
No response	1	

Appendix 7F – Culture question – box and whisker plots for healthcare



Chapter 8 appendices

Appendix 8A – Additional PRISMA summary

SCI – safety-critical industry

PRISMA	2000 – 2018 May	2018 Jun – 2021	2022
	Healthcare and SCI	SCI	SCI
Identified through database searching		11,093	2167
Duplicates removed		9,634	2154
Screening title and abstract		9,634	2154
Excluded		9,571	2138
Full-texts assessed		63	16
Excluded		47	8
Included in synthesis:	84 (102 healthcare)	16	8

Appendix 8B – Frequency counts – academic articles (safety-critical industry scoping review 2000 –2022)

Year	Count
2000 – 2009	34
2010 – 2017	47
2018 A/B*	3/3
2019	7
2020	2
2021	4
2022	8
Total:	108

*2018A (January to end May) 2018B (June to end December 2018)

Type of article	2000 – 2017	2018 A/B	2019 – 2021	2022	Total
Book chapter	4	0	0	0	4
Opinion	10	0	1	0	11
Research	63	3/3	12	7	88
Review	4	0	0	1	5
Total:	81	6	13	8	108

Research	2000 – 2017	2018 A/B	2019 – 2021	2022	Total
Mixed methods	11	0/1	1	3	16
Qualitative	16	1/0	5	0	22
Quantitative	36	2/2	6	4	50
<i>nonexperimental</i>	36	2/2	6	4	50
Total:	63	6	12	7	88

Focus area	2000 – 2017	2018	2019 – 2021	2022	Total
Definitions	15	0	0	0	15
Reporting	28	4	9	5	46
Analysis and learning	53	4	5	6	69
Impact and change	24	0	2	0	26

Country (top 5)	2000 – 2017	2018 A/B	2019 – 2021	2022	Total
United States of America	41	0/2	2	1	46
Italy	5	0	1	3	9
United Kingdom	6	1/0	0	0	7
Australia	4	0/1	2	0	7
China	1	1/0	1	1	4
Finland	3	0	1	0	4
Netherlands	3	0	1	0	4
South Korea	4	0	0	0	4
...	14	1/0	5	3	23
Total:	81	6	13	8	108

Industry	2000 – 2017	2018 A/B	2019 – 2021	2022	Total
Aviation	6	0	2	0	8
Disaster	4	0	0	0	4
Fire	4	0	0	0	4
Maritime	11	1/0	6	4	22
Military	2	0	0	0	2
Multiple	10	0/1	0	1	12
Nuclear	6	0	0	0	6
Processing*	25	0	3	3	31
Rail	10	2/2	2	0	16
Space	3	0	0	0	3
Total:	81	6	13	8	108

*Includes chemical, oil and gas, and mining

Appendix 8C – Publication types, countries, and specialties of the academic articles (safety-critical industry scoping review 2000 – 2018)



Appendix 8D – Included academic articles (safety-critical industry scoping review 2000 – 2022) (n=108)

Y – Yes, N – No

OR – Original Research, RV – Review, OP – Opinion/commentary

D – Definitions, R – Reporting, A – Analysis, L – Learning, I – Impact

NM – Near Miss, GC – Good Catch, CC – Close Call

Processing – includes chemical, oil and gas, and mining

Reference	NM alone	Country	Type	Main focus	Industry	Primary term
Ansaldi et al., 2019	Y	Italy	OR	A	Processing	NM
Banerjee et al., 2019	Y	USA	OR	R	Rail	NM
Baran et al., 2013	Y	USA	OR	L	Fire	NM
Barnes et al., 2007	Y	USA	OR	D,R	Disaster	CC
Baysari et al., 2008	N	Australia	OR	A	Rail	Incident
Baysari et al., 2009	N	Australia	OR	A	Rail	Incident
Bhattacharyya et al., 2014	Y	India	OR	R,I	Maritime	NM
Bicen and Celik, 2022	Y	Turkey	OR	A	Maritime	NM
Bliss et al., 2014	Y	USA	OR	D	Multiple	CC
Boafo et al., 2017	N	Canada	OR	R,A	Nuclear	Faults
Breithaupt et al., 2022	Y	USA	OR	R	Maritime	NM
Brooker, 2005	Y	UK	OR	R,I	Aviation	Airprox
Bruin and Swuste, 2008	N	Netherlands	OR	A	Processing	NM
Bugalia et al., 2021	Y	Japan	OR	R	Rail	NM
Button and Drexler, 2006	Y	USA	RV	I	Aviation	Air misses
Carra et al., 2022	N	Italy	OR	A	Processing	NM
Cavalieri and Ghislandi, 2010	Y	Italy	OR	D	Processing	NM

Colwell, 2002	Y	USA	OP	L	Space	NM
Corcoran, 2004	Y	USA	Book	D	Multiple	Precursor
Davies et al., 2000	Y	UK	OP	R,A,I	Rail	NM
Di Maio et al., 2015	Y	France	OR	D,R,A	Nuclear	NM
Di Maio et al., 2017	N	Italy	OR	R,A	Nuclear	NM
Dillon and Tinsley, 2005	Y	USA	OR	I	Multiple	NM
Dillon and Tinsley, 2008	Y	USA	OR	I	Space	NM
Dillon et al., 2011	Y	USA	OR	I	Disaster	NM
Dillon et al., 2014	Y	USA	OR	I	Disaster	NM
Dillon et al., 2016	Y	USA	OR	R	Space	NM
Du et al., 2021	Y	Finland	OR	R	Maritime	NM
Fabiano and Currò, 2012	Y	Italy	OR	R,A	Processing	NM
Fang et al., 2020	Y	China	OR	R	Maritime	NM
Fukuda et al., 2016	Y	Japan	OR	A	Rail	NM
Georgoulis and Nikitakos, 2019	Y	Greece	OR	R	Maritime	NM
Gnoni and Lettera, 2012	Y	Italy	OR	A	Multiple	NM
Gnoni and Saleh, 2017	Y	Italy	RV	D,A	Multiple	NM
Gnoni et al., 2022	Y	Italy	RV	R,A,L	Multiple	NM
Gordon et al., 2005	N	Scotland	OR	A	Processing	NM
Grabowski et al., 2007a	N	USA	OR	R,A,I	Maritime	NM
Grabowski et al., 2007b	N	USA	OR	I	Multiple	NM
Haas and Yorio, 2019	Y	USA	OR	A	Processing	NM

Hasanspahić et al., 2021	Y	Croatia	OR	R	Maritime	NM
Hasanspahić et al., 2022	Y	Croatia	OR	R,A,L	Maritime	NM
Hodges and Sanders, 2014	N	USA	OP	D	Nuclear	NM
Hughes et al., 2018	Y	UK	OR	A	Rail	CC
Kadri et al., 2013	Y	USA	OP	L,I	Processing	NM
Kanse and van der Schaaf, 2001	N	Australia	OR	A	Processing	NM
Killgore et al., 2008	Y	USA	OR	I	Military	CC
Kim and Yoon, 2013	N	South Korea	OR	A	Rail	NM
Kim et al., 2010	N	South Korea	OR	A	Rail	NM
Kim et al., 2017	Y	South Korea	OR	R	Maritime	NM
Kirwan et al., 2008	N	France	OR	A	Aviation	NM
Koo et al., 2009	N	South Korea	OR	A	Processing	NM
Lappalainen et al., 2011	N	Finland	OR	R	Maritime	NM
Madsen et al., 2016	Y	USA	OR	I	Aviation	NM
Mazaheri et al., 2015	N	Finland	OR	A	Maritime	Near grounding
McSweeney et al., 2013	Y	USA	OR	R,A	Maritime	NM
Meel et al., 2007	N	USA	OR	A	Processing	NM
Meel et al., 2008	Y	USA	OR	R,A	Processing	NM
Morris and Moore, 2000	Y	USA	OR	I	Aviation	CC
Morrison, 2004	N	USA	OP	L,A	Processing	NM
Multer et al., 2013	Y	USA	Book	A,I	Rail	CC

Nesmith et al., 2013	Y	USA	OP	R,A,I	Processing	NM
Nivolianitou et al., 2006	N	Greece	OP	R	Processing	NM
Pariyani et al., 2010	N	USA	OR	D,A	Processing	NM
Pariyani et al., 2012	Y	USA	OR	R,A	Processing	NM
Phimister et al., 2003	Y	USA	OR	D,R,A,I	Processing	NM
Pope and Orr, 2017	N	Australia	OR	I	Military	NM
Rasmussen et al., 2013	Y	Denmark	OR	A,I	Processing	NM
Rathnayaka et al., 2011	N	Canada	OR	R,A	Processing	NM
Reinach and Viale, 2006	N	USA	OR	A	Rail	Incident
Rudan et al., 2012	Y	Croatia	OR	D	Maritime	NM
Saleh et al., 2013	Y	USA	RV	D	Multiple	NM
Sattison, 2004	Y	USA	Book	A	Nuclear	Precursor
Sepeda, 2006	N	USA	RV	A,L	Processing	NM
Shimazoe and Burton, 2013	Y	USA	OR	R,I	Multiple	NM
Shorrock and Kirwan, 2002	N	UK	OR	A	Aviation	NM
Skogdalen and Vinnem, 2012	Y	Norway	OR	A	Processing	Precursor
Smith and Borgonovo, 2007	Y	USA	OR	A	Nuclear	Precursor
Storgård et al., 2012	N	Finland	OR	R,L,I	Maritime	NM
Szłapczyński and Niksa-Rynkiewicz, 2018	Y	Poland	OR	R,A	Maritime	NM
Szłapczyński and Szłapczyński, 2021	Y	Poland	OR	R	Maritime	NM

Tamuz, 2004	Y	USA	Book	D,A	Multiple	Precursor
Taylor and Lacovara, 2015	Y	USA	OP	R,L,I	Fire	NM
Taylor et al., 2014	Y	USA	OR	A	Fire	NM
Taylor, J. A. et al., 2015	Y	USA	OR	A	Fire	NM
Taylor et al., 2015	N	UK	OR	A	Multiple	Near hit
Thoroman et al., 2018	Y	Australia	OR	R,A	Multiple	NM
Thoroman et al., 2019	Y	Australia	OR	A	Aviation	NM
Thoroman et al., 2020	Y	Australia	OR	A,L,I	Aviation	NM
Tinsley et al., 2012	Y	USA	OR	D,I	Disaster	NM
Uth and Wiese, 2004	N	Germany	OR	R,A,L	Processing	NM
Vallerotonda et al., 2022	N	Italy	OR	A,L	Processing	NM
van der Schaaf and Kanse, 2004	N	Netherlands	OR	R	Processing	NM
van Westrenen and Ellerbroek, 2017	Y	Netherlands	OR	R	Maritime	NM
Vastveit et al., 2015	N	Norway	OR	L	Processing	NM
Vastveit et al., 2017	N	Norway	OR	A	Processing	NM
Vaughen and Muschara, 2011	N	USA	OP	A	Processing	NM
Verschoor and Zitman, 2019	N	Netherlands	OP	A	Processing	NM
Wallace et al., 2003	Y	UK	OR	A	Rail	Minor events
Wincek, 2016	Y	USA	OP	D,R,A, L,I	Processing	NM
Wright and van der Schaaf, 2004	N	UK	OR	D,A	Rail	SPADs
Xin et al., 2022	Y	China	OR	R	Maritime	NM

Zaman et al., 2018	Y	USA	OR	R	Rail	NM
Zeqiri et al., 2022	Y	Kosovo	OR	R,A	Processing	NM
Zhang et al., 2015	Y	USA	OR	R	Maritime	NM
Zhang et al., 2016	Y	China	OR	R	Maritime	NM
Zhang et al., 2018	Y	USA	OR	R	Rail	NM
Zhou and Lei, 2018	N	China	OR	A	Rail	Incident
Zhou et al., 2019	Y	Singapore	OR	R	Maritime	NM

Chapter 9 appendices

Appendix 9A – NVivo grounded theory axial coding

NM – Near Miss

SMS – Safety Management System

Axial coding (>10 files)	Files (99)	References (1678)
Phenomena 1 – safety in safety-critical industries	72	451
1A causal conditions	45	138
Factors influencing a focus on safety	43	125
Catastrophes	17	30
History of poor safety culture	10	15
Standards regulations policy etc.	30	71
Learning from others	10	13
1B actions	51	164
Creating a safety culture	26	70
Developing the culture	17	40
Facets of culture	16	30
Safety improvement	31	53
Investigation	19	29
Learning bodies	15	22
Safety focus	14	24
Safety Management Systems	21	41
Industries with SMS	10	11
Intelligence sources	14	30
1C consequences	39	87
Incidents and harm	14	19
Significant incidents	12	14
Measurement of safety	22	36
Culture	10	11
Perception of current safety levels	23	32
Safety maturity	18	23
1D context	20	35
Industry particulars	14	23
1E human influence	11	14
Workforce	10	12
Phenomena 2 - reporting the near miss	67	479
2A causal conditions	60	267
Encouragement to report	28	65
Benefit	11	16
Confidentiality	12	18
Incentivisation	12	16

NM itself	45	124
Encourages	10	13
Inhibits	41	111
Varying definitions	33	79
A near miss is...	28	66
Usable NM reporting systems	28	61
Accessibility	15	22
Usability	18	35
2B actions	26	47
Reporting process	23	37
System organisation	17	25
2C consequences	27	72
Reporting rates	27	72
Under-reporting	16	23
2D context	37	81
Obligation to report	20	40
2E human influence	10	12
Phenomena 3 - response to NM reports	72	748
3A causal conditions	15	20
Ability to focus on NM	10	12
3B actions	67	493
Early actions	35	103
Assessing risk	16	33
Investigation level	26	47
Investigating near misses	57	284
Analysis methods	40	138
Specific techniques	35	103
Barrier	20	49
Investigators	20	43
Trending	34	95
Coding frameworks	15	37
Purpose	16	29
Sharing learning	37	106
Sharing methods	34	81
Databases	13	21
3C consequences	36	206
Impact of NM analysis	27	139
Demonstrable impact	26	79
Measurement limitations	10	15
Outcome of analysis	29	67
Learning shared	22	43
Action	11	17
3D context	19	29
Health and safety vs operational	10	12
Investigation and learning	11	17

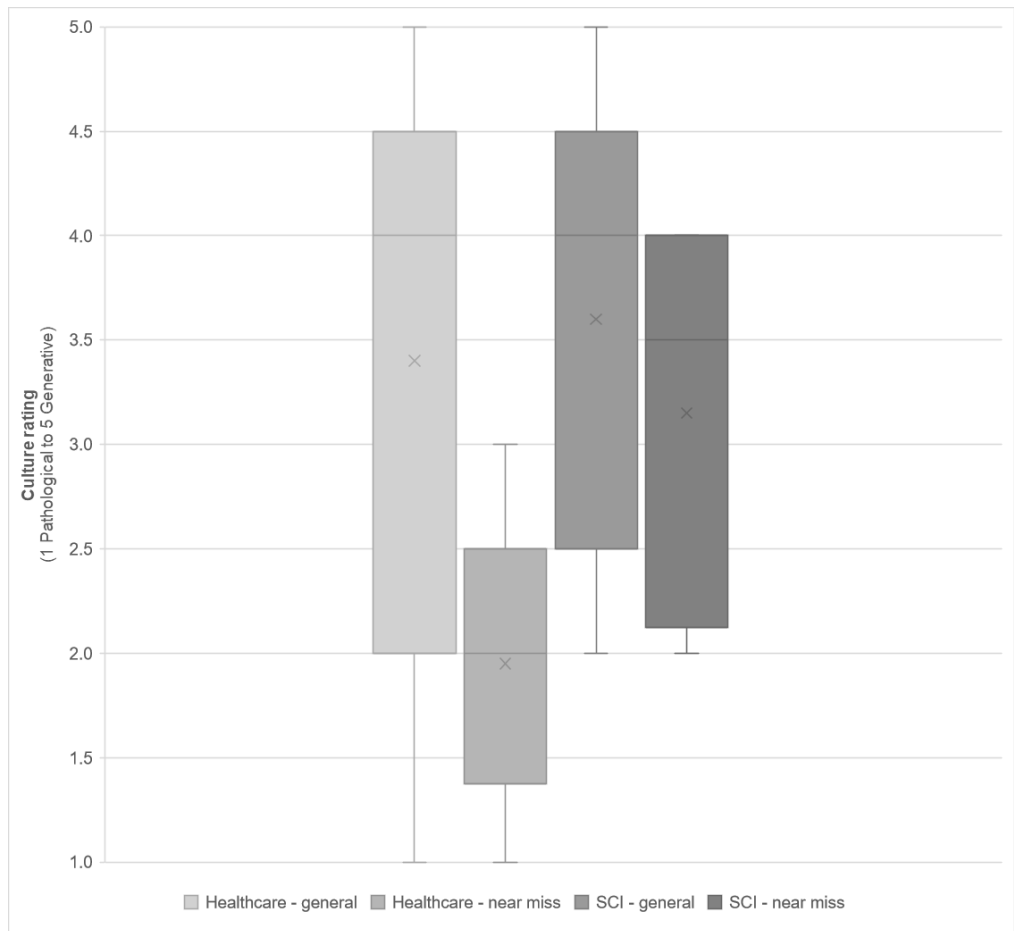
Appendix 9B – Culture question – safety-critical industry responses

Culture		General	Near miss
N	Valid	23	14
	Missing	0	9
Mean		3.4	3.5
Median		4.0	3.5
Std. Deviation		1.19	0.85
Interquartile range		3.0 – 4.0	2.3 – 4.0

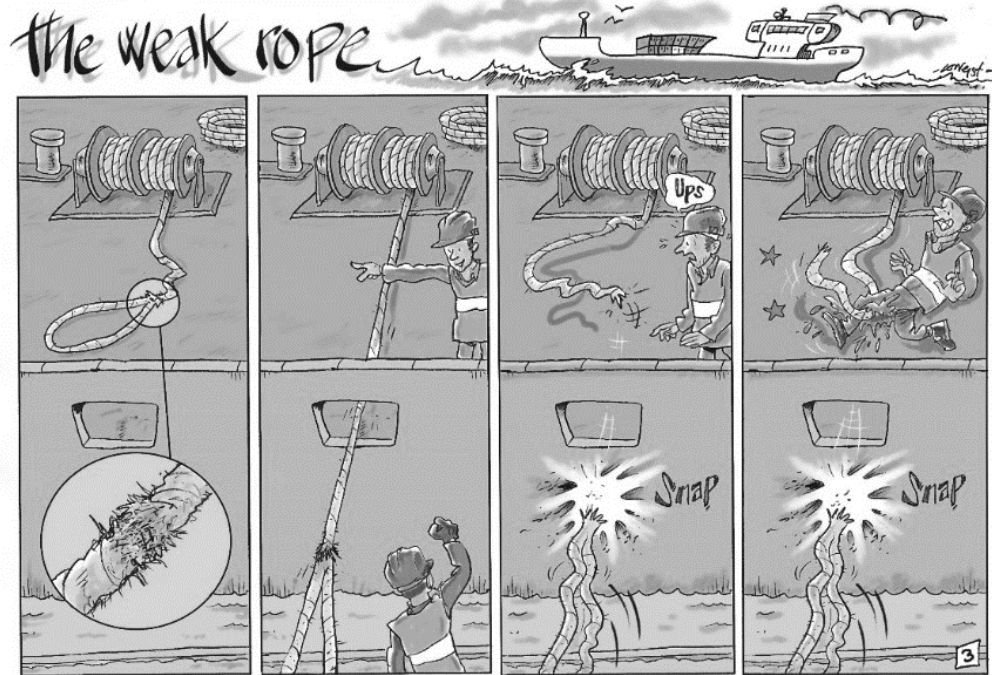
Culture – frequency		
	Freq	Valid %
General		
Pathological (1)	0	0.0
Reactive	3	13.0
Bureaucratic	8	34.8
Proactive	10	43.5
Generative (5)	2	8.7
Total	23	100.0
Near miss		
Pathological (1)	0	0.0
Reactive	4	28.6
Bureaucratic	3	21.4
Proactive	7	50.0
Generative (5)	0	0.0
Total	14	100.0
No response	9	

Culture – per industry					
General					
	Reactive	Bureaucratic	Proactive	Generative	Total
Maritime	2	0	2	1	5
Rail	0	3	1	0	4
Aviation	0	3	2	1	6
Nuclear	1	2	5	0	8
Total:	3	8	10	2	23
Near miss					
Rail	0	1	1	0	2
Aviation	1	1	2	0	4
Nuclear	3	1	4	0	8
Total:	4	3	7	0	14

Appendix 9C – Culture question – box and whisker plots for safety-critical industries (healthcare included for comparison)



Appendix 9D – 'The weak rope' information poster with permission from Nearmiss.dk (n.d.)



Unsafe condition. • Unsafe act • Near miss • Accident



Appendix 9E – Definition question – safety-critical industry responses

Setting of participants		
	Freq	Valid %
Aviation	5	22.7
Maritime	5	22.7
Nuclear	8	36.4
Rail	4	18.2
Total	22	100.0

Terminology of scenarios		
	Freq	Valid %
Scenario 1		
Incident	22	100.0
Scenario 2		
Incident	14	63.6
Near miss	8	36.4
Scenario 3		
Incident	1	4.8
Near miss	14	66.7
Non event	6	28.6
No response	1	
Scenario 4		
Incident	0	0.0
Near miss	1	4.5
Non event	21	95.5

Fleiss Kappa						
	Kappa	Asymptotic			95% Confidence Interval	
		Standard Error	z	Sig.	Lower Bound	Upper Bound
Scenario 1						
Agreement	1.00	0.38	26.33	0.00	0.93	1.00
Scenario 2						
Agreement	0.27	0.04	7.18	0.00	0.20	0.35
Scenario 3						
Agreement	0.23	0.04	5.74	0.00	0.15	0.31
Scenario 4						
Agreement	0.86	0.04	21.51	0.00	0.78	0.94

Appendix 9F – NVivo grounded theory theoretical coding structure

NM – Near Miss

SCI – Safety-Critical Industry

SMS – Safety Management System

Theoretical coding final	99	1843
NMs are part of structured and regulated SMSs	27	64
Safety varies in parts of some SCIs	22	41
SCIs do not have fixed approaches to NM analysis but often use barrier analysis	44	180
SCIs prioritise NMs for analysis and aggregate all against a framework	47	198
Just culture supports reporting of NMs with confidentiality	49	157
SCIs refer to NMs as specific situations where interruptions resulted in almost events	25	49
Impact measurement of NM learning is immature and difficult	14	36
SCIs act following learning from NMs with perceived impact	28	97
Significant harm leads to greater motivation	17	30
SCIs recognise the importance of safety culture with a preference for just	37	81
SCIs use NMs as one source of SMS intelligence	10	12
SCIs operate within different contexts with different risks and priorities	17	29
Incidents, accidents and harm still occur	14	19
Safety and risk varies across and between SCIs	23	32
SCIs are willing to learn from others	10	13

Chapter 10 appendices

Appendix 10A – Factors contributing to limited management of patient safety near misses identified in this research

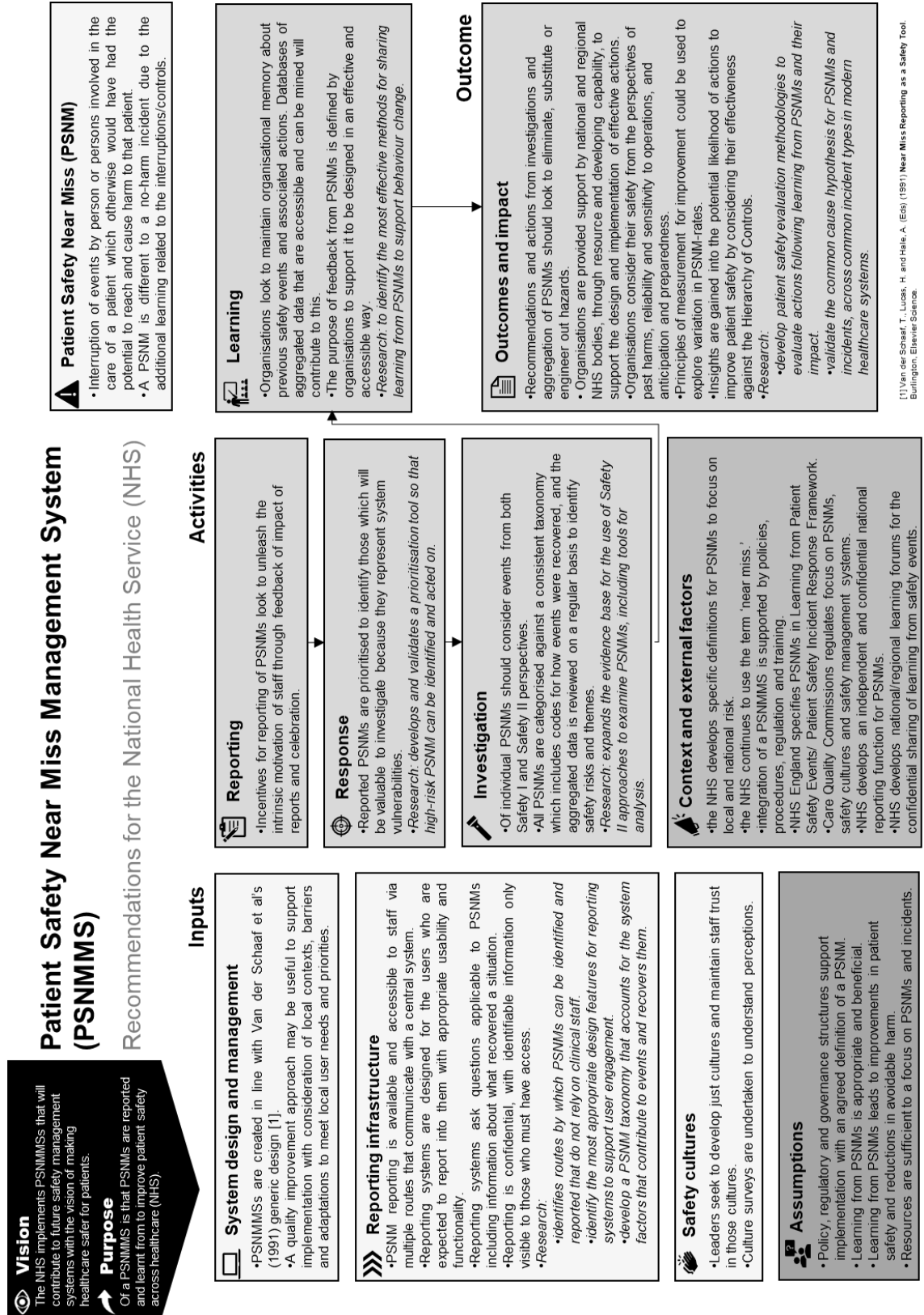
PSNM – Patient Safety Near Misses

Outcome of process:	PSNMs are not learned from
Process affected:	Management of PSNMs
Work system factors negatively influencing the process	
External	No universally agreed and used definition for a PSNM
	Demand and workforce shortages divert focus from safety
	Variation in regulatory requirements for reporting and learning from PSNMs results in 'mixed messages'
	Research focuses on reporting of PSNM and not management and learning processes
	National bodies are reactive, focused on harm and provide no direction for managing PSNMs
	PSNMs are not recognised for their value
	There are limited national bodies focussed on PSNMs
	A blame-orientated culture persists across healthcare preventing reporting of near misses
Organisation	Local processes focus on incidents
	Staff fear punitive responses to reporting PSNMs with concerns around confidentiality
	Leadership does not encourage focus on PSNMs, exacerbated by high-staff turnover

	Limited safety resources
Tools and technology	Poor design of reporting systems limits access to and engagement. Systems are not always available or interoperable with other systems
	Specific questions are not asked about the interruptions involved in a PSNM
Environment	Affects access to reporting systems due to limited hardware or infrastructure such as Wi-Fi
Task	It takes time to report PSNMs and the usability of reporting systems causes frustration
	Organisations do not know which PSNMs to prioritise, and there is rarely aggregation
	Learning is lost and not shared with limited or no feedback to reporters
People	The characteristics of a PSNM and lack of feedback mean staff do not consider them important
	There is not enough time for clinical care, let alone reporting PSNMs

Chapter 13 appendices

Appendix 13A – Patient safety near miss management system – an evidence-based logic model



Appendix 13B – Supplement to draft interruption/recovery taxonomy in Figure 13

PSNM – Patient Safety Near Miss

Conditions of use:		Reported PSNM Consider all contributors and each interruption	
1	Variance	Initiating situation/events/hazards	
2	Detection (D1)	Human detects planned (Hp) or unplanned (Hu)	Identifies variance; may be planned (via a procedure) or unplanned
3		System detects (S)	System designed/planned to identify variance, e.g. functionality in a prescribing system detects dose discrepancy
4		Not detected (n)	Detection does not occur
5	Decision (D2)	Human made (H)	Interpretation of detected information and decision on action
6		System made (S)	System, following detection, interprets information and decides whether to enact a process e.g. provide alert or prevent prescribing
7	Interruption (I)	No interruption (n)	An interruption is not initiated due to lack of detection, decision, or action; may also represent luck
8		Human initiated planned (Hp) or unplanned (Hu)	Undertaking the interruption by following a procedure, or unplanned action e.g. patient refuses medicine
9		System initiated (S)	System undertakes automated interruption e.g. forcing prescribing of a correct dose

10	Outcome (O)	Level of success (U, P, S)	The effectiveness of the interruption
----	--------------------	-------------------------------	--

Examples using the above table:

- **D1S/D2S/IS/OS** – PSNM – system designed to successfully detect/respond to variances; may not always be considered a PSNM (11.3.2.1).
- **D1Hu/D2H/IHu/OS** – PSNM – required a human interruption, representing system vulnerabilities.
- **D1Hu/D2H/In/OS** – PSNM – did not result in an incident because of luck; assumes events did not reach the patient.
- **D1Hu/D2H/IHu/OP** – incident – may not be a PSNM as events have reached the patient; outcome less significant than was possible.
- **D1n or D1Hu/D2H/In/OU** – incidents – which may or may not have resulted in harm.